The Honorable John L. Holahan

STATE OF MINNESOTA — DISTRICT COURT

COUNTY OF HENNEPIN — FOURTH JUDICIAL DISTRICT

MARY WEISS, on her own behalf, and as the next of kin and Trustee of the Estate of DAN MARKINGSON, deceased Plaintiff, v. BOARD OF REGENTS FOR THE UNIVERSITY OF MINNESOTA; DR. STEPHEN OLSON; DR. CHARLES SCHULZ; INSTITUTIONAL REVIEW BOARD FOR THE UNIVERSITY OF MINNESOTA; ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA LP, and ZENECA, INC., Defendants.	Civ. File No: 27-CV-07-1679 **PLAINTIFF'S MEMORANDUM IN OPPOSITION TO DEFENDANTS DR. STEPHEN OLSON'S AND DR. CHARLES SCHULZ'S MOTIONS TO DISMISS PLAINTIFF'S COMPLAINT PURSUANT TO MINN. STAT. Sec. 145.682 AND FOR SUMMARY JUDGMENT**

Plaintiff, Mary Weiss, has alleged a medical malpractice action against Drs. Olson and Schulz and negligence actions against the University of Minnesota and its Institutional review Board and the pharmaceutical company, AstraZeneca, for the wrongful death of her only son, Dan Markingson. Plaintiff submits this brief in opposition to Dr. Olson's and Dr. Schulz's motion to dismiss plaintiff's complaint for failure to comply with Minnesota Statute Sec. 145.682 and for summary judgment.

I.
INTRODUCTION

Mary Weiss brings this medical malpractice action against Dr. Olson and Dr. Schulz because they negligently enrolled and retained her son Dan in a mismanaged clinical drug trial. During the drug trial, Olson and Schulz failed to properly monitor or care for Dan. As opined by international experts in the field of psychiatry (Professors Harrison Pope and James Hudson of Harvard Medical School and others), defendants' treatment was negligent and fell far below the standards of care for psychiatrists and clinical drug trials. Defendants' gross violations of the standards of care included A) willfully and negligently ignoring repeated, clear, documented warnings from his mother that Dan was deteriorating into a violent, psychotic state, B) willfully and negligently ignoring repeated, clear, documented warnings in the results of their own research study and related files including a test form in which Dan stated he had ceased taking all medications, C) willfully and negligently ignoring repeated, clear, documented warnings in therapist notes that Dan's Daily Living ratings were deteriorating, that he wore the same unwashed clothing day after day, and that he had increasingly irrational thoughts and plans. The standard of care in psychiatry required defendants' to note these dire warnings, take Dan out of the study, change and refine his medication plan until positive results were obtained, and closely monitor his progress.

These Defendants', burdened by unethical financial conflicts of interest, including visit-by-visit ongoing payments for Dan to remain in the study, failed to do any of the essential acts required by minimal standards of care. Defendants' multiple and negligent failures to monitor and act upon the many warnings of Dan's demise were negligent omissions that caused Dan to suffer the horrors of untreated psychotic illness for weeks causing Dan to commit suicide on

May 8, 2004. An autopsy proved that the many warnings received by Defendants', including repeated warnings from Dan's mother, were exactly accurate. Blood testing documented Dan was completely untreated at the time of his death, with zero traces of medication in his body. Further, Dan's personal diary documents his predictable descent into a living hell of psychosis -- exactly as Dan's mother, testing records, and therapist notes indicated. During the last desperate months of his life, Dan was erroneously portrayed on Defendants' study records as taking his medication and doing fine while Dan's journals and the official autopsy prove he was grossly psychotic and receiving no medication whatsoever.

Dr. Schulz signed a formal document agreeing to be an active investigator and supervisor but, in fact, he did nothing to monitor, supervise, or control Dr Olson.

Defendants, Drs. Olson and Schulz begin their memorandum by explaining the purpose behind Minn. Stat. Sec. 145.682 and they point out that the statue was promulgated to "curb the number of non-meritorious medical malpractice claims." This case is clearly not one of those cases. In contrast, gross negligence in psychiatry is rarely so well documented and conclusively proven by independent coroner testing, patient journals, and therapy records as in this case.

Mary Weiss has presented defendants with medical disclosures from four eminently qualified experts in this case. Plaintiff's experts are Dr. 1) Dr. Harrison G. Pope, M.D., Professor of Psychiatry and Director of the Biological Psychiatry Laboratory at Harvard Medical School, 2) Dr. James Hudson, M.D., Professor of Psychiatry and Director of McLean Clinical Trials Center at Harvard Medical School, 3) Dr. Keith Horton, M.D., a board certified licensed psychiatrist in the state of Minnesota and long time faculty member of the University of

Minnesota Medical School, and 4) Dr. Paul Root Wolpe, M.D., Professor of Sociology in Psychiatry, Department of Psychiatry, University of Pennsylvania and current President of the American Society for Bioethics and Humanities.

Plaintiff's affidavits by Dr. Pope and Dr. Hudson were submitted to meet all the specifications of Minn. Stat. Sec. 145.682, while Dr. Horton;s and Dr. Wolpe's are supplemental affidavits focused on trial issues. Dr. Pope's and Dr. Hudson's affidavits meet all requirements of MN. STAT. 145.682 and fully support plaintiff's complaint that Dr. Olson and Dr. Schult's negligence directly caused Dan Markingson's death. We all believe that Dr. Horton's affidavit, though brief, meets all applicable standards. Under MN. STAT. 145.682 only one affidavit need survive analysis. Each of plaintiff's experts provide clear and applicable standards of care that Dr. Olson and Dr. Schulz owed to Dan Markingson and each of plaintiff's experts discuss the chain of causation linking Doctor Olson's and Dr. Schulz's breachs of the applicable standards and the acts and omissions that caused Dan's Markingson's horrific death.

II.
DOCUMENTS UPON WHICH PLAINTIFF RELIES

1) Clinical Study Agreement
2) Adult Consent Form
3) Applicable portions of agreement between AstraZeneca and University of North Carolina
4) Study Protocol
5) October 22, 2003 letter from AstraZeneca to Stephen Olson, MD and University of MN
6) Applicable portion of Dr. Olson's deposition dated May 1, 2007.
7) Email From Jennie Kenney dated October 21, 2003.
8) Memorandum from Dr. Jeffrey Lieberman dated December 15, 2003.
9) Fairview-University Medical Center Admission Note
10) Applicable portion of Fairview Patient Progress Record
11) Examiner's Statement in Support of Petition for Commitment
12) Report of Pre-Screening Team
13) Findings of Fact, Conclusions of Law and Order for Stayed Commitment

14) Adult Consent Form

15) Summary of Medical Charges to Dan Markingson from University of Minnesota Physicians

16) University of Minnesota Online Tutorial on the Informed Consent Process - Selecting Participants

17) Deposition of Charles Schulz

18) Discharge Instructions for Dan Markingson dated 12/8/03 (Referred to as "Aftercare Instructions" in the Court's Stayed Commitment.)

