STATE OF MINNESOTA
COUNTY OF HENNEPIN

DISTRICT COURT
FOURTH JUDICIAL DISTRICT

Mary Weiss, on her own behalf, and as Next-of-Kin and Trustee of the estate of Dan Markingson, deceased,

Plaintiff,

v.

Board of Regents for the University of Minnesota; Dr. Stephen C. Olson; Dr. Charles Schulz; Institutional Review Board for the University of Minnesota; AstraZeneca Pharmaceuticals LP; AstraZeneca LP; and Zeneca Inc.,

Defendants.

Court File No. 27-CV-07-1679

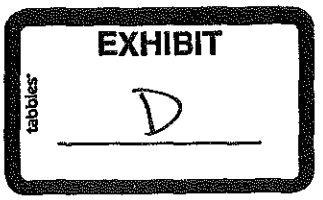
ORDER & MEMORANDUM GRANTING PARTIAL SUMMARY JUDGMENT

The above-entitled matter came before The Honorable John L. Holahan on December 11, 2007, pursuant to Defendants' motions for summary judgment; Defendants' motion to strike several of Plaintiff's exhibits; and Plaintiff's motion to add a claim for punitive damages.

Gale Pearson, Esq. and Stephen Randall, Esq., of Pearson, Randall & Schumacher, P.A., 1012 Grain Exchange Building, 400 South Fourth Street, Minneapolis, MN 55415, appeared on behalf of Plaintiff, on her own behalf, and as Next-of-Kin and Trustee of the estate of Dan Markingson, deceased.

Linda Svitak, Esq., of Faegre & Benson, 2200 Wells Fargo Center, 90 South Seventh Street, Minneapolis, MN 55402-3901, and Earl Austin, Esq., of Baker Botts LLP, 2001 Ross Avenue, Dallas, Texas 75201-2980, appeared on behalf of AstraZeneca LP, AstraZeneca Pharmaceuticals LP, and Zeneca Inc.

Charles Gross, Esq., and David Hutchinson, Esq., of Geraghty, O'Loughlin & Kenney P.A., Alliance Bank Center, Suite 1100, 55 East Fifth Street, St. Paul, MN 55102-1852, appeared on behalf of the Board of Regents for the University of Minnesota and the Institutional Review Board for the University of Minnesota.



Angela Nelson, Esq., of Gislason & Hunter LLP, 701 Xenia Avenue South, Suite 500, Minneapolis, MN 55416, appeared on behalf of Dr. Stephen C. Olson and Dr. Charles Schulz.

Based upon the files, records, and proceedings herein, and being fully informed in the premises, the Court makes the following:

ORDER

1. AstraZeneca's motion to strike the Second Affidavit of Harrison Pope is granted to the extent Plaintiff intended to use the affidavit against AstraZeneca in connection with the motion to add a claim for punitive damages.
2. All motions by Defendants to strike exhibits in connection with Plaintiff's motion to add a claim for punitive damages are denied.
3. The motion for summary judgment by the Board of Regents for the University of Minnesota and the Institutional Review Board for the University of Minnesota is granted on the basis that they are statutorily immune from liability. All claims against both parties are dismissed with prejudice.
4. The motion to dismiss and for summary judgment by Dr. Stephen Olson is granted with respect to Count 2.
5. The motion to dismiss and for summary judgment by Dr. Charles Schulz is granted. All claims against Dr. Schulz are dismissed with prejudice.
6. The motion for summary judgment by AstraZeneca LP, AstraZeneca Pharmaceuticals LP, and Zeneca Inc. is granted. All claims against them are dismissed with prejudice.
7. Plaintiff's motion to add a claim for punitive damages is denied.
8. The accompanying memorandum is made part of this order.
9. Copies of this order shall be dispatched to party representatives which shall constitute proper service for all purposes.

Dated: February 11, 2008

The Honorable John L. Holahan
Judge of Hennepin County District Court

MEMORANDUM

Facts

Around the spring or summer of 2003, Dan Markingson, a 26-year-old celebrity-tour-bus driver in Los Angeles, began demonstrating dramatic symptoms of schizophrenia. Plaintiff is Markingson's mother. In August of 2003, after a long period of isolation from her son, Plaintiff visited Markingson in California. Instead of a thriving son, Plaintiff found a mentally ill individual whose life had deteriorated into a series of delusions. Markingson believed his family, including Plaintiff, belonged to the "Illuminati" and was keeping secrets from him. He thought an alien had burned a spot on his carpet, and he had arranged wooden posts around his bed to create an "astral field."

