

No. 68513-9-I

**COURT OF APPEALS
STATE OF WASHINGTON**

TERRENCE J. MULLAN, et al.,

Appellants,

v.

NORTH CASCADE CARDIOLOGY, et al., and
ST. JUDE MEDICAL, INC., et al.,

Respondents.

**BRIEF OF APPELLANTS
TERRENCE J. MULLAN, ET AL.**

William E. Pierson, Jr., WSBA No. 13619
LAW OFFICE OF WILLIAM E. PIERSON, JR. | PC
600 First Avenue, Suite 233
Seattle, WA 98104
Telephone: (206) 254-0915
Facsimile: (206) 254-0916
bill.pierson@weplaw.com

Attorneys for Appellants
TERRENCE J. MULLAN, et al.

2012 JUN 18 PM 3:18
COURT OF APPEALS DIV I
STATE OF WASHINGTON
FILED

TABLE OF CONTENTS

I.	ASSIGNMENTS OF ERROR	1
II.	STATEMENT OF THE CASE	2
	A. Factual Background	2
	1. Nature of the Dispute Between the Parties.....	3
	2. The Estate’s Contentions.....	5
	B. Procedural Background	11
	1. Initial Pleadings.....	11
	2. Defendants’ Motions for Summary Judgment.....	12
III.	LEGAL ARGUMENT.....	13
	A. Standard of Review.....	13
	B. The Trial Court Below Abused Its Discretion In Failing To Grant The Estate’s Request For A CR 56(f) Continuance.....	15
	C. The Trial Court Erred As A Matter Of Law In Holding Plaintiff’s Claims Against Defendant St. Jude Medical Were Barred By The Learned Intermediary Doctrine.....	28
	D. Plaintiffs Presented Sufficient Facts To State A Claim Against Defendant Cardiologists For Violation Of RCW 7.70.030(2).....	32
IV.	CONCLUSION	36

TABLE OF AUTHORITIES

Cases

<i>Colwell v. Holy Family Hosp.</i> , 104 Wn. App. 606, 15 P.3d 210 (2001).....	14
<i>Estate of LaMontagne v. Bristol-Myers Squibb</i> , 127 Wn.App. 325, 111 P.3d 857(2005).....	30,31
<i>Guile v. Ballard Cmty. Hosp.</i> , 70 Wn. App. 18, 851 P.2d 689 (1993).....	14,15
<i>Hansen v. Virginia Mason Medical Center</i> , 113 Wn.App. 199, 53 P.3d 60 (2002).....	32, 33,35
<i>Herron v. Tribune Publishing Co., Inc.</i> , 108 Wn.2d 162, 736 P.2d 249 (1987).....	13
<i>Kahn v. Salerno</i> , 90 Wn. App. 110, 951 P.2d 321 (1998).....	13
<i>Magana v. Hyundai Motor America</i> , 167 Wn.2d 570, 220 P.3d 191 (2009).....	26
<i>McEwen v. Ortho Pharmaceutical Corp.</i> , 270 Or. 375, 528 P.2d 522 (1974).....	29
<i>McLaughlin v. Cooke</i> , 112 Wn.2d 829, 774 P.2d 1171 (1989).....	15
<i>Momah v. Bharti</i> , 144 Wn.App.731, 182 P.3d 455, (2008).....	16
<i>Pelton v. Tri-State Memorail Hospital.</i> , 66 Wn.App. 350, 831 P.2d 1147 (1992)..	16
<i>Redding v. Virginia Mason Med. Ctr.</i> , 75 Wn. App. 424, 878 P.2d 483 (1994).....	13
<i>Ruff v. King County</i> , 125 Wn.2d 697, 887 P.2d 886 (1995).....	13
<i>Seybold v. Neu</i> , 105 Wn.App. 666, 19 P.3d 1068 (2001).....	14,15
<i>State ex rel. Clark v. Hogan</i> , 49 Wn.2d 457, 303 P.2d 290 (1956).....	25
<i>State ex rel. Carroll v. Junker</i> , 79 Wn.2d 12, 482 P.2d 775 (1971).....	25
<i>Terhune v. A.H. Robins Co.</i> , 90 Wn.2d 9, 577 P.2d 975 (1978).....	28,29
<i>Turner v. Kohler</i> , 54 Wn.App. 688,775 P.2d 474 (1989).....	16

Statutes

RCW 7.70.030.....	1,2,32,34,35, 36
-------------------	------------------

Rules

CR 56(c)	13
----------------	----

CR 56 (e).....	15
CR 56(f).....	1,2,15,16,17
Pattern Jury Instructions	19
WPI 301.02.....	34

I.