19) Two Letters from Mary Weiss to Dr. Stephen Olson dated 11/20/2003 and 11/24/2003

20) Three Letters from Mary Weiss to Dr. S. Charles Schulz dated 3/4/2004, 3/15/2004, and 4/26/2004

21) Letter from Dr. S. Charles Schulz to Mary Weiss dated 4/28/2004

22) Patient Report on Dan Markingson from University of Minnesota Psychiatry dated 4/15/2004

23) Coroner's Report on Dan Markingson

24) WCST-64 Computer Version for Windows; Research Edition by Robert K. Heaton, PhD

25) Workbook Sheet #5 (Self Evaluation of Dan Markingson)

26) 21 CFR 50 - Protection of Human Subjects

27) Operations Manual - University of Minnesota - Research Subjects' Protection Programs and Institutional Review Board: Human Subjects Committee

28) 45 CFR 46 - Protection of Human Subjects

29) Affidavit of Harrison G. Pope, Jr., MD, MPH with CV

30) Affidavit of James I. Hudson, M.D., SCD with CV

31) Expert Report of Paul Root Wolpe, Ph.D. with CV

32) Expert Report of Keith A. Horton, MD with CV

III
MATERIAL FACTS

In May of 2002, Dr. Olson, in conjunction with The Regents of the University of Minnesota, agreed with AstraZeneca Pharmaceuticals, LP to be a study site and a principal investigator in a multi-center clinical study of Seroquel. (*See* Ex. 1 at p10, unless otherwise

stated, all references to exhibits are exhibits attached to the Affidavit of Stephen J. Randall.) The study was sponsored by AstraZeneca and was entitled "Efficacy and Tolerability of Olanzapine, Quentiapine and Risperdone in the Treatment of First Episode Psychosis: A Randomized Double Blind 52 Week Comparison." (*See* Ex. 1 at p.1.) The short name for the study was the CAFÉ study and its purported purpose was to compare the effectiveness and side effects of three antipsychotic medications: olanzapine, (Zyprexsa); quetiapine; (Seroqueol); and risperidone, (Risperdal) for the treatment of schizophrenia, schizophreniform, of schitzoaffective disorder. (Ex. 2 at p. 2.) The study was led and conducted by principal investigator Dr. Jeffrey Lieberman of the University of North Carolina. (See Exhibit Ex. 3 at p.1 and 12.) AstraZeneca manufactures and sells qutiapine (Seroquel).

As a principal investigator at the University of Minnesota, Dr. Olson agreed to conduct the CAFÉ study in accordance with the following: 1) the contract with AstraZeneca, 2) the protocol for the CAFÉ study, 3) good clinical and medical practice, and 4) all applicable laws, rules, regulations and guidelines relating to the conduct of clinical investigations, including, without limitation, 21 CFR, Parts 50, 54, 56, and 312. (*See* Ex. 1 at P. 1.) The study protocol called for subjects who suffered from a first episode of non-affective psychotic disorder (schizophrenic and related disorders). (*See* Ex. 4 at p. 9.) The study consisted of a baseline visit to determine eligibility for the study and then a 52-week double blind randomized treatment phase of the study. The study subject was randomly assigned one of the three study drugs and then the subjects have weekly visits with the study physician for visits 1-6, biweekly visits for visits 6-12, and then monthly visits thereafter. (*Id.*) Also, and importantly for this case,

generally study subjects were not allowed to use concomitant antipsychotic medications. (Id. at 15.)

AstraZeneca paid the University of Minnesota and Dr. Olson personally for conducting the study. The University of Minnesota was paid on a sliding scale for each subject who entered the CAFÉ study. The amount of money paid for each subject depended upon the number of visits that the patient completed. (*See* Ex. 5) AstraZeneca paid the University of Minnesota $15,648.00 for each study subject who completed all 19 visits. (*Id.*) In turn, the University of Minnesota funded a portion of Dr. Olson's salary from the AstraZeneca payments. (*See* Ex. 6, Olson depo, pp. 28-29.) The Café' study brought overhead money into the University coffers in the amount of approximately $30,000.00 on total revenue of in excess of $150,000.00. (See Ex. 6, Olson depo at p. 51.) In addition to financial incentives, Dr Olson had professional incentives to do the study. (Id. at 50.)

As part of Dr. Olson's obligations as a principal investigator, he was in charge of recruiting subjects to participate in the CAFÉ study. (*See* Ex. 1, p. 2.) Dr. Olson acknowledges that is difficult to recruit subjects for research trials and, in fact, in a prior clinical trial Dr. Olson didn't get paid because he was unable to recruit. (*See* Ex. 6, Olson Aff. P.25.) Dr. Olson was an attending physician at the University of Minnesota Hospital and he recruited patients for the CAFÉ study from Station 12 (the psychiatric ward), outpatient units, outpatient clinics, student health center and Olson's own clinic. (*See* Ex. 6, Olson Aff. at p. 42.) In October of 2003, Dr. Olson's study site was spotlighted and designated as a "good" site because Dr. Olson had improved subject enrollment and retention in the study. (*See* Ex. 7.) But in spite of this

improved enrollment, Dr. Lieberman applied even more pressure on investigators, including Dr. Olson, when he issued a December 15, 2003 memorandum telling investigators to step up enrollment in order to avoid the "risk for not meeting our goal of 400 subjects." (*See* Ex. 8.) In sum, as well-documented in email correspondence, Dr. Olson and his employees, such as staffer Jeannie Kenney, were under tremendous financial, professional, and personal pressure to find additional subjects or lose the entire, very lucrative, very important project. (*See* Ex. 8.) They were thus on a highly motivated and time-limited hunt for subjects experiencing an initial psychotic episode.

Dr. Olson's pressured search for research subjects struck pay dirt on November 12, 2003, when Dan Markingson was brought to Fairview-Riverside University Medical Center after initially being taken to Regions Hospital by the police. (*See* Ex. 9, pp. 1-3.) His mother called the police because of concerns about Dan's "beliefs." (*Id.*) Dan's admitting physician was Dr. Olson and, upon admission, Dr. Olson diagnosed Dan with 1) Psychosis not otherwise specified, 2) Mood disorder, not otherwise specified, 3) Rule out bipolar affective disorder with psychosis, 4) Rule out schizophrenia. (*Id.*) Dr. Olson admitted Dan to the psychiatric ward on a 72-hour involuntary hold due to delusions, impaired judgment, and risk of harm to others. (*Id.*) Dan quickly learned from this experience that at the stroke of a pen Dr. Olson could have him confined to a hospital against Dan's will. This was Dan's first experience with Dr. Olson having complete power to control Dan's liberty. It would not be the last.

Dr. Olson continued to treat Dan and on November 13, Dr. Olson indicated that Dan would remain on 72-hour hold and that commitment proceedings would be initiated. (*See* Exhibit

10, at page 9.) He also noted that Dan refused any antipsychotic medication but Dr. Olson elected to write a prescription for Risperdal and indicated the need for a diagnostic workup for a first psychosis. (*Id.*) Interestingly, Dr. Olson also noted that "Hopefully his mother will be able to come in and we'll be able to flesh out more details of his past history tomorrow or next week." (Id).

On November 14, 2007, Dr. Olson examined Dan again and completed an "Examiners Statement in Support of Petition for Commitment." (*See* Ex. 10 at p. 11 and See Ex. 11.) In the Examiner's Statement, Dr. Olson diagnosed psychosis NOS, paranoid schizophrenic versus psychotic mania versus psychosis secondary to medical condition. (*See* Ex. 11) He was of the opinion that Dam Markingson was in need of compulsory treatment, should be committed to a treatment facility and recommended compulsory treatment with Neuroleptic medication. Importantly, Dr. Olson stated that "The above-named person [Dan Markingson] *lacks the capacity to make decisions regarding his treatment* because Dan did not believe he was mentally ill. (*Id.*) [Emphasis added]. Dr. Olson also said that Dan lacked insight because of his "persistent rejection of any acknowledgment he has a mental illness." (*Id.*) This was exactly the state an untreated Dan regressed to when he died. In his forensic opinion, Dr. Olson failed to inform the court that Olson would quickly attempt to obtain "voluntary consent" from psychotic patient Dan Markingson to enroll Dan as an experimental research subject in a drug trial study in which Dr. Olson had direct financial and professional interests. (*See* Ex. 11.)

On November 17, 2007, Ken Geister prepared a Report of the Pre-Petition Screening Team in the matter of Daniel Markingson's civil commitment proceedings. In the report, Mr.