Markingson also believed "he was to play a special role in the new world order," which would require him to kill people in an upcoming "ultimate storm." Plaintiff, desperate to get Markingson to move back to Minnesota with her, manipulated this particular delusion by posing as angels, including the spirit of Markingson's deceased grandmother, who communicated with Markingson via email. Markingson wrote of being called to kill people in the "ultimate storm," and Plaintiff, through her angel personas, tried to convince Markingson that the storm would happen in Minnesota. The ruse worked and Markingson returned to Minnesota.

On November 12, 2003, Markingson told Plaintiff's live-in boyfriend that his role in a satanic ritual in Duluth would require him to slit his mother's throat. Markingson was taken to Regions Medical Center for an evaluation of psychiatric symptoms. He was subsequently transferred to Fairview University Medical Center Hospital, Riverside Campus (FUMC). He was admitted to the hospital and placed under the care of Dr. Stephen Olson, a psychiatrist with the University of Minnesota Department of Psychiatry.

Dr. Olson completed an Attending Physician Statement for the Court on November 14, 2003, in which he opined that Markingson was mentally ill and lacked the capacity to make decisions regarding his medical treatment. Commitment proceedings were initiated against Markingson in Dakota County. Those proceedings were stayed by a Judge of District Court on November 20, 2003, on the condition that Markingson comply with a treatment plan. Although the Court found that Markingson was "mentally ill and in need of

treatment," the Court made no judicial determination that Markingson was incompetent; nor did it appoint a legal guardian to handle Markingson's affairs.

The following day, Markingson signed a consent form agreeing to participate in a clinical research study (hereinafter Café Study) that compared three FDA-approved antipsychotic drugs. The consent form consisted of ten pages that provided basic information relating to potential conflicts of interests of investigators; the background of research studies; the purpose of the Café Study; the description of the Café Study; risks and inconveniences of the Café Study; possible benefits to participants; alternative treatments; compensation for adverse events; payment for participation; expenses; the voluntary nature of the Café Study; confidentiality; contact information for further inquiry; and the right of a patient to withdraw and terminate the study. Two days later, Markingson began participating in the study.

Dr. Olson was the Principal Investigator for the Café Study. The study was not an experimental study. In fact, by the time of the study, all three drugs had been approved by the Food and Drug Administration (FDA) as safe and effective for the treatment of schizophrenia. One of the drugs was Quetiapine, sold under the trade name Seroquel. The study was funded by AstraZeneca,[1] the manufacturer of Seroquel, and it was conducted through the Department of Psychiatry. Dr. Charles Schulz is head of the department and is a paid consultant of AstraZeneca. Dr. Schulz saw Markingson as a patient on one occasion, November 29, 2003. The University of Minnesota Institutional Review Board (IRB) approved and supervised the study.

Markingson continued inpatient treatment at FUMC for two weeks. On December 8, 2003, Markingson was discharged from FUMC and released to the Boston Theo House, a halfway house for the mentally ill. Dr. Olson was the physician identified to monitor Markingson.

Markingson's mental illness became progressively worse throughout the study. Plaintiff warned Dr. Olson and Dr. Schulz of her sons deteriorating condition on multiple occasions and only Dr. Schulz ever responded. Plaintiff believes her warnings were ignored. In April 2004, Plaintiff called her son's caregivers pleading for help and asking something to the effect, "What does my son have to do, hurt himself?" On May 8, 2004, exactly five

[1] All references to "AstraZeneca" include, as appropriate, AstraZeneca LP, AstraZeneca Pharmaceuticals LP, and Zeneca Inc.

months after being discharged from FUMC, Markingson expired on his own volition. Autopsy results reported no study medication in Markingson's system at the time of death.