ASSIGNMENTS OF ERROR

The trial court below erred as follows in dismissing appellants' wrongful death lawsuit in this matter:

1. The trial court refused to grant appellants', TERRENCE J. MULLAN, individually, and as Personal Representative of the Estate of DANA MULLAN, MATTHEW D. MULLAN, MICHAEL P. MULLAN, and CHRISTOPHER R. MULLAN (hereinafter referred to as the "Estate"), request for a continuance in accordance with CR 56(f) of respondents' respective motions for summary judgment.

2. The trial court held the Estate's claims in this lawsuit against respondent, St. Jude Medical, Inc. (hereinafter referred to as "St. Jude Medical"), are barred by the learned intermediary doctrine.

3. The trial court held the Estate failed to present sufficient facts to state a claim under RCW 7.70.030(2) against respondents, North Cascade Cardiology, Andrew Coletti and Maria Healey (hereinafter referred to as "North Cascade Cardiology").

The issues presented for review by this appeal are:

1. Did the trial court abuse its discretion in refusing to grant the Estate's request for a continuance in accordance with

CR 56(f) of respondents' respective motions for summary judgment?

2. Are the Estate's claims in this lawsuit against St. Jude Medical, Inc. barred by the learned intermediary doctrine?

3. Has the Estate presented sufficient facts to state a claim against North Cascade Cardiology for breach of RCW 7.70.030(2)?

II. STATEMENT OF THE CASE

A. Factual Background.

Dana Mullan died on October 12, 2008 due to an irregular heartbeat. [CP 3; CP 223]

Prior to her death, Ms. Mullan had been implanted with a pacemaker manufactured by St. Jude Medical. A pacemaker is a medical device designed to compensate for an irregular heart beat and thereby keep its recipient alive. [CP 223]

Prior to her death, Ms. Mullan was diagnosed as pacemaker dependent. If her pacemaker did not work properly, she could die. [CP 224]

By St. Jude's own admission, as a matter of law, a pacemaker is an inherently dangerous device. [RP p. 43, lines 12-13]

Before the Estate's experts could examine the pacemaker at issue in this lawsuit, the trial court below dismissed the

Estate's wrongful death lawsuit on the grounds that the Estate had failed to present any evidence that Ms. Mullan's pacemaker had failed (other than the obvious fact of her death).

This appeal ensued.

1. Nature of the Dispute between the Parties.

Dana Mullan was implanted with a Synchrony II, Model 2023 Pacesetter pacemaker, device serial number 124184, on May 25, 1994. This pacemaker was manufactured by St. Jude Medical. [CP 223]

On September 11, 2008 Ms. Mullan went to the offices of North Cascade Cardiology to have the operation of her pacemaker checked. [CP 224] After the examination ("interrogation") of her pacemaker, Ms. Mullan was informed by North Cascade Cardiology that the power for the battery for her pacemaker was approaching its end of life. [CP 142] Ms. Mullan was informed by North Cascade Cardiology that it would contact St. Jude Medical in order to get a more accurate determination as to how much longer the battery for her pacemaker was likely to last. [CP 142] In the mean time, North Cascade Cardiology made arrangements with Ms. Mullan to have the operation of her pacemaker checked on a monthly basis via telephone. [CP 142, 146]

North Cascade Cardiology contacted St. Jude Medical on or about September 12, 2008. [CP 142, 146] Based on the information acquired from the interrogation of Ms. Mullan's pacemaker by North Cascade Cardiology on September 11, 2008, St. Jude Medical informed North Cascade Cardiology that the battery for Ms. Mullan's' pacemaker had another five (5) to six (6) months left before it had to be replaced. [CP 142] On September 12, 2008 North Cascade Cardiology informed Ms. Mullan her pacemaker had another 5-6 months left before it had to be replaced. [CP 142, 143] Ms. Mullan replied, in reliance on this information, that she would try and make arrangements to have the battery for her pacemaker replaced by the end of the year. [CP 143]

On Sunday, October 12, 2008, one month after her first visit to North Cascade Cardiology and one day before the first telephonic check of her pacemaker by North Cascade Cardiology, Dana Mullan died. [CP 1] Her cause of death was determined by the San Juan County Coroner's Office to be due to cardiac arrhythmia. [CP 3] Cardiac arrhythmia is a medical condition involving an irregular heartbeat that a pacemaker is designed to treat. [CP 222, 223]

