No. _____

In the Supreme Court of the United States

Ludwig P. Samson, Trustee for the Heirs and Next of Kin of Christine R. Samson,

Petitioner,

vs.

Jack W. Gordon, M.D.,

Respondent,

Essentia Health d/b/a Virginia Convalescent Center and/or f/k/a Virginia Regional Medical Center, et al.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE MINNESOTA SUPREME COURT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED FOR REVIEW

1) Is a litigant denied due process in the primary sense of having an opportunity to present his case when a state's highest court overrules a consistent line of procedural decisions and expands a state statute retroactively surprising the litigant and failing to provide the opportunity to invoke his substantive rights under the 5th and 14th Amendments of the U.S. Constitution (equality of treatment).

2) Do the rules for a state's highest court prohibiting the filing of a motion for rehearing on a denial of a petition for review deprive a litigant of the opportunity to be heard on allegedly unconstitutional claims the overruling of a consistent line of procedural decisions and expanding a state statute retroactively.

List of Parties

1) LUDWIG P. SAMSON, Plaintiff and Petitioner;

2) JACK W. GORDON, M.D., Defendant and Respondent; and

3) ESSENTIA HEALTH, Defendant and Respondent.

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The Order denying the petition for review dated April 17, 2018 by the Minnesota Supreme Court is found at page A-1 of the Appendix. The unpublished decision of the Minnesota Court of Appeals of January 16, 2018 is found at page A-2 of the Appendix. The Order dismissing the claim of the Plaintiff of the trial court dated March 5, 2017 and filed March 6, 2017 is found in the Appendix at page A-14.

JURISDICTION

The Minnesota Supreme Court issued its order denying the petition for review on April 17, 2018. A copy is attached at page A-1 in the Appendix. The Minnesota Court of Appeals pursuant to the Minnesota Supreme Court's Order entered judgment and an amended judgment on the appeal on April 27, 2018. A copy of the amended judgment is attached to the Appendix at page A-28. The Minnesota Rules for Civil Appellate Procedure, Rule 140.01 provides:

> No petition for reconsideration or rehearing of a denial of a petition for review provided by Rule 117 … shall be allowed in the Supreme Court.

This Court's jurisdiction is invoked under 28 U.S.C. § 1254 (1), 1257 (1).

CONSTITUTIONAL PROVISIONS, STATUTES AND POLICIES AT ISSUE

U.S. Const. Amend. 5:

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offense to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

U.S. Const. Amend. 14:

1. All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

U.S. Const. Art. VI:

This Constitution, and the laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the

authority of the United States, shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the Constitution or laws of any State to the contrary notwithstanding.

Minn. Stat. § 145.682:

Subdivision 1. **Definition.** For purposes of this section, "health care provider" means a physician, surgeon, dentist, or other health care professional or hospital, including all persons or entities providing health care as defined in section 145.61, subdivisions 2 and 4, or a certified health care professional employed by or providing services as an independent contractor in a hospital.

Subd. 2. **Requirement.** In an action alleging malpractice, error, mistake, or failure to cure, whether based on contract or tort, against a health care provider which includes a cause of action as to which expert testimony is necessary to establish a prima facie case, the plaintiff must: (1) unless otherwise provided in subdivision 3, paragraph (b), serve upon defendant with the summons and complaint an affidavit as provided in subdivision 3; and (2) serve upon defendant within 180 days after commencement of discovery under the Rules of Civil Procedure, rule 26.04(a) an affidavit as provided by subdivision 4.

Subd. 3. **Affidavit of expert review.** The affidavit required by subdivision 2, clause (1), must be by the plaintiff's attorney and state that:

(a) the facts of the case have been reviewed by the plaintiff's attorney with an expert whose qualifications provide a reasonable expectation that the expert's opinions could be admissible at trial and that, in the opinion of this expert, one or more defendants deviated from the applicable standard of care and by that action caused injury to the plaintiff; or

(b) the expert review required by paragraph (a) could not reasonably be obtained before the action was commenced because of the applicable statute of limitations. If an affidavit is executed pursuant to this paragraph, the affidavit in paragraph (a) must be served on defendant or the defendant's counsel within 90 days after service of the summons and complaint.

Subd. 4. **Identification of experts to be called.** (a) The affidavit required by subdivision 2, clause (2), must be signed by each expert listed in the affidavit and by the plaintiff's attorney and 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. Answers to interrogatories that state the information required by this subdivision satisfy the requirements of this subdivision if they are signed by the plaintiff's attorney and by each expert listed in the answers to interrogatories and served upon the defendant within 180 days after commencement of discovery under the Rules of Civil Procedure, rule 26.04(a).

(b) The parties or the court for good cause shown, may by agreement, provide for extensions of the time limits specified in subdivision 2, 3, or this subdivision. Nothing in this subdivision may be construed to prevent either party from calling additional expert witnesses or substituting other expert witnesses.

(c) In any action alleging medical malpractice, all expert interrogatory answers must be signed by the attorney for the party responding to the interrogatory and by each expert listed in the answers. The court shall include in a scheduling order a deadline prior to the close of discovery for all parties to answer expert interrogatories for all experts to be called at trial. No additional experts may be called by any party without agreement of the parties or by leave of the court for good cause shown.

Subd. 5. **Responsibilities of plaintiff as attorney.** If the plaintiff is acting pro se, the plaintiff shall sign the affidavit or answers to interrogatories referred to in this section and is bound by those provisions as if represented by an attorney.

Subd. 6. **Penalty for noncompliance.** (a) Failure to comply with subdivision 2, clause (1), within 60 days after demand for the affidavit results, upon motion, in mandatory dismissal with prejudice of each cause of action as to which expert testimony is necessary to establish a prima facie case.

(b) Failure to comply with subdivision 2, clause (2), results, upon motion, in mandatory dismissal with prejudice of each cause of action as to which

expert testimony is necessary to establish a prima facie case.

(c) Failure to comply with subdivision 4 because of deficiencies in the affidavit 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:

(1) the motion to dismiss the action identifies the claimed deficiencies in the affidavit or answers to interrogatories;

(2) the time for hearing the motion is at least 45 days from the date of service of the motion; and

(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 deficiencies.

Subd. 7. **Consequences of signing affidavit.** The signature of the plaintiff or the plaintiff's attorney constitutes a certification that the person has read the affidavit or answers to interrogatories, and that to the best of the person's knowledge, information, and belief formed after a reasonable inquiry, it is true, accurate, and made in good faith. A certification made in violation of this subdivision subjects the attorney or plaintiff responsible for such conduct to reasonable attorney's fees, costs, and disbursements.

Minn. R. Civ. App. P., Rule 140.01:

No petition for rehearing shall be allowed in the Court of Appeals.

A petition for rehearing in the Supreme Court may be filed within ten days after the filing of the decision or order unless the time is enlarged by order of the Supreme Court within the ten-day period. The petition shall set forth with particularity:

> (a) any controlling statute, decision or principle of law; or
>
> (b) any material fact; or
>
> (c) any material question in the case which, in the opinion of the petitioner, the Supreme Court has overlooked, failed to consider, misapplied or misconceived.

No petition for reconsideration or rehearing of a denial of a petition for review provided by Rule 117, or of a petition for accelerated review provided by Rule 118, shall be allowed in the Supreme Court.

STATEMENT OF THE CASE

In 2004 the deceased, Christine R. Samson, was admitted for care at the Virginia Convalescent Center where she remained until her death on October 11, 2012. While at the Respondent Essentia Health and/or Essentia Health Virginia, LLC formerly known as Virginia Convalescent Center, the deceased, Christine R. Samson, was under the care of the Respondent Jack W. Gordon, M.D. In January 2010 the Respondent prescribed levothyroxin, commonly known as Synthroid, to the deceased, Christine R. Samson, and maintained her on an increased regimen for the same through her death on October 11, 2012. Christine R. Samson passed away as a result of CHF or cardiac arrest pursuant to the death certificate signed by the Respondent.

The Petitioner had been appointed Trustee by the court under Minn. Gen. R. Prac., Rule 144 and Minn. Stat. § 573.02 to prosecute the wrongful death action in the Minnesota District Court as a result of medical malpractice. Pursuant to Minn. Stat. § 145.682 Petitioner timely served the expert affidavit of Dr. Barry Singer wherein he described the relevant facts and opinions upon which he testified that it is his opinion that the standard of care is not to administer Synthroid to an individual approaching 100 years of age and that Dr. Gordon administration of such drug more likely than not caused her cardiac arrest as determined by the Respondent on her death certificate, a risk well known for Synthroid.

The reader is referred to the Supplemental Affidavit and Identification of Expert Barry L. Singer, M.D., of November 30, 2016 at page A-31 of the Appendix. On March 5, 2017 the District Court, upon motion, dismissed the case or claim of the Petitioner ruling that the affidavit did not comply with the requirements of 145.682. (A-14)

The Appellate Court confirmed (A-2) the District Court's finding that "There is nothing in Dr. Singer's expert affidavit that indicated Ms. Samson's heart failure was directly caused by the administration of Synthroid." wherein the District Court observed:

> Dr. Singer merely states Dr. Gordon breached the standard of care by prescribing and administering Synthroid to Ms. Samson and that as a result her cardiac status deteriorated. Dr. Singer's expert affidavit does not assert any opinions or discussion directly linking Ms. Samson's deterioration or death to Synthroid.

The Appellate Court further stated that "appellant fails to connect the second link in his chain—that "Synthroid is known to cause cardiac arrest, heart failure and death"—with the third link—that, in fact, "Synthroid caused cardiac arrest and heart failure" in this case."

The Court of Appeals overlooked that **the link is the risk**. At paragraph 20 Dr. Singer states

"Synthroid has long been known to put the elderly at risk for cardiac events." *Stedman's Medical Dictionary* 1701 (28th ed. 2006) defines risk as "The probability that an event will occur." Probable is defined by the *American Heritage Dictionary* 1397 (4th ed. 2009) as "Likely to happen or to be true." i.e. more likely than not as also defined by MINN CIVJIG 14.15. Dr. Singer further describes in paragraph 20 "The Physician's Desk Reference (PDR) directs one to "Exercise caution when administering … to the elderly in whom there is an increased risk of occult cardiac disease."" Occult is defined by *Stedman's Medical Dictionary* 1355 (28th ed. 2006) as "Hidden; concealed; not manifest."

The Appellate Court is critical at page 8 that "there is no reference in the affidavit to Ms. Samson suffering any of the side effects associated with over-replacement, such as arrhythmia or toxic thyroid, during the nearly three years she was on Synthroid. … And it is hyperthyroidism caused by over-replacement, and not the administration of Synthroid itself, that Dr. Singer claims would have put Ms. Samson at an elevated risk of adverse cardiovascular effects." Dr. Singer never makes any such claim that she had hyperthyroidism in his affidavit nor do any of his peer-reviewed articles describe such risk. His claim is that there is over-replacement. It is over-replacement of the synthetic drug, not hyperthyroidism, which causes the occult cardiac disease and her heart failure. The occult disease has not manifested itself until it causes her death.

This is supported by the studies which Dr. Singer references at paragraph 21 of his affidavit. The first is a FDA study of 89,069 people reported to have side effects when taking Synthroid. 641 of those people had the side effect of cardiac arrest with 100% suffering death therefrom. The remaining patients in the study had overt side effects, i.e. atrial fibrillation and osteoporotic fractures.

A second recent FDA study of 132,313 people reflected that 775 people had cardiac arrest with 100% of those passing on. The remainder incurred side effects described above[1].

It is the Petitioner's expert who has set forth these peer-reviewed articles as foundational reliability as determined by the Minnesota Supreme Court in the landmark decision of *Doe v. Archdiocese of St. Paul*, 817 N.W.2d 150, 164 (Minn. 2012) "Finally, we clearly stated that the proponent of evidence about a given subject must show that it is reliable in that particular case." *Id.* at 166. Reliability in *Doe*, or the lack thereof, was based upon research articles.

Evidence-based medicine is almost the universally accepted standard since 1990 when diagnosing and treating patients, AMA Journal of Ethics, Vol. 13, No. 1:26-30 (January 2011), described as follows:

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[1] See paragraphs 8c and 16 of the Supplemental Affidavit and Identification of Expert Barry L. Singer, M.D., of November 30, 2016 at page A-31 of the Appendix.

> (t)he conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient. It means integrating individual clinical expertise with the best available external clinical evidence from systematic research. Sackett, et al., *Evidence Based Medicine: What it Is and What it Isn't*, 312 BMJ 71-72, 71 (1996).

The physician utilizes scientific peer-reviewed articles and literature for the benefit of individual patients and his or her overall continuing education. Evidence Based Medicine – New Approaches and Challenges, Miokovic and Muhamedagic (2008): http://www.ncbi.nlm.nih.gov/pmc/articles/pmc3789163/.

Such medical evidence is rated in a hierarchical system as described in the above articles and in Guyatt, et al., *Users' Guide to Medical Literature: A Manual for Evidence-Based Clinical Practice*, ch. 2, the Philosophy of Evidence-Based Medicine (2d ed. 2008).

Evidence-based medicine is the reliable scientific evidence which meets the foundational reliability requirements of *Doe v. Archdiocese of St. Paul*, 817 N.W.2d 150 (Minn. 2012). As the Advisory Committee directs in its Comment to Rule 703 of the Minn. R. Evid.:

> The requirement that the facts and data be of the type reasonably relied upon by

> experts in the field provides a check on the trustworthiness of the opinion and its foundation.

The practice of evidence based medicine incorporates the same concept as the requirement for expert testimony as determined by the Third District in *In re Paoli Railroad Yard PCB Litigation*, 35 F.3d 717, 741-43 (3d Cir. 1994) "… that the expert's opinion must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'" by "… proof that the research and analysis supporting the proffered conclusions have been subjected to normal scientific scrutiny through peer review and publication" in a "… generally-recognized scientific journal that conditions publication on a bona fide process of peer review. See Daubert, --- U.S. at ---, 113 S.Ct. at 2797 … The Journal's Peer-Review Process, 321 New Eng.J.Med. 837 (1989)." and is "… in a reputable scientific journal after being subjected to the usual rigors of peer review is a significant indication that it is taken seriously by other scientist, i.e., that it meets at least the minimal criteria of good science." The court concluded "Under our case law on Rule 703, "the proper inquiry is not what the court deems reliable, but what experts and their relevant discipline deem it to be" *Id*. at 747.

Under a 145.682 motion the court has to accept the facts as set forth by the expert and his medical evidence and opinions. Dr. Singer has done that buttressed by peer-reviewed articles establishing the chain of causation. The trial court and the Appellate

Court have inserted their own medical opinions in lieu of the peer-reviewed articles overruling the expert's opinion. Simply put it is their "subjective believe or unsupported speculation". The extension of *Doe v. Archdiocese of St. Paul* to incorporate evidence-based medicine as a means, if not the only means of establishing foundational reliability aids the courts and the trial bar not only in medical malpractice cases but all cases involving scientific testimony under Minn. R. Evid., Rule 702.

Finally and most importantly the District Court and the Court of Appeals expressed that 145.682 requires that the Plaintiff and his expert must rule out "all other causes of death". The Appellate Court attempts to justify this language by interpreting what the district court is saying, but it is a basis, if not the basis of the ruling.

