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THE UNIVERSITY OF TEXAS SYSTEM | FOURTEEN INSTITUTIONS, UNLIMITED POSSIBILITIES.

Session 9

The Death of Dan Markingson: A Research Scandal & a Cover-Up at The University of Minnesota

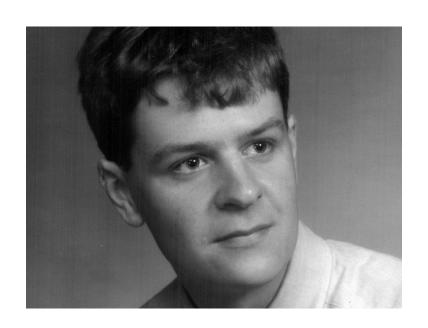
Presented by:

Matt Lamkin

Associate Professor

The University of Tulsa College of Law

September 29, 2017 | 9:30-10:30 am



The Death of Dan Markingson

A Research Scandal & a Cover-Up at the University of Minnesota



OLORED PEOPLE Do You Have Bad Black Anee Blood Rests Bree Treatment



The Nuremberg Code

"The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion...."

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The New York Times

Syphilis Victims in U.S. Study Went Untreated for 40 Years

By JEAN HELLER

The Associated Press

WASHINGTON, July 25—For 40 years the United States Public Health Service has conducted a study in which human beings with syphilis, who were induced to serve as guinea pigs, have gone without medical treatment for the disease and a few have died of its late effects, even though an effective therapy was eventually discovered.

The study was conducted to determine from autopsies what the disease does to the human body.

Officials of the health service who initiated the experiment have long since retired. Current officials, who say they have serious doubts about the morality of the study, also say that it is too late to treat the syphilis in any surviving participants.

Doctors in the service say they are now rendering whatever other medical services they can give to the survivors while the study of the disease's effects continues.

Dr. Merlin K. DuVal, Assistant Secretary of Health, Education and Welfare for Health and Scientific Affairs, expressed shock on learning of the study. He said that he was making an immediate investigation.

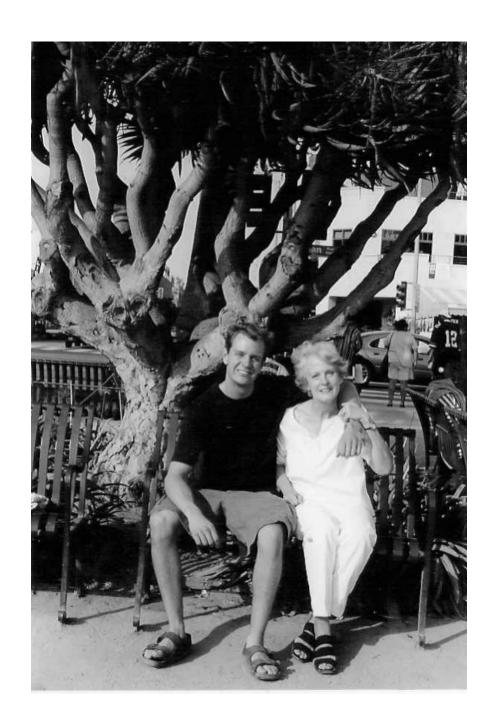
The experiment, called the Tuskegee Study, began in 1932 with about 600 black men,

The Belmont Report

"Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them."

- Give subjects time and opportunity to make their own decisions.
- No coercion or undue influence
- Special protections for people with diminished capacity





"I'm aware that people can cast spells that can hurt you at a distance."

"I'm aware that some people can read minds."

"I'm aware that some people might actually be 'hybrids' and not altogether human."

"... I'm especially eager to attend this storm and SLAY those who deserve slaying. I will choose victims immediately...."

"I HAVE NO EMOTIONAL ATTACHMENTS.
I KILL FOR FUN!!"