2. The Estate's Contentions.

Dana Mullan originally had a pacemaker implanted in November 1989 because she was suffering from fainting spells due to a condition known as congenital third degree heart block. [CP 222] Heart block is a problem that occurs with the heart's electrical system. [CP 222, 223] This system controls the rate and rhythm of heartbeats. [CP 223] "Rate" refers to the number of times your heart beats in a minute. [CP 223] "Rhythm" refers to the pattern of regular or irregular pulses produced when the heart beats over time. [CP 223] With each heartbeat, an electrical signal spreads across the heart from the upper to the lower chambers. [CP 223] As it travels, the signal causes the heart to contract and pump blood. [CP 223] This process repeats with each new heartbeat. [CP 223] Heart block occurs if the electrical signal is slowed or disrupted as it moves from the upper to the lower chambers of the heart. [CP 223]

Heart block is a type of arrhythmia. [CP 223] Cardiac arrhythmia is a problem with the rate or rhythm of the heartbeat. [CP 223] During an arrhythmia, the heart can beat too fast, too slow, or with an irregular rhythm. [CP 223] In Ms. Mullan's case, she suffered from her heart beating too slowly. [CP 223]

A pacemaker was implanted in Ms. Mullan's chest at

Sacred Heart Hospital in Spokane, Washington on November 17, 1989 to correct her irregular heart rate. [CP 223]

On May 25, 1994, Ms. Mullan's original pacemaker was replaced with a Synchrony II pacemaker, Model No. 2023, serial number 124814, manufactured by Pacesetter, Inc. [CP 223] Pacesetter, Inc. was later acquired by St. Jude Medical.

On June 13, 2007, Dr. Robert B. Stewart, a cardiologist with Pacific Northwest Cardiology, diagnosed Dana Mullan as pacemaker dependent. [CP 224] Pacemaker-dependent patients have inadequate intrinsic heart rhythms and therefore can suffer significant symptoms or cardiac arrest if their pacemaker stops working as designed. [CP 224]

Dana Mullan went to North Cascade Cardiology on September 11, 2008. [CP 142, 200] She was examined first by Maria Healey, R.N. and then by Andrew Coletti, M.D. [CP 224] One of the purposes of this visit was to check the operation of Ms. Mullan's pacemaker. [CP 224]

Nurse Healy indicates she checked the lead information, programmed parameters, lead settings and general pacemaker data involved in the operation of Ms. Mullan's pacemaker on September 11, 2008. [CP 142, 200, 224] The procedure described by Nurse Healy is commonly known as a pacemaker interrogation. [CP 224] Pacemaker interrogation is a process for

checking on the function of a pacemaker to make sure it is working properly and the batteries are in good condition. [CP 224] In this procedure, a doctor, nurse, or other qualified individual places a wand or “programmer head” connected to a computer (also known as a “programmer”; it looks like a laptop computer) over the patient's chest. [CP 224] The wand and pacemaker communicate wirelessly, allowing the computer to extract data from the pacemaker's memory. [CP 224] The computer will also check on the pacemaker's battery life. [CP 224] Patients usually receive a pacemaker interrogation during follow-up appointments after the initial pacemaker implantation. [CP 224] The doctor, nurse, or other qualified individual will retrieve information about cardiac events from the memory of the pacemaker, confirm that the batteries are still in good condition, and make sure the leads are working properly. [CP 224] If necessary, the wand can be used to change the programming of the pacemaker. [CP 224]

Nurse Healey determined that the battery for Ms. Mullan's pacemaker, as of September 12, 2008, would last another five to six months. [CP 142, 148] She made this determination after faxing the results of her September 11, 2008 pacemaker interrogation to St. Jude Medical for review. [CP 142, 146, 201]

The lithium-iodide battery utilized in Ms. Mullan's pacemaker has an estimated longevity of 10-12 years based on its own internal "shelf life". [CP 199] The battery in Ms. Mullan's pacemaker, according to St. Jude Medical's Synchrony Technical Manual, had a mean longevity of 11.3 years, with a projected range in useful safe life of 7.1 to 15.5 years. [CP 199] At the time of Ms. Mullan's death, the pacemaker had been implanted in Ms. Mullan's chest for 14.4 years. [CP 199]

After Ms. Mullan's death, St. Jude Medical made an initial assessment of the operation of Ms. Mullan's pacemaker but St. Jude Medical has yet to specify the date of that assessment. [CP 203] On October 16, 2008 the pacemaker removed from Ms. Mullan's body during her autopsy was given to St. Jude Medical for examination and analysis. [CP 203] An interrogation of Ms. Mullan's pacemaker by St. Jude Medical at that time determined the battery voltage for the pacemaker on that date was 2.14V, well below St. Jude Medical's specified end-of-life (EOL) threshold of 2.2V for the battery for the pacemaker. [CP 203]