In January 2007, Plaintiff filed a Complaint against Defendants alleging the following nine counts: (1) medical negligence against Dr. Olson, Dr. Schulz, the IRB, and the Board of Regents; (2) negligence against Dr. Olson, Dr. Schulz, the IRB, and the Board of Regents for failing to obtain informed consent (under the Minnesota Patient's Bill of Rights); (3) negligence against AstraZeneca for overstating the benefits of Seroquel and minimizing and downplaying the risks; (4) negligence against AstraZeneca for failing to warn physicians and patients of the serious risks associated with Seroquel; (5) a violation of the Minnesota Consumer Protection Statutes by AstraZeneca for failing to disclose certain material facts and information that caused the death of Markingson; (6) consumer fraud against AstraZeneca because it knew, and failed to disclose that Seroquel was associated with serious side effects, thereby misleading treating physicians and patients; (7) unlawful trade practices against AstraZeneca for marketing and advertising Seroquel as a safe and effective drug when it knew, and failed to disclose, that Seroquel was associated with serious risks and side effects; (8) breach of implied warranties against AstraZeneca; and (9) breach of an express warranty of merchantability against AstraZeneca.

Six motions are now before the Court. First, AstraZeneca has requested that the Second Affidavit of Dr. Harrison Pope be stricken on the grounds that it violated the deadlines for expert disclosures and violated Rules 115.04(a)(3) and 115.04(c) of the General Rules of Practice. Second, the Board of Regents and the IRB moved to strike certain exhibits to Plaintiff's motion to add a claim for punitive damages, and the remaining Defendants subsequently joined in the motion and included additional exhibits to strike. Third, the Board of Regents and the IRB have moved for summary judgment. Fourth, Dr. Olson and Dr. Schulz have moved to dismiss the Complaint pursuant to Minn. Stat. § 145.682 and for summary judgment. Fifth, AstraZeneca has moved for summary judgment on all claims. Sixth, Plaintiff has moved to amend the Complaint to add a claim for punitive damages against all Defendants.

For reasons set forth below, all claims are dismissed except Plaintiff's medical negligence claim (Count 2) against Dr. Olson.

Standard of Review

Summary judgment shall be rendered "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with any affidavits, if any, show that there is no genuine issue as to any material fact and that either party is entitled to a judgment as a matter of law." MINN. R. CIV. 56.03. A fact is material if it would affect the result or outcome of the case depending on its resolution. Zappa v. Fahey, 245 N.W.2d 258, 259-60 (Minn. 1976).

The sole function of the trial court on motion for summary judgment is to determine whether an issue of material fact exists to be tried, and not to weigh evidence or resolve issues of fact. Anderson v. Twin City Rapid Transit Co., 84 N.W.2d 593, 605 (Minn. 1957) (stating, "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."); *see also* Murphy v. Country House Inc, 240 N.W.2d 507, 512 (Minn. 1976). But, "[w]here the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party," no genuine issue for trial exists. DLH, Inc. v. Russ, 566 N.W.2d 60, 69 (Minn. 1997) (alteration in original) (quoting Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986)). In other words, "where reasonable minds can arrive at only one conclusion," questions of fact may be transformed into questions of law for the court to decide. Lubbers v. Anderson, 539 N.W.2d 398, 402 (Minn. 1995) (citing Wartnick v. Moss & Barnett, 490 N.W.2d 108, 115 (Minn. 1992)).

A non-moving party must present affirmative, probative evidence tending to support every essential element of a cause of action to defeat a motion for summary judgment. Carlisle v. City of Minneapolis, 437 N.W.2d 712, 715 (Minn. Ct. App. 1989). A party may not rely on mere averments made in pleadings or upon unsupported allegations of fact. Musicland Group, Inc. v. Ceridian Corp., 508 N.W.2d 524, 530-31 (Minn. Ct. App. 1993). The evidence should be viewed in the light most favorable to the non-moving party, and doubts and factual inferences must be resolved in their favor. Vieths v. Thorp Finance Co., et al., 232 N.W.2d 776, 778 (Minn. 1975); Nord v. Herreid, 305 N.W.2d 337, 339 (Minn. 1981).

Motions to Strike Affidavits and Exhibits

AstraZeneca is moving to strike the Second Affidavit of Harrison Pope to the extent Plaintiff intends to use the affidavit against AstraZeneca in connection with her motion to add a claim for punitive damages.[2] The affidavit was submitted simultaneously with Plaintiff's Reply brief. The Court will grant this motion, limited in scope, as the General Rules of Practice do not expressly permit the submission of exhibits or affidavits with reply briefs. *See* MINN. GEN. R. PRAC. 115.04(c).

