UNIVERSITY OF TORONTO
FACULTY OF LAW

Trudo Lemmens, LicJur, LLM (bioethics), DCL
Scholl Chair in Health Law & Policy
Associate Professor
Faculty of Law, University of Toronto
39 Queen's park
Toronto, ON, Canada M5S 2C3
Tel: 416-978 4201
Fax: 416-946 3744
Trudo.Lemmens@utoronto.ca

President Eric Kaler (Chair), Professor Eva von Dassow (Vice-Chair), and Senators of the
University of Minnesota Senate
University of Minnesota
427 Morrill Hall
100 Church St SE
Minneapolis, MN 55455

October 21, 2013,

Dear President Kaler, Professor von Dassow, and Members of the University of Minnesota Senate,

As scholars with expertise in research ethics, bioethics, health law, and biomedical research, and as members of the academic community, we have become greatly concerned with the controversies surrounding the suicide of Dan Markingson in a clinical trial at the University of Minnesota's Fairview Hospital in 2004. The circumstances surrounding his suicide while enrolled in the CAFÉ study provide sufficient reason for an independent investigation. Other red flags raised by the way the CAFÉ study was conducted at the University of Minnesota Fairview Hospital add urgency to the need for an independent inquiry. In light of the absence of an adequate response by University administrators, we are hereby calling upon the University of Minnesota Senate to help address the several serious issues associated with Mr. Markingson's death, by requesting the setting up of such an inquiry.

As has been discussed elsewhere in detail, including by faculty members at the University of Minnesota and independent commentators and investigative journalists, Mr. Markingson's death and the way the CAFÉ study was conducted raise substantial concerns about the enrollment of vulnerable and potentially incompetent research subjects in clinical trials, the appropriateness of specific informed consent and capacity assessment procedures in mental health research, the potential impact of conflicts of interest on the behavior of clinical investigators and university administrators, the qualifications of research personnel, and the overall integrity of medical research at major medical schools and their hospitals.

The CAFÉ study is certainly not the only clinical trial that raises such concerns, but the gruesome suicide of Mr. Markingson in the context of medical research conducted by faculty members of the University of Minnesota—following his mother's repeated pleas to remove him from the study before he harmed himself or others—certainly stands out. It should be used as an opportunity for a careful, independent examination of how vulnerable subjects are recruited and kept in studies, of the factors that may have contributed concretely to Dan Markingson's recruitment and suicide, and of the troubling manner in which the University of Minnesota responded.

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In direct response to Dan Markingson's suicide, the Minnesota legislature recognized that the legal protection of vulnerable psychiatric patients was in need of strengthening and adopted in 2009 more protective legislation. The Minnesota Board of Social Work for its part investigated allegations of professional violations by the CAFÉ study coordinator, Jeanne Kenney, and concluded the investigation with an agreement of Corrective Action in 2012, in which it noted numerous disturbing professional violations, including her unlicensed dispensing of prescription drugs, her performing tasks outside of the competence of a social worker, her initialing documents for doctors, and her omitting critical documentation relevant for suicide prevention. It is worth emphasizing here that these professional violations occurred under direct supervision of senior faculty members in a university research setting.

This highly critical assessment of the conduct of a key research coordinator in the CAFÉ study by an independent professional body and the firm legislative initiative taken in direct response to Dan Markingson's suicide contrast sharply with the University's reaction so far, which has amounted to near-complete denial of any problems. Up to this point, the university administration has refused to publicly engage in a transparent, open, and critical assessment of what went wrong in this study and whether the research governance system of the university or the research incentive structures may have shortcomings that directly or indirectly contributed to these tragic events. As a consequence, the University administration has failed to use the disturbing revelations from this incident to find and fix problems that may well continue to threaten other extremely vulnerable individuals who become subjects of medical research at the University of Minnesota.