The Supreme Court of Minnesota denied the petition for review, overruling a consistent line of procedural decisions determining the requirements of the affidavit as to a prima facie case and a more probable than not standard, accepting the expansion by the Appellate Court and the District Court of Minn. Stat. § 145.682 to require ruling out "all other causes of death" and retroactively applying such to Plaintiff's case. Minn. R. Civ. App. P., Rule 140.01 prohibits the filing of a motion for rehearing precluding the Petitioner from raising the constitutional issue and denying him the opportunity to be heard under due process of law.

ARGUMENT

Introduction

In the days of judicial activism which not only encroach upon stare decisis but the province of the legislative and executive branch as recently exemplified in the Trump Executive Order Immigration cases such activism has not only infected the Federal Courts but the State Courts also.

Activism in the legal system results in the tipping of the playing field in favor of the elite. Such elitism legislatively in the law is exhibited in this case by the passage of § 145.682 of the Minnesota Statutes, a statute providing protection to physicians of medical malpractice suits unavailable to other litigants[2] purchased by lobbyists for the insurance companies under the guise of a "medical malpractice insurance crisis" of the 1980s.[3] But more importantly, in this case, the elitism is found judicially in the Minnesota Court's expansion of the statute retroactively disregarding or overruling its prior procedural decisions. This elitism is one of the factors which created the populous movement which found President Trump as its spokesman.

The crisis now, though, is (and probably has always been) medical malpractice. In 1999 the Institute of Medicine issued a report To Err Is Human estimating that 100,000 Americans die each

[2] Except lawyers and other professionals pursuant to Minn. Stat. § 544.42, sister statute to 145.682.

[3] Minn. Stat. § 145.682 was enacted in 1986.

year from preventative, adverse events on medical errors.[4] In 2014 before the Senate Subcommittee on Primary Health and Aging, Ashish Jha, MD, professor of health policy and management at Harvard School of Public Health testified that 1,000 deaths per day resulted from medical errors as reported in Healthcare IT News on July 18, 2014[5] and Joanne Disch, RN, clinical professor at the University of Minnesota School of Nursing testified that there are also 10,000 serious complications cases resulting from medical errors every day. That is over 365,000 deaths per year or over 3,650,000 serious complications.

In this crisis, the victim's right to access to the courts have been infringed. This case is just such an example of such activism in support of the elite.

In the last century this Court forged a tool against such infringement in *Brinkerhoff-Faris Trust & Savings Co. v. Hill*, 281 U.S. 673, 50 S.Ct. 451, 74 L.Ed. 1107 (1930) protecting the due process rights of litigants in State Court actions guaranteeing them the right of the opportunity to be heard as substantive right under the Federal Constitution to equality of treatment. Such due process is denied by the State Judiciary in the course of overruling a consistent line of procedural decisions and expanding otherwise valid state statute retroactively denying a

[4] Linda T. Kohn, Janet M. Corrigan and Molla S. Donaldson, eds., To Err is Human : Building a Safer Health System (Institute of Medicine, 2000).

[5] Erin McCann. Deaths by medical malpractice hit records (Healthcare IT News.com, July 18, 2014)

litigant the opportunity to present its case and be heard.

Question Presented

1) A Litigant is Denied Due Process in the Primary Sense of having an Opportunity to Present His Case when a State's Highest Court Overrules a Consistent Line of Procedural Decisions and Expands a State Statute retroactively Surprising the Litigant and Failing to Provide the Opportunity to Invoke His Substantive Rights Under the 5th and 14th Amendments of the U.S. Constitution (Equality of Treatment).

A. Minn. Stat. § 145.682 and Procedural Decisions.

Due process is denied when a state's highest court overrules a consistent line of procedural decision and expands a state statute retroactively.

Minn. Stat. § 145.682 requires, at a minimum, that the expert's affidavit must set forth "the applicable standard of care, the acts of omission that the plaintiff's alleged violated the standard of care and an outline of the chain of causation that allegedly resulted in damage to them." *Sorenson v. St. Paul Ramsey Med. Ctr.*, 457 N.W.2d 188, 193 (Minn. 1990). This does not require the Plaintiffs to try their case on the merits of an expert affidavit but that the statute simply requires expert testimony to establish

a *prima facie* case. *Demgen v. Fairview Hospital,* 621 N.W.2d 259, 265 (Minn. App. 2001). A *prima facie* case is supported by evidence which suffices to establish the fact unless rebutted, *Tousignant v. St. Louis County*, *MN*, 615 N.W.2d 53, 59 (Minn. 2000) and the Court should not consider rebuttal evidence *Id.* at 60. This is so that the District Court can determine if the case is frivolous and should be dismissed. *Sorenson v. St. Paul Ramsey Med. Ctr.*, 457 N.W.2d 188, 191 (Minn. 1990). As long as a medical expert's opinion is "based on an adequate foundation" the expert "is permitted to make legitimate inferences, which have probative value in determining disputed fact questions." *Blatz v. Allina Health Sys.,* 622 N.W.2d 376, 387 (Minn. App. 2001), review denied (Minn. May 16, 2001). Section 145.682 was not passed to prevent meritorious cases from being determined by the fact finder; the statute was passed to identify and aid the dismissal of *meritless* lawsuits in the early stages of litigation when a plaintiff cannot demonstrate that a qualified expert believes that the alleged malpractice directly caused the plaintiff's injury. *Broehm v. Mayo Clinic Rochester,* 690 N.W.2d 721, 725 (Minn. 2005).

The Certificate of Death of Christine R. Samson, prepared by the Respondent Jack W. Gordon, M.D., attributes death to heart failure and that under the standard in Minnesota more likely than not, in Dr. Singer's opinion, her heart failure was the result of the overdose of the Synthroid.

In *Teffeteller v. University of Minnesota*, 645 N.W.2d 420, 427 (Minn. 2002) the Minnesota Supreme Court held at page 430:

> **The Affidavit…must provide more than a sneak preview…at a minimum, a "*meaningful disclosure*" is required setting forth the standard of care, the act or omissions violating that standard, and the chain of causation. (Emphasis supplied)**

As long as a medical expert's opinion is "based on an adequate factual foundation", the expert "is permitted to make legitimate inferences which have probative value in determining disputed fact questions." *Blatz v. Allina Health Sys.*, 622 N.W.2d 376, 387 (Minn. App. 2001), *review denied* (Minn. May 16, 2001). Such legitimate inferences have been made.

In *Leubner v. Sterner*, 493 N.W.2d 119, 121 (Minn. 1992) the Court stated that "**a plaintiff must prove, among other things, that it is more probable than not that his or her injury was a result of the defendant health care provider's negligence**. See, e.g., *Plutshack v. University of Minnesota Hospitals*, 316 N.W.2d 1 (Minn. 1982); *Cornfeldt v. Tongen*, 295 N.W.2d 638, 640 (Minn. 1980)."(Emphasis supplied.) There is no discussion about ruling out all other possible causes. The Court continues that "The guiding principle behind this rule is that a jury should not be permitted to speculate as

to possible causes of a plaintiff's injury or whether different medical treatment could have resulted in a more favorable prognosis for the plaintiff. See *Smith v. Knowles*, 281 N.W.2d 653, 656 (Minn. 1979); *Cornfeldt v. Tongen*, supra" and concluded "This court has reaffirmed the "more probable than not" standard for establishing causation in medical malpractice claims in case after case. See, *Harvey v. Fridley Medical Center, P.A.,* 315 N.W.2d 225, 227 (Minn. 1982); *Silver v. Redleaf*, 292 Minn. 463, 465, 194 N.W.2d 271, 273 (1972)."

As shown above, Dr. Singer in his original affidavit and through his supplemental affidavit testified that Christine Samson was prescribed and administered Synthroid when her TSH was in the normal range for her age group and that such over replacement, which is replacing too much thyroid hormone by use of synthetic mediations, more likely than not caused her "heart failure" (see page A-34 of Appendix), cardiac arrest resulting in her death. Such over replacement is a potential adverse cardiovascular effect (see pages A-38 to A-39 of Appendix) as Synthroid has been described by the manufacturer as putting "the elderly at **risk** for cardiac events."(Emphasis supplied.) (see pages A-43 and A-44 of Appendix.) A risk is described by the *Attorney's Illustrated Medical Dictionary* R31 (1997) as "The probability of suffering harm or loss." *Stedman's Medical Dictionary* 1701 (28th ed. 2006) defines risk as "The probability that an event will occur." Probable is defined by the *American Heritage Dictionary* 1397 (4th ed. 2009) as "Likely to happen or to be true." i.e. more likely than not.

As stated at page 10 above and Dr. Singer's affidavit at paragraph 21 the FDA studies reflected that a side effect of Synthroid was cardiac arrest with 100% of those patients suffering death therefrom in both studies.

The Minnesota Court of Appeals addressed this issue head-on in *Karedla v. Obstetrics & Gynecology Assocs., P.A.,* A11-1423 (June 11, 2012) (A-49) in addressing Minn. Stat. §145.682. The Court sized up the case "Respondents also argue that "nothing in the expert affidavits establishes that antihypertensives will *inevitably* avoid all strokes."" The Court held:

> … While it is true that the affidavits do not rule out **other possible causes** for Karedla's stroke, **at this stage** appellants' burden is only to show that it is more likely that treatment with antihypertensives would have prevented Karedla's stroke than it is that such treatment would not have prevented her stroke. (Emphasis supplied.)

B. Expanding Minn. Stat. § 145.682 and Overruling Procedural Decision.

The Minnesota Supreme Court by denying the Petition for Review upheld Minnesota Appellate Court's decision expanding Minn. Stat. §145.682 overruling the consistent line of procedural decisions thereunder of a "meaningful disclosure" that "is more probable" that the decedent's death "was a result of

the Defendant healthcare providers negligence not contained in speculation as to "possible causes" and affirming the "more probable than not" standard of establishing causation in medical malpractice claims which does not include ruling "out other possible causes" but "at this stage" the burden is "only to show that it is more likely than not" that treatment with Synthroid caused her cardiac arrest and death and not to "rule out all other causes of death" retroactively applying such expansion to the Petitioner's case.

When the State Supreme Court overrules a consistent line of procedural decisions or construes an otherwise valid state statute as expanded by judicial construction, unforeseeably and retroactively denying a litigant a hearing in a pending case, he is denied due process of law. *Bouie v. City of Columbia*, 378 U.S. 347, 352, 354, 84 S.Ct. 1697, 12 L.Ed.2d 894 (1964).

Both of these situations occurred in the instant case.

The Fifth Amendment to the Constitution of the United States guarantees in pertinent part that:

> … nor shall any person … be deprived of life, liberty, or property, without due process of law; … U.S. Const. Amend. 5.

The Fourteenth Amendment of the United States Constitution states in pertinent part:

> Section 1 … No state shall make or enforce any law which shall abridge the

> privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws. U.S. Const. Amend. 14 § 1.

The due process rights guaranteed by both the Fifth Amendment and the Fourteenth Amendment protect individuals as extensively from the state government, as from the national government. *Curry v. McCanless*, 307 U.S. 357, 370, 59 S.Ct. 900, 907, 83 L.Ed. 1339 (1939).

Due process is "deeply rooted in this [n]ation's history and tradition"[6] protecting fundamental rights and liberties and "implicit [to] the concept of ordered liberty."[7] These roots travel back to the Magna Carta, specifically Chapter 29 which required that "[n]o free man shall be arrested or imprisoned, or disseised or outlawed or exiled or in any way victimized, neither will we attack him or send anyone to attack him, except by the lawful judgment of his peers or by the law of the land."[8] as constraints placed upon Parliament, the king, and his courts have the overarching fundamental law.[9]

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[6] *Moore v. City of East Cleveland*, 431 U.S. 494, 503 (1977).

[7] *Palko v. Connecticut*, 302 U.S. 319, 325 (1937).

[8] MAGNA CARTA ch. 29 (1225), *translated in* WILLIAM F. SWINDLER, MAGNA CARTA: LEGEND AND LEGACY 244, 316-317 (1965).

[9] Thomas C. Grey, *Origins of the Unwritten Constitution: Fundamental Law in American Revolutionary Thought*, 30 STAN. L. REV. 843, 855 (1978).

Article VI of the Constitution of the United States provides:

> This Constitution, and the laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the authority of the United States, shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the Constitution or laws of any State to the contrary notwithstanding.

"The Federal guarantee of due process extends to state actions through its judicial as well as legislative, executive and administrative branch of government." *Brinkerhoff-Faris Trust & Savings Co. v. Hill*, 281 U.S. 673, 680, 50 S.Ct. 451, 74 L.Ed. 1107. The plaintiff is entitled to an opportunity to be heard, *Id* at 678, because "due process of law" "in its primary sense is an opportunity to be heard."

Brinkerhoff applied to property rights but Justice Kennedy reinforced the above in *Stop the Beach Renourishment, Inc., v. Fla. Dep't. of Envtl. Prot.,* 560 U.S. 702, 724, 130 S.Ct. 2592, 177 L.Ed. 2d 184 (2009) that due process referred to "liberty of the person both in its facial and its more transcendent dimensions" citing *Lawrence v. Texas,* 539 U.S. 558, 562, 123 S.Ct. 2472, 156 L.Ed.2d 508 (2003) and that the due process clause, in both its substantive and procedural aspects, is a central limitation upon the exercise of **judicial power**. (Emphasis supplied.)

As this Court put forth in *McKesson Corp. v. Division of Alcoholic Beverages and Tobacco, Dep't. of Business Regulation of Florida*, 496 U.S. 18 n. 12, 110 S.Ct. 2238, 110 L.Ed. 17 (1989):

> "Upon the State courts, equally with the courts of the Union, rests the obligation to guard, enforce, and protect every right granted or secured by the Constitution of the United States and the laws made in pursuance thereof, whenever those rights are involved in any suit or proceeding before them. … If they fail therein, and withhold or deny rights, privileges, or immunities secured by the Constitution and laws of the United States, the party aggrieved may bring the case from the highest court of the State in which the question could be decided to this court for final and conclusive determination." *Robb v. Connolly*, 111 U.S. 624, 637, 4 S.Ct. 544, 551, 28 L.Ed. 542 (1884). See also *Brinkerhoff-Faris Trust & Savings, Co. v. Hill*, 281 U.S. 673, 681, 50 S.Ct. 451, 454, 74 L.Ed. 1107 (1930). ("[T]he plaintiff's claim is one arising under the Federal Constitution and, consequently, one on which the opinion of the state court is not final"); *Martin v. Hunter's Lessee*, 1 Wheat. 304, 347-348, 4 L.Ed. 97 (1816). (plenary appellate jurisdiction of Supreme Court motivated in part by "the importance, and even necessity of

> uniformity of decisions throughout the whole United States, upon all subjects within the purview of the constitution").

As Justice Cardozo stated in *Herndon v. State of Georgia*, 295 U.S. 441, 447, 55 S.Ct. 794, 79 L.Ed. 1530 (1935):

> … The settled doctrine is that when a constitutional privilege or immunity has been denied for the first time by a ruling made upon appeal, a litigant thus surprised may challenge the unexpected ruling by a motion for rehearing, and the challenge will be timely. *Missouri v. Gehner*, 281 U.S. 313, 320, 50 S.Ct. 326, 74 L.Ed. 870; *Brinkerhoff-Faris Trust & Savings, Co. v. Hill*, 281 U.S. 673, 678, 50 S.Ct. 451, 74 L.Ed. 1107; *American Surety Co. v. Baldwin*, 287 U.S. 156, 164, 53 S.Ct. 98, 77 L.Ed. 231, 86 A.L.R. 298; *Great Northern R. Co. v. Sunburst Oil & Refining Co.*, 287 U.S. 358, 367, 53 S.Ct. 145, 77 L.Ed. 360, 85 A.L.R. 254; *Saunders v. Shaw*, 244 U.S. 317, 320, 37 S.Ct. 638, 61 L.Ed. 1163.