The Board of Regents and the IRB have also moved to strike certain exhibits to Plaintiff's motion to add a claim for punitive damages. The remaining Defendants subsequently joined in the motion and moved to strike additional exhibits. Defendants argue that the objectionable exhibits were presented with an intent to harass the parties and overburden the Court with documents that are immaterial, irrelevant, unduly prejudicial and designed to confuse the issues, in contravention of Minn. R. Civ. P. 11.02(a) and (c), and Minn. Stat. § 549.211, subd. 2(1) and (3). Plaintiff, aside from objecting to the substance of Defendants' arguments, objects to AstraZeneca's motion practice with respect to its motion to strike. The Court denies all motions to strike, but the Court did not rely on the objectionable exhibits to resolve the issues before the Court. Moreover, Plaintiff should not assume from this ruling that any or all of these exhibits would be admissible at trial, particularly certain media exhibits. Lastly, counsel should note that the failure to cite references within lengthy documents is poor craft, serves no one, and may not only fail to support one's argument, but may in fact undermine it.[3]

Motion for Summary Judgment by the University of Minnesota

The Board of Regents and the IRB have moved for summary judgment on multiple grounds. First and foremost, they argue that they are immune from liability. As a general

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[2] The affidavit, itself, states that it is directed at Dr. Olson's and Dr. Schulz's motion to dismiss, not Plaintiff's motion to add a claim for punitive damages.

[3] In the same vein, the Court notes that, due to the nature of certain briefs in this case, the Court was required to expend valuable time and resources stripping hyperbole from argument, attempting to locate legal authorities for uncited propositions, deciphering abnormally ambiguous allegations, and attempting to correlate general arguments to particular claims. These ambiguities, understandably, spawned further ambiguities in responsive briefs.

rule, since the Minnesota Legislature enacted the Tort Claims Act in 1976,[4] the state of Minnesota, including the University, has been subject to tort liability. *See* MINN. STAT. § 3.736, subd. 1; MINN. STAT. § 3.732, subd. 1(1) (defining "state" to include the University of Minnesota). At the same time, the Legislature has provided numerous exceptions to this general rule. *See* MINN. STAT. § 3.736, subd. 3(a)-(r). The state and its employees are immune, for example, for any "loss caused by the performance or failure to perform a discretionary duty...." MINN. STAT. § 3.736, subd. 3(b). This "discretionary" exception has been characterized by the Minnesota Supreme Court as "statutory immunity." Janklow v. Minnesota Bd. of Exam'rs, 552 N.W.2d 711, 716 (Minn. 1996). Statutory immunity applies to policymaking or planning-level activities, as opposed to operational activities.[5] *See* Nusbaum v. County of Blue Earth, 422 N.W.2d 713, 722 (Minn. 1988). Whether immunity applies is a question of law and is appropriate for resolution on motion for summary judgment. Johnson v. State, 553 N.W.2d 40, 45 (Minn. 1996). The party asserting immunity has the burden of demonstrating its application. Rehn v. Fischley, 557 N.W.2d 328, 333 (Minn. 1997).

The first step in a statutory immunity analysis is to "identify and focus on the precise governmental decisions being challenged." Norton v. County of Le Sueur, 565 N.W.2d 447, 450 (Minn. Ct. App. 1997). The core decisions at issue relate to the IRB's review, approval, and monitoring of the Café Study, particularly with respect to the informed consent process.[6] The IRB argues that its conduct was policymaking or planning-level activity and thus immune from liability. Plaintiff argues that the IRB's conduct cannot be characterized as discretionary because federal regulations governed and dictated the IRB's actions.

The Court has conducted exhaustive research on the issue, and it has been unable to find a single case in any jurisdiction involving similar claims against an IRB, let alone the potential applicability of immunity under an analogous Tort Claims Act. In fact, the Court

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[4] The discretionary function exception is also present in the Federal Tort Claims Act, 28 U.S.C. § 2680(a), and consists of virtually identical language to that used in Minn. Stat. § 3.736, subd. 3(b).