Geister confirmed that the "Respondent [Dan Markingson] is believed *not to have the capacity to make decisions regarding Neuroleptic medications*." (*See* Ex. 12.) [Emphasis added]. The petition for Dan's civil commitment was filed on November 17, 2003. (*See* Ex. 13.) By Hospital note dated November 18, 2003, Dr. Olson indicated Dan (under a forced hold and confined to the hospital) was doing well, was compliant, and taking his prescribed Risperdol. (*See* Ex. 10, p. 14.) Also, Dr. Olson discussed the CAFÉ study with Dan as this was a first time psychotic episode for him. (*Id.*) On November 19, 2003 Dr. Olson again discussed the CAFÉ study with Dan and with his mother. Dr. Olson noted that Dan was tolerating Risperdal without difficulty. (*Id.* at 15.) On November 20, 2003 Dan's chart indicates that medical personal were already concerned that Dan was cheeking his medication and was not compliant. (*Id.*at p. 16.)

On November 20, 2003, Judge Carolan of the Dakota County District Court -- knowing nothing about Olson's personal, financial, and professional plans and incentives to put Dan into Dr. Olson's experimental drug study -- found that Dan Markingson was mentally ill, that *Dan should be committed to the Anoka Metro County Treatment Center and that the commitment should be stayed for six months as long as Dan complied with Court imposed conditions*. (*Ex.* 13). [Emphasis added]. The conditions included: that Dan remain hospitalized, cooperate with the treatment plan at Fairview University Medical Center until medically discharged, and f*ollow all of the aftercare recommendations of the treatment team* [the team headed by Dr. Olson], that Dan enter, participate in, and satisfactorily complete the inpatient/outpatient treatment program at and aftercare recommendations as determined by a social worker, that Dan cooperate with the treatment plan and follow the rules at any living facility as arranged by his social worker, that

Dan consent to admission or readmission to a hospital or other appropriate facility as determined by the social worker, and *that Dan take drugs or medications only as prescribed* [by Dr. Olson], and abstain from the use of any non-prescribed drugs or alcohol. (*Ex*. 13.) [Emphasis and other information added].

On November 21, 2003 *the day after Dan Markingson was legally found to be mentally ill and given a stay of commitment ordering him to obey Dr. Olson and take the medication Olson prescribed*, and seven days after Dr. Olson signed an examiner's statement in support of commitment declaring that Dan lacked the capacity to make his own treatment decisions, Dr. Olson had Dan meet with Jennie Kenney to sign an informed consent to enter the CAFÉ study. (*Id*. at p.17, Ex. 6, Olson depo. P. 31.) Jeannie Kenney assisted Dr. Olson as the CAFÉ study coordinator and her salary was partially paid for with funds from AstraZeneca. (*See* Ex. 6, p. 31-32.) During the meeting, Dan signed the consent form to enter the CAFÉ study. (*See* Ex 14.) Other than Dan, the only two people present at the meeting were people with conflicting financial and professional interests in having Dan enter the CAFÉ study as a subject, Jeannie Kenny, who signed the consent form as "Person Obtaining Consent" and Dr. Olson who signed the consent as "Witness." (*Id.* at p. 10, Ex. 6, Olson depo. pp.83-84.)

The "consent" procedure used in this case by Dr. Olson on Dan Markingson, was contrary to the published, online rules and guidelines of the University of Minnesota stating, "recruitment of participants needs to be done in a nonbiased, non-power-based manner. It is important that none of the participants ever feel that if they do not participate in the study, they be penalized". (*See* Ex 16). Similarly, the published online guidelines of the University of

Minnesota state, "Doctor-patient relationships between the investigator and participants should be avoided, when possible, to eliminate any power-based coercion. Patients can say no to someone they do not expect to see in the future, but it is very difficult for people to say no when they rely on someone for ongoing medical care." (*Id*.).

In violation of local, national, and international standards of care, as well as Minnesota Health Care Bill of Rights, the "informed consent form" Dr. Olson and his paid employee Jeannie Keeney had Dan Markingson sign contained no (zero) information on the known risks and benefits of Alternative Treatments. (See, Deposition of Dr. Olson, Exhibit 6, pg 182-183). There was no mention, for example of the risks and benefits of ECT therapy, no mention of the risks and benefits of other medications, no mention of the risks and benefits of other medications or obtaining treatment from non-study physicians. (See, Deposition of Dr. Olson, Exhibit 6, pp. 182-183). Compare the mandatory legal requirements of Minn. Stat. Sec. 144.651 Health care Bill of Rights, Subd 9, which reads, "Patients *shall be given* by their physicians *complete and current information* concerning their diagnosis, treatment, *alternatives, risks* and prognosis as required by the physicians legal duty to disclose.." [Emphasis added].

In violation of such local, national, and international standards of care, the "informed consent form" Dr. Olson and his paid employee Jeannie Keeney, had Dan Markingson sign contained no (zero) disclosure of the most serious risk of the study, that is, an increased risk of suicide: "DR. BARDEN Q. Could you show me anywhere on this form where the risk of suicide is disclosed?... DR OLSON A. It's not here... Q. The word suicide as a risk of the use of these drugs is not disclosed anywhere on your informed consent form, correct?... A. Correct."

(*See* Ex 6,p 172.)

Dr. Shultz was the head of the University of Minnesota Psychiatry Department. (See Ex 17, Schulz depo. Pp. 4-5.) Dr. Schulz was also a co-investigator on the CAFE drug research study. As co-investigator Dr. Schulz shared responsibility for the CAFÉ study with Dr. Olson. (See Ex 17, Shulz depo p 28.)

On December 8, 2003, Dan's treatment team headed by Dr. Olson prepared detailed, explicit instructions for Dan to enter Olson's own CAFE drug study and comply with Dr. Olson's instructions or face forced incarceration in a mental hospital. In fact, Dr. Olson's treatment team threatened Dan in no uncertain terms writing, "Consequences for not following this plan could result in court commitment to the hospital". (*See* Ex 18).

Throughout Dan's treatment and participation in the CAFE study, Dr. Olson served multiple, powerful, and conflicting roles in this case as: 1) Dan's treating and admitting physician who provided legal documentation to the Court recommending civil commitment because Dan was mentally ill and incapable of making his own treatment decisions; 2) Dan's personal treating physician; 3) the principal investigator in the CAFÉ study of which Dam became a subject; and 4) the CAFÉ study physician who saw Dan as part of the research project. (*See* Ex. 6, depo of Olson at pp. 80-81.)

True to his stay of commitment conditions, Dan remained hospitalized after the commitment hearing. During Dan's hospitalization, Dr. Olson had no less than 20 examination visits with Dan on almost a daily basis. (*See* Ex. 15.) During this hospitalization, Dr. Olson continued to prescribe Risperdal and Dan continued to improve on this standard, non-research

medication. (See Ex. 10 at p. 26). On December 5, 2003 Dan completed his baseline visit to enter the CAFÉ study. The baseline visit was administered by non-physician Jeannie Kenny and not Dr. Olson. (See Ex 16, Ex 6, Olson depo at pp. 217-218.) Dan remained hospitalized until December 8, when he was discharged to a halfway house called the Theo house located at 1312-14 Livingston, West St. Paul, MN 55118.

While Dan Markingson was living at the Theo house over a period of weeks and months, plaintiff, Mary Weiss, clearly and repeatedly warned Dr. Olson, Schulz and their staff that Mary's son Dan demonstrated obvious and increasing deterioration, agitation, and rage throughout Dan's stay in Dr. Olson's drug study. Mary sent five letters to Dr. Olson and Dr. Schulz repeated informing them of Dan's deterioration and asking for help. Two letters dated November 20, 2003 and November 24, 2003 were sent directly to Dr. Olson. (See Ex. 19) Three letters were sent to Dr. Schultz dated March 4, 2004 March 15, 2004 and April 26, 2004. (See Ex 20). Although Mary did receive a response to her third letter because she sent it registered mail she received no response to her first four letters and no action was ever taken regarding her concerns. (See Ex. 21.) Finally, an exasperated Mary Weiss even sent a message recorded in the medical files stating, *"Do we have to wait until he kills himself or someone else before anyone does anything?* (See Exhibit 22) [Emphasis added]. Dr. Olson and Dr. Schulz admitted that they had both been aware of the dire warnings of Mary Weiss but did not heed them. (See Ex 6, at p. and 242 and Ex 17 at p. 16-17.)