2) Rules for a State's Highest Court Prohibiting the Filing of a Motion for Rehearing on a Denial of a Petition for Review Deprive a Litigant of the Opportunity to be Heard on Allegedly Unconstitutional Claims the Overruling of a Consistent Line of Procedural Decisions and Expanding a State Statute Retroactively.

As Judge Cardozo states above a litigant can raise a constitutional issue in the highest court of the state on a motion for rehearing. *Brinkerhoff-Faris Trust & Savings Co. v. Hill*, 281 U.S. 673, 678, 50 S.Ct. 451, 74 L.Ed. 1107 (1930).

This is the challenge in this case.

The Supreme Court of Minnesota precludes such, on a denial of a petition for review, by its rule. Minn. R. Civ. App. P., Rule 140.01 provides **"No petition for reconsideration or rehearing of a denial of a petition for review** provided by Rule 117, or of a petition for accelerated review provided by Rule 118**, shall be allowed in the Supreme Court."**[10] (Emphasis supplied.)

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[10] Rule 117 provides:

Rule 117. Petition in Supreme Court for Review of Decisions of the Court of Appeals

Subdivision 1. Filing of Petition. Any party seeking review of a decision of the Court of Appeals shall separately petition the Supreme Court. The petition with proof of service shall be filed with the clerk of the appellate courts within 30 days of the filing of the Court of Appeals' decision. A filing fee of $550 shall be paid to the clerk of the appellate courts.

The Petitioner timely filed his petition for review with the Minnesota Supreme Court.[11] The court denied review on April 17, 2018 (see page A-1 of the Appendix).

The rule precluding the motion for rehearing denies a litigant his constitutional access to the court. As provided in *Brinkerhoff-Faris Trust & Savings Co*., supra., "We are of the opinion that the judgment of the Supreme Court of the Missouri must be reversed because it has denied the plaintiff "due process of law" – using the term in its primary sense of an opportunity to be heard and to defend his substantive rights." The Court held that the practical effect of the judgment deprives the plaintiff of property without according it [him] at any time an opportunity to be heard in its [his] defense. The Court made it clear that it is the transgression of the due process clause by the state judiciary in construing an otherwise valid state statute as discussed above.

This Court expanded upon this concept in *Bouie v. City of Columbia*, 373 U.S. 347, 354, 84 S.Ct. 1697, 12 L.Ed.2d 894 (1964) finding "the basic due process concept involved is the same as that which

[11] The petition was filed on February 15, 2018 within thirty (30) days from the decision of the Court of Appeal on January 16, 2018 pursuant to Minn. R. Civ. App. P., Rule 117, Subd. 1., which states "Any party seeking review of a decision of the Court of Appeals shall separately petition the Supreme Court. The petition with proof of service shall be filed with the clerk of the appellate courts within 30 days of the filing of the Court of Appeals' decision. A filing fee of $550 shall be paid to the clerk of the appellate courts."

the court has often applied in holding that an unforeseeable and unsupported state court decision on a question of state procedure does not constitute an adequate ground to preclude the court's review of the federal question." Such is that case at bar. It was unforeseeable and unsupported by any state court decisions that the court would expand the statute and overrule consistent line of procedural decision. The Petitioner's appeal to the Minnesota Court of Appeals was that the district court (trial court) had wrongfully interpreted the statute. The Court stated that "when a state court overrules a consistent line of procedural decisions with a retroactive effect of denying a litigant a hearing on a pending case, it there by deprives them of due process of law" "in its primary sense of an opportunity to be heard and to defend his substantive rights." citing *Brinkerhoff-Faris Trust & Savings Co. v. Hill*, 281 U.S. 673, 678, 50 S.Ct 451, 453, 74 L.Ed. 1107. The Court further commented that "the violation is nonetheless clear when that result is accomplished by the state judiciary in the course of construing an otherwise valid *** state statute", *Id.*, 281 U.S. at 679-680, 50 S.Ct. at 454.

The Minnesota Supreme Court recognizes this as the law of the land in *Cambridge State Bank v. James,* 514 N.W.2d 565, 570-571 (Minn. 1994) citing *Brinkerhoff-Faris Trust & Savings Co. v. Hill* in discussing the due process violation by the Missouri Supreme Court in denying relief to the litigant.

This is true even though its own rule precludes such a process on its denial of a petition for review.

The practical effect of the Minnesota Supreme Court's decision in denying review when coupled with its rule prohibiting a motion for reconsideration or rehearing effectively deprives the petitioner of his constitutional rights without affording him an opportunity to be heard.

Justice Cardozo's comment in *Herndon v. State of Georgia*, 295 U.S. 441, 448, 55 S.Ct. 794, 79 L.Ed. 1530 (1935) is illustrative that there can be no requirement to raise the constitutional challenges before the motion for rehearing in the highest court in the state. His response to the argument that the securities of the Constitution should have been invoked at trial was "It is novel doctrine that a defendant who has had the benefit of all he asks, and indeed of a good deal more, must place a statement on the record that if some other court at some other time shall read the statute differently, there will be a denial of liberties that at the moment of the protest are unchallenged and intact." *Id*. at page 448. Cardozo reiterated that the appellant was now asking the court for an opportunity to be heard and by not raising such in trial he had not acquiesced.

The Minnesota Supreme Court has denied the opportunity for a motion for rehearing. The litigant's right to enforce his constitutional rights cannot be revoked by the rule of court.

As the Supreme Court of Missouri stated in *Witte v. Director of Revenue*, 829 S.W.2d 436, 442 (Mo., 1992) "otherwise the judicial system has effectively mouse trapped the taxpayer."

The rule is the mousetrap and litigants are in its snare.

CONCLUSION

Based on the foregoing, Petitioner respectfully submits that this Petition for Writ of Certiorari should be granted.

Dated: July 16, 2018 Respectfully submitted,

LAW OFFICES OF
RICHARD E. BOSSE, CHARTERED

s/
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INDEX TO APPENDIX

STATE OF MINNESOTA

IN SUPREME COURT

A17-0721

Ludwig P. Samson, Trustee for the Heirs and Next of Kin of Christine R Samson, deceased,

Petitioner,

vs.

Jack W. Gordon, M. D.,

Respondent,

Essentia Health d/b/a Virginia Convalescent Center and/or f/k/a Virginia Regional Medical Center; et al.,

Respondents.

ORDER

Based upon all the files, records, and proceedings herein,

IT IS HEREBY ORDERED that the petition of Ludwig P. Samson for further review be, and the same is, denied.

Dated: April 17, 2018

BY THE COURT:

s/_____

Lorie S. Gildea

Chief Justice

Ludwig P. Samson, Trustee for the Heirs and Next of Kin of Christine R. Samson, deceased, Appellant,

v.

Jack W. Gordon, M. D., Respondent, Essentia Health d/b/a Virginia Convalescent Center and/or f/k/a Virginia Regional Medical Center; et al., Respondents.

A17-0721

STATE OF MINNESOTA
IN COURT OF APPEALS

January 16, 2018

This opinion will be unpublished and may not be cited except as provided by Minn. Stat. § 480A.08, subd. 3 (2016).

Affirmed
Smith, **Tracy M.**, **Judge**

St. Louis County District Court
File No. 69DU-CV-15-3179

Richard E. Bosse, Law Offices of Richard E. Bosse, Chartered, Henning, Minnesota (for appellant)

Katherine A. McBride, Rodger A. Hagen, Meagher & Geer, P.L.L.P., Minneapolis, Minnesota (for respondent Jack W. Gordon, M.D.)

William L. Davidson, Eric J. Steinhoff, João C. Medeiros, Lind, Jensen, Sullivan & Peterson, P.A., Minneapolis, Minnesota (for respondent Essentia Health)

Considered and decided by Hooten, Presiding Judge;

Reyes, Judge; and Smith, Tracy M., Judge.

UNPUBLISHED OPINION

SMITH, **TRACY M.**, Judge

Appellant Ludwig Samson, son of 99-year-old decedent Christine Samson, contends that, in dismissing his medical-malpractice action for failure to comply with the expert-affidavit requirements in Minn. Stat. § 145.682 (2016), the district court (1) abused its discretion in determining that the expert affidavit did not sufficiently show a chain of causation and (2) applied an incorrect standard by requiring appellant to disprove all other causes of death. We affirm.

FACTS

In 2004, Ms. Samson, who suffered from Alzheimer's disease and dementia, was admitted to the Virginia Convalescent Center for long-term care. Four years later, Dr. Jack Gordon assumed Ms. Samson's care. In January 2010, Dr. Gordon diagnosed Ms. Samson with hypothyroidism.[1] Hypothyroidism is characterized by a high thyroid-stimulating-hormone (TSH) concentration. To treat Ms. Samson's hypothyroidism, Dr. Gordon started her on a 25 mcg dose of levothyroxine, a synthetic form of thyroid hormone commonly known as Synthroid.

In March 2010, based on Ms. Samson's TSH levels, Dr. Gordon increased her Synthroid dose to alternate between 25 mcg and 50 mcg per day. A few months later, Dr. Gordon increased her dose to 50 mcg per day. Ms. Samson's TSH levels subsequently normalized.

In June 2011, endocrinologist Dr. Robert

Sjoberg evaluated Ms. Samson. Appellant expressed concern that his mother's Synthroid dosage was making her condition worse. After reviewing Ms. Samson's lab results, Dr. Sjoberg concluded that the 50 mcg daily dosage of Synthroid was appropriate and not harmful.

Eleven months later, Ms. Samson's family placed Ms. Samson on comfort measures and no further labs were taken. In October 2012, Ms. Samson passed away due to congestive heart failure.

Appellant commenced this medical-malpractice action against Dr. Gordon and Essentia Health (Essentia), which does business as Virginia Convalescent Center and was formerly known as Virginia Regional Medical Center, based on the allegedly negligent prescription of Synthroid and subsequent increase in dosage to Ms. Samson, claiming that this medication contributed to the degeneration of her health and ultimately caused her cardiac arrest. Appellant identified Barry Singer, M.D., as an expert witness and served Dr. Singer's affidavit on respondents.

Dr. Singer opined that Dr. Gordon did not comply with accepted standards of care when he prescribed Synthroid, which can carry an increased risk of adverse cardiovascular effects, to Ms. Samson, a woman approaching 100 years of age. Dr. Singer explained that "[e]lderly patients are more likely to develop arrhythmias and complications from doses greater than 25 micrograms."[2] Dr. Singer concluded that Ms. Samson was not a candidate for synthetic hormone treatment, and that "more likely than not the higher dose of thyroid replacement contributed to her overall deterioration of the cardiac status" and caused her to have congestive heart failure.

Respondents moved for dismissal of the action

under Minn. Stat. § 145.682, subd. 6(c), on the ground that the expert affidavit failed to comply with the substantive requirements of the statute. Appellant responded with a supplemental affidavit from Dr. Singer to bolster his showing of violation of the duty of care and the chain of causation, including by describing recent medical studies that discussed the normalcy of elevated TSH levels in elderly populations and warned about the adverse effects from artificial hormone over-replacement. After a hearing, the district court granted respondents' motion to dismiss. This appeal followed.[3]

DECISION

A plaintiff in a medical-malpractice case must submit two affidavits when expert testimony is required to establish a prima facie case. Minn. Stat. § 145.682, subd. 2. First, when serving the summons and complaint, a plaintiff must include an attorney affidavit stating that the plaintiff's attorney has reviewed the facts of the case with "an expert whose qualifications provide a reasonable expectation that the expert's opinions could be admissible at trial." *Id.*, subds. 2(1), 3(a). Second, the plaintiff must, within 180 days after commencement of discovery, serve an affidavit, signed by each expert who is expected to testify, containing the substance of the facts and opinions to which the expert plans to testify, and summarizing the grounds for those opinions. *Id.*, subds. 2(2), 4(a). The expert affidavit must also include "specific details" about "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 that allegedly resulted in damage to them." *Sorenson v. St. Paul Ramsey Med. Ctr.*, 457 N.W.2d 188, 193

(Minn. 1990). If the plaintiff fails to satisfy these affidavit requirements, the plaintiff's malpractice claim must be dismissed with prejudice. Minn. Stat. § 145.682, subd. 6(c).

We must resolve whether the district court abused its discretion when it determined that Dr. Singer's expert affidavit failed to establish a sufficient chain of causation between the administration of Synthroid to Ms. Samson and her death. To establish causation, the expert affidavit must illustrate the "how" and "why" that connects the alleged malpractice to the injury. *Teffeteller v. Univ. of Minn.*, 645 N.W.2d 420, 429 n.4 (Minn. 2002). Conclusory statements do not satisfy this requirement. *Stroud v. Hennepin Cty. Med. Ctr.*, 556 N.W.2d 552, 556 (Minn. 1996). It is not enough for the plaintiff to merely state "that the defendants 'failed to properly evaluate' and 'failed to properly diagnose'" because such statements "are empty conclusions which, unless shown how they follow from the facts, can mask a frivolous claim." *Sorenson*, 457 N.W.2d at 192-93 (citation omitted).

Dr. Singer's overarching conclusion was that "the original administration of Synthroid and later the increased dosage led to [Ms. Samson's] cardiac arrest resulting in her death." To support this conclusion, appellant argues that he established, through his expert affidavit, the following chain of causation:

> [1] There was an administration of Synthroid to an elderly person approaching 100 years
> [2] Synthroid is known to cause cardiac arrest, heart failure and death
> [3] Synthroid caused cardiac arrest and heart failure
> [4] Cardiac arrest and heart failure caused the

death of Christine R. Samson

To explain his theory regarding Ms. Samson's death, appellant directs us to Dr. Singer's opinions that (1) Synthroid is known to cause cardiac arrest and heart failure, (2) more likely than not the higher dose of thyroid replacement contributed to the overall deterioration of Ms. Samson's cardiac status, and (3) Synthroid caused deterioration of Ms. Samson's clinical status and eventually her death. Appellant also points to the affidavit's references to a number of studies on natural age-related increases in TSH and the adverse cardiovascular effects of synthetic thyroid over-replacement, as well as the manufacturer's warning label advising against giving a full hormone-replacement dose to the elderly due to the prevalence of cardiovascular disease in this population. Based on this cited information, appellant asserts:

> Synthroid is known in the medical community to cause cardiac arrest and failure in the elderly . . . [and] the Respondent prescribed such medication for over two years when such was not indicated due to the TSH levels not being over 7.5, thus not having a diseased thyroid and that such medication, unindicated, more likely than not caused [Ms. Samson's] demise or death . . . .

(Emphasis removed.)

The district court found appellant's explanation deficient, stating, "There is nothing in Dr. Singer's expert affidavit that indicated Ms. Samson's heart failure was directly caused by the administration of Synthroid." The court observed:

> Dr. Singer merely states Dr. Gordon breached the standard of care by prescribing and administering Synthroid to Ms. Samson and

> that as a result her cardiac status deteriorated. Dr. Singer's expert affidavit does not assert any opinions or discussion directly linking Ms. Samson's deterioration or death to Synthroid.

