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University must investigate suicide in psychiatric research study

The University of Minnesota must set up independent inquiry to examine what happened in clinical trial that led to the 2004 death of Dan Markingson, say scholars

Over one hundred seventy leading scholars in health law, bioethics and medical research have called on the University of Minnesota to investigate the 2004 death of a psychiatric research subject, charging that university administrators have "refused to publicly engage in a transparent, open, and critical assessment of what went wrong in this study." The letter, led by Trudo Lemmens, the Scholl Chair of Health Law and Policy at the University of Toronto, and five colleagues from leading U.S. institutions, urges the Faculty Senate of the University of Minnesota to request an immediate, public inquiry into the troubled study.

Dan Markingson was acutely psychotic when University of Minnesota psychiatrists enrolled him into an AstraZeneca-sponsored study of antipsychotic drugs. He had been repeatedly judged incompetent to make his own medical decisions and was also under an involuntary commitment order that legally required him to obey the recommendations of the psychiatrists. His mother, Mary Weiss, attempted to get her son out of the study for months, warning that he was in danger of killing himself, but her warnings were ignored. On May 8, 2004, Markingson committed a violent suicide.

A 2009 investigation of Markingson's death by the *St. Paul Pioneer Press* found that the university psychiatrists had received large payments from antipsychotic drug manufacturers, including the study sponsor. "There was an overt conflict of interest, and there is reason to believe that the boy's death was an indirect consequence of the financial inducements of the study," says Dr. Jerome Kassirer, a former editor of *The England Journal of Medicine* and a signatory of the letter. In 2012, an investigation by the Minnesota Board of Social Work found that the study coordinator overseeing Markingson's care, who was working under the supervision of senior faculty members of the University of Minnesota, had committed an alarming number of professional violations, including fraudulently initialing for physicians on study charts and dispensing drugs without a license.

An inquiry is crucial, the scholars argue, because the Markingson study raises serious and ongoing concerns about the enrollment of vulnerable patients in research, the impact of conflicts of interest on the behavior of clinical investigators and university administrators, the qualifications of research personnel, and the integrity of medical research at major medical schools.

In addition to Lemmens, the letter was organized by Alice Dreger of Northwestern University, Raymond De Vries of the University of Michigan, Lois Shepherd of the University of Virginia, Susan Reverby of Wellesley College, and Jerome Kassirer of Tufts University. Reverby, a historian, uncovered the notorious Guatemala syphilis studies that led to a formal apology by President Obama in 2010. Other notable signatories include Marcia Angell of Harvard University, also a former editor of the *New England Journal of Medicine*; Richard Smith, a former editor of the *British Medical Journal*; Virginia Barbour, a former editor of *PLoS Medicine*; George Annas, a leading Health Law and Human Rights Professor from Boston University; and Daniel Callahan, the co-founder of The Hastings Center.

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To schedule an interview contact **Trudo Lemmens**, by phone at **416 978 4201 or 647-878 6752**; or e-mail: trudo.lemmens@utoronto.ca; or **Lois Shepherd**, by phone at **434-249-4489** or by e-mail at LLS4B@hscmail.mcc.virginia.edu