Tragically, Mary Weiss' motherly predictions proved all too accurate. In stark contrast to Dr. Olson's erroneous CAFE drug trial study "data" claiming Dan was improving and doing

well in the CAFE study, the most reliable evidence consisting of Dan's personal journal, clearly documents that he was, in fact, suffering from the horrors of untreated psychosis. (See, Ex. 29) Similarly, in stark contrast to Dr. Olson's erroneous CAFE drug trial study "data" claiming that Dan was taking his research medication, the official autopsy proved conclusively that Dan was taking no medication at all. (See Ex 6, Depo of Olson, pg. 256 and Ex 23). On March 2, 2004, a few short weeks before his death, Mr. Markingson completed a WCST-64 exam. Under the "Client Information" section of page one, the test results clearly document that Dan reported he was not taking any medication. This serves as yet another confirmation of the autopsy report and the repeated warnings of Mary Weiss, documenting that Dan was not on any medication at all. This document extends proof of Dan's lack of treatment back more than a month prior to his death. (See Ex 24). Incredibly, Dr. Olson was not even aware of this stunning test data until it was shown to him on May 1, 2007 in his deposition in this case. (See Ex 6, depo of Olson, page 231).

As further evidence that Dan had slipped back into a fully delusional psychotic state, in which he denied suffering from any mental illness, Dan filled out a self evaluation form on March 31, 2007, indicating he was fully recovered with no symptoms and functioning well. (See Ex. 25.) Dr. Olson also admitted that during this time frame, therapy notes also showed Dan had cancelled several therapy appointments and was not talking in sessions. Again these warning signs were missed or ignored by Dr. Olson and Dr. Schulz. (See Ex 6, depo of Olson, page 239).

Despite the fact that Dr. Olson's and Dr. Schulz's own records show Dan had returned to his pretreatment psychotic state, Olson chose to ignore or minimize this dire warnings and failed

to take Dan out of his lucrative study for treatment with alternative meds, injectable meds, liquid meds, ECT, or combinations of meds. Dr. Olson failed to act on any of this information or take any steps to correct Dan's deterioration. Dr. Olson failed to even meet with Dan and evaluate him. He did nothing. Such acts and omissions fell far below the standard of care for psychiatrists and frankly below the standard of care for common sense of a typical adult.

As Dan deteriorated, his mother frantically worked to gain attention and help for her only son. *"Do we have to wait until he kills himself or someone else before anyone does anything?* (Ex 6, depo Olson, p 242, Ex 11). [Emphasis]. Burdened by financial conflicts of interest, Drs. Olson and Schulz ignored her many warnings.

IV

ARGUMENT

A. Summary Judgment Standard of Review

Under Rule 56.03, Minn. R. Civ. P., a summary judgment may be granted to either party if "there is no genuine issue as to any material fact." In construing this rule, the Minnesota State Supreme Court has held that "the moving party has the burden of proof and . . .the nonmoving party has the benefit of that view of the evidence which is most favorable to him." Sauter v. Sauter, 244 Minn. 482, 484, 70 N.W. 32d 351, 353 (1955); See 2 J Hetland & O. Adamson, Minnesota Practice 571 (1970). All doubts and factual inferences must be resolved against the moving party. Anderson v. Twin City Rapid Transit Co., 250 Minn. 167, 186, 84 N.W.2d 593, 605 (1957); Hetland & O Adamson, supra at 572. However, as the Anderson court stated, "it is

no part of the court's function to decide issues of fact but solely to determine whether there is an issue of fact to be tried." Id. at 605. The care with which an inquiry required by Rule 56.03 should be conducted was emphasized by this court in Donnay v. Boulward, 275 Minn. 37, 144 N.W. 2d 711 (1966). There, we stated that "[s]ummary judgment is a "blunt instrument' and . . .should be employed only where it is perfectly clear that no issue of fact is involved." Id. At 45, 144 N.W.2d at 716. Summary Judgment is not a substitute for trial when there are factual issues to be determined. Vacura v. Haar's Equip., Inc., 364 N.W.2d 387, 391 (Minn.1985)

Defendants University Regents and the IRB have not challenged the qualifications and, expertise of plaintiff's IRB experts from Harvard University, nor have they challenged their liability and causation opinions. Because plaintiff Mary Weiss has submitted detailed and conclusive evidence in the form of expert reports, deposition transcripts, documents and affidavits that support her contentions and raise issues of material fact as identified below with regard to her negligence claims against the University Regents and its IRB, this court must find that there exists triable issues of material fact, and deny defendants' summary judgment motion.

B. **Standard For Expert Affidavit Under Minn. Stat. Sec. 145.682**.

Under Minn. Stat. 145.682, in cases where expert testimony is necessary to establish a prima facie case the required affidavits of identification of experts must state the identity of each person whom plaintiff expects to call as an expert witness at trial to testify with respect to the issues of malpractice or causation, the substance of the facts and opinions to which the expert is expected to testify, and a summary of the grounds for each opinion and be served on defendant within 180 days after commencement of the suit against the defendant. Minn. Stat. 145.682

Subd. 4. The purpose of section145.682 is not to deprive plaintiffs of legitimate lawsuits, but to weed out actions without evidentiary support. *Hempel v. Faiview Hospitals & Healthcare*, 504 N.W.2d 487, 492 (Minn.App.1993). In order for a medical witness to be competent to testify as an expert, the witness must have both sufficient scientific knowledge of and practical experience with the subject matter of the offered testimony. *Cornfeldt v. Tongen*, 262 N.W.2d 684, 692 Minn. 1977). The affidavit must disclose specific details concerning their experts' expected testimony, including the applicable standard of care, the acts or omissions that plaintiffs allege violated the standard of care and an outline of the chain of causation between the violation and the standard of care and the plaintiff's damages. *Lindberg v. Health Partners, Inc.*, 599 N.W.2d 572, 577 (Minn. 1999). Failure to comply with the affidavit requirements of Minn. Stat. Sec. 145.682 results in mandatory dismissal with prejudice of each cause of action as to which expert testimony is necessary to establish a prima facie case. Minn. Stat. Sec. 145.682 Subd. 6.

C. Plaintiff's Expert Affidavits Satisfy the Requirements of Minn. Stat. Sec. 145.682 and her Case Should Proceed to Trial

1. <u>Plaintiff's Expert Qualifications</u>

Plaintiff retained Dr. Harrison Pope to testify to the negligence of Dr. Olson and Dr. Schulz. Dr. Pope is a licensed psychiatrist and Professor of Psychiatry at Harvard Medical School. (Pope Aff., para 2.) Dr. Pope has thirty years of clinical experience treating psychiatric patients with psychotic disorders similar to Dan Markingson's mental illness and similar to Dan's commitment and halfway house history. (Pope Aff, para 2.) Dr. Pope is qualified to testify about the conduct of psychiatric clinical trials as he has authored numerous peer reviewed

articles, chapters and books on many areas of psychiatry and he has participated in numerous clinical trials of psychiatric medications similar to the CAFÉ study. (Pope, para. 3.) Dr. Pope is familiar with informed consent issues as he has been on the McClean Hospital ethics committee and he has published hundreds of peer-reviewed articles on informed consent. (Pope, para 4.) Dr. Pope also teaches about proper clinical management of patients with chronic psychotic disorders at Harvard Medical School. (Pope, para. 5.)

Dr. James Hudson is a licensed psychologist and Professor of Psychiatry at Harvard Medical School. (Hudson, para 2) He has more than 25 years of clinical experience in the treatment of psychotic patients including patients with mental illness similar to Dan Marknigson. (Hudson, para 2). Dr, Hudson is the author of over 200 peer reviewed articles and he has participated in numerous clinical studies. (Hudson para 2 and 4). Both Dr. Hudson and Dr. Pope are among the most commonly cited psychiatric researchers in the world.