St. Jude Medical proceeded to complete three tests on the battery for Ms. Mullan's pacemaker on or about October 28, 2008. [CP 203] St. Jude Medical claims the first test indicated "[d]evice ERI characteristics were noted." [CP 203] Much more

than that was noted in the first test. [CP 203] The pacemaker's battery was noted to be "depleted" at 2.22 volts, or at the battery's end of life (EOL) threshold. [CP 203] A "depleted battery" is understood to mean one that does not have enough electrical energy to make the pacemaker run properly, not one that has run out of electrical energy altogether. [CP 204] At 2.22 volts, Ms. Mullan's pacemaker would most probably not have operated sufficiently to maintain its programmed pacing ability. [CP 204]

The second test described completed by St. Jude Medical was run by programming the pacemaker to its "as-returned programmed settings" which produced "[d]evice ERI characteristics." [CP 204] However, from an engineering standpoint, the data derived from this second test (battery voltage at 2.37V) is inherently unreliable because there is no record of the supposed "as returned programmed settings". [CP 204] To the contrary, these settings were probably erased in order to conduct the first test. [CP 204] Without proper documentation corroborating the actual "as returned programmed settings, in violation of accepted scientific methodology to run such a test, no scientific validity can be accorded the test results produced by this second test. [CP 204]

Finally, the reported battery voltage resulting from this second test (2.37V) is at odds with the actual reliability laboratory report from the second test which reports a battery voltage (2.42V). [CP 204] This suggests the distinct possibility that there is additional testing information in the possession of St. Jude Medical that has not been disclosed to date since this difference in test results is not explained anywhere in the materials produced by St. Jude Medical to date. [CP 204]

More importantly, the test parameters used in St. Jude Medical's second test were not substantially similar to the condition of Ms. Mullan's pacemaker at the time she was examined by North Cascade Cardiology on September 11, 2008 or that was present at the time of her death. [CP 204] In running the second test, St. Jude Medical utilized an electrical resistance that was 30% higher than the resistance reading actually reported taken by North Cascade Cardiology. [CP 204] This difference in electrical resistance utilized in St. Jude Medical's second test likely substantially increased the battery voltage reading found in this second test. [CP 204] This difference in electrical resistance utilized in this second test most likely renders the battery readings utilized in support of St. Jude Medical's motion for summary judgment scientifically unreliable. [CP 204, 205]

The root cause of the depleted condition of the battery for Ms. Mullan's pacemaker's battery at the time of her death cannot be reliably determined at present based upon the medical records provided and the documentation supplied by St. Jude Medical to date. [CP 202] Several reasonable hypotheses exist to explain why Ms. Mullan died that cannot be tested without access to the pacemaker itself. [CP 202] The Estate has yet to gain access to the pacemaker in this lawsuit; it remains exclusively in the possession of defendant, St. Jude Medical. [CP 202]

Furthermore, no scientifically reliable conclusion can be made at the moment as to the root cause for the depletion in voltage for the battery in Ms. Mullan's pacemaker from September 11, 2008 because St. Jude Medical's "reliability" testing was not conducted under conditions similar to what were present on September 11, 2008, the date of Ms. Mullan's visit to North Cascade Cardiology, and October 12, 2008, the date of Ms. Mullan's death. [CP 206]

B. Procedural Background.

1. Initial Pleadings.

Plaintiffs filed their complaint for wrongful death in San Juan County Superior Court on July 25, 2011. [CP 1-5]

Defendant North Cascade Cardiology filed a notice of appearance on August 19, 2011, [CP 6-8], and filed their answer on October 26, 2011. [CP 100-104]

Defendant St. Jude Medical was served on August 25, 2011. [CP 9-10] St. Jude Medical filed a notice of appearance on October 14, 2011. [CP 11-13]

2. Defendants' Motions for Summary Judgment.

St. Jude Medical filed its motion for summary judgment on October 24, 2011. [CP 17-38]

North Cascade Cardiology filed their motion for summary judgment on December 14, 2011. [CP 105-117]

The original hearing date for St. Jude Medical's motion for summary judgment set for December 16, 2011. [CP 14-16] St. Jude Medical then re-scheduled hearing date for its to January 13, 2012, then re-scheduled again for January 27, 2012. [CP 231-233; 234-236]

Oral argument on defendant's motions for summary judgment occurred before the Honorable Donald E. Eaton on January 27, 2012. [CP 317-319]

The trial court issued a letter opinion on February 9, 2012 granting defendants' motions for summary judgment. *Id.* The trial court issued an order granting St. Jude Medical's motion for summary judgment on February 27, 2012. [CP 327-329] The

trial court issued an order granting North Cascade Cardiologist's motion for summary judgment on February 22, 2012. [CP 321-326]

Plaintiffs' filed their notice of appeal of both orders on March 9, 2012. [CP 330-344]

III. LEGAL ARGUMENT

A. Standard of Review.

An appellate court reviews a trial court's ruling on summary judgment *de novo*, performing the same inquiry as the trial court. *Herron v. Tribune Publishing Co., Inc.*, 108 Wn.2d 162, 169, 736 P.2d 249 (1987).