[5] Plaintiff alleges that "the critical determination is whether the nature of the official actions is discretionary or ministerial." (Pl.'s Mem. Opp. at 18.) This is incorrect. The distinction between discretionary and ministerial functions applies only to official immunity, not statutory immunity.

[6] Presumably, the IRB's actions are imputed to the Board of Regents, but Plaintiff has failed to articulate the precise relationship between the Board of Regents and the IRB.

has found only four cases nationwide in which an IRB has been sued at all.[7] Only two such cases have been published, and every case was in federal district court. In no case has an IRB been sued for negligence. This appears, therefore, to be a matter of first impression.

On November 20, 1985, Congress passed the Health Research Extension Act of 1985. PUB. L. NO. 99-158, 99 Stat. 820 (codified as amended at 42 U.S.C. § 289 *et seq.*). The act required the Secretary of Health and Human Services (HHS) to promulgate regulations to govern particular research projects or programs involving the conduct of biomedical or behavioral research of human subjects. The act stated, *inter alia*:

> The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that it has established . . . a board (to be known as an 'Institutional Review Board') to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research.

42 U.S.C.A. § 289. The Secretary subsequently promulgated such regulations that did, in fact, confer certain non-discretionary obligations on IRBs. *See* Protection of Human Subjects, 45 C.F.R. § 46 *et seq.* These regulations dictate, among other things, IRB membership composition (45 C.F.R. § 107), written procedures (45 C.F.R. § 108(a)), and basic elements of informed consent documents and procedures (45 C.F.R. § 46.116).[8] With regard to these general dictates, Plaintiff is correct in stating that, "[w]hether or not to comply with such requirements is not discretionary." (Pl.'s Mem. Opp. Univ. Summ. J. at 20.)

In addition to these non-discretionary duties, however, the federal regulatory scheme also confers particular spheres of discretionary authority on IRBs, including demarcating the outer limits of the informed consent process. According to the regulations, "[t]he IRB may require that information, in addition to that specifically mentioned in § 46.116, be given to

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[7] *See e.g.*, Mason, By and Through Mason v. Inst. Rev. Bd. for Human Research, Medical Univ. of South Carolina, 953 F.2d 638 (C.A.4 (S.C.) 1992) (Unpublished); Sterling v. Univ. Medical Ctr., 2006 WL 859252 (S.D. Miss. 2006) (Not reported); Marinoff v. City College of New York, 357 F.Supp.2d 672 (S.D.N.Y. 2005); Halikas v. Univ. of Minnesota, 856 F.Supp. 1331 (D.Minn. 1994). Note: These research results may not account for other unpublished opinions, such as state district court proceedings.

[8] The regulations grant IRBs authority to depart from these basic elements under certain circumstances. *See* 45 C.F.R. § 116(d).

the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects." 45 C.F.R. 46.109(b). This provision explicitly vests IRBs, therefore, with discretion to depart from federal baseline standards by providing research subjects greater protection. The decision whether or not to depart from such standards, itself, is fundamentally a policy-making decision. It necessitates line-drawing with respect what protections should be afforded research subjects in light of risks associated with research studies. This type of risk analysis is a key function of IRBs in implementing federal regulations. IRBs are directed to exercise judgment to ensure that risks "are reasonable in relation to anticipated benefits," 45 C.F.R. § 46.111(2), and to *minimize* those risks "[b]y using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk...." 45 C.F.R. § 46.111(1).

Furthermore, IRBs are expected "to ascertain the acceptability of proposed research in terms of institutional commitments and...standards of professional conduct and practice." 45 C.F.R. § 46.107(a). They are required to make "equitable" assessments of subject selection by accounting for "the purposes of the research and the setting in which the research will be conducted." 45 C.F.R. § 46.111(3). These responsibilities do not merely require mechanical application of regulations, but rather keen judgment in terms of weighing local priorities. It is for this reason that federal regulations require IRBs to be "sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects." 45 C.F.R. § 46.107(a).

