

Psychiatric research abuse at the University of Minnesota

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Imagine for minute that you work in a medical school. Your job is to make sure that human subjects in medical experiments are protected from harm. Then imagine that you learn there has been a horrific, unexpected death in a psychiatric study. Five months after a young man was signed up for the study over the objections of his mother, his body has been found in a blood-soaked bathroom. It has been nearly decapitated. A box-cutter is frozen in the man's hand, which he apparently managed to jam into a gaping wound in his abdomen before he died. What do you do?

Here at the University of Minnesota, the answer seems to be: "Nothing special." If you don't believe me, have a look at this testimony (1) by Richard Bianco, the university official responsible for overseeing human research. The young man whose body was found in the bathroom was named Dan Markingson.

Q: Has the IRB (the university's research ethics board) done any investigation into the death of Dan Markingson?

A: Not a formal investigation, no.

Q: Has the university done any investigation into the death of Dan Markingson?

A: No.

And later:

Q: To the best of your knowledge, did anyone at the IRB, at the University of Minnesota, or anyone under your office investigate this case, actually look at the records and see the court documents that I'm describing, and if so, could you give me the name of that person?

A: Not to my knowledge.

Q: Nobody did that.

A: No.

For the record, let me make sure this is clear. The bloody corpse of a young research subject is found in the bathroom of a halfway house; he has mutilated himself violently with a box-cutter, nearly severing his own head; and the university's research oversight body *decides there is nothing worth investigating*. What could possibly explain this choice?

Nobody's talking, but it's a good guess that university officials thought it would all blow over. And to be honest, that wasn't a bad bet. By the time Markingson killed himself in 2004, the Department of Psychiatry had already staggered through several spectacular research fiascos without anyone much noticing, even as local news reports made the university psychiatry ward look like a cross between *One Flew Over the Cuckoo's Nest* and *Fargo*.

For, example, there was Dr. James Halikas, a psychiatrist who was "disqualified" by the FDA for recruiting unwitting Hmong opium addicts (2)– without informed consent -- into a trial of a powerful, potentially

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dangerous CNS depressant called GHB. GHB a drug is illegal in many countries, is commonly used as a date rape drug, and goes by street names such as “Easy Lay” and “Georgia Home Boy.”

Then there was Dr. Barry Garfinkel, the Head of Child and Adolescent Psychiatry. Garfinkel was sentenced to federal prison for research fraud – but only after a nearly 4-year cover-up (3) by the university in which the Dean of the Medical School inexplicably signed a written agreement with the psychiatrist to keep the fraud secret.

Perhaps most alarming of all was the case of Dr. Faruk Abuzzahab, (4) a clinical faculty member and former professor in the department who was investigated by the state medical board and found to be responsible for the deaths and injuries of 46 separate patients under his care. Many of these unfortunate patients were psychotic, drug-dependent and suicidal -- in other words, perfect candidates for industry-sponsored drug studies.(5) One study subject left the ward on a day pass and plunged off a bridge into the Mississippi River.

Yet even against this spectacularly lethal backdrop, the case of Dan Markingson (6) stands out. This 26 year-old man was so floridly delusional when he was admitted to the psychiatry ward that he reportedly thought his mother was a lizard. A county court placed Markingson under a civil commitment order that legally required him to obey the recommendations of his psychiatrist. Unfortunately for Markingson, that psychiatrist turned out to be Dr. Stephen Olson, the director of the University of Minnesota schizophrenia program and a paid researcher and speaker for the pharmaceutical company AstraZeneca. Olson promptly recruited Markingson into an AstraZeneca-funded study of antipsychotic drugs (the so-called CAFÉ study) – despite the fact that Markingson had been repeatedly judged incompetent to make his own medical decisions.

His mother, Mary Weiss, tried desperately to extricate her son from the CAFÉ study, repeatedly warning Olson and Dr. Charles Schulz, the Chair of the Department of Psychiatry, that her son’s condition was getting dangerously worse. In mid-April of 2004 she left a message with the study coordinator, asking, “Do we have to wait until he kills himself or someone else before anyone does anything?” Three weeks later, Markingson’s mutilated corpse was found in the shower, along with a note that said, “I left this experience smiling.”