We agree with the district court that there is a missing link in appellant's theory of causation. Specifically, appellant fails to connect the second link in his chain—that "Synthroid is known to cause cardiac arrest, heart failure and death"—with the third link—that, in fact, "Synthroid caused cardiac arrest and heart failure" in this case. Appellant relies on the discussions in the manufacturer's warning and the *Physicians' Desk Reference* regarding prescribing Synthroid to elderly patients. As Dr. Gordon points out, however, neither the manufacturer's warning, nor the *Physicians' Desk Reference*, states that any specific dosage of Synthroid carries an increased probability of cardiac arrest in older patients. Rather, these sources advise physicians to prescribe lower doses of Synthroid to elderly patients, because this population has a greater likelihood of hidden heart disease, and warn about the possible adverse reactions related to hyperthyroidism[4] due to therapeutic overdosage, including arrhythmias and cardiac arrest. Yet, there is no evidence that Ms. Samson ever suffered from hyperthyroidism, which is marked by a patient's TSH levels dropping below the normal reference range.

Appellant further appears to suggest that Ms. Samson was subject to synthetic hormone over-replacement because Dr. Gordon needlessly placed her on and continued to administer Synthroid, despite the fact that her TSH levels were in a normal, although elevated, range for someone of her age group based on recent medical studies. However,

Dr. Singer's affidavit cites no evidence to support this alleged over-replacement theory. Dr. Sjoberg, an endocrinologist, reviewed Ms. Samson's dosage levels in 2011 and concluded that the 50-mcg dosage was appropriate and that her recorded TSH levels normalized on this dose. Dr. Singer opines that Ms. Samson was "not a candidate for thyroxine replacement" given her age and TSH levels. But his affidavit never states that Ms. Samson's TSH levels dropped below the normal range in the year and a half following Dr. Sjoberg's visit and before her death or that Ms. Samson's recorded levels were unacceptable or reflected any over-replacement of hormones that would give rise to concerns of adverse consequences.

Apart from TSH levels, there is no reference in the affidavit to Ms. Samson suffering any of the side effects associated with over-replacement, such as arrhythmia or toxic thyroid, during the nearly three years she was on Synthroid. In fact, Dr. Singer specifically notes in his affidavit that there is no evidence of this. And it is hyperthyroidism caused by over-replacement, and not the administration of Synthroid itself, that Dr. Singer claims would have put Ms. Samson at an elevated risk of adverse cardiovascular effects. Moreover, we note that the sources cited by Dr. Singer say nothing about an increased risk of Ms. Samson's specific cause of death: congestive heart failure.

In sum, while Dr. Singer's affidavit states that irregular heartbeat and cardiac arrest can be heightened risks in elderly people, and that these adverse side effects are more likely to occur with over-replacement of artificial thyroid hormone and resulting hyperthyroidism, the affidavit does not show that Ms. Samson suffered from any such

therapeutic overdosage. The expert affidavit is deficient because it never explains how the Synthroid dosage given to Ms. Samson directly (and most likely) caused her to suffer congestive heart failure. Therefore, as in *Stroud*, appellant's expert affidavit fails to set forth the complete chain of causation—specifically a chain that connects Dr. Gordon's administration of Synthroid to Ms. Samson with her death, as required by the statute. *See* 556 N.W.2d at 557. Because of this missing link, the affidavit fails to "set out a precise explanation of why respondents' failure to follow the applicable standard of care caused the death" of Ms. Samson. *Cf. Demgen v. Fairview Hosp.*, 621 N.W.2d 259, 263 (Minn. App. 2001), *review denied* (Minn. Apr. 17, 2001).

Appellant argues that an expert affidavit is fundamentally intended to provide "meaningful disclosure" and correctly observes, "This is not a situation where the Defendants are required to guess or search out for the Plaintiff['s] theory of the case." However, the Minnesota Supreme Court has made clear that "absence of prejudice to defendant, [or a] failure of defendant to prove plaintiff's claim is frivolous . . . will not excuse or justify an affidavit of expert identification falling short of the substantive disclosure requirement." *Lindberg v. Health Partners, Inc.*, 599 N.W.2d 572, 578 (Minn. 1999); *see also Broehm v. Mayo Clinic Rochester*, 690 N.W.2d 721, 726 (Minn. 2005) ("So as not to undermine the legislative aim of expert review and disclosure, we have stressed that plaintiffs must adhere to strict compliance with the requirements of Minn. Stat. § 145.682.").

Finally, appellant argues that the district court, in evaluating the sufficiency of the expert affidavit, erroneously required him to "disprove all other

[possible causes] of death." This claim stems from the following language at the end of district court's memorandum in its dismissal order: "While Dr. Singer certainly has provided evidence it is possible the Synthroid caused Ms. Samson's death, there are also so many other possible causes for cardiac arrest in a 99 year old woman."

A logical reading of the court's statement, particularly when considered in context, is that the district court was referring to the fact that Dr. Singer failed to demonstrate the necessary causal link that it was more likely than not that it was Synthroid that caused Ms. Samson's death. To explain its decision to dismiss appellant's case, the district court stated:

> Not only is there no detailed chain of causation linking the alleged negligence (Dr. Gordon's administration of Synthroid) with the claimed injury (Ms. Samson's death), but the conclusion drawn is a classic logical fallacy. While Dr. Singer certainly has provided evidence it is possible the Synthroid caused Ms. Samson's death, there are also so many other possible causes for cardiac arrest in a 99 year old woman. There is no medical evidence to support the conclusion of Dr. Singer that Synthroid was more likely than not the cause in this case.

Based on this language, rather than improperly shifting the burden onto appellant to disprove all other possible causes of death, the district court appears to have been explaining how appellant's chain of causation is missing a link that would permit the conclusion that Synthroid more likely than not caused Ms. Samson's congestive heart failure.

Appellant asserts that, as in *Pfeiffer ex rel.*

Pfeiffer v. Allina Health Sys., 851 N.W.2d 626 (Minn. App. 2014), *review denied* (Minn. Oct. 14, 2014), the district court improperly acted as a factfinder "when it made its decision that all other causes of death have not been ruled out when none have been brought forward by [respondents]." This argument is unavailing. To establish causation, a plaintiff must show that the "defendant's action or inaction was a direct cause of the injury. . . . A mere possibility of causation is not enough to sustain a plaintiff's burden of proof." *McDonough v. Allina Health Sys.*, 685 N.W.2d 688, 697 (Minn. App. 2004) (citations omitted). Here the district court determined, within its discretion, that Dr. Singer's affidavit failed to show how Ms. Samson's congestive heart failure was directly caused by the artificial thyroid hormone she was given for nearly three years with no recorded adverse side effects and normalized TSH levels, as opposed to the result of preexisting maladies or old age. The district court did not erroneously require appellant to disprove all other causes of death.

In sum, we conclude that the district court did not abuse its discretion in dismissing appellant's medical-malpractice claim.

Affirmed.

Footnotes:

1. Hypothyroidism occurs when there is insufficient production of thyroid hormones. *The American Heritage Dictionary* 891 (3d ed. 1992).

2. An arrhythmia is an irregularity in the force or rhythm of the heartbeat. *The American Heritage Dictionary* 102 (3d ed. 1992).

3. In addition to its motion to dismiss, Essentia also moved for summary judgement. The district court did not find it necessary to rule on Essentia's

summary-judgment motion because appellant's claim was dismissed. Because we conclude that the district court acted within its discretion in dismissing appellant's medical-malpractice action for noncompliance with the statutory expert-disclosure requirements, we need not consider Essentia's arguments for summary judgment.

4. Hyperthyroidism occurs from pathologically excessive production of thyroid hormones. *The American Heritage Dictionary* 889 (3d ed. 1992).

STATE OF MINNESOTA DISTRICT COURT

COUNTY OF ST. LOUIS SIXTH JUDICIAL DISTRICT

File No. 69DU-CV-15-3179

Ludwig P. Samson, Trustee for the Heirs and Next of Kin of Christine R. Samson, deceased,

Plaintiff,

v. **ORDER**

Jack W. Gordon, M.D., Essentia Health d/b/a Essentia Health Virginia d/b/a Essentia Health Virginia Care Center f/k/a Virginia Convalescent Center and/or f/k/a Virginia Regional Medial Center; and Essentia Health Virginia, LLC, d/b/a Essentia Health Virginia d/b/a Essentia Health Virginia Care Center f/k/a Virginia Convalescent Center and/or f/k/a Virginia Regional Medical Center,

Defendants.

The above-entitled matter came before the Court, the Honorable Jill A. Eichenwald presiding, on December 5, 2016, on a motion to dismiss brought by Dr. Jack Gordon, M.D., and a motion to dismiss and for summary judgment brought by Essentia Health et al. Richard Bosse, Esq., appeared on behalf of the plaintiff. Elie Biel, Esq., appeared on behalf of the defendant Dr. Jack Gordon, M.D. Amber Garry, Esq., appeared on behalf of the defendant Essentia

Health et al. The parties submitted briefs prior to the hearing, and the matter was taken under advisement on December 5, 2016.

The Court, being fully advised of the premises, and having considered the arguments of counsel, applicable law and the entire record before the Court, now makes the following:

ORDER

1. Defendants Dr. Jack Gordon, M.D., and Essentia et al.'s motion to dismiss is GRANTED.
2. This matter is dismissed with prejudice for failing to meet the expert affidavit requirements of Minnesota Statute §145.682.
3. The attached Memorandum is hereby incorporated into this Order by reference.

BY THE COURT:

s/_____
The Honorable Jill A. Eichenwald
Judge of the District Court

Memorandum

This matter is before the Court pursuant to Defendant Dr. Jack Gordon, M.D.'s ("Dr. Gordon") motion to dismiss pursuant to Minnesota Statutes § 145.682, and Defendant Essentia Health et al.'s ("Essentia") motion to dismiss pursuant to Minnesota Statutes § 145.682 or, in the alternative, for summary judgment. Defendants allege that Plaintiff's affidavits of expert disclosure are insufficient. Plaintiff contends that the expert affidavits are sufficient.

Background

In October, 2004, 91-year-old Christine Sampson was admitted to the Virginia Convalescent Center for long-term care. At the time of her admission, Ms. Sampson was noted to have significant Alzheimer's disease and dementia. In June, 2008, Dr. Gordon assumed care of Ms. Sampson. In September, 2008, Neurologist Kevin Cowens, M.D., examined Ms. Sampson on a referral from Dr. Gordon. Dr. Cowens concluded that Ms. Sampson had severe Alzheimer's disease as well as Parkinson's disease. On January 10, 2010, Dr. Gordon diagnosed Ms. Sampson with hypothyroidism and started her on a 25 mcg dose of Synthroid (also known as levothyroxine), a synthetic form of thyroid hormone and standard treatment for hypothyroidism.[1] Based on Ms. Samson's thyroid-stimulating hormone (TSH)[2] levels, on March 9,

[1] See Hypothyroidism (underactive thyroid), Mayo Clinic, at http://www.mayoclinic.org/diseases-conditions/hypothyroidism/diagnosis- treatment/treatment/txc-20155362

[2] TSH levels are a marker for identifying abnormal thyroid function, American Thyroid Association, at http://www.thyroid

2010, Dr. Gordon gradually increased Ms. Samson's Synthroid dose so it would alternate between 25 mcg per day and 50 mcg per day. On August 17, 2010, Ms. Samson's Synthroid was increased to 50 mcg per day, after which her TSH levels stabilized. Ms. Samson remained on this dose level until her death. On June 29, 2011, Ms. Samson was evaluated by Endocrinologist Robert Sjoberg, M.D. Dr. Sjoberg reviewed Ms. Samson's medical records and, based on lab tests, concluded that the Synthroid was not harming Ms. Samson and the Synthroid doses were the appropriate dose. On May 12, 2012, Ms. Samson's family placed her on comfort measures. Ms. Samson passed away on October 11, 2012 from heart failure. She was 99 years old.

Plaintiff alleges that Ms. Samson's death was a result of the negligence of Dr. Gordon and the agents and employees of Essentia to exercise the proper degree of standard of care by prescribing and treating Ms. Samson with Synthroid, a medication which is known to cause cardiac arrest, and which caused such cardiac arrest and heart failure of Ms. Samson. Defendants Dr. Gordon and Essentia deny that they and their employees acted negligently and caused the death of Ms. Samson.

Applicable Law

To bring a medical malpractice action in Minnesota, Plaintiff is required to comply with the substantive and procedural requirements set forth in Minnesota Statute §145.682. Minnesota Statute § 145.682 was enacted by the legislature to eliminate frivolous medical-negligence lawsuits by requiring that plaintiffs file affidavits verifying that their

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.org/hypothyroidism/

alleged claims are well founded. *Stroud v. Hennepin County Med. Ctr.,* 556 N.W.2d 552, 555 (Minn.1996). First, the plaintiff must serve with the complaint an affidavit of the plaintiff's attorney stating that the attorney has reviewed the case with an expert whose qualifications provide a reasonable expectation that the expert's opinions could be admissible at trial and that in the expert's opinion the defendant injured the plaintiff due to a deviation from the applicable standard of care. *See* Minn. Stat. § 145.682, subds. 2, 3. Second, the plaintiff must serve an affidavit identifying the experts who will testify at trial, the substance of their testimony, and a summary of the grounds for their opinions within 180 days of the commencement of the suit. *See* Minn. Stat. § 145.682, subds. 2, 4.

Minnesota Statute 145.682, subd. 2, specifically limits its application to those medical malpractice actions "as to which expert testimony is necessary to establish a prima facie case." *Tousignant v. St. Louis Cty.*, 615 N.W.2d 53, 58 (Minn. 2000). Most medical malpractice claims require expert testimony to establish a prima facie case. *Sorenson v. St. Paul Ramsey Med. Ctr.*, 457 N.W.2d 188, 191 (Minn. 1990). This is because most medical malpractice cases "involve complex issues of science or technology, requiring expert testimony to assist the jury in determining liability." *Tousignant* at 58. If a plaintiff fails to provide the required expert testimony, the action is frivolous *per se*. *Sorenson* at 191.

To establish a prima facie case of negligent care and treatment, plaintiffs must introduce expert testimony demonstrating (1) the standard of care recognized by the medical community as applicable to the particular defendant's conduct, (2) that the

defendant in fact departed from that standard, and (3) that the defendant's departure from the standard was a direct cause of [the patient's] injuries. *Plutshack v. University of Minnesota Hospitals*, 316 N.W.2d 1, 5 (Minn. 1982). "In order to establish a prima facie case of medical malpractice in this state, a plaintiff must prove, among other things, that it is more probable than not that his or her injury was a result of the defendant health care provider's negligence." *Leubner v. Sterner*, 493 N.W.2d 119 (Minn. 1992). When expert testimony is essential to a plaintiff's proof, it "must demonstrate a reasonable probability that defendant's negligence was the proximate cause of the injury." *Walton v. Jones*, 286 N.W.2d 710, 715 (Minn.1979). Alternatively stated, testimony must establish that "it was more probable that (the injury) resulted from some negligence for which defendant was responsible than from something for which he was not responsible." *Harvey v. Fridley Med. Ctr., P. A.*, 315 N.W.2d 225, 227 (Minn. 1982).