Dr. Keith Horton is Board certified licensed psychiatrist in the State of Minnesota. (Horton, para.2). He has extensive experience in clinical care of psychiatric patients and has treated hundreds of psychiatric patients similar to Dan Markingson. (Horton, para. 9.)

Dr. Paul Root Wolpe is a Professor of Sociology in Psychiatry in the Department of Psychiatry at the University of Pennsylvania. (Wolpe, para. 2.) Dr. Wolpe currently serves as the President of the American Society for Bioethics and Humanities. (Wolpe, para 3) He is a also a senior fellow at U. Penn's Center for Bioethics. (Wolpe, para. 2.)

2. Plaintiff's expert affidavits set out clearly defined standards of care applicable to the conduct of Dr. Olson and Dr. Schulz.

Our discussions with respect to Dr. Pope's expert disclosures shall apply for Dr. Hudson's expert disclosures and our discussions of Dr. Hortons' expert disclosure shall apply to Dr. Wolpe's disclosure.

The bases for Dr. Pope's opinion is set out in paragraph 7 of his report and includes a review of the relevant records pertaining to Dan's mental illness including the medical records, legal records and personal records of Dan Markingson and Mary weiss, and depositions taken in this case. His opinions are also based on his education, knowledge, training and experience. (Pope, para 7.)

Dr. Pope states in his affidavit that "the opinions that I express below... are offered to a reasonable degree of medical certainty." (Pope, para 8.)

Dr. Pope's opinion critiques the multiple and conflicting roles that Dr. Olson undertook with respect to his care for Dan Markingson. He notes Dr. Olson was simultaneously 1) the principal investigator (PI) in charge of the overall, lucrative CAFÉ study, 2) the study physician personally in charge of Dan Markingson's participation in the CAFÉ study, and 3) the sole treating physician for Dan Markingson. (Pope, para. 16.) For each of these roles, Dr. Pope has set out specific standards of care based upon his knowledge training, and experience supplemented by national and international treatises, guidelines, and codes of conduct.

Dr. Pope opines that despite holding multiple conflicting roles, "as PI, study physician, and Mr. Markingson's treating physician, Dr. Olson was obligated to offer competent and ethical clinical care in both of these areas." (Pope, para 16.)

Defendant, Dr. Olson, argues that the standard of care set out by Dr. Pope as the IP and the study physician is mysteriously invalid because some of the bases for the standard are published guidelines. (Defendants' Brief page 22). Dr. Pope specifically points to 45 CFR part 46, FDA regulations and guidelines on protection of Human Subjects including interpretation of those guidelines by the International Conference on Harmonization, (ICH) Good Clinical Practice Guideline. (Pope, Para 18, and *See* 21 CFR 50.) Dr. Pope explains that these documents were founded upon the ethical principals embodied in important underlying and earlier international documents including the Nuremberg Code, the declaration of Helsinki and the Belmont Report. The background, development and text of these documents have been briefed in Plaintiff's previously filed Motion to Amend the Complaint to Claim Punitive damages and will not be reproduced here. Clearly such publications can and should be part of any discussion of standards of care as should clinical experience and judgment.

Doctor Olson makes the strained argument that there can be no standard of care in medicine unless such standards are explicitly written down somewhere. Medicine, of course, has never worked like this. Peer review processes in hospitals and clinics as well as the malpractice legal process depend upon human beings exercising wise judgment. Physicians don't go from bed to bed in the hospital with their nose in a book, they practice medicine in real time and under time and other pressures. If Defendant's strained and artificial analysis were the law, medical malpractice cases would all disappear. Almost all standards of care are established by a combination of written materials, research and *experience*. Dr. Pope makes clear that these elements form the basis of his opinion on the standard of care for Dr. Olson acting as a PI and

study physician. (Pope, para 7).

Dr. Olson cannot avoid compliance with the CFRs and characterize important foundational bioethics documents (e.g., Nuremberg Code, the Declaration of Helsinki and the Belmont Report) and principles simply by stating that the documents contain general disclaimers. (Defendant Brief at p. 22.) Health care standards are simply what health care providers do and think and how they act. Such standards have always been guided but not controlled by documents and guidelines. Dr. Olson knows this well. The contract he signed with AstraZeneca specifically states that the Investigator (Dr. Olson) and the Institution (The University of Minnesota) "shall" conduct the study entitled "Efficacy and Tolerability of Olanzapine, Quentiapine and Risperdone in the Treatment of First Episode Psychosis: A Randomized Double Blind 52 Week Comparison" in accordance with … 21 CFR. Parts 50, 54, 56 and 312. For instance, code of regulation 21 CFR 50 comes from the Food and Drug Title of the Federal Code and Sec. 50.20 is entitled "General Requirements for Informed Consent." (See Ex. 26, p 4.)

In addition to the contract Dr. Olson had with AstraZeneca binding him to the principles contained in the CFRs, a review of the *Operations Manual for the University of Minnesota Research Subject's Protection Programs and Institutional Review Board: Human Subjects Committee* confirms that the University of Minnesota, Dr. Olson's employer, formally applies the CFRs to its treatment of human study subjects. For example, the operations manual has a section specifically designated for the treatment of vulnerable populations such as Dan Markingson. (See Ex. 27, pp. 143-151.) The section pertaining to the "Decisionally Impaired"

talks about the special care that needs to be taken with schizophrenic patients like Dan Markingson with "fluctuating capacity." (See Ex 27, p.147.) This section of the manual specifically references the 45 CFR 46, which is the Code of Federal Regulation pertaining to the Department of Human Service and is specifically entitled "Protection of Human Subjects." (See Ex 27, p. 147-148, and Ex 28). Dr Pope, Dr. Hudson, and the University of Minnesota agree on such points including the sections in the Operations Manuel entitled "Consent Process." (See Ex 27, pp. 152-170.) This section is replete with references to Title 21 and Title 45 of the CFRs.

The Operation Manual also discusses the importance of the Declaration of Helsinki, the Code of Federal Regulation, the Nuremberg Code and the Belmont Report in its section entitled Guiding Principals. (See Ex. 27). The section begins:

> "The IRB authority is founded in and guided by many sources, including regulatory statutes, institutional policies, ethical cannons, and members' own perceptions of community and professional standards. While interpretive differences between these governing principals may exist, it should be noted that *regulations offering the most stringent guidelines for the protection of human subject are followed.* [emphasis added]" Furthermore, these principles are to followed without regard to whether the research is subject to federal regulation, with whom the research is conducted, or the source of support for the research. (Id. at p. 10.) Dr Pope, Dr. Hudson, and the University of Minnesota agree on such points. The standards of care about not controversial in such matters.

The manual goes on to say that basic principals of "the Nuremberg code serve as

the cornerstone for modern regulations." (Id at p. 11.) The Belmont report "provides the most succinct description of the mandate for review of research involving human subjects " and *Respect for Persons, Beneficence and Justice* are fundamental elements human subject research. (Id at p. 12) The declaration of Helsinki "charges the investigator with the responsibility of engaging in only well-informed, proper scientific research with regard for the welfare of human subjects." (Id at 13.) There is no question that the University of Minnesota, AstaZenca and Dr. Olson, both as an employee and as an medical researcher are bound by the very standards articulated in detail in Dr. Pope's expert affidavit.

Further evidence that Dr. Olson, as a PI and study physician, is bound by the standards set out in Dr. Pope's affidavit is contained in the University of Minnesota's online informed consent policy. (*See* Exhibit 16.) This online policy indicates that Doctor-patient relationships between the investigator and participant should be avoided to eliminate any power-based coercion. (*Id.*) Dr. Olson violated his own institution's policy by recruiting Dan into his CAFÉ study while being his treating physician. (Pope, para 22 C, p. 19.) Dan's treating physician, Dr. Olson held coercive power over Dan and Dr. Olson understood the principal that it would be very difficult for Dan to say no to the study when Dan was relying on Dr. Olson for ongoing care. (Ex 6, Olson depo at p. 189-190.) This University of Minnesota policy is a reflection of article 10 of the declaration of Helsinki which states "When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely

independent of this official relationship." (Pope, para 22 C, p. 19.)