Moreover, although not determinative, the HHS has issued informal guidance for IRBs that further demonstrates the spheres of discretion that federal regulators have conferred on local IRBs. For example, the IRB has attached as Exhibit F a chapter from the "Institutional Review Board Guidebook," downloaded from the HHS website, which details the type of discretionary decision-making responsibilities of the IRB. Most notably, the Guidebook defines the risk to be weighed by the IRB as "[t]he probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study." (Univ. Mem. Supp. Summ. J., Ex. F at 1.) By definition, therefore, IRBs are responsible for accounting for societal impacts in reviewing, approving, and monitoring

research studies. These are precisely the types of considerations that the Minnesota Supreme Court previously determined to be within the scope of activity insulated from judicial review. *See* Holmquist v. State, 425 N.W.2d 230, 231-32 (Minn. 1988) ("It is...the evaluation and weighing of social, political, and economic considerations underlying public policy decisions...which invokes the discretionary function exception affording governmental immunity.").

Based on the foregoing, the Court concludes that the IRB's decisions at issue involved the type of discretionary functions that are protected under the meaning of the Tort Claims Act. Thus, the IRB and the Board of Regents are statutorily immune from liability. Plaintiff's claims against the Board of Regents and the IRB are dismissed with prejudice.

Motion to Dismiss and for Summary Judgment by Doctors

Count 1

In Count 1, Plaintiff alleges medical negligence against Dr. Olson and Dr. Schulz for failing to provide "proper care and treatment." Both doctors have moved to dismiss the Complaint on the grounds that Plaintiff failed to satisfy the requirements for expert affidavits as set forth under Minn. Stat. § 145.682. Specifically, the doctors argue that Plaintiff's expert affidavits fail to state the authoritative standard of care or to provide specific details outlining the chain of causation between the doctors' alleged negligence and Markingson's suicide.[9]

To resolve this particular issue, the Court must decide whether the information provided in the expert affidavits is sufficient under Minn. Stat. § 145.682. The statute requires that, in any action alleging medical malpractice requiring expert testimony, a plaintiff must submit an affidavit of expert review. MINN. STAT. § 145.682, subd.2. The affidavit must contain "the substance of the facts and opinions to which the expert is expected to testify, and a summary of the grounds for each opinion." MINN. STAT. § 145.682, subd.4(a).

[9] The doctors have also raised various legal arguments in their Reply brief that were not raised (or should have been raised) in their initial brief, and were not raised by Plaintiff's responsive memorandum. Rule 115.03(c) of the General Rules of Practice limits matters raised in Reply briefs to "new legal or factual matters raised by an opposing party's response to a motion...." Otherwise, the moving party could advance arguments without rebuttal from the other side. As a result, the Court disregards the Doctors' new arguments raised in the Reply brief.

Failure to comply with these requirements results in "in mandatory dismissal with prejudice of each action as to which expert testimony is necessary to establish a prima facie case." MINN. STAT. § 145.682, subd.6(c). But in 2002, the Legislature amended the statute to negate mandatory dismissal where a plaintiff serves a defendant with an amended affidavit prior to a hearing on the matter. MINN. STAT. § 145.682, subd.6(c)(3). In effect, the amendment blunted the previously harsh effects of an initial inadequate affidavit.[10]

Plaintiff retained Dr. Harrison Pope to provide expert testimony regarding the alleged negligence of Dr. Olson and Dr. Schulz. Dr. Pope, a licensed psychiatrist and professor of psychiatry at Harvard Medical School, has submitted two affidavits (both prior to the hearing on this matter). The First Affidavit was cloaked in broad, conclusory, and often grandiose verbiage relating to standards of care and causation. Aside from references to the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report—none of which directly related to the specific standard of care in this case—Pope concluded, "Dr. Olson was obliged to conduct psychiatric research on a human subject...*in a competent and ethical matter* [sic]." (Pope Aff. at 11 (emphasis added).) Again, "Dr. Olson was obligated to offer *competent and ethical clinical care* to his patient." (Pope Aff. at 11. (emphasis added).) Such conclusory statements appear to fall short of the requirements for expert affidavits as described in *Teffeteller v. Univ. of Minnesota*, 645 N.W.2d 420 (Minn. 2002).