To meet a prima facie case, and avoid dismissal under Minnesota Statute §145.682, the expert affidavit must (1) disclose specific details concerning the expert's expected testimony, including the applicable standard of care, (2) identify the acts or omissions that the plaintiff alleges violated the standard of care, and (3) include an outline of the chain of causation between the violation of the standard of care and the plaintiff's damages. *Teffeteller v. University of Minnesota*, 645 N.W.2d 420, 428 (Minn. 2002) (citing *Sorenson v. St. Paul Ramsey Med. Ctr.*, 457 N.W.2d 188, 190 (Minn. 1990)). The Expert Affidavit also must "provide specific details concerning their experts' expected testimony, including the applicable standard of care,

the acts or omission that plaintiffs allege violated the stated of care and an outline of the chain of causation that alleged resulted in damage to them." *Sorenson* at 193.

It is not enough to "simply repeat the facts in the hospital or clinic record (*Sorenson* at 192) or contain a simple identification of the expert expected to testify and/or a "general disclosure." *Lindberg v. Health Partners, Inc.*, 599 N.W.2d 572, 578 (Minn. 1999). A disclosure that merely puts defendant on "notice" of the proposed testimony is also not sufficient. *Teffeteller* at 430. An expert affidavit stating that the defendants "failed to properly evaluate" or "failed to properly diagnose" was insufficient. *Sorenson* at 192. Those were "empty conclusions" as to causation which could mask a frivolous claim in the absence of a showing as to how the defendant's alleged failure to properly diagnose the illness of the decedent's mother led to decedent's death. *Sorenson* at 192-93. An affidavit that provides only broad and conclusory statements as to causation is also insufficient because the affidavit fails to "provide an outline of the chain of causation between the alleged violation of the standard of care and the claimed damages." *Stroud* at 556. See also *Lindberg* at 578 and *Mercer v. Andersen*, 715 N.W.2d 114, 123 (Minn. Ct. App. 2006). An expert affidavit is insufficient if it fails to "clearly set forth the standard of care, the defendant's acts or omissions that allegedly violated that standard, and the chain of causation between these violations and the plaintiff's injury." *Anderson v. Rengachary*, 608 N.W.2d 843, 848 (Minn. 2000).

The primary purpose of an expert affidavit is to illustrate "how" and "why" the alleged malpractice caused the injury. *Teffeteller* at 429 n. 4. The

affidavit should "set out how the expert will use those facts to arrive at opinions of malpractice and causation." *Stroud* at 555 and *Sorenson* at 192. The expert affidavit must set for a specific and detailed chain of causation linking the alleged negligence with the claimed injury. *Teffeteller* at 429. *See also Maudsley v. Pederson*, 676 N.W.2d 8, 13–14 (Minn. Ct. App. 2004).

Failure by the plaintiff to strictly satisfy the requirements under Minnesota Statute § 145.682, subd. 4(a) results in dismissal of the claim with prejudice. *Teffeteller* at 430-31 (dismissal of malpractice action mandated where expert disclosure contained only broad and conclusory statements); *Anderson* at 848 (dismissal mandated where expert disclosure clearly failed to fulfill the statutory requirements); *Lindberg* at 578 (dismissal mandated where expert disclosure falls short of the substantive disclosure requirements).

Analysis

There is no dispute in this matter that expert testimony is required and that Plaintiff filed both the statutorily required expert affidavits timely. Plaintiff also filed a supplemental expert affidavit. The dispute in this matter is whether the expert affidavits comply with the substantive expert disclosures required by Minnesota Statute §145.682. Plaintiffs claim that the Affidavits and Identification of Expert Barry L. Singer, MD ("Dr. Singer"), meets the requirements of Minnesota Statute §145.682 and this matter should not be dismissed. Defendants claim that Dr. Singer's expert affidavits are insufficient under Minnesota Statute §145.682 as they provide scant factual detail, lack any substantive discussion as to the grounds for his

standard of care, and fail to outline a specific chain of causation linking the alleged negligence with the claimed injury; therefore this matter should be dismissed.

In his Supplemental Affidavit of expert disclosure, Dr. Singer sets forth his medical opinion in paragraph 7 a and b of his affidavit (Singer Supp. Aff. ¶ 7a and ¶ 7b) and states the brief summary of facts on which he bases his opinion in paragraph 5 a-f (Singer Supp. Aff. ¶ 5a-f). Dr. Singer asserts (or will assert) that it is a standard of care not to administer thyroid replacement, i.e. Levothyroxine, commonly known as Synthroid, to patients approaching 100 years of age, particularly when the patient's TSH levels are not above 7.5, and it is not the standard of care to increase administration of Synthroid from 25 mcg to 50 mcg in patients approaching 100 years of age, particularly when the patient's TSH levels are not above 7.5, (Singer Supp. Aff. ¶ 6a and ¶ 6b). Dr. Singer asserts that Synthroid is a medication which is known to cause cardiac arrest and heart failure (Singer Supp. Aff. ¶ 7a) and elderly patients are more likely to develop arrhythmias and complications from doses above 25 mcg per day (Singer Supp. Aff. ¶ 7b). Dr. Singer asserts the following: Dr. Gordon deviated from the standard of care by prescribing Synthroid to Ms. Samson, Synthroid can cause arrhythmias; it is most likely Ms. Samson did not benefit from Synthroid; it is more likely than not that the higher dose of Synthroid contributed to Ms. Samson's overall deterioration of cardiac status; and it is more likely than not as a result of the administration and increase dosage of Synthroid led to Ms. Samson's cardiac arrest, resulting in her death (Singer Supp. Aff. ¶ 8a-d).

Defendant Dr. Gordon argues that Dr. Singer's expert affidavit and opinions appeared to be based on the following facts: 1) Ms. Samson was diagnosed with hypothyroidism in January, 2010 at the age of 96; 2) Dr. Gordon treated Ms. Samson by starting her on a daily dose of 25 mcg of Synthroid, which he later raised to 50 mcg per day; 3) Dr. Sjoberg confirmed in June, 2011 that Ms. Samson was tolerating the doses; and 4) from age 96 to 99, Ms. Samson allegedly experienced a deterioration in her overall medical condition. Defendant Dr. Gordon argues that this lack of factual detail is a general disclosure. Defendant Dr. Gordon also argues that Dr. Singer's standard of care, as well as his discussion of Dr. Gordon's alleged standard of care breach, is also lacking in detail sufficient enough to satisfy Minnesota Statute § 145.682.

Plaintiff contends that Dr. Singer's facts and discussion of standard of care are sufficient. Dr. Singer's first expert affidavit didn't contain detailed support of his stated standard of care. However, it is clear that in his supplemental expert affidavit, Dr. Singer details a great number of studies which address use of Synthroid in elderly patients. (Singer Supp. Aff. ¶ 9-23).

Defendants Dr. Gordon and Essentia also argue that Dr. Singer's expert affidavit fails to provide a detailed chain of causation linking either Dr. Gordon or Essentia's alleged negligence to Ms. Samson's death.

Plaintiff contends that Dr. Singer provides a short, simple chain of causation: 1)There was administration of Synthroid to an elderly person approaching 100 years; 2) Synthroid is known to cause cardiac arrest; 3) Synthroid caused cardiac arrest and heart failure; and 3) Cardiac arrest and

heart failure caused the death of Ms. Samson.

In *Demgen v. Fairview Hosp.*, 621 N.W.2d 259, 263-264 (Minn. Ct. App. 2001), the Court of Appeals held that the district court abused its discretion by dismissing appellants' lawsuit based on the sufficiency of the affidavit. The affidavit in *Demgen*, the affidavit laid out facts and an opinion indicating that

> (d) the combination of these findings would require an immediate caesarean section; (e) failure to administer the appropriate tests delayed a caesarean section; (f) "[h]ad such an emergency caesarean section been timely performed, a live birth would have resulted"; and (g) if appellants had followed the applicable standard of care, including delivery by caesarean section, the fetus would have been born "prior to the cessation of the fetus's cardiac activity."

Id. "Unlike the conclusory statements in *Lindberg*, Dr. Soderberg's affidavit provided an explanation of the standard of care, the nurse's specific deviations from the standard of care, and a chain of causation resulting from the deviation." *Id.* Compare *Demgen* and *Blatz v. Allina Health System*, 622 N.W.2d 376, 387 (Minn. Ct. App. 2001) (upholding the district court's denial of a motion for judgment notwithstanding the verdict or new trial where the expert testimony on causation based on delay emphasized a five minute window to avoid brain damage) *with Maudsley v. Pederson*, 676 N.W.2d 8, 13-14 (Minn. Ct. App. 2004). In *Maudsley*, the expert's affidavit stated

> It is more likely than not that if treatment had been initiated on June 27, rather than June 28, Leslie Maudsley would not have lost the vision

> in her right eye. She may have suffered some impairment to that vision, but she would not have lost it totally. When infections are present it is generally the rule that better outcomes are the result of earlier treatment; in fact every hour counts. It is more likely then [sic] not that if treatment had been initiated on June 27, 1999 that Leslie Maudsley would have recovered from the infection and had the vision she had at the time surgery was performed on June 17, 1999.

Maudsley at 13-14. The court held the affidavit was not sufficient to satisfy the strict standard for expert affidavits because it failed to illustrate "how" and "why" the alleged malpractice caused the injury. *Maudsley* at 14. Likewise, in *Teffeteller,* the court held that the affidavit was insufficient because, while the affidavit stated "that defendants should have immediately recognized that [the patient] was experiencing morphine toxicity" and outlined "what should have been done to comply with an acceptable level of care thereafter," the affidavit was insufficient because it treated "the cause of death summarily" and simply stated that "the departures from accepted levels of care, as *identified*, were a direct cause of Thad Roddy's death." *Teffeteller* at 429.

Dr. Singer's expert affidavit states that Dr. Gordon deviated from the standard of care by prescribing and administering Synthroid to a patient approaching 100 years of age (Singer Supp. Aff. ¶ 8a). Dr. Singer further states that arrhythmias as well as toxic thyroid states can occur (Singer Supp. Aff. ¶ 8b). Dr. Singer states that Ms. Samson more likely than not did not benefit from the Synthroid and more likely than not the Synthroid contributed to her overall deterioration of cardiac status, but also concedes there is no mention of arrhythmia in Ms.

Samson's record. (Singer Supp. Aff. ¶ 8c). Dr. Singer concludes that it is his opinion that Ms. Samson was not a patient for Synthroid and that it was more likely than not that as a result of the administration of Synthroid led to her cardiac arrest, resulting in her death. (Singer Supp. Aff. ¶ 8d).

The Court finds that this chain of causation is more similar to the broad, conclusory statements found in *Stroud, Sorenson*, *Lindberg*, and *Teffeteller* than the affidavit in *Demgen* and *Blatz*. Dr. Singer's expert affidavit, while supporting his standard of care with numerous studies, does not state the how and why the alleged breach of standard of care caused the injury. The affidavit must provide more than a sneak peek; it must, at the least, provide a **meaningful** disclosure setting forth the standard of care, the act or omission breaching that standard, and the **chain of causation**. *Teffeteller* at 430 (emphasis added). There is nothing in Dr. Singer's expert affidavit that indicated Ms. Samson's heart failure was directly caused by the administration of Synthroid. Much like *Teffeteller*, Dr. Singer's expert affidavit treats the cause of Ms. Samson's death summarily, only stating that Synthroid can cause arrhythmias and cardiac arrest and that Ms. Samson died of cardiac arrest. Dr. Singer merely states Dr. Gordon breached the standard of care by prescribing and administering Synthroid to Ms. Samson and that as a result her cardiac status deteriorated. Dr. Singer's expert affidavit does not assert any opinion or discussion directly linking Ms. Samson's deterioration or death to Synthroid. Not only is there no detailed chain of causation linking the alleged negligence (Dr. Gordon's administration of Synthroid) with the claimed injury (Ms. Samson's death), but the conclusion drawn is a classic logical

fallacy. While Dr. Singer certainly has provided evidence it is possible the Synthroid caused Ms. Samson's death, there are also so many other possible causes for cardiac arrest in a 99 year old woman. There is no medical evidence to support the conclusion of Dr. Singer that Synthroid was more likely than not the cause in this case. That makes this case like *Stroud* and *Sorenson*, and like the affidavits in those cases, Dr. Singer's affidavit with broad, conclusory statements as to causation does not satisfy the Statute.

Conclusion

The question before the Court is not whether Plaintiff will be able to prevail at trial or even survive a motion for summary judgment. This is a Motion to Dismiss, based upon a specific and narrow statutory requirement. Applying the standards of Minnesota Statute § 145.682 to Dr. Singer's expert disclosure affidavits, the Court finds that Dr. Singer's expert affidavits are insufficient to satisfy the requirements of Minnesota Statute § 145.682. Dr. Singer's expert affidavits do have sufficient information as to the standard of care but the chain of causation is based on empty, broad, and conclusory statements. Therefore, Defendants' Motions to Dismiss are granted.

Since the expert affidavits are insufficient under Minnesota Statute § 145.682 and this matter must be dismissed, there is no need for this Court to address Defendant Essentia et al.'s motion for summary judgment.

J.A.E.

STATE OF MINNESOTA COURT OF APPEALS

AMENDED JUDGMENT

Appellate Court #A17-0721

Trial Court # 69DU-CV-15-3179

Ludwig P. Samson, Trustee for the Heirs and Next of Kin of Christine R. Samson, deceased, Appellant, vs. Jack W. Gordon, M. D., Respondent, Essentia Health d/b/a Virginia Convalescent Center and/or f/k/a Virginia Regional Medical Center; et al., Respondents

Pursuant to a decision of the Minnesota Court of Appeals duly made and entered, it is determined and adjudged that the decision of the St. Louis County District Court, Duluth Office herein appealed from be and the same hereby is affirmed and judgment is entered accordingly.

It is further determined and adjudged that Jack Gordon, M D., herein, have and recover of Ludwig P. Samson, Trustee for the Heirs and Next of Kin of Christine R. Samson, deceased, herein the amount of $649.84 as costs and disbursements in this cause, and that execution may be issued for the enforcement thereof

It is further determined and adjudged that Essentia Health dl bla Virginia Convalescent Center and/or flk/a Virginia Regional Medical Center; et al., herein, have and recover of Ludwig P. Samson, Trustee for the Heirs and Next of Kin of Christine R. Samson, deceased, herein the amount o/$615.13 as

costs and disbursements in this cause, and that execution may be issued for the enforcement thereof

Dated and signed: April 27, 2018 FOR THE COURT

Attest: AnnMarie S. O'Neill
Clerk of the Appellate Courts

By: s/ _____

Statement For Judgment

Costs and Disbursements in the Amount of: $1,264.97
Attorney Fees in the Amount of:
Other in the Amount of:

Total: $1,264.97

Satisfaction of Judgment filed: _____
Dated

Therefore the above judgment is duly satisfied in full and discharged of record

Attest: AnnMarie S. O'Neill By: _____
Clerk of the Appellate Court Assistant Clerk

STATE OF MINNESOTA COURT OF APPEALS

TRANSCRIPT OF JUDGMENT

I, AnnMarie S. 0 *'Neill, Clerk of the Appellate Courts, do hereby certify that the foregoing is a full and true copy of the Entry of Judgment in the cause therein entitled, as appears from the original record in my office ; that I have carefully compared the within copy with said original and that the same is a correct transcript therefrom.*

Witness my signature at the Minnesota Judicial Center,

In the City of St. Paul. April 27, 2018
Dated
Attest: AnnMarie S. O'Neill
Clerk of the Appellate Courts

By: s/_____
Clerk of the Appellate Courts

STATE OF MINNESOTA IN DISTRICT COURT

COUNTY OF ST. LOUIS SIXTH JUDICIAL DISTRICT

Court File No. 69DU-CV-15-3179
Case Type: Wrongful Death
Judge: Jill Eichenwald

Ludwig P. Samson, *as* Trustee of the
Heirs and Next of Kin of
Christine R. Samson, deceased,
Plaintiffs,

vs.