The above-named person has blacks the capacity Reasons for this opinion:	
all Sx to sleep deprivation for a fair days	
Date: 1/14/03 / COUNTY Signature FILED BROSTROM, Court Administrator VAN A BROSTROM.	Name: STEPHEN OLSON, MS Address: FUMC
NOV 27,2003	Phone: 6/2-273-8//2 100132

RE:

Daniel Markingson, RESPONDENT

REPORT OF PRE-PETITION SCREENING TEAM

The undersigned, having been appointed to conduct an investigation pursuant to M.S. 253 B.07, Subd. 1, hereby makes the following written report:

- A personal interview with the above Respondent on 11/14/03, and with staff of Fairview University Medical Center;
- 2. The Team also reviewed the medical records of Respondent at Fairview University Medical Center;
- 3. The following specific conduct of the Respondent is the basis for the Team's conclusions:

Respondent is believed not to have the capacity to make decisions regarding Neuroleptic medications. Treatment with Neuroleptic medication is being recommended. The Respondent does

from the media. He then began to believe that many people in the public were aware of him and that a dossier regarding him had been distributed through the public.

A week ago, the Respondent believed his mother was a lizard. The police were called, when on the date of admission (11/12/03), the Respondent made threats to his mother's boyfriend about slitting his mother's throat. The Respondent believed that he was to participate in a satanic ritual and that he was a "chosen one". He believed that potentially "certain people will have to be killed " and that he may be asked to kill people and was prepared to do so. The Respondent was first brought to Regions Hospital but was transferred to Fairview University Medical Center due to bed availability. Records indicate the Respondent showed no insight into why he was brought to the hospital. He was reported to be in a suphoric state when relating to the nurse about being "chosen" by this satanic cult and that it would be a privilege to do whatever they asked including kill people. He was initially unwilling to undergo an MRI or to accept offered medication.

The Respondent was diagnosed with:

Psychosis Not Otherwise Specified Mood Disorder Not Otherwise Specified Rule out Bipolar Affective Disorder with Psychosis Rule out Schizophrenia



James L. Jacobson, Ph.D., LP Licensed Psychologist

Bloomington, MN 55425-2517 (952) 888-5253

STATE OF MINNESOTA County: Dakota

Court File No. PX-03-10

In Re:

REPORT OF EXAMINER Mr. Daniel Markingson Report Date: November 19, 2003

Respondent's DOB November 25, 1976

I, James L. Jacobson, Ph.D, Licensed Psychologist, having been duly appointed by the Dakota Court to examine the above named Respondent report that the examination occurred at the Fairview University Medical Center (FUMC), on November 19, 2003; that the following persons were present: Mr. Daniel

Is there a Gross Impairment of Judgment, Behavior, Capacity to Recognize Reality, Capacity to Reason or Understand? Yes

Respondent's Involvement: Refusal____Partial_ Adequate_XX_ 1. The Respondent is Mentally III: Axis_I: Psychosis, NOS R/O Mood Disorder, NOS, R/O Bipolar Disorder, with Psychosis R/O Schizophrenia.

Identification and background information:

Mr. Daniel Markingson, (DOB November 25, 1976) is a 26-year-old, single male, who does not have a history of mental illness. He is not currently employed, but had worked in California. He came home to visit his mother and exhibited behaviors that appeared to need attention in a hospital setting. About two years ago, Mr. Markingson may have been exhibiting some different behaviors according to his mother. Recently, he appears to have developed a delusional belief that his mother is really his grandmother and, that his mother's boyfriend is really his biological father and that the actress Angelina Jolie is really his sister. He apparently told others that this would be difficult to explain how he came to have these ideas because it was "... hundreds of little

709

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STATE OF MINNESOTA

DISTRICT COURT

COUNTY OF DAKOTA

FIRST JUDICIAL DISTRICT

In the Matter of the Civil Commitment of:

Respondent.

FILE NO. PX-03-10465

Dan Markingson,

FINDINGS OF FACT, CONCLUSIONS OF LAW

AND ORDER

FOR STAYED COMMITMENT

a) That the Respondent remain hospitalized, cooperate with the treatment plan at Fairview University Medical Center until medically discharged, and follow all of the aftercase recommendations of the treatment team;

FINDINGS OF FACT

- That all persons required by law have been provided with at least 24 hours written notice of this hearing.
- That a commitment petition has been filed with the Court alleging the Respondent to be mentally ill.
- That Respondent waives his right to have a preliminary hearing and final hearing in this matter and agrees to the STAYED commitment.