Dr. Pope then discusses specific standards of care for getting informed consent based on the underlying documents set out above. He discusses the following standards: 1) potential study subjects should receive a thorough description of the risks and benefits of the study, assurance that they can decline to participate or withdraw at anytime without prejudice to themselves or their treatment, and for psychiatric treatments a clear explanation of alternative treatments including getting treatment from another Doctor. (Pope, para 19.) These standards must be followed with even greater care when dealing with vulnerable populations, such as Dan, with compromised ability to understand, seek or obtain treatment. (Id.) Standards of informed consent require that potential subjects be competent to understand informed consent and may dictate that an individual can not give informed consent because of in competency. (Pope, para 20.) The informed consent must be obtained in a manner that is non-coercive and non-exploitive. (Pope, para. 20).

Dr. Pope also clearly set out the standard of care required of a PI and a study physician, of which Dr. Olson was both to Dan Markingson, while conducting a clinical trial. Dr. Olson was responsible to for meeting the standards of Good Clinical Practice. (Pope, para. 30). Dr. Pope lists a large number of specific authorities detailing various obligations of Dr. Olson to include the following: 1) Dr. Olson is responsible for the conduct of the trial, 2) he must maintain a list of qualified people who he delegates duties to, 3) a qualified physician should make all trial related medical decisions, 4) the experiment should be conducted by only scientifically qualified person and under the supervision of a clinically competent medical person and 5) the study

should be subject to sound research design with no unnecessary risk to subjects. (Pope, p. 30). He summarizes by stating that Dr. Olson is charged with the duty that a study physician must provide careful care to research subjects that reflects sound clinical judgment and minimizes risks to the subject. (Pope, para 31.)

Again, for the same reasons that were stated with respect to the consent document, these standards applied to Dr. Olson as he conducted the CAFÉ study. For instance, the contract between AstraZeneca and Dr. Olson governing the CAFÉ study specifically requires Dr. Olson to engage in good clinical and medical practice. (See Ex 1.) Dr. Pope is an eminently qualified psychiatrist and he set out the standard of care for a PI and study physician based on well recognized international and national documents and based upon his extensive experience as psychiatrist involved in clinical trials.

Because Dr. Shultz had a different position with respect to the CAFÉ study and Dan's care in the study than did Dr. Olson, Dr. Pope attributes to him a different standard of care. As chairman of the Department of Psychiatry at the University of Minnesota, Dr. Schultz was obligated to ensure that both clinical practices and research practices within the Department of Psychiatry were conducted in a competent and ethical manner. (Pope (Schultz) para. 12) In addition Dr. Schultz was a co-investigator on the CAFÉ study and was obliged to avoid any conflicts of interest that might be caused by the fact that he was a co-investigator in this study. (Pope (S) para 13) Dr. Pope states that these standards of care apply to Dr. Schulz as the head of a Department of Psychiatry he must ensure that informed consent is being obtained in the CAFÉ study in an ethical manner. (Pope, S para 14) This duty was heightened even further

because he was also a co-investigator in the CAFÉ study. (Pope (S) pare14).

III Plaintiff's expert affidavits outline the chain of causation between the Defendant Doctors' breaches of the standard of care and Mr. Markingson's suicide with sufficient specificity to comply with the requirements of Minn. Stat. Sec. 145.682

The Minnesota Court of Appeals has stated that Minn. Stat. Sec. 145.682 was not meant to require plaintiffs to try their cases in pre-trial affidavits. *Klanderud-Overbaugh v. Unity Radiation Therapy Cente,* 2004 Minn. App. Lexis 535, 14(2004), citing *Demgen v. Fairview Hosp.*, 621 N.W.2d 259, 265 (Minn. App. 2001). Nor does the statute require every link in the chain of causation to be described and explained. (*Id*.) Minn Stat. Sec. 145.682, subd. 4(a) does not require an expert affidavit to refute adverse opinions. *Demgen*, 621 N.W.2d at 266.

Defendants Drs. Olson and Schulz claim that Dr. Pope's affidavits pertaining to Drs. Olson and Drs. Schulz fail to adequately explain the chain of causation between the violated standard of care and Dan Markingson's death and accuses Dr. Pope of simply espousing broad, conclusory statements regarding causation. The Defendant puts forth case law that tells the Plaintiff what is not sufficient. The Court of Appeals in the *Klanderud* decision tells plaintiff what affidavits are sufficient. In the *Klanderud*.case plaintiff appealed from summary judgment.when the district court found her expert affidavit insufficient. 2004 Minn. App. LEXIS 535, 2. The decedent received radiation as part of her treatment for breast cancer. *Id.* at 2. After the radiation, tissue in her chest eventually became necrotic and infected. *Id.* at 3. She died as a result. *Id.* at 3. The trustee for her next of kin brought a wrongful death action against her Doctor and the Hospital. *Id*. at 3. The Court of Appeals reversed and remanded the case

because they determined that the plaintiff's expert affidavit was sufficient. *Id.* at 19. The Court described the affidavit as follows:

> Dr. Littman's affidavit asserts that a treating radiation oncologist, upon learning of a possible radiation induced injury, would participate in an investigation of the cause and extent of the injury, would report their findings to the patient, would assist all treating medical providers with the best information available based upon their findings, and carefully explain to the patient the possible treatment options. Dr. Littman then accounted in detail how Unity employees inaction under the circumstances deviated from those standards. He noted that, but for respondents' failure to adequately investigate and manage Klanderud's injuries, her exposure to radiation would not have been fatal.

Id. at 10. the Court concluded that the report did more than the general disclosure the statute was designed to prevent. *Id.* at 10.

The chain of causation opinions set out by Dr. Pope are vastly more than sufficient covering several dozen pages of specific facts, detailed discussions of acts and omissions, and chains of causation explicating how defendants negligence was a substantial factor in causing Dan's untimely death. The Pope and Hudson affidavits are a national model of completeness and clarity. As discussed, Dr. Pope adequately sets out the standard of care for Dr. Olson both as a PI and a study investigator and as a treating physician. First, as a PI and study investigator, Dr. Olson is obliged to conduct psychiatric research on a human subject, Mr. Markingson, in a competent and ethical manner including having an independent physician obtain consent. He breached this standard by not getting adequate informed consent, ie threatening and coercing Dan

into the CAFÉ study from which Olson profited. The consent was not valid because 1) Dan Markingson lacked capacity to sign the consent.[1] (Pope para 22 A); 2) Jeannie Kenny who administered the informed consent was not medically qualified and also had a financial interest in the study, (Pope para 22 A); 3) Dan Markingson had no independent representation by a social worker until after he had entered the CAFÉ study; (Pope para. 22 A); 4) no independent observer was present at the informed consent signing to protect Dan as a vulnerable person, (Pope, para 22B); 5) Dr. Olson was both Dan's treating physician and study physician thereby creating undue pressure on Dan to sign the consent followed by undue, tainted pressure to retain Dan (the subject/patient) in the study to Dan's (subject/patient) detriment and Olson's profit via reputation and/or finances, (Pope, para. 22C); 6) Dr. Olson coerced Dan Markingson into signing the consent with threats of commitment, (Pope, para. 22 D); 7) In clear and rather brazen violation of the MN. Health Care Bill of Rights, the consent form did not set out <u>any</u> risks and benefits of alternative treatments, contained nothing about alternative antipsychotic medications, other independent physicians, or concomitant medications (Pope, Para.22E); 8) Dr. Olson's request to the Court on April 28, 2004, to extend Dan's stay of commitment was another clear indication that Dan was never competent to give continued consent to the study. (Pope, Para 22F); Dr. Olson exploited Dan as an impoverished institutionalized patient. (Pope, para. 22 G).