When reviewing an order granting summary judgment, a court engages in the same inquiry as the trial court, considering all facts and reasonable inferences in the light most favorable to the nonmoving party. *Kahn v. Salerno*, 90 Wn.App. 110, 117, 951 P.2d 321 (1998). Summary judgment is appropriate if the record before the court shows that there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. CR 56(c); *Ruff v. King County*, 125 Wn.2d 697, 703, 887 P.2d 886 (1995). An appellate court may affirm a trial court's disposition of a summary judgment motion on any basis supported by the record. *Redding v. Virginia Mason Medical Center*, 75 Wn.App. 424, 426, 878 P.2d 483 (1994).

A defendant moving for summary judgment in a medical negligence case bears the initial burden of showing that: (1) there is no genuine issue of material fact or, alternatively, (2) that the plaintiff lacks competent evidence to support an essential element of his claim. *Seybold v. Neu*, 105 Wn. App. 666, 676, 19 P.3d 1068 (2001).

If the defendant shows that the plaintiff lacks sufficient evidence to support his or her case, the burden shifts to the plaintiff to produce evidence that supports a reasonable inference that the defendant was negligent. *Id.* The plaintiff must respond with affidavits or other documents setting forth specific facts showing that there is a genuine issue for trial. *Id.*

Expert medical testimony is generally required to establish the standard of care and to prove causation in a medical negligence action. *Guile v. Ballard Community Hospital*, 70 Wn. App. 18, 25, 851 P.2d 689 (1993). Therefore, to defeat summary judgment in most medical negligence cases, the plaintiff must produce competent medical expert testimony establishing that the injury complained of was proximately caused by a failure to comply with the applicable standard of care. *Seybold*, 105 Wn. App. at 676. "If the plaintiff in a medical negligence suit lacks competent expert testimony, the defendant is entitled to summary judgment." *Colwell v. Holy Family Hospital*, 104 Wn.App. 606,

611, 15 P.3d 210 (2001).

CR 56(e) provides that affidavits made in support of, or in opposition to, a motion for summary judgment must be based on personal knowledge, set forth admissible evidentiary facts, and affirmatively show that the affiant is competent to testify to the matters therein. Expert testimony must be based on the facts of the case and not on speculation or conjecture. *Seybold*, 105 Wn. App. at 677. Such testimony must also be based upon a reasonable degree of medical certainty. *McLaughlin v. Cooke*, 112 Wn.2d 829, 836, 774 P.2d 1171 (1989). "Affidavits containing conclusory statements without adequate factual support are insufficient to defeat a motion for summary judgment." *Guile*, 70 Wn. App. at 25.

B. The Trial Court Below Abused Its Discretion In Failing To Grant The Estate's Request For A CR 56(f) Continuance.

The Estate requested a continuance in accordance with CR 56(f) in order to conduct discovery that the Estate believed would develop sufficient factual bases to defeat St. Jude Medical's and North Cascade Cardiologists' respective motions for summary judgment. The trial court concluded the Estate's request for a continuance was "not well taken" and denied this request. [CP

318]

CR 56(f) allows a party to request a continuance to complete discovery. Should it appear from the affidavits of a party opposing a summary judgment motion that he or she cannot, for reasons stated, present by affidavit facts essential to justify his or her opposition, the court may refuse the application for judgment or may order a continuance to permit affidavits to be obtained or depositions to be taken or discovery to be had or may make such other order as is just. *Momah v. Bharti*, 144 Wn.App.731, 754, 182 P.3d 455 (2008). The trial court can deny a continuance under CR 56(f) if: (1) the requesting party does not offer a good reason for the delay in obtaining the desired evidence; (2) the requesting party does not state what evidence would be established through the additional discovery; or (3) the desired evidence will not raise a genuine issue of material fact. *Turner v. Kohler*, 54 Wn.App. 688, 693, 775 P.2d 474 (1989). Only one of the qualifying grounds is needed for denial. *Pelton v. Tri-State Memorial Hospital*, 66 Wn.App. 350, 356, 831 P.2d 1147 (1992).