SUPPLEMENTAL AFFIDAVIT AND IDENTIFICATION OF EXPERT BARRY L. SINGER, M.D.

Jack W. Gordon, M.D.,
Essentia Health, d/b/a Essentia Health Virginia
d/b/a Essentia Health Virginia Care Center f/k/a
Virginia Convalescent Center and/or
f/k/a Virginia Regional Medical Center; and
Essentia Health Virginia, LLC, d/b/a
Essentia Health Virginia d/b/a
Essentia Health Virginia Care Center f/k/a
Virginia Convalescent Center and/or f/k/a
Virginia Regional Medical Center,
Defendants.

STATE OF CALIFORNIA)
) ss
COUNTY OF SAN DIEGO)

Barry L. Singer, M.D., being first duly sworn

upon oath, states and deposes as follows:
(with supplements in **bold)**

1. Your Affiant is Barry L. Singer, M.D., who is expecting to testify with respect to the issues of negligence, malpractice and causation.

2. Your Affiant, Barry L. Singer, M.D., is a licensed physician who is board certified by the American Board of Internal Medicine, Board of Oncology and Board of Hematology and is a diplomat of each of these Boards and who practices in Norristown,

Pennsylvania. See my Curriculum Vitae attached hereto and my schedule of cases in which I have testified at deposition or in trial in the past four (4) years.

3. Your Affiant has reviewed the following medical records of Christine R. Samson bate-stamped Rl-R2208.

4a. All opinions expressed herein are made within a reasonable degree of medical certainty.

b. The term standard of care as used herein is that national standard according to the customary and usual practice of the ordinary skilled and careful practitioner of the same school.

BRIEF SUMMARY OF FACTS

5. The substance of the facts and opinions to which the expert is expected to testify are as follows:

a. At 96 years old, in January 2010 the patient was diagnosed with hypothyroidism.

b. The initial dose of Levothyroxine was 25 micrograms daily *as* prescribed by Dr. Jack W. Gordon.

c. A few months later, in March 2010, the dose was increased to 25 alternating to 50 micrograms and then finally to *50* micrograms by Dr. Jack W. Gordon.

d. On information from her son, who saw her daily, the patient manifested worsening dementia as well as overall medical condition deterioration while on thyroxine replacement, and while on the higher doses the patient's tremors and lethargy got worse.

e. On June 29, 2011 she was seen by an endocrinologist regarding this problem and it was the opinion of Dr. Robert J. Sjoberg that this patient was on the medication but not at hypothyroid levels but he further commented that he did not know whether the thyroid replacement was of any benefit to her at all.

f. The patient was apparently tolerating the doses according to Dr. Sjoberg but he only saw her briefly in June of 2011 and the patient died **over a year** later on October 11, 2012.

STANDARD OF CARE

6 a. It is the standard of care not to administer thyroid replacement i.e. Levothyroxine commonly known as Synthroid to patients approaching 100 years of age **particularly when the patient's TSH is not above 7.5.**

b. **It is the standard of care not to increase the administration of Synthroid from 25 mg to 50 mg in patients approaching 100 years particularly when the patient's TSH is not above 7.5.**

DEVIATION FROM THE STANDARD OF CARE (VIOLATION OF THE STANDARD OF CARE)

7. My opinion and the summary of the grounds of said opinion as to Dr. Jack W. Gordon falling below the standard of care are as follows:

a. Dr. Gordon deviated from the standard of care by prescribing and administering a thyroid replacement, i.e. Levothyroxine commonly known as Synthroid to a patient approaching 100 years of age. **He prescribed and administered such in January 2010 when her TSH was at 5.97 and not above 7.5. It is well known that elderly above 80 years old naturally have elevated TSH above a 5.0 limit for those of lesser years.** Synthroid is a medication which is known to cause cardiac arrest and heart failure. **Christine R. Samson died from cardiac heart failure or congestive heart disease. More likely than not such heart failure was the result of the Syntbroid.**

b. There is significant risk in administering thyroid replacement in a patient approaching a hundred (100) years of age. Elderly patients are more likely to develop arrhythmias and complications from doses greater than 25 micrograms. This patient was given a dose twice that **of** 50 micrograms and according to the family, particularly the son, her condition worsened on this dose. **Dr. Gordon deviated from the standard of care on August 17, 2010 when he increased the administration of Synthroid from 25 mg to 50 mg. Elderly patients are more likely to develop arrhythmias from doses higher than 25 mg.**

The patient's TSH was at 4.14 on that date, not above 7.5. The patient's TSH was not above the 4.82 upper limit utilized by the Virginia Regional Clinic laboratory for those less than 80 years old nor the 5.0 upper limit utilized by St. Mary's Duluth Clinic laboratory on January 10, 2011. According to the patient's son, who was with her daily, while OD the higher doses her tremors and lethargy grew worse. More likely than not Christine R. Samson's heart failure was the result of the administration of Synthroid with doubling of its dose and such administration is not indicated.

CAUSATION AND DAMAGES

8. a. Dr. Jack W. Gordon deviated from the standard of care by prescribing and administering a thyroid replacement, i.e. Levothyroxine commonly known as Synthroid to Christine R Samson, a patient approaching 100 years of age.

b. Arrhythmias as well as toxic thyroid states can occur. When this patient was seen in June by the endocrinologist her thyroid levels were normal on Levothyroxine however he did not want to discontinue the drug because he felt that there might be a withdrawal symptom. If the patient had never been started on the medication of course there would not be withdrawal symptoms.

c. More likely than not this patient did not benefit from the thyroid replacement and more likely than not the higher dose of thyroid replacement contributed to her overall deterioration of the cardiac status. There is no mention of arrhythmia in the record but the patient was not monitored on a

constant basis as in an ICU so arrhythmias could not be picked up.

d. It is my opinion from review of the records that at age 99 this patient was not a candidate for thyroxine replacement. **Her TSH was not above 7.5 when initially administered. There was no benefit to the utilization of such treatment and the risk of such administration was arrhythmias and cardiac arrest which occurred. More likely than not the administration of this drug caused her cardiac arrest resulting** in **her death, as evidenced by her death certificate.** This patient had multiple problems including dementia and Alzheimer's disease. This patient, in my opinion, was not a candidate for higher doses of thyroid replacement **when at that time her TSH was not even above the upper limit for younger persons. More likely than not as a result of the original administration of Synthroid and later the increased dosage led to her cardiac arrest resulting** in **her death as evidenced by her death certificate.**

SUPPLEMENT

9. The thyroid is a 2-inch-long, butterfly-shaped gland located in the front of the neck below the voice box which bas two lobes on either side of the windpipe. The thyroid is part of the endocrine system which systems produces and stores hormones and releases them into the bloodstream to direct the activity of the body's cells. The thyroid hormones regulate metabolism that is the way the body uses the energy. It affects nearly every organ in the body including brain development,

breathing, heart and nervous system functions, body temperature, muscle strength and cholesterol levels. The thyroid produces two hormones, thyroxine (T_4) and triiodothyronine (T_3).

10. Thyroid-stimulating hormone (TSH) is produced by the pituitary gland in the brain, regulates thyroid hormone production. When thyroid hormone levels in the blood are low, the pituitary releases more TSH and when the levels are high the pituitary decreases TSH production. The TSH blood test checks how well the thyroid is working by measuring the amount of TSH a person's pituitary is secreting. It is the most accurate test for diagnosing. It is high with hypothyroidism when the thyroid does not make enough thyroid hormone for the body's needs and low with hyperthyroidism when the thyroid produces too much hormone.[1]

11. The diagnoses of hypothyroidism relies heavily upon laboratory tests because of the lack of specificity of the typical clinical manifestations. It is characterized by a high TSB concentration. The upper limit for normal TSH concentrations for an adult is typically 4 to 5 mU/L in most laboratories.[2]

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[1] See National Institute of Health - *National Institute of Diabetes and Digestive and Kidney Diseases (NJDDK), Thyroid Tests,* www.niddk.nih.gov/health-information/health-topics/diagnostic-tests/thyroid-tests attached hereto as Exhibit A.

[2] See UpToDate: *Diagnosis of and screening of hypothyroidism in nonpregnant adults*- www.uptodate.com/contents/dlagnosls-of-and -screening-for-hypothyroidism-in-nonpregnant-adults attached hereto as Exhibit B. UpToDate is an online system by Wolters Kluwer which provides a point of care medical resource

12. The TSH upper limit of normal is as high as 8 mU/L in healthy octogenarians.[3] This has been known for some time. Age-based normal ranges for TSH were established in 2007 by an analysis of 16,533 individuals in the National Health and Nutrition Examination Survey m (NHANES III) in 2007. This study confirmed the age related shift for higher TSH concentrations in older patients, those over age 80, to an upper limit of 7.49 and that 70% of this group TSH was greater than 4.5 mU/L and were still within the normal range for their age.[4] The conclusion of the study in 2007 was that TSH distribution progressively shifts toward higher concentrations with age. 70% of older patients with TSH greater than 4.5 mIU/liter were within their age specific reference range with the 97.5 centile being 7.49 mIU/liter.

13. In April of 2009 it was reported in the Journal for Clinical Endocrinology Metabolism titled *High frequency of and/actors associated with thyroid hormone over-*

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for the healthcare practitioner. It is an evidence based clinical resource obtaining a collection or medical and patient information written by over 5,700 physician authors, editors and peer reviewers. All articles are anonymously peer reviewed.

[3] See UpToDate: *Diagnosis of and screening of hypothyroidism in nonpregnant adults* - www.uptodate.com/cootents/diagoosls-of-and -screening-for-hypothyroidism-in-nonpregnant-adults attached hereto as Exhibit B.

[4] See Surks MI, Hollowell JG. *Age-specific distribution of serum thyrotropin and antithyroid antibodies In the US population: implications for the prevalence of subclinical hypothyroidism*. J Clin Endocrinol Metab. 2007 Dec; 92(12): 4575-81. Epub 2007 Oct 2 attached hereto as Exhibit C.

replacement and under-replacement in men and women aged 65 and over[5] **that there is a very high prevalence thyroid function testing abnormalities in older people taking thyroid hormone preparations causing over-replacement, which is replacing too much thyroid hormone by use of synthetic medication. Synthroid is such a synthetic replacement which Christine R. Samson was being administered by Dr. Gordon. The study warned of the potential adverse cardiovascular effects.**[6] **In May of 2012 the Journal of Clinical Endocrinology Metabolism published an article titled *Age-related changes in thyroid function: a longitudinal study of a community-based cohort* in which the authors found that aging is associated with increased serum TSH concentrations which arises from age-related alteration in the TSH set point.**[7]

14. In 2013 the Journal of Clinical

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[5] See Somwaru LL, Arnold AM, Joshi N, Fried LP, Cappola AR. *High frequency of and factors associated with thyroid hormone over-replacement and under-replacement in men and women aged 65 and over.* J Clin Endocrinol Metab. 2009 Apr;94(4): 1342-5. doi: 10.1210/jc.2008-1696. Epub 2009 Jan6 attached hereto as Exhibit D.

[6] See Somwaru LL, Arnold AM, Joshi N, Fried LP, Cappola AR. *High frequency of and factors associated with thyroid hormone over-replacement and under-replacement in men and women aged 65 and over.* J Clin Endocrinol Metab. 2009 Apr;94(4): 1342-S. doi: 10.1210/jc.2008-1696. Epub 2009 Jan6 attached hereto as Exhibit D.

[7] See Bremner AP, Feddema P, Leedman PJ, Brown SJ, Beilby JP, Lim EM, Wilson SG, O'Leary PC, Walsh JP. *Age-related changes in thyroid function: a longitudinal study of a community-based cohort.* J Clin Endocrinol Metab. 2012 May; 97(5): 1554-62. Doi: J0.1210/jc.2011-3020. Epub 2012 Feb 16 attached hereto as Exhibit E.

Endocrinology Metabolism reported a study in Scotland titled *Age- and gender-specific TSH reference intervals in people with no obvious thyroid disease in Tayside, Scotland: the Thyroid Epidemiology, Audit, and Research Study (TEARS)*[8] in which researchers concluded that the use of age-specific reference intervals for TSH, especially in those over 70 years old, would result in the reclassification of many TSH results from "abnormal" to "normal" (within the 95th centile reference interval) and avoid unnecessary treatment.

15. The UpToDate article *Laboratory Assessment of Thyroid Function* last updated December 19, 2014 the authors noted that age-based normal ranges for TSH are important and that for over 80 years such is 7.49 mU/L with 70% of the subjects over the age of 80 being within a TSH greater than 4.5 mU/L for normal ranges for their age.[9]

16. Finally the American Thyroid Association published *Guidelines for the Treatment of Hypothyroidism* in November 2014 and determined that "It should be recognized that normal serum thyrotropin ranges are higher in older populations (such as those over 65 years), and that higher serum thyrotropin targets may be appropriate." If further found

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[8] See Vadiveloo T, Donnan PT, Murphy MJ, Leese GP. *Age- and gender-specific TSH reference intervals in people with no obvious thyroid disease in Tayside, Scotland: the Thyroid Epidemiology, Audit, and Research Study (TEARS).* J Clin Endocrinol Metab. 2013;98(3):1147 attached hereto as Exhibit F.

[9] See UpToDate: *Laboratory assessment of thyroid function* - www.uptodate.com/contents/laboratory-assessment-of-thyroid-function attached hereto as Exhibit G.

that:

> **The elderly are more susceptible to the adverse effects of thyroid hormone excess, especially atrial fibrillation and osteoporotic fractures…**

It concluded this guideline:

> **In addition to lower dose requirements related to T_4 metabolism, the target serum TSH should likely be raised in older persons, especially the oldest old (patients> 80 years), given data showing that serum TSH levels rise with age in normal individuals who are free of thyroid disease. Indeed, the 97.5% confidence interval for serum TSH in healthy elderly persons is 7.5 mIU/L, There are observational data showing decreased mortality rates and improved measures of well- being in elderly persons with TSH levels that are above the traditional reference range (i.e., 0,5-4.5 mlU/L) for the general population.[10]**

17. Christine R. Samson's date of death was October 11, 2012 at which time she was 99 years old. Two years and ten months before that on January 10, 2010 Dr. Gordon prescribed and administered the first dose of 25 mg of Synthroid. This was based upon laboratory reports of TSH levels of 5.8 on November 9th,

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[10] See excerpts from Jonklass J, Bianco A, Bauer A, Burman K, et al. *Guidelines/or the Treatment of Hypothyroidism.* THYROID Volume 24, Number 12, 2014 attached hereto as Exhibit H.

5.79 on December 9th, and 5.97 on January 8th. He increased the dosage alternating 25 to 50 on March 9, 2010 based upon a lab report of TSH at 5.75 which resulted in a TSH of 3.72 being reported on May 10, 2010. On August 17, 2010 he increased the Synthroid to 50 mg based upon a TSU reported of 4.14 not in excess of the 4.82 upper limit utilized by the reporting laboratory. She remained on this dose for over two years until her death on October 11, 2012. Dr. Gordon on her death certificate reported the cause of death as CHF i.e. congestive heart failure.