[1] It is disingenuous for Dr. Olson to argue that Dan Markingson's completed "Evaluation to Sign Consent" (See Ex 29) in any way establishes capacity because Dr. Olson had supplied a Examiner's Report in Support of Commitment on November 14, 2003 to Dakota County Court determining that Dan was incompetent. This conclusion was supported by the Prepetition Screening Report submitted to the Court on November 17, 2003. (See Ex. 12) That Statement resulted in an adjudication that Dan was mentally ill on November 20, <u>*just one day*</u> before he signed the informed consent. Further, Dr. Olson was financially motivated to manipulate Dan

If Dr. Olson had appropriately assessed and properly respected Dan Markingson's incapacity to sign the informed consent form, Dan Markingson would not have been coercively entered into the CAFÉ study that resulted in his death. Pope, para 24.) Alternatively, if Dan had been competent to sign the consent form, and then would have been appropriately informed about alternative treatments and about his freedom to decline study participation or to withdraw form the study he would have done so and would have done so before his suicide. As an obviously matter of logic, Dan was threatened with commitment because he would not have freely chosen to obey Dr. Olson. (Pope, para 24).

Dr. Pope's chain of causation continues. Dan's inappropriate entry into the study and inappropriate maintenance in the study seriously compromised his treatment for his serious psychotic disorder, leading to persistent untreated symptoms which were the essential link in the chain of causation to Dan's death. (Pope, para 25). Because of Dr. Olson's obvious and well documented conflict of interest, Dr. Olson had no incentive to refer Dan to another psychiatrist or to get a second opinion and therefore Dan was improperly retained in a study in which his health was grossly deteriorating. (Pope, para 25). Dan's participation in the study specifically prevented blood test confirmations that Dan was taking his medication which would have been a reasonable alternative given the Fairview and the Theo house had information that was at times cheeking his medication. (Pope, para 25.) The study protocol also prevented Dan from switching to alternative drugs. Dr. Olson was not motivated to try alternatives for Dan because the financial interest to retain Dan as a subject until the end of the year. (Pope, para. 27). Dr.

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into signing the consent. (Pope, para 22B).

Pope even mentions the benefits of another alternative, a liquid injectible drug that would ensure Dan was getting his medication. (Pope, para. 28).

Dr. Pope then appropriately completes the chain by stating that Dr. Olson failed to get a second opinion, failed to get a blood test and failed to try a different antipsychotic medication. These specific facts and references to specific acts and omissions, were violations of the standard of care that caused Dan to remain in an untreated, severely psychotic state which caused his horrific death by psychotic, ritualized, suicide on May 8, 2003.

Dr. Pope's affidavit also details the chain of causation concerning Dr. Olson failures as the Principal Investigator and study physician to engage in Good Clinical Practice as required by the standard of care in psychiatry as well as common sense. Again, Dr. Pope sets out the standard of care and then discusses the chain of causation. Good Clinical Practices require the PI and study physician to provide careful research that reflects sound clinical judgment while minimizing the risks of the study to the subject. (Pope, para 31). The specific facts demonstrate Dr. Olson failed (omissions) to provide the necessary care. He had virtually zero contact with Dan during the last, tragic, agonizing six months of Dan's life. Once Dan was put in the drug trial and began reaping subject payments for Olson's study, Olson forgot him. (Pope, para 32A). Dr. Olson saw Dan on December 8, 2003 and May 8, 2004. Then there was a third meeting with Dan and hiss mother on April 9, 2004. (Pope, para 32 A). Although Dr. Olson maintains he saw Dan more than just these three times, Olson's claim is not supported by any record. (Pope, para 32 A). The Pope affidavit points out that, at any rate, Dr. Olson did not monitor Dan closely but was an absent PI who delegated his work to unqualified assistants like Kenney. (Pope, para

32B). Dr. Olson then continues with this chain of causation by explaining that Dr. Olson's failure (omission) to recognize the severity of Dan's symptoms and failure to appropriately treat Dan (only 3 visits in months for a psychotic patient not taking any medication) was an essential and significant link in the chain of causation to Dan's death. (Pope, para 33 and 34). Further, Pope explains that Dr. Olson's failure to relay to the IRB any of the multiple written and oral complaints lodged by Ms. Weiss about Dan's inadequate care failed to trigger further inquiry which would have lead to the discovery of Dan's worsening condition and Dan's rescue. (Pope, para. 36). In turn this discovery would certainly have led to a change in care and prevention of Dan's suicide. (Pope, para 36). Dr. Pope also explains that if Dan had not been entered into the study Dr. Olson would have seen Dan on a much more regular basis as he did at Fairview during Dan's initial hospitalization. Dr. Olson's lack of direct contact with Dan caused him to completely miss the many signs and indications of Dan's mental deterioration and to fail (omissions) to make the appropriate changes to Dan's medical treatment to prevent Dan's unnecessary suicide. (Pope, para 37).

Finally, Dr. Pope explicitly opined on the link in the chain of causation between Dr. Olson's failure to abide by the standards of a care for a treating psychiatric physician and Dan's suicide. Dr. Olson had an obligation to do what was in the best interest of his patient Dan Markingson and be diligent in monitoring the patient's condition including Dan's medication usage. (Pope, para 39). Dr. Pope documented in detail specific warning signs that Dr. Olson simply missed because he was not providing proper care to Dan. These signs are set out thoroughly in the six bullet points contained in paragraph 41 of Pope's affidavit. (Pope, para

41). Pope also pointed out that Dr. Olson should have paid attention to Mary as she knew Dan best and spent the most time with him. She had the best data on Dan's progress and Olson ignored her thus missing yet another opportunity to rescue Dan. (Olson, para 42). Dr. Pope concludes his discussion about Dr. Olson's role as a treating physician by explaining that if Dr. Olson had simply monitored Dan Markingson's condition properly Dr. Olson would have made appropriate changes to Dan's treatment plan (e.g. injectable meds, liquid meds, change of meds, change to regular treatment schedule, paying more attention to mother's warnings, reviewing therapists notes, reviewing research documents showing deterioration, etc). Pope opined that to a reasonable degree of medical certainty, these many failures (the many detailed and documented acts and omissions above) clearly were a substantial factor in the chain of causation of Mr. Markingson's suicide. (Pope, para 43). Dr. Pope notes that proper monitoring would have led to changes in Dan's treatment plan to include rehospitalization. (Pope, p. 38). Pope concludes, that "Dr. Olson's failure to change Mr. Markingson's treatment in any significant way, despite all of these warnings, was a highly significant and essential link in the chain of causation that produced Mr. Markingson's suicide." (Pope, para 44).

Dr. Schulz. As in Dr. Pope's affidavit regarding Dr. Olson, Dr. Pope's affidavit regarding Dr. Schulz is extremely detailed and greatly exceeds the requirements of Minn. Stat. 145.682. Plaintiff will address defendant's specific points pertaining to the affidavits regarding Dr. Schulz. Dr. Shultz was the chairman of the Department of Psychiatry at the University of Minnesota at the time Dan Markingson was enrolled in the Café' study. (Pope S 12) Thus, Dr. Schulz was obligated to ensure that both clinical practices and research practices within the Department of

Psychiatry were conducted in a competent and ethical manner. (Pope S 12) Additionally Dr. Schultz was a co-investigator and therefore was obliged to avoid any conflict of interest that might be caused by this fact. (Pope S 13)

Defendant again argues that Pope's references to international documents that form supportive bases for the standard of care in psychiatry somehow magically make the standard inapplicable. This argument has previously been addressed and refuted and the standard of care as set out by Dr. Pope involving clinical experience, professional judgment and appropriate documentation and guidelines is not only appropriate but again the gold standard, model approach.