The trial court below acknowledged that the Estate had requested a continuance of both defendants' motions for summary judgment in order to conduct additional discovery. [CP 317] The primary reason given by the Estate for this request for

a continuance was the fact that they had not had sufficient time, from the point in time when St. Jude Medical first appeared in this lawsuit, to serve a request to inspect the pacemaker that is believed to have been the cause of Ms. Mullan's death, much less actually inspect the pacemaker itself. [RP, p.72, line 12 – p. 73, line 23] The Estate filed this wrongful death lawsuit on July 25, 2011. St. Jude Medical filed its notice of appearance in this case on October 14, 2011. Ten days later, St. Jude Medical filed its motion for summary judgment on October 24, 2011.

In response, the trial court held that the Estate had had the results of St. Jude Medical's "reliability" tests for Ms. Mullan's pacemaker since August of 2009, which the trial court felt was more than an adequate period of time to have had those results reviewed and evaluated. [CP 318] The trial court went further and concluded, "And, as St. Jude points out, any test of the battery at this time would be meaningless due to the passage of over three years since the device was explanted." [CP 318]

Given this reasoning employed by the trial court, the Estate believes the trial court grossly abused its discretion in denying its request for a CR 56(f) continuance for the following reasons.

First, the trial court stated that the only reasons given for the request for a continuance were those offered by counsel for

the Estate during oral argument. [CP 317] This was obviously incorrect. The basis for the request for a continuance was contained in expert declarations filed by the Estate in opposition to the two summary judgment motions. [CP 196-219; 220-230] The trial court, in its letter decision [317-319], appeared to completely ignore the declaration of the Estate's electrical engineering expert, Louis Bilancia, who explained there is presently no scientifically reliable explanation for Ms. Mullan's death thereby underlying why a continuance of defendants' motions was needed:

29. No scientifically reliable conclusion can be made at the moment as to the root cause for the depletion in voltage for the battery in Ms. Mullan's pacemaker from September 11, 2008 to the time of her death on October 12, 2008 until the pacemaker can be accessed by plaintiffs to determine if the programmed settings present and condition of the device components in the pacemaker at the time of Ms. Mullan's death can be retrieved and/or examined. [206]

Second, as set out in the expert declaration from the Estate's electrical engineering expert (Mr. Bilancia), the results of St. Jude's tests were believed by to be inherently unreliable and therefore of no utility in explaining Ms. Mullan's death. [CP 202-206] The court, without explanation and without even any reference to the Estate's experts' declaration testimony,

summarily dismissed the notion that the cause of Ms. Mullan's death could not at the moment be determined in a scientifically reliable manner. The sole reason given by the trial court for this conclusion was that St. Jude Medical said it could. By refusing to take into consideration the Estate's experts' conclusions, the trial court abused its discretion in denying plaintiff's motion for CR 56(f) continuance.

Third, the Estate requested a continuance to: (1) acquire and review undisclosed technical literature from St. Jude Medical and engineering calculations made by St. Jude Medical before Ms. Mullan's death, that could then be used to reliably determine the cause of Ms. Mullan's death; (2) acquire and evaluate what its electrical engineering expert considered to be reliable data through retrieval from Ms. Mullan's pacemaker; and (3) conduct forensic testing on Mullan's pacemaker to test certain hypotheses to explain Ms. Mullan's death.

The Estate seeks undisclosed to date proprietary technical information from St. Jude Medical to confirm how long the battery for Ms. Mullan's pacemaker should have lasted. This technical information is contained in an annual battery lifetime report published by Wilson Greatbatch, the manufacturer of the battery installed inside Ms. Mullan's St. Jude Medical pacemaker, and provided to St. Jude Medical [CP 201] This

annual report provides statistical information regarding the life expectancies of all Wilson Greatbatch batteries, including the one utilized in Ms. Mullan's pacemaker, based on actual life expectancies experienced in samples retained by Wilson Greatbatch for that purpose. [CP 201]

Using information from the Wilson Greatbtach annual report for the battery for Ms. Mullan's pacemaker, plus the information provided by North Cascade Cardiology on or about September 11, 2008, St. Jude Medical made an internal engineering calculation on September 11, 2008 to forecast the remaining longevity for the battery for Ms. Mullan's pacemaker. [CP 201] No such information is contained in the St. Jude Medical "Technical Manual" produced for the first time in support of St. Jude Medical's summary judgment motion. [CP 201] This internal engineering calculation led St. Jude Medical to predict that the battery for Ms. Mullan's pacemaker would last another 5-6 months [CP 201], when in fact it only lasted another month. Acquiring this internal calculation would obviously go a considerable distance in determining St. Jude Medical's relative fault in this lawsuit. It would also provide to the Estate the opportunity to run the same calculations regarding the condition of the battery to Ms. Mullan's pacemaker at the time of her death to explain why she died of a cardiac arrythmia which here

pacemaker was supposed to prevent from harming her.