18. Dr. Gordon initially prescribed Synthroid in January 2010 with TSH readings below 7.49, even though three years before in 2007 it bad been reported that 7.49 was the upper recommended limit for those 80 years plus.[11] Four years earlier in an article published in JAMA (Journal of American Medical Association) titled *Thyroid status, disability and cognitive function, and survival in old age*[12] the researchers reported that elderly people who are 85 years of age with high TSH levels have a prolonged lifespan. A year before the initiation of Synthroid, in 2009 the Journal of Clinical Endocrinologists

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[11] See Surks MI, Hollowell JG. *Age-specific distribution of serum thyrotropin and antithyroid antibodies in tile US population: implications for the prevalence of subclinical hypothyroidism*. J Clin Endocrinol Metab. 2007 Dec; 92(12): 4575-82. Epub 2007 Oct 2 attached hereto as Exhibit C.

[12] See Gussekloo J, van Exel E, de Craen AJ, Meinders AE, Frolich M, Westendorp RG 2004 *Thyroid status, disability and cognitive function, and survival in old age.* JAMA 292:2591-2599 attached hereto as Exhibit I.

Metabolism published the study[13] warning of the adverse cardiovascular effects of over replacement. Such was below the standard of care.

19. During the administration of Synthroid to Christine R. Samson two more studies here published. In May 2012 the article *Age-related changes in thyroid/unction: a longitudinal study of a community-based cohort* in the Journal of Clinical Endocrinology Metabolism[14] warning of the TSH increases arising from age-related alterations in TSH and the August 2012 article of *Hypothyroidism in the elderly: diagnosis and management*[15] of higher TSH levels in elderly over 85 yean. Dr. Gordon failed to adhere to these warnings and reduce and eliminate such Synthroid treatment which fell below the standard of care.

20. Synthroid bas long been known to put the elderly at risk for cardiac events. The manufacturer's instructions included with this drug cautions:

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[13] See Somwaru LL, Arnold AM, Joshi N, Fried LP, Cappola AR. *High frequency of and/actors associated with thyroid hormone over replacement and under-replacement in men and women aged 65 and over.* J Clio Endocrinol Metab. 2009 Apr;94(4): 1342-5. doi: J0.1210/jc.1008-1696. Epub 2009 Jan6 attached hereto as Exhibit D.

[14] See Bremner AP, Feddema P, Leedman PJ, Brown SJ, Beilby JP, Lim EM, Wilson SG, O'Leary PC, Walsh JP, *Age-related changes In thyroid/unction: a longitudinal study of a community-based cohort.* J Clin Endocrinol Metab. 2012 May**;** 97(5): 15S4-61. Doi: 10.1210/jc.2011-3020. Epub 1012 Feb 16 attached hereto as Exhibit E.

[15] See Bensenor I, Olmos R, Lotufo P. *Hypothyroidism in the elderly: diagnosis and management.* Clinical Interventions in Aging 2012 :7 97-111 attached hereto as Exhibit J.

> **Because of the increased prevalence of cardiovascular disease among the elderly, levothyroxine therapy should not be initiated at the full replacement dose**

It describes as an adverse drug reaction cardiac arrest and again warns under the heading Cardiovascular that it should be used with caution in the elderly who have a greater likelihood of cardiac disease.[16] The Physician's Desk Reference (PDR) directs one to "Exercise caution when administering ... to the elderly in whom there is an increased risk of occult cardiac disease." It further warns

> **Overtreatment with levothyroxine sodium may have adverse cardiovascular effects such as an increase in heart rate, cardiac wall thickness, and cardiac contractility and may precipitate angina or arrhythmias.[17]**

21. I understand that Ludwig P. Samson, Christine R. Samson's son discussed the PDR warnings with Dr. Gordon. These are supported by an FDA study of 89,069 people reported to have side effects when taking Synthroid among whom 641 people bad a cardiac arrest as reported in eHealthMe in

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[16] See Synthroid - Summary Product Information. Synthroid Tablets Version 09, 03 March 2016 attached hereto as Exhibit K.

[17] See Synthroid -www.pdr.net/full-prescribing-information/synthroid?druglabelid=26 attached hereto as Exhibit L.

2015.[18] Of those having cardiac arrest 73.6 % were female the 63.48% being over the age of 60 with 100% being most severe i.e. death. eHealthme reported[19] just recently 775 people with cardiac arrest out of 132,313 people who reported side effects when taking Synthroid with 71.41% of those suffering cardiac arrest being female and with 63.58% of them being over the age of 60 and with 100% having most severe that is death.

22. In March of 2010 a study at Washington University in St. Louis was published in the Journal of Geriatric Psychiatry Neurology titled *Thyroid medication use and subsequent development of dementia of the Alzheimer type.*[20] Before the publication of this study there had been several studies as to the association between Alzheimer's disease and thyroid disease particularly a study known as the Framingham Study reported in Arch Intern Med 2008 titled Thyroid function and the risk of Alzheimer disease: the Framingham Study which reported a strong association between hypothyroidism and dementia of the Alzheimer's type (DAT). But the March 2010 reported Washington

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[18] See *eHealthMe study from FDA and social media reports* re: side effects when taking Synthroid attached hereto as Exhibit M.

[19] See *Review: could Synthroid cause Cardiac Arrest?* www.ehealthme.com/ds/synthrold/cardiac%20arresst#print attached hereto as Exhibit N.

[20] See Harper P, Roe C. *Thyroid medication use and subsequent development of dementia of the Alzheimer type.* J Geriatr Psychiatry Neurol. 2010 March; 23(1): 63. doi: 10.1177/0891988709342723 attached hereto as Exhibit O.

University Study supported an earlier study by the Mayo published in Neurology in 1991 titled The association between Alzheimer's disease and thyroid disease in Rochester, Minnesota[21] that it found no statistical correlation. The Washington University Study, though, found that there is a correlation between the utilization of thyroid medication and the development of DAT. The report of the study concluded that taking thyroid medication is associated with a faster rate of DAT diagnosis in time an increase of 67% compared to the non-medicated counterparts. Mr. Samson was noting this and was expressing this to Dr. Gordon and the healthcare providers as I understand, though his mother was extremely shy, particularly with healthcare providers.

23. **Physicians rely on oral histories from their patients and their families in treatment. It is the first criteria in the method of documentation for patient's charts known as SOAP (an acronym for subjection, objection, assessment and plan). It is the initial information elicited under subjective**.

FURTHER AFFIANT SAITH NOT.

Dated: 11/30/16 s/_____
Barry L. Singer, M.D.

Subscribed and sworn to before me

[21] See Yoshimasu F, Kokmen E, Hay ID, Beard CM, Offoard KP, Kurualnd LT. *The association between Alzheimer's disease and thyroid disease In Rochester, Minnesota.* Neurology 1991; 41(11): 1745-1747 (PubMed: 1944903} attached hereto as Exhibit P.

this ____ day of November, 2016.

(SEE ATTACHED)

_____
Notary Public

(SEAL and/or STAMP)

This Affidavit identifies the person whom the undersigned attorney expects to call as an expert witness at trial to testify with respect to the issues of negligence, malpractice or causation, the substance of the facts and opinions to which the expert is expected to testify and the summary of the grounds for each opinion.

Dated: 12/2/16 LAW OFFICES OF
RICHARD E. BOSSE, CHARTERED
By s/_____
Richard E. Bosse (#0245501)
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CALIFORNIA ALL-PURPOSE
ACKNOWLEDGMENT CIVIL CODE § 1189

[A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this is attached, and not the truthfulness, accuracy, or validity of that document]

State of California)
County of San Diego)

On November 30, 2016 before me, Leslie Michelle Laurer, Notary Public personally appeared Barry L. Singer, MD who proved to me on the basis of satisfactory evidence to be the person whose name is subscribed to the within instrument and to me that he executed the same in his authorized capacity, and that his signature on the instrument the person or the entity upon behalf of which the person acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.
s/_____
Signature *of Notary Public*

Krishnaveni Karedla, et al., Appellants,
v.
Obstetrics & Gynecology Associates, P. A., d/b/a Associates in Women's Health, et al.,
Respondents,
Allina Health System,
d/b/a Abbott Northwestern Hospital,
Defendant.

A11-1423

STATE OF MINNESOTA
IN COURT OF APPEALS

Filed June 11, 2012

This opinion will be unpublished and may not be cited except as provided by Minn. Stat. § 480A.08, subd. 3 (2010).

Reversed and remanded
Collins, Judge[*]

Hennepin County District Court
File No. 27-CV-10-19754

Wilbur W. Fluegel, Fluegel Law Office, Minneapolis, Minnesota; and
Reed K. Mackenzie, John M. Dornik, Mackenzie & Dornik, P.A., Minneapolis, Minnesota (for appellants)
William M. Hart, Cecilie M. Loidolt, Damon L. Highly, Meagher & Geer, P.L.L.P., Minneapolis, Minnesota (for respondents)

Considered and decided by Wright, Presiding Judge; Hudson, Judge; and Collins, Judge.

UNPUBLISHED OPINION

COLLINS, Judge

Appellants contend that in dismissing their medical-malpractice action for failing to comply with the requirements for affidavits of expert identification in Minn. Stat. § 145.682 (2010), the district court: (1) applied an incorrect standard of proof to assess their affidavits; (2) erroneously decided the standard of care by impermissibly relying on rebuttal materials; and (3) incorrectly held that the submitted affidavits did not sufficiently show causation. We agree and reverse.

FACTS

Appellant Krishnaveni Karedla became pregnant with her second child in 2006. Karedla visited Associates in Women's Health (AWH) on July 20, 2006, and it was noted that she had elevated blood pressure and protein levels in her urine, indicating preeclampsia.[1] Karedla was sent home with orders for bed rest, though she reported that she attended a barbeque over the weekend before returning to AWH on July 24 with similar complaints. At that visit, Karedla was referred to a clinic for diagnostic tests, and she was subsequently admitted to Abbott Northwestern Hospital. On July 25 and 26, Karedla was monitored in the hospital, including periodic blood-pressure tests. On July 27, at 2:10 p.m., Karedla became dizzy, and her blood pressure was recorded as 204/99. Karedla complained of a headache, but she was lethargic and it was "hard to assess her discomfort." Dr. Susan Dahlin was summoned to the hospital to perform a cesarean section to deliver Karedla's baby. Dr. Dahlin arrived at 3:38 p.m. and found Karedla unable to move her right arm or leg. Dr. Dahlin ordered the administration of Hydralazine, which is a blood-pressure-reducing or antihypertensive medication.

Karedla's healthy baby boy was born at 5:04 p.m. A CT scan at 6:03 p.m. showed that Karedla had suffered a serious stroke, described by one of her doctors as a "massive left intracerebral hemorrhage. . . and left to right shift." Karedla was taken into surgery; her doctor noted that "[t]he likelihood of survival is regrettably small." Karedla did survive, but is left with cognitive deficits and physical impairments.

Appellants commenced this medical-malpractice action based on the failure to properly treat Karedla's preeclamptic symptoms prior to her stroke. In addition to the affidavit of expert review filed with the complaint, appellants disclosed affidavits during discovery identifying Dr. Baha Sibai and Dr. Adrian J. Goldszmidt as medical experts that could testify in support of appellants' theory of causation. These affidavits state that Karedla's medical condition indicated the presence of severe preeclampsia because she had systolic blood pressures over 160 mm Hg on two occasions at least six hours apart. According to appellants' medical experts, the standard of care for severe preeclampsia requires the administration of an antihypertensive medication to reduce systolic blood pressure to below 160 mm Hg. These medical experts opine that, because this blood pressure regulation was not done as the standard of care required, Karedla's elevated blood pressures exerted untenable pressure on the blood vessels in her brain and caused her stroke.

Respondents moved for dismissal of the action on the ground that the affidavits failed to sufficiently show causation. Appellants responded with supplemental affidavits from both doctors to bolster the chain of causation. After a hearing, the district court issued an order granting the respondents'

motion to dismiss. Respondents moved for an amended order reflecting the district court's consideration of the supplemental affidavits. The district court issued an amended order on July 14, 2011. This appeal followed.

DECISION

Appellants challenge the district court's dismissal of their medical-malpractice action for failure to comply with Minn. Stat. § 145.682. When expert testimony is required to establish negligence, a plaintiff in a medical-malpractice case must submit two affidavits. Minn. Stat. § 145.682, subd. 2. First, the plaintiff must serve the summons and complaint with an attorney affidavit stating that the plaintiff's attorney reviewed the facts of the case with "an expert whose qualifications provide a reasonable expectation that the expert's opinions could be admissible at trial." *Id.,* subds. 2(1), 3(a). This affidavit was duly served and is not at issue in this appeal.

The second affidavit must be served within 180 days after commencement of the action and must identify, and be signed by, each expert witness that the plaintiff intends to present at the trial. *Id.,* subds. 2(2), 4(a). This affidavit must contain the substance of the facts and opinions to which the expert is expected to testify and summarize the grounds for those opinions. *Id.,* subd. 4(a). The affidavits and supporting grounds must show a prima facie case in order for the action to proceed. To establish a prima facie case of medical malpractice, a plaintiff must submit evidence sufficient to demonstrate: (1) the standard of care; (2) the defendant departed from the standard of care; (3) direct causation between the defendant's departure and the plaintiff's injury; and (4) damages.

Tousignant v. St. Louis Cnty., 615 N.W.2d 53, 59 (Minn. 2000). If the plaintiff fails to satisfy any such affidavit requirement, the malpractice action must be dismissed with prejudice. Minn. Stat. § 145.682, subd. 6(c). We review the district court's dismissal of a medical-malpractice action based on the insufficiency of an expert affidavit for abuse of discretion. *Anderson v. Rengachary,* 608 N.W.2d 843, 846 (Minn. 2000).

I. Did the district court apply the correct standard of proof?

Appellants argue that the district court applied the incorrect standard of proof in reviewing the affidavits of expert identification because the district court stated that appellants "fail to cite to any medical proof that such treatment would have undoubtedly prevented Ms. Karedla's stroke." To establish a prima facie case of causation, a plaintiff must submit evidence sufficient to demonstrate that it is more probable that the plaintiff's injury "resulted from some negligence for which defendant was responsible than from something for which he was not responsible." *Plutshack v. Univ. of Minn. Hosp.,* 316 N.W.2d 1, 7 (Minn. 1982) (quotation omitted); *see also Leubner v. Sterner,* 493 N.W.2d 119, 121 (Minn. 1992) ("In order to establish a prima facie case of medical malpractice in this state, a plaintiff must prove, among other things, that it is more probable than not that his or her injury was a result of the defendant health care provider's negligence."). Minnesota courts have never held that plaintiffs must prove their allegations to an absolute lack of doubt.

Appellants argue that the "undoubtedly" statement indicates that the district court applied the wrong standard of proof. Respondents argue that

the district court was not indicating the standard it was applying, but that using "undoubtedly" was "nothing more than an isolated, albeit unfortunate, word choice." But the "undoubtedly" statement provides the only indication of the standard of proof the district court applied. Case law represented above informs that "more likely than not" is the correct standard of proof. To the extent that the district court applied an "undoubtedly" standard to the appellants' allegations, the district court erred.

At this stage, the only evidence to be assessed is the appellants' expert-identification affidavits, which are meant to indicate how medical errors led to the damages complained of. Because it is unclear whether the district court applied the correct standard of proof, it is unclear whether the district court abused its discretion on this point. Therefore, we review the affidavits to determine whether they satisfy the correct more-likely-than-not standard for proving a medical-malpractice claim.