Dr. Pope opined that Dr. Schultz breached his duty when he failed to ensure that Dr. Olson obtained valid consent within ethical guidelines. Dr. Pope's affidavit regarding Dr. Olson firmly established that there was no valid, ethical informed consent from Dan. (Pope S para 19) Even though he was the co-investigator on the study as well as the Chairman of the Department, is no evidence that Dr. Schulz took any action whatsoever to investigate or correct the violations. (Pope para 19). Defendant Doctors attack this statement as mere conclusion. Yet, if Dr. Schulz took no action to ensure that informed consent was being obtained appropriately then he was violating his duty to oversee his department to ensure the safety of Dan Markingson. (Pope, Para 19). If the Chairman of the Department and co-investigator has no duty to oversee then who does? Defense would like a world where This is the violation. Dr. Pope then makes reference to the chain of causation already set out in the Olson affidavit. In other words, Dr. Schulz's breach failed to prevent or correct Dr. Olson's breach and therefore Dan Markingson

committed suicide. (Pope Para 23-25).

Further, Dr. Pope points out that, as the head of the department and as a co-investiagtor, Dr. Schultz must abide by Good Clinical Practice for the safety and benefit of the subjects. (Pope Aff para 27). Dr. Schulz was informed by Ms. Weiss on three occasions, by letter that Dan's health was deteriorating and he was informed that Dan had virtually no contact with his treating physician Dr. Olson. (Pope Aff. Para 30-31). Dr. Shulz should have reasonably understood that this lack of contact was detrimental to Dan Markingson health. (Schulz, para 33). Dr. Pope then places Dr. Schulz's breach of his to duty ensure good clinical practices into the chain of causation. "[B]ecause of the lack of good clinical practice in the study, the study personnel failed to recognize the severity of Mr. Markingson's persistent psychotic symptoms and therefore failed to treat these symptoms. If these symptoms had been appropriately treated, then to a reasonable degree of medical certainty Mr. Markingson would not have committed suicide. (Pope, Para 34). Dr. Schulz also did not take proper action with respect to reporting complaints about the CAFÉ study he received from Mary Weiss to the IRB. (Pope aff 38, 41-42).

Although defendants state Dr. Schulz has no obligation as a clinical physician to Dan Markingson, Dr. Pope points out that he has an obligation to Dan Markingson as the department head and respond to complaints about the clinical care of patients being treated in his department. (Pope, para Sec 43)

HORTON AND WOLPE AFFIDAVITS

Plaintiffs expert, Keith A. Horton, M.D., is a licensed and Board Certified psychiatrist

who has practiced in Minnesota and served on the faculty of the University of Minnesota for decades. Dr. Horton is a member of the same profession working with the same kinds of patients using the same kinds of medications, in the same kinds of institutions as the defendants in this action. Dr. Horton examined many documents and files in this case including hospitalization, treatment, research, and related records of Dan Markingson. All of Dr. Horton's opinions are offered to a reasonable degree of psychiatric certainty.

Standards: Dr. Horton's opinions are offered to a reasonable degree of medical certainty and are based on a number of well accepted standards of care including A) international guidelines, rules, and Declarations (Helsinki, the Belmont Report), B) an entire federal website www.hhs.gov/ohrp/faq.html listing a number of appropriate biomedical standards, rules, regulations and aids, C) the University of Minnesota guidelines, rules and regulations as published on their website D) the American Psychiatric Association's Code of Ethics, and E) Dr. Horton's knowledge, training, and experience in the filed of psychiatry. Dr. Horton notes, as did other experts, that international rules forbid a psychiatrist engaging in conflicts of interest and maintaining excessive, coercive power over vulnerable patients as Dr. Olson did in this case.

Olson's violations: Upon reviewing these many files and records, Dr. Horton agrees with Drs Pope and Hudson that Dr. Olson violated many important standards of care. Violation One – need for independent consent assessment: Dr Horton agrees with national and international standards that psychotic patients like Dan Markingson are entitled to special protections from the kind of coercion, manipulation and abuse so clearly demonstrated by Dr. Olson in this case.

As indicated on the U of Mn's own website Olson should have had an independent physician obtain informed consent for Olson's research study when interviewing Olson's own vulnerable patients. To prevent patient abuse, manipulation, or injury, international standards require that the physician obtaining informed consent for a research study may NOT be the subject's main treating physician. Dr. Olson violated this clear and simple standard of care (see cites above) which caused Dan to enter the Cafe study. Violation Two – improper, abusive, coercive roles: Dr. Horton opined, "I have never before in my career seen a case record in which one physician has assumed so many invasive, conflicting, life-controlling, legally enforced, boundary violating roles in the treatment of a psychiatric patient." Violation three – insufficient contact for treatment: Dr. Horton noted, "I also understand that Dr. Olson's treatment contact with Dan Markingson during the time Dan was in the research study was very minimal, no more than a few hours over a multi-month period." These few hours were insufficient monitoring of Dan's very severe problems. Violation four – treatment by threat: Dr Horton found the treatment plan from Riverside (Olson Depo, Exh 13) an abusive way to organize treatment and research and far below the standard of care which require respect for the rights of others. Violation five – ignoring family members' warnings that Dan was untreated and dangerous: Psychiatrists have a duty to obtain corroborating information from the patient's family members. In this case, Mary Weiss offered repeated warnings, some in writing, of Dan's deterioration and risk of harm. Olson rudely and coldly ignored. (Depo of M. Weiss).

Harm caused by Dr. Olson by violations of the standard of care: With regard to the

coercive, abusive roles, insufficient time spent, threat to enter research study and other violations of the standards of care, Dr. Horton opined, "Olson's negligent (abusive, disrespectful) care predictably caused a severe psychotic regression manifested by increasing "negative symptoms", refusal of medication (treatment resistance), and other reactions to this unavailable but incredibly powerful doctor. Olson's negligent care predictably led to Dan's deterioration, treatment resistance, rage (anger at abusive treatment), and other complications that were predictable, foreseeable, and substantial factors in causing the death of Dan Markingson. With regard to ignoring Mary Weiss's warnings that her son was untreated, deteriorating, and in danger, Dr. Olson's negligence here was the direct cause of Dan's death. Obviously, had Dan been properly monitored injectable medications, hospitalization, improved therapy or other methods could easily have saved him but instead Olson's neglect led to a slide into psychosis then suicide. Dr. Olson's cold ignoring of a very troubled patient and the patient's mother was the direct cause of Dan's death by a psychotic suicide ritual. Suicide is more common in schizophrenics than the normal population but still relatively rare, thsu but for, Olson's rage inducing coercion and neglect, ignoring so many warnings, Dan Markingson would be alive today.

Chain of causation: Dr. Horton concluded that, "To a reasonable degree of psychiatric certainty, Olson's negligent coercive mistreatment, abusive violations of Mr. Markingson's rights including his right to informed consent and other rights, ignoring the dire warning of Mary Weiss and other errors were all substantial factors the chain of causation leading from Olson's coercive methods of obtaining legal control over Dan, thus causing Dan Markingson's rage, refusal to take

medications, exacerbated psychosis, and causing Dan's untimely death by psychotic ritual suicide."

4. Summary Judgment is not warranted when plaintiffs have presented the Court with adequate affidavits pursuant to Minn Stat. Sec. 145.682.

As previously argued plaintiffs affidavits more than fulfill the obligations of Minn Stat. Sec.145.682. Therefore, plaintiffs have presented the court a prima facie case of medical malpractice against defendants Drs. Olson and Shulz and summary judgment is not warranted. Further, Minnesota Statute Sec. 145.682 Subd. 6 (C) states failure to comply with subdivision 4 because of deficiencies in the affidavits or answers to interrogatories results, upon motion , in mandatory dismissal with prejudice of each action as to which expert testimony is necessary to establish a prima facie case, provided that: ….(3) before the hearing on the motion, the plaintiff does not serve upon the defendant an amended affidavit or answers to interrogatories that correct the claimed defect. Plaintiff has provided what we view as the national gold standard for expert affidavits in this case. Nonetheless, with an abundance of caution and given the draconian possibilities and the changing law in this area, plaintiffs attach an additional affidavit from Dr. Pope (Exh ____) intended to answer claimed deficiencies, clarify important issues, and assist the court. Under Minnesota Statute Sec. 145.682 Subd. 6 (C), plaintiff reserves the right to serve additional affidavits at any time prior to the hearing of this matter.