In the years since the suicide, the behavior of university officials has hardly been reassuring. In fact, had you tried to draw a caricature of a guilty man – defensive, sweaty, fake smile frozen in place like Nixon with the camera on – you could hardly do better. First university attorneys tried to block Mary Weiss from seeing all of her son’s medical records.(7) Later, when they managed to get her lawsuit thrown out of court on grounds of statutory immunity, they proceeded to file a counter-action (8) against her, demanding \$57,000 in legal costs. (Yes, you read that correctly: the university demanded \$57,000 from a mother whose son had committed suicide in a university research study.) Last fall, evidence emerged indicating that the Institutional Review Board panel that approved the CAFÉ study (and then failed to investigate Markingson’s death) had been chaired by Dr. David Adson, an AstraZeneca-funded colleague (9) of the study investigator.

University officials have repeatedly claimed (10) to have been investigated and exonerated by various legal and regulatory bodies. But with the exception of a single, deeply flawed investigation (11) by the FDA, those claims have fallen apart.(12) In fact, with each damning new revelation over the years – a \$520 million fraud settlement against AstraZeneca, newspaper reports (13) linking Schulz to manipulated AstraZeneca studies (14) -- the university has steadfastly refused to discuss the issues. Instead, it has

played rope-a-dope, hoping that its attackers would exhaust themselves.

The growing scandal

But the issue has not gone away. If anything, the pressure for a full-blown investigation has steadily grown, not least because of the bluster and evasiveness of university officials themselves. It now seems entirely possible that the research misconduct in the Department of Psychiatry may extend far beyond the case of Dan Markingson.

The first hint of a larger scandal came in November 2012, when the Minnesota Board of Social Work issued a “corrective action” (15) against the CAFÉ study coordinator, Jean Kenney. The findings of the Board were damning. Despite the fact that Kenney had no medical training, she was directed to administer prescription drugs to subjects and make formal judgments of the side-effects. She also failed to inform Markingson that the drugs he was taking could cause diabetes and hyperglycemia. Her record-keeping was “devoid of any clearly articulated, consistent set of treatment goals;” she omitted crucial information relevant to suicide prevention; and she failed to respond adequately to warnings that Markingson was in danger of killing himself. She even forged the initials of physicians on study charts.

All that came from a single botched case. During her years in the Department of Psychiatry, however, Kenney was responsible for the care of many other subjects in a whole range of psychiatric studies – supervised by the same psychiatrist, quite possibly with the same degree of incompetence. How did the University of Minnesota respond? “Jean Kenney is no longer an employee at the University of Minnesota and hasn't been for a number of years,” the General Counsel, Mark Rotenberg, told the press. (16) The university would not be looking any further into misconduct by Kenney or by the psychiatrist supervising her.

Shortly after the “corrective action” came a new revelation: the possibility that study documents may have been faked. (17) Over the years, university officials have consistently claimed that Markingson was fully capable of giving his informed consent to the CAFÉ study. As evidence, university officials pointed to a document called an “evaluation to sign consent” form, which was signed by Jean Kenney. The “evaluation to sign consent” forms consisted of six questions about the research which prospective subjects were expected to be able to answer. The answers on this form supposedly proved that Markingson had full decision-making capacity.

Yet the documents provided by the University of Minnesota in the litigation over Markingson's death were confusing. The university provided two slightly different versions of the same “evaluation to sign consent” form. In most ways the forms were identical, all the way down to the handwritten answers and signatures, but each form had slightly different blacked-out marks in the space marked for the subject's initials. Later, the families of other research subjects claimed on social media sites that their files also contained near-identical “evaluation to sign consent” forms. These claims raised the possibility that researchers were using photocopied forms with the answers already filled in. But when University of Minnesota officials were asked to investigate, they first refused, (18) and then turned the matter over to the Office of General Counsel, which – yet again -- denied (19) any irregularity or wrongdoing.