After the Doctors objected to the content of the First Affidavit, however, Dr. Pope submitted a Second Affidavit, which occurred prior to the hearing in this case. The Second Affidavit more clearly sets forth not only the standard of care, but also the purported chain of causation. It states, among other things, that the Doctors failed to monitor Markingson's treatment compliance and failed to note and act upon multiple, independent sources of evidence that Markingson was not taking medication and remained "floridly psychotic." (Pope Second Aff. at 25.) It also states that the doctors failed "to properly inform Dan Markingson of the risks and benefits of alternative treatments." (Pope Second Aff. at 8.) With regard to causation, the Second Affidavit states that by withholding information on the risks and benefits of alternative treatments and the risk of suicide, Defendants "caused Dan

[10] Defendants quote from *Lindberg v. Health Partners, Inc.*, 599 N.W.2d 572 (Minn. 1999), for the proposition that an inadequate affidavit results in mandatory dismissal "and while we certainly recognize that the statute may have harsh results in some cases, it cuts with a sharp but clean edge." (Doctors' Mem. Supp. Dismissal and Summ. J. at 18.) But this case predated the Legislature's 2002 amendment and, therefore, has been superseded. Strangely, Plaintiff makes no mention of this.

to enter a drug study in which he was inadequately monitored, untreated, with this lack of treatment causing his psychosis to persist, thus causing his death by ritualistic, psychotic, suicide." (Pope Second Aff. at 11.) The Court finds these affirmations to be sufficiently detailed with regard to Dr. Olson under Minnesota statutes.

With regard to Dr. Schulz, however, Plaintiff has advanced insufficient evidence to support the medical negligence claim. Dr. Schulz saw Markingson on one occasion, November 29, 2003. There is no evidence that the physician-patient relationship subsisted beyond that date. No expert affidavit has been submitted that is critical of the care provided by Dr. Schulz in that single visit. Without expert support, the medical malpractice claim against Dr. Schulz must fail.

Count 2

In Count 2, Plaintiff alleges negligence against the doctors for failing to obtain Markingson's informed consent by not informing him of the voluntary nature of the study, any conflicting interests of the researcher, or the risks associated with the study. Count 2 must be dismissed, however, based on several undisputable facts. First, Plaintiff has advanced no evidence indicating Markingson was deemed legally incompetent by a Court.[11] Second, Markingson signed the informed consent document at issue. Third, the informed consent document informed Markingson of the voluntary nature of the study, any conflicting interests of the researcher, and the risks associated with the study. These facts dispose of Count 2 with respect to all Defendants.

Motion for Summary Judgment by AstraZeneca

Plaintiff has asserted seven counts against AstraZeneca based on two apparent theories: study-sponsorship and product-liability. In Count 3, Plaintiff asserts a claim for negligence relating to AstraZeneca's sponsorship of the Café Study. In Counts 5, 6, 7, 8, and 9, Plaintiff has alleged various product-liability claims including failure to warn (Count 4), violations of consumer protection statutes (Counts 5-7), and breaches of warranties (Counts 8-9). AstraZeneca has moved for summary judgment on all claims. AstraZeneca

[11] Plaintiff seeks merely to impute the medical judgment of a doctor to a level of legal significance. This is insufficient.

and Plaintiff both agree that "to prevail on any theory, whether premised on negligence or strict liability, [Plaintiff] must produce evidence of duty, breach and causation."

A. Study-Sponsorship Claim

To prevail on a claim for negligence, a plaintiff must prove: (1) the defendant has a legal duty to the plaintiff to take some action; (2) there was a breach of that duty; (3) the breach of the duty was the proximate cause of the harm to the plaintiff; and (4) damage. *See* Hudson v. Snyder Body, Inc., 326 N.W.2d 149, 157 (Minn. 1982).

The Court first examines the threshold question: whether AstraZeneca owed Plaintiff a legal duty. In Count 3, Plaintiff alleges, "AstraZeneca had a duty to conduct its research and testing in such a way that the wellbeing and interests of the subjects participating in the research took priority over its interests and those of the research and researchers." (Compl. at 12.) Furthermore, Plaintiff alleges that "AstraZeneca breached its duty to its research subjects and prospective research subjects by creating incentives that motivated its researchers to solicit and retain subjects who were harmed by its research." (Compl. at 12.) Plaintiff has failed, however, to advance any legal authority whatsoever to evidence or support the duty alleged in the Complaint. Plaintiff's memorandum contains not a single mention of this specifically pled duty—not a peep. Instead, Plaintiff apparently devotes her arguments exclusively to the product-liability claims.[12] And, try as it may, this Court's independent research has unearthed not a single case or statute to evidence or support such an alleged duty.