We strongly believe that a university, and particularly a publicly funded state medical school, fulfills a crucial public role. It should not only be concerned about the production of the 'best science,' but also take the lead in promoting the highest ethical standards in medical research. Its educational mandate also requires it to be exemplary at all levels—to lead in terms of compassionate care of the people of its state. It is troubling that an institution with such an important public calling remains unwilling to properly investigate what can be learned from past mishaps and, on the contrary, uses legalistic and public relations tactics to evade its ethical obligations to the people it has been established to serve.

We are, for example, particularly troubled by the fact that instead of organizing an independent inquiry, the university filed a "notice to assess costs" action against Dan Markingson's mother, Mary Weiss, after a county court dismissed in 2008 her lawsuit against the university with a partial summary judgment. The university agreed to stop the procedure to recover costs if Mary Weiss agreed not to appeal the summary judgment. The use of this legal tactic is highly problematic, particularly when used by a public institution against a mother who lost her son in troubling circumstances.

We are aware that officials within your university have suggested that various investigations have already taken place. However, such claims hold only at the most superficial level. While an FDA investigator conducted a limited and superficial inquiry, focusing on FDA regulations, no full and independent investigation has been conducted into how the study was established and run, and into the alleged failures in research and research ethics governance.

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A legal finding of statutory immunity by a court in the 2008 summary procedure, which is one of the elements invoked by university officials to deny any further responsibility, is clearly only just that: a narrow legal finding of non-liability, which has no bearing whatsoever on the ethical responsibility of the investigators and the institution. It certainly does not qualify as a careful assessment by a court into what happened. In fact, in the context of medical research, statutory immunity is in part connected to the idea that an appropriate ethical governance system surrounds research, which is exactly one of the contested issues in this case.

We therefore ask the University of Minnesota Senate, a key governance body of the university, to take the moral responsibility of a public institution seriously, and to explicitly endorse and request the establishment of a fully independent, transparent, and detailed inquiry. This inquiry should be given the mandate to evaluate what happened; what can be done to prevent similar events from happening again; whether and how University guidelines, policies and procedures for research ethics review and monitoring of research can be improved; and how institutional responses can be improved when horrific events like Dan Markingson's suicide occur. In the interest of the credibility of such an inquiry, and out of respect for those who have been directly affected by Dan Markingson's death and by the lack of response of the University, we also urge you to recommend that Dan's mother and those who have been supporting her be involved in the establishment of the inquiry.

We thank you in advance for considering our request.

Yours sincerely,

Trudo Lemmens, LLM, DCL
Scholl Chair in Health Law and Policy and Associate Professor
Faculty of Law and Faculty of Medicine
University of Toronto
Toronto, Ontario

Raymond De Vries, PhD
Professor
Center for Bioethics and Social Sciences in Medicine
University of Michigan Medical School
Ann-Arbor, Michigan

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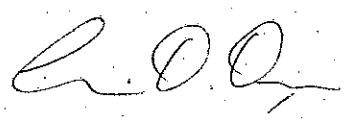
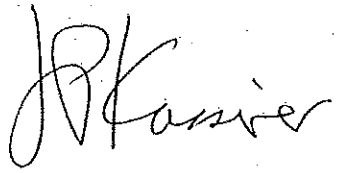


Alice Dreger, PhD
Professor
Medical Humanities and Bioethics Program
Northwestern University Feinberg School of Medicine
Chicago, Illinois

Lois Shepherd, JD
Peter A. Wallenborn, Jr. and Dolly F. Wallenborn Professor of Biomedical Ethics; Professor of Public Health Sciences; Professor of Law
University of Virginia, Virginia

Susan M. Reverby, PhD
Marion Butler McLean Professor in the History of Ideas and Professor of Women's and Gender Studies
Wellesley College
Wellesley, Massachusetts



Jerome P. Kassirer, M.D.
Distinguished Professor
Tufts University School of Medicine
Boston, Massachusetts

In attachment: 171 additional signatories confirmed by e-mail