In late 2013, still more evidence of research misconduct emerged: a 2009 letter (20) written by Dr. Susan Berry, the Executive Chair of the Institutional Review Board, asking the Vice-President of Research for a review of research practices in the Department of Psychiatry, based on “numerous complaints” to the IRB concerning every aspect of engagement with human subjects. The letter cited worries about the “extremely

vulnerable” population of subjects and recommended an investigation by “outside, independent expert(s)”. Yet again, university officials ignored the flashing warning signals and commissioned a superficial report (21) by a group of bureaucratic insiders.

Most recently have come two more alarming investigative news reports. In November 2013, a KMSP television segment (22) told the story of an anonymous patient who was pressured by Dr. Stephen Olson to enroll in an industry-sponsored study of an unapproved antipsychotic drug called bifeprunox. Like Markingson, this patient was psychotic and unable to give proper consent. The patient said bifeprunox has caused physical side-effects so severe that he considered suicide, but his complaints about the drug were ignored. Shortly afterwards, the FDA rejected (23) the sponsor’s application to license bifeprunox, in part because of questions about its link to the death of another patient.

In late February, KMSP aired a second report. In 2010, a 17 year-old boy named Michael Swanson had stolen his parents’ car and killed two convenience store clerks in Iowa. Before the killings, however, he had been seen by University of Minnesota psychiatrist Jonathan Jensen. Jensen had diagnosed Swanson with bipolar affective disorder and recommended the antipsychotic drug Abilify. “There’s a real concern about his use of force,” Jensen wrote. “It would seem to me that likelihood of his repeating the theft of guns, robbery of people is probable and that without anti-psychotic medication, he may carry out these behaviors.”

Yet instead of treating Swanson, Jensen had recommended that he be enrolled in a research clinic at the University of Minnesota. In fact, Swanson’s parents did not even see Jensen’s report until 4 months later when their attorneys got a copy for the murder trial. Then they learned that Jensen was concerned their son was a “risk to society if un-medicated.” Swanson’s parents claim Jensen delayed treatment in order to enroll him in a research study.

Calls to investigate

As the ten-year anniversary of Markingson’s death approaches, there is growing public pressure for the University of Minnesota to give a proper accounting for its psychiatric scandals. On December 5, 2013, in a measure titled “Resolution on the Markingson Case,” the University of Minnesota Faculty Senate voted overwhelmingly to endorse an external investigation (24) into psychiatric research practices at the university. The vote came in response to a letter from University of Toronto law professor Trudo Lemmens and signed by 181 scholars, asking the Senate for an investigation. That same day, Mike Howard, a close friend of Mary Weiss, delivered a petition (25) to the governor of Minnesota, also asking for an external investigation. Both the letter and the petition attracted a number of influential supporters: (26) former *New England Journal of Medicine* editors Marcia Angell, Arnold Relman and Jerome Kassirer; Richard Horton, the editor of the venerable British journal *The Lancet*; Daniel Callahan, the pioneering bioethicist who co-founded The Hastings Center; Richard Smith, the former editor of the *British Medical Journal*; and Susan Reverby, the Wellesley College historian who uncovered the Guatemala syphilis studies, which led to a formal apology by President Obama.

Despite the pressure, University of Minnesota officials appear resolute in their efforts to weasel their way out of responsibility. In January, Eric Kaler, the president of the University of Minnesota, suggested in an interview (27) that while he would comply with the Senate resolution, the investigation would not include any review of the death of Dan Markingson -- or in fact, any past cases of misconduct. Instead, it would be “forward-looking” and concentrate on “current policies and practices.” This is the kind of language

that university functionaries use when they mean: “We intend to whitewash the entire affair.”

Then, perhaps to emphasize the point, university officials decided that the “investigation” would be performed not by a panel of experts in research ethics and regulation, or by a law enforcement body, but by a private consulting firm. In early February, officials posted a “Request for Proposals” (28) on the university’s “Purchasing Services” website, soliciting “bids” by firms interested in conducting an investigation.

So far, apparently, no firms have applied.

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