EXHIBI7

M 000063

FILED DAKOTA COUNTY VAN A. BROSTROM, Count Administrator

NOV 2 0 2003

CAFE: Comparison of Atypicals for First-Episode Psychosis



---- Original Message -----

From: Jeannie Kenney <kenne097@umn.edu> Date: Tuesday, September 3, 2002 10:38 am

Subject: [cafesc] Re: CAFE Study Coordinator Teleconference Minutes

- > Hi Jody,
- > I'm from Dr. Stephen Olson's site at the University of Minnesota.
- > not notified of the CAFE coordinator Teleconference. I started
- > here just
- > as our site got up in June and we have definitely been struggling > to get
- > patients. None of the recruitment really started until after I
- > got here
- > and got trained in so hopefully the work I've been putting in the > last few
- > months will start to pay off.

Amy.VandenEynden@quintiles.com, 12:52 09/29/2002 -0500, CAFE - Newest Protocol and consent

To: Amy.VandenEynden@quintiles.com

From: Jeannie Kenney <kenne097@umn.edu>

Subject: CAFE - Newest Protocol and consent changes

Cc: danielle.simons@quintiles.com

Bcc:

Attached:

Hello,

I know that our site is on hold/probation for CAFE recruitment but I have some things I want to

I did get the revision changes for the August Protocol and submitted them to the IRB here. They want to see the changes reflected in the consents. Could you please send a copy of how the consents have been changed to reflect the protocol change?

The death of Subject 13



PIONEER PRESS: SHERRI LAROSE-CHIGLO

The back of a halfway house on Livingston Avenue in West St. Paul where Dan Markingson was transferred from the hospital in December 2003. He was described at the halfway house as often reclusive but showing no delusions or psychotic episodes there. But in May 2004, he killed himself at the house.

copy to man

Dan Markingson 12/8/03

Dan, Your discharge plan is based upon your agreement with the Dakota County Court and your FUMC treatment team that you will follow through with the following discharge plan. You have received papers from the court about your Stay of Commitment.

The following are appointments and recommendations for your after care:

- Keep appointments with FUMC clinic's Café Study. Your contact person in Jenney Kenney 612-627-4363.
- Keep all future appointments with your outpatient psychiatrist, Dr. Olson.

Dan, Your treatment team wishes you a safe, smooth return to the community. Please know that it is important that you follow this aftercare plan, which you agreed to with your treatment team at FUMC and for which you are being held accountable to by the court. Consequences for not following this plan could result in court commitment to the hospital.

following this plan could result in court commitment to the hospital.

I. Den Markingson, understand and agree to follow through with the above expectations.

Dan Merkingson

Date Date

OM .000165

"Do we have to wait until he kills himself or someone else before anyone does anything?"

-- Mary Weiss, voice message to CAFÉ study coordinator, April 2004

"[W]hen a research subject dies in one of your studies, the public and the private message should be, 'We are really sorry about this and we are going to do whatever we can do to make sure this never happens again.'"

-- Mary Faith Marshall

Minnesota Bioethicists Critique Their University, SCIENCE MAGAZINE, Dec. 7, 2010.

Minnesota Board of Social Work Corrective Action for Jean Kenney

- "consistently fell below the minimum standards of practice for a clinical social worker."
- improperly made medical diagnoses and administered prescription drugs
- was improperly entrusted with assessing the severity of potentially dangerous adverse events
- maintained records were "devoid of any clearly articulated, consistent set of treatment goals"

Minnesota Board of Social Work Corrective Action for Jean Kenney

- omitted critical information relevant to suicide prevention
- failed to respond adequately to Mary's alarming voicemail messages about her son's condition
- made significant mistakes about Dan's diagnosis and his medication dosages
- repeatedly forged a physician's initials in Markingson's chart

"Jean Kenney is no longer an employee at the University of Minnesota and hasn't been for a number of years. The University was not a party in the Corrective Action — that is a voluntary agreement between Ms. Kenney and the Minnesota Board of Social Work."