St. Jude Medical placed great emphasis in support of its motion on certain “reliability” testing it performed after Ms. Mullan’s death to argue its pacemaker was working properly at the time of Mullan’s death. However, as the Estate’s medical and electrical engineering experts testified to in their declarations, the test parameters used were not substantially similar to the condition of Ms. Mullan’s pacemaker at the time she was examined on September 11, 2008 or that was present at the time of her death. [CP 204-205; 227-228] In running the test (second) meant to simulate these conditions, St. Jude Medical utilized an electrical resistance that was 30% higher than the resistance reading taken on September 11, 2008. *Id.* This difference in electrical resistance utilized in St. Jude Medical’s “reliability” test likely substantially increased the battery voltage reading leading to an ultimate result St. Jude Medical presented as evidence that the pacemaker was working properly at the time of Mullan’s death. *Id.* The Estate’s experts concluded this difference in electrical resistance utilized in St. Jude Medical’s “reliability test” most likely rendered the battery readings relied upon by St. Jude Medical scientifically unreliable. *Id.*

The trial court completely ignored the declarations of the Estate’s experts, who explained why the “reliability” testing

relied upon by St. Jude Medical was likely not scientifically reliable, in concluding the Estate was not entitled to a continuance of defendants' motions to acquire what the Estate's experts believe would be scientifically reliable information.

Moreover, without taking into consideration the Estate's expert's contrary opinion, the trial court accepted as if it were undisputed St. Jude Medical's expert's conclusory statement that any test of the battery in 2012 would be meaningless due to the passage of over three years since the pacemaker was removed from Ms. Mullan's dead body. St. Jude Medical's expert stated in a rebuttal declaration that, based solely on his experience without any further technical or engineering explanation, that any test of the battery for Ms. Mullan's pacemaker would be meaningless at this time. [CP 276] At oral argument, counsel for St. Jude Medical represented to the trial court, "There's a leakage that just happens, because you can't prevent electrons from discharging." [RP p. 55, lines 18-19] This inconvenient truth probably explains why Ms. Mullan died. The trial court, however, seemed to accept this representation from St. Jude Medical's counsel when it stated at oral argument, "It seems to me that really [the Estate] in the end, keeps coming back to: We just need more time, we just need more time, and I understand from [St. Jude Medical] that more time is not going to help,

there's nothing they're going to come up with that going to make any difference." [RP p. 117, lines 6-11]

In actuality, the Estate told the trial court over and over again at oral argument, "We've had virtually no time at all yet!"

Notwithstanding, what St. Jude Medical conveniently failed to mention, and the trial court was either unaware of or chose to ignore, was that St. Jude Medical's own engineering expert also testified in his rebuttal declaration that the mean longevity of the battery for Ms. Mullan's pacemaker was 7.7 to 18.5 years. [CP 272] Ms. Mullan's pacemaker was implanted in May, 1994. If St. Jude Medical and its experts are correct, then the battery for Ms. Mullan's pacemaker could last until October, 2012. Based on St. Jude Medical's own engineering expert's testimony, there is no basis to conclude there is no chance there is nothing to gain from inspecting and examining the condition of the battery for Ms. Mullan's pacemaker at this juncture.

The trial court also seemed to take exception to the Estate not completing more *informal* discovery prior to commencing this lawsuit in July, 2011. [RP 73] It would have been exceptionally unwise for the Estate to conduct forensic testing on the pacemaker outside the confines of litigation. If St. Jude Medical did not conduct itself as promised, if St. Jude Medical did not produce information requested before or after testing,

and/or if testing was not conducted in a manner consistent with agreed protocols, the Estate would be without recourse and stuck with permanently altered physical evidence. No competent counsel mindful of his or her client's best interests would agree to conduct forensic testing that would be potentially destructive outside the parameters set down by and remedies afforded by Civil Rules 26 through 37.

At oral argument, counsel for St. Jude Medical stated, "St. Jude, as a matter of practice, likes to avoid litigation, so we will work with patients and patients experts to do our reliability testing prior to litigation. They just have to ask." [RP p. 123, lines 1-2] There was no basis in the record before the trial court to substantiate this representation. In point of fact, St. Jude Medical is required by the U.S. Food & Drug Administration to complete such testing any time one of St. Jude Medical's medical devices is implicated in any way in the death of a patient implanted with one of St. Jude Medical's devices. 21 CFR §803.10.

The Estate's engineering expert testified the root cause of the depleted condition of the battery for Ms. Mullan's pacemaker's battery at the time of her death cannot be reliably determined at present based upon the medical records provided and the "reliability" testing supplied by St. Jude Medical to date.