II. Did the district court err in determining the standard of care?

Appellants argue that the district court erroneously determined that the standard of care did not require the treatment indicated by appellants' experts. They argue that in deciding the standard of care, the district court erred by considering rebuttal evidence submitted by respondents. Appellants point to the district court's stated conclusion that "ACOG Bulletin Number 33[2] is the current recommended standard of care." Respondents argue that the standard of care was not the basis of the district court's decision, that appellants' experts opened the door for the ACOG Bulletin by citing to an article that cited the bulletin, and that the district court did not err in determining this standard of care because

the ACOG Bulletin is the standard of care.

Appellants submitted a total of four affidavits from two medical experts. These affidavits indicate that "[p]reeclampsia is severe when . . . the following are present: systolic blood pressure of 160 mm Hg or higher or diastolic pressure of 110 mm Hg or above on 2 occasions at least 6 hours apart while the patient is on bed rest," among other various factors. According to the affidavits, the standard of practice indicates that "[e]xpectant management can be employed in the clinical setting of . . . severe preeclampsia." However, "[i]f expectant management is implemented in a patient with severe preeclampsia the accepted standard of practice requires . . . use of antihypertensives to keep the diastolic between 90 and 105 mm Hg and the systolic below 160 mm Hg." Dr. Sibai noted that this standard of care is supported by a 2005 article by Dr. James Martin (Martin article).

Respondents submitted a copy of the ACOG Bulletin and argued that this practice bulletin indicates that antihypertensives were not required unless the diastolic pressures reached 105 to 110 mm Hg. Despite that, respondents also stated repeatedly at the motion hearing, and in their appellate brief, that they were not challenging the standard of care based on systolic pressure. Rather, respondents argue that they only argued the motion challenging causation, and that the district court decided the motion to dismiss solely on that issue. Appellants served supplemental affidavits from their medical experts that addressed the issue of causation, and which disputed that the ACOG Bulletin's standard of care based on diastolic pressure controlled. Appellants also disclosed a number of published articles supporting the standard of care based on

systolic pressure, which Dr. Sibai noted did "not negate the information in the [ACOG] Bulletin; [but] refine[d] it."

The district court made a finding that the ACOG Bulletin "recommends antihypertensive therapy be used for treatment of pregnancy induced hypertension when diastolic blood pressures reach 105-110 mm Hg or higher." The district court concluded as a matter of law that the ACOG Bulletin "is the current recommended standard of care." The court's memorandum of law reiterated that the ACOG Bulletin standard controlled, and stated that it "cannot allow the jury to speculate on what the appropriate standard of care was."

The prima facie case required at this stage must be supported by "evidence which suffices to establish the fact unless rebutted, or until overcome, by other evidence." *Tousignant,* 615 N.W.2d at 59 (emphasis and quotations omitted). When determining whether the appellants met their prima facie burden, a district court should not consider rebuttal evidence. *Id.* at 60 (stating that the district court's analysis "related to the [defendants'] *rebuttal* of [plaintiff's] case, not whether [plaintiff] established a prima facie case"); *Demgen v. Fairview Hosp.,* 621 N.W.2d 259, 267 (Minn. App. 2001) (noting that "conflicting evidence is not considered in determining whether a plaintiff has established a prima facie case"), *review denied* (Minn. Apr. 17, 2001). A district court that does consider rebuttal evidence has erred. *See Demgen,* 621 N.W.2d at 267 ("[T]he district court erred in relying on a defendant's rebuttal expert affidavit in balancing and weighing . . . [plaintiff's] expert affidavit to see if it met the statutory requirements of Minn. Stat. § 145.682, subd. 4(a).").

Throughout its order and memorandum, the

district court shows that it considered the ACOG Bulletin's standard based on diastolic pressure to be the applicable standard of care. But it appears that the ACOG Bulletin was before the district court having been submitted by respondents for the purpose of rebutting appellants' asserted standard of care based on systolic pressure. Respondents had no other reason to offer it. Respondents argue that appellants "opened the door" for the ACOG Bulletin because Dr. Sibai cited to the Martin article in which the ACOG Bulletin is cited. But arguing that Dr. Sibai's citation to the Martin article opened the door for the ACOG Bulletin admits that the ACOG Bulletin was, indeed, offered as rebuttal evidence. Because rebuttal evidence is not properly considered at this stage, we conclude that the district court erred by considering the ACOG Bulletin in determining the applicable standard of care.

Respondents argue that, rather than relying on the ACOG Bulletin directly, the district court could adopt the standard of care based on diastolic pressure because the documentation disclosed with appellants' expert affidavits cites to the ACOG Bulletin. Respondents argue that the Martin article suggests using the systolic pressure as an indicator for the use of antihypertensives but does not require it. But again, this would mean the district court would go beyond determining whether appellants made a prima facie showing. Appellants' medical experts, who are the only medical experts to have offered an opinion, both indicate that the standard of care is clear; they endorse the standard of care based on systolic pressure, and include an article written by Dr. Sibai, which indicates that the standard of care based on systolic pressure is the applicable best practice. Even if the Martin article indicated that a

shift should occur from the still-controlling 2002 ACOG Bulletin, there was other significant evidence indicating that the standard of care in 2006 was predicated on the systolic blood pressure. At this stage of the case, the district court is not in a position to determine what standard applied to the actions of medical professionals presented with these circumstances.

III. Did the affidavits sufficiently outline causation?

Appellants argue that the district court erred in deciding that they were asserting an "earlier is better" theory of causation and in deciding that the affidavits did not set forth a sufficient outline of causation.

A. Is the appellants' theory of causation an "earlier is better" theory?

Respondents argue, and the district court concluded, that this case presents an impermissible "earlier is better" theory of causation. *See Leubner,* 493 N.W.2d at 122 (holding delay in diagnosis to be an insufficient theory of causation); *Maudsley v. Pederson,* 676 N.W.2d 8, 14 (Minn. App. 2004) (same). Appellants argue that this conclusion misconstrues the facts of the case and their theory of causation. Rather than an "earlier is better" theory, appellants argue that the standard of care dictated that treatment was warranted immediately upon Karedla's hospital admittance, and at each spike in systolic blood pressure above 160 mm Hg. While it is implicit in that argument that immediate treatment is better than delayed treatment, this is not a simple time-based argument.

According to appellants' theory of causation, the catastrophic result of the failure to regulate

Karedla's blood pressure could have happened at any time. Under this theory, treatment to reduce blood pressure would have nearly eliminated the risk of that catastrophic result, so while it would be better to provide that treatment immediately upon its indication, the treatment would still be effective at any time before that catastrophic result occurred. A true "earlier is better" theory involves a condition that is progressively worsening over time, making the effects of that condition both more damaging and more difficult to treat. Simply because the failure to act was not immediately catastrophic does not mean that action should not have been taken after each instance of elevated blood pressure. Instead, each subsequent spike in systolic pressure was a renewed call to action. We conclude that this is not an "earlier is better" case.[3]

B. Did appellants' affidavits sufficiently outline causation?

At this stage, a plaintiff must identify the facts and expert opinions that will support a prima facie case of negligence against the defendants. Essentially, this is so that the district court can determine if the case is frivolous and should be dismissed. *Sorenson v. St. Paul Ramsey Med. Ctr.,* 457 N.W.2d 188, 191 (Minn. 1990). In order to make a prima facie case, a plaintiff must "make an initial showing of all of the elements of a medical malpractice claim" such that it would "prevail[] in the absence of evidence invalidating it." *Tousignant,* 615 N.W.2d at 59 (quotations omitted). The expert affidavit must include "specific details" about "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 that allegedly resulted in damage to them." *Sorenson,* 457

N.W.2d at 193. A plaintiff must show that the "defendant's action or inaction was a direct cause of the injury[;][a] mere possibility of causation is not enough to sustain a plaintiff's burden of proof." *McDonough v. Allina Health Sys.,* 685 N.W.2d 688, 697 (Minn. 2004) (citations omitted).

Establishing a prima facie showing of causation may be accomplished by "provid[ing] an outline of the chain of causation between the alleged violation of the standard of care and the claimed damages." *Stroud v. Hennepin Cnty. Med. Ctr.,* 556 N.W.2d 552, 556 (Minn. 1996). "The gist of expert opinion evidence as to causation is that it explains to the jury . . . 'how' and . . . 'why' the malpractice caused the injury." *Teffeteller v. Univ. of Minn.,* 645 N.W.2d 420, 429 n.4 (Minn. 2002). The plaintiff must provide more than "broad, conclusory statements as to causation." *Id.* at 428. It is not enough for the plaintiff to state "that the defendants 'failed to properly evaluate' and 'failed to properly diagnose'" because those statements "are empty conclusions which, unless [it is] shown how they follow from the facts, can mask a frivolous claim." *Sorenson,* 457 N.W.2d at 192-93. But as long as a medical expert's opinion is "based on an adequate factual foundation," the expert "is permitted to make legitimate inferences, which have probative value in determining disputed fact questions." *Blatz v. Allina Health Sys.,* 622 N.W.2d 376, 387 (Minn. App. 2001), *review denied* (Minn. May 16, 2001).

Respondents argue that appellants' affidavits are insufficient as to causation. In particular, respondents claim that "the affidavits needed to provide the *details* supporting that opinion, namely (1) that treatment with antihypertensives would have lowered elevated blood pressure, and (2) that

such a decrease in her blood pressure would have prevented the stroke." Appellants point to the expert affidavits addressing both points.

First, Dr. Sibai noted that "[t]he cause of stroke in patients with preeclampsia is thought to be related to loss of cerebral autoregulation." As explained by Dr. Goldszmidt:

> Typically the initial vascular response to mild or moderate increases in blood pressure is vasoconstriction of the arterial or arteriolar vessels. This is the body's healthy attempt to maintain tissue perfusion to the brain at a relatively constant level. As the systemic blood pressure continues to increase, the ability to regulate the blood flow is lost. The high pressure in the arterioles and capillaries forces leakage of fluid through the walls of the capillaries leading to cerebral edema.

In order to prevent the body from encountering pressures that cause it to lose the ability to self-regulate pressure, both doctors indicated that antihypertensives should be administered. Dr. Goldszmidt stated that "[a]nti-hypertensives must be administered to keep the blood pressure under control at safe levels to avoid complications." In his supplemental affidavit, Dr. Sibai stated that "Hydralazine lowers blood pressure by exerting a peripheral vasodilating effect through a direct relaxation of vascular smooth muscle. Hydralazine, by altering cellular calcium metabolism, interferes with the calcium movements within the vascular smooth muscle that are responsible for initiating or maintaining the contractile state." This effect decreases the arterial blood pressure, which "reduce[s] the risk of a rupture of the vessels."

Respondents also argue that appellants'

affidavits were insufficient in showing whether a decrease in blood pressure would have prevented the stroke. Dr. Goldszmidt stated that,

> [a]s the vessels relax and dilate, the vessel size increases without increasing the volume of blood circulating through the vessel. This in turn lowers the pressures exerted on the walls of the blood vessel. The lower the pressure on the walls of the blood vessel, the less likely the vessel wall will rupture as a result of high pressure.

Dr. Sibai added that "[t]he decreased pressure inside the blood vessels serves to reduce the risk of a rupture of the vessels." The appellants' affidavits show with ample detail that administration of antihypertensive medication such as Hydralazine would have reduced Karedla's blood pressure, and that the reduction of blood pressure would have lowered the risk of a blood-vessel rupture.

Respondents also argue that "nothing in the expert affidavits establishes that antihypertensives will *inevitably* avoid all strokes." While it is true that the affidavits do not rule out other possible causes for Karedla's stroke, at this stage appellants' burden is only to show that it is more likely that treatment with antihypertensives would have prevented Karedla's stroke than it is that such treatment would not have prevented her stroke. Indeed, appellants' experts acknowledge that there are other causes of strokes, but after lengthy discussions of the details, both experts opined that reducing Karedla's blood pressure would more likely than not have prevented her stroke.

As to the district court's assessment of the sufficiency of the affidavits on the element of causation, three other important statements were

erroneous. First, the district court stated that "[n]either of plaintiff's experts defined what would have been adequate treatment." But Dr. Sibai's supplemental affidavit addressed that issue, stating that a variety of antihypertensives could have been adequate treatment in the correct dose. He adds that "[t]he specific dose required would depend on the specific medication chosen by the obstetrician," but that an adequate treatment of Hydralazine would be "5-10 mg doses [given] intravenously every 15-20 minutes until the desired response is achieved."

Second, the district court misconstrued the affidavits in stating that "[t]he existence of high blood pressure does not automatically result in the conclusion that antihypertensive medication should be administered and failure to do so would constitute malpractice." But the affidavits indicate the opposite; the experts opine that Karedla's elevated levels of blood pressure should have automatically resulted in the administration of anithypertensives, and failure to do so in this situation is malpractice. Appellants' expert affidavits provide the only medical evidence to be considered at this stage.

Finally, respondents argue, and the district court concluded, that appellants' expert affidavits were conclusory or insufficiently detailed. In *Lindberg v. Health Partners, Inc.,* 599 N.W.2d 572, 578 (Minn. 1999), the plaintiff's expert affidavit stated that the doctor was "familiar with the applicable standard of care but fail[ed] to state what it was or how the appellants departed from it," failed to "recite any facts upon which [the doctor] will rely as a basis for his expert opinion," failed "to outline a chain of causation" and failed "to even identify the medical condition for which Ms. Lindberg allegedly was not given attention." In *Teffeteller,* the plaintiff's

expert affidavit treated the cause of the death "summarily" by stating that "the departures from accepted levels of care, as above identified, were a direct cause of Thad Roddy's death." 645 N.W.2d at 429. Here, however, appellants' expert affidavits reflect a considered level of detail that readily distinguishes them from the insufficiently detailed affidavits in other cases. While these affidavits contain conclusions, restating and summarizing the information throughout an affidavit does not render the affidavit merely conclusory. The district court's statement that the affidavits contain "only broad, conclusory statements regarding causation" is in error.

Appellants' theory of causation is that although the failure to administer antihypertensive medication does not inexorably result in a stroke, the administration of that treatment will more likely than not prevent that result. While it remains to be seen whether appellants can prevail on a full presentation and consideration of evidence from both sides, at this stage the viability of appellants' case is to be judged only on the sufficiency of their affidavits of expert identification. We conclude that when assessed by the proper "more likely than not" standard, appellants' expert affidavits are sufficiently detailed to establish a prima facie case.

Reversed and remanded.

Notes:

*. Retired judge of the district court, serving as judge of the Minnesota Court of Appeals by appointment pursuant to Minn. Const. art. VI, § 10.

1. Preeclampsia is a condition that precedes or indicates a likelihood for eclampsia, which "is defined

as the presence of new-onset grand mal seizures in a woman with preeclampsia," and engenders additional risk of hemorrhagic stroke. Preeclampsia symptoms include elevated blood pressure and elevated proteinuria, or protein in urine.

2. American College of Obstetricians and Gynecologists Practice Bulletin, January 2002 (ACOG Bulletin).

3. Further illustrating this point is the contrast between this theory of causation, and Dr. Goldszmidt's statement in his first affidavit regarding post-stroke treatment that "[e]arly treatment can limit the size of the hemorrhage [and] the extent of the damage, and improve [the] clinical outcome."