CITY PAGES^{*} U of M paid legal bills of former employee sanctioned over Dan Markingson case

BY ANDY MANNIX

MONDAY, NOVEMBER 19, 2012 AT 10:35 A.M.

The University of Minnesota wasn't a party in the recent sanction of a former employee over a controversial 2004 drug trial, but the same cannot be said about the school's pocketbook.

The U paid a total of \$22,773 to cover a portion of Jean Kenney's legal bills in her case with the state Board of Social Work, City Pages learned through a data request. That breaks down to \$18,909 for Kenney's attorney, and \$3,864 to Dr. Frederic Reamer, an expert witness who testified on Kenney's behalf.

Q: Has the IRB 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.

Deposition of Richard BiancoAssociate Vice President for ResearchUniversity of Minnesota

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.

Deposition of Richard Bianco
 Associate Vice President for Research
 University of Minnesota

- Colleague of Dr. Olson, CAFÉ Principal Investigator
- Reported to Dr. Shulz, Chair of the Psychiatry Department, and CAFÉ Principal Investigator
- Director, Ambulatory Research Center, which housed the CAFÉ study
- Chaired IRB Panel from 1998-2005
- \$650,000 in payments from drug companies over 8 years
- \$149,000 from AstraZeneca, CAFÉ study sponsor
- Member, Academic Health Center Conflict Review & Management Committee, 1998-2008

Texas Rules of Professional Conduct Rule 2.1. Advisor

In representing a client, a lawyer shall exercise independent professional judgment and render candid advice.

Oklahoma Rules of Professional Conduct Rule 2.1. Advisor

In representing a client, a lawyer shall exercise independent professional judgment and render candid advice. In rendering advice, a lawyer may refer not only to law but to other considerations such as moral, economic, social and political factors, that may be relevant to the client's situation.

Texas Rules of Professional Conduct Rule 2.1. Advisor

Comments:

[2] Advice couched in narrowly legal terms may be of little value to a client, especially where practical considerations, such as cost or effects on other people, are predominant. Purely technical legal advice, therefore can sometimes be inadequate. It is proper for a lawyer to refer to relevant moral and ethical considerations in giving advice. Although a lawyer is not a moral advisor as such, moral and ethical considerations impinge upon most legal questions and may decisively influence how the law will be applied.

The New York Times

A Drug Trial's Frayed Promise

Forbes

Why The U. Of Minnesota Research Scandal Threatens Us All

SCIENTIFIC AMERICAN^T

Minnesota Attorney General Confirms They Did Not Exonerate UMN in Markingson Death



Human subjects protections under fire at the University of Minnesota

MPRNews

U's handling of drug study suicide earns an 'F' among peers

Stanford LawSchool

How not to run a drug study: The University of Minnesota puts on a clinic

THE CHRONICLE

Review Finds Flaws in U. of Minnesota's Handling of Vulnerable Human Subjects

★StarTribune

Former Minnesota Medical School cardiologist: What did they do to my U?



A Clinical Drug Study at the University of Minnesota Department of Psychiatry: The Dan Markingson Case

Special Review

March 19, 2015

"[T]he Markingson case raises serious ethical issues and numerous conflicts of interest, which University leaders have been consistently unwilling to acknowledge. They have repeatedly claimed that clinical research at the University meets the highest ethical standards and dismissed the need for further consideration of the Markingson case by making misleading statements about past reviews. This insular and inaccurate response has seriously harmed the University of Minnesota's credibility and reputation."

-- Legislative Auditor Report

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-- Legislative Auditor Report



U halts recruiting for psychiatric drug studies

Freeze comes after review raised ethics concerns.

Kaler acknowledges U misstatements on drug study

Regents take steps to deal with fallout from scathing auditor's report.

Markingson case: University of Minnesota can't regain trust under current leadership

Years of stonewalling have done too much damage.