Based on the foregoing, the Court is left to wonder: what legal authorities may exist to support this amorphous "incentive" duty? Under what circumstances is such a duty imposed? Which courts have imposed it? What precise incentives did AstraZeneca create? Plaintiff is silent, and the Court is left without answers. In short, this Court has no idea where this duty comes from or what it entails, and Plaintiff has failed to establish either. Even if such a duty existed, the claim would fail for reasons set forth below.

[12] It appears that Plaintiff may even have been attempting to advance an entirely new ground for negligence. (*See* Pl.'s Mem. Opp. AstraZeneca Summ. J. at 24 (appearing to argue that AstraZeneca was negligent for its partial drafting of the informed consent document—an issue not raised in the Complaint)).

B. Product-Liability Claims

Plaintiff's product liability claims essentially allege that AstraZeneca breached its duty to adequately inform the doctors conducting the Café Study and Markingson, himself, of the risks associated with Seroquel, including—in the words of Plaintiff—"the increased risk of suicide."[13] But Plaintiff's product-liability claims against AstraZeneca fail to establish any casual link whatsoever, whether by expert testimony or otherwise, between AstraZeneca's actions and Markingson's death. No evidence indicates Markingson was using Seroquel at the time of his suicide. No evidence indicates Seroquel increased the risk of suicide in *adult* patients, like Markingson, at the time of Markingson's death. No evidence indicates that AstraZeneca failed to provide information to the study investigator or IRB as required by regulations. And, by regulation, the IRB is ultimately responsible for the informed consent process, not sponsors. As a result, Plaintiff's claims against AstraZeneca are dismissed with prejudice.

Motion to Amend the Complaint by Plaintiff

Plaintiff has moved to amend the Complaint to add a claim for punitive damages against Defendants. In light of the foregoing, however, Plaintiff's motion is moot with respect to all Defendants except Dr. Olson. Punitive damages are allowed in civil actions "upon clear and convincing evidence that the acts of the defendant show deliberate disregard for the rights or safety of others." MINN. STAT. § 549.20, subd. 1(a).[14] A defendant acts with deliberate disregard for the rights or safety of others if defendant knows, or intentionally disregards, facts that create a high probability of injury to the rights or safety of others, and deliberately disregards or is indifferent to that risk. *See* MINN. STAT. § 549.20, subd. 1(b).

In response to Plaintiff's motion, Dr. Olson has raised—for the first time in this action—the argument that he is entitled to statutory immunity with respect to punitive damages, like the Board of Regents and the IRB.[15] Plaintiff asserts, without citing a single case or statute, that "[t]he

[13] The Court notes that Plaintiff is not alleging Seroquel, an FDA approved drug, was somehow defective.
[14] Clear and convincing evidence is defined as "[e]vidence indicating that the thing to be proved is highly probable or reasonably certain. This is a greater burden than preponderance of the evidence, the standard applied in most civil trials, but less than evidence beyond a reasonable doubt, the norm for criminal trials." BLACK'S LAW DICTIONARY, Evidence (8th ed. 2004); see also State v. Kennedy, 585 N.W.2d 385, 389 (Minn. 1998) (citing Weber v. Anderson, 269 N.W.2d 892, 895 (Minn.1978) ("The clear and convincing standard is met when the truth of the facts sought to be admitted is 'highly probable.").
[15] Neither Dr. Olson nor Dr. Schulz raised this defense in connection with the negligence claims against them.

physicians at the University of Minnesota have never, in the history of our jurisprudence, been found to be immune from their acts of negligence."[16] Plaintiff's assertion is, of course, beside the point. The issue on this motion is whether Plaintiff can seek punitive damages against physicians at the University of Minnesota. Assuming *arguendo* that Dr. Olson does not fall within the discretionary exception to the Tort Claims Act, the fact remains that the state of Minnesota and its employees have not waived their immunity to the extent punitive damages are sought. *See* MINN. STAT. § 3.736, subd.3 ("The state will not pay punitive damages."). Therefore, Plaintiff's motion to add a claim for punitive damages must fail against Dr. Olson.

J.L.H.

[16] Plaintiff incorporates by reference her immunity argument presented in opposition to the IRB's motion for summary judgment, but her arguments in that motion had nothing to do with physicians.