Several reasonable hypotheses exist to explain why Ms. Mullan died that cannot be tested without access to the pacemaker itself. The Estate has yet to gain access to the pacemaker in this lawsuit; it remains exclusively in the possession of St. Jude Medical. Rather than allow the Estate the opportunity to complete this desired testing, the trial court effectively ruled the Estate must accept without exception the testing results submitted by St. Jude Medical in support of its motion for summary judgment, even when the Estate's experts have concluded these results are scientifically unreliable.

Judicial discretion is a composite of many things, among which are conclusions drawn from objective criteria; it means a sound judgment exercised with regard to what is right under the circumstances and the law, and which is directed by the reasoning conscience of the judge to a just. *State ex rel. Clark v. Hogan*, 49 Wn.2d 457, 462, 303 P.2d 290 (1956).

Whether this discretion is based on untenable grounds, or is manifestly unreasonable, or is arbitrarily exercised, depends upon the comparative and compelling public or private interests of those affected by the order or decision and the comparative weight of the reasons for and against the decision one way or the other. *State ex rel. Carroll v. Junker*, 79 Wn.2d 12, 26, 482 P.2d 775 (1971).

A reasonable opportunity to conduct discovery is a fundamental part of due process of law. *Magana v. Hyundai Motor America*, 167 Wn.2d 570, 220 P.3d 191 (2009).

St. Jude Medical argued to the trial court that the Estate had failed to controvert the evidence put forth by St. Jude Medical in support of its motion for summary judgment that Ms. Mullan's pacemaker was "sensing and pacing as programmed", *i.e.* was working. This contention, if accepted at face value, is highly misleading because it camouflages the relevant inquiry called for in this lawsuit. The question is not whether Ms. Mullan's pacemaker was working, but whether it was working strongly enough to keep her alive, *i.e.* was it working *properly*. To claim, as St. Jude Medical did, that Ms. Mullan's pacemaker was "sensing and pacing as programmed" begs the relevant inquiry posed by its motion for summary judgment: was the level of electrical performance by Ms. Mullan's pacemaker at the time of her death strong enough, robust enough, energetic enough to keep her alive?

By way of analogy, a car battery may be working, but may not be strong enough to start the car's engine.

In opposition to St. Jude Medical's motion, the Estate introduced expert testimony that this question could not be answered in this lawsuit yet because: (a) plaintiffs' experts had

not been given the opportunity to access the pacemaker to examine and retrieve data from it; (b) the “reliability” testing relied upon by St. Jude Medical in support of its motion was inherently unreliable from a scientific standpoint; and (c) the Estate’s experts wished to conduct its own forensic testing on the battery to Ms. Mullan’s pacemaker to explain the cause of Ms. Mullan’s death.

The trial court, without explanation, chose to ignore all of these requests put forth by the Estate and granted St. Jude Medical’s motion for summary judgment. The Estate submits that to completely ignore all these requests made by the Estate was completely untenable, totally arbitrary and manifestly unreasonable. The Estate’s experts were just as qualified as St. Jude Medical’s experts with regard to the design and operation of Ms. Mullan’s pacemaker, *if not more so*. St. Jude Medical’s testing relied upon a key assumption that the Estate’s experts identified as scientifically unjustifiable. Most importantly, the Estate amply demonstrated it had not had enough time yet in this lawsuit to request to inspect the pacemaker involved in Ms. Mullan’s death, much less gain access to it and examine it to procure relevant information to explain Ms. Mullan’s death.

Nevertheless, the trial court chose to completely ignore what the Estate’s experts testified to, held whatever discovery the

Estate felt they needed should have been concluded *informally and before* the lawsuit was filed and chose to accept, without qualification, the reliability of St. Jude Medical’s “reliability” testing which the Estate’s’ experts felt was inherently unreliable. Whether this Court characterizes these conclusions by the trial court as untenable, arbitrary or unreasonable, the Estate urges this Court to hold that they constitute a gross abuse of the trial court’s discretion warranting a reversal of the trial courts’ dismissal of the Estate’s wrongful death lawsuit in this case.

If this Court accepts the Estate’s argument in this regard with respect St. Jude Medical’s motion for summary judgment, then it should likewise reverse the trial court’s dismissal of the Estate’s claims against North Cascade Cardiology for the same reasons.

C. The Trial Court Erred As A Matter Of Law In Holding Plaintiff’s Claims Against Defendant St. Jude Medical Were Barred By The Learned Intermediary Doctrine.

St. Jude Medical contends the Estate’s claims are barred by the “learned intermediary doctrine” as recognized by Washington courts. *See e.g. Terhune v. A.H. Robins Co.*, 90 Wn.2d 9, 577 P.2d 975 (1978).

St. Jude Medical correctly observes that the Estate’s

theory of recovery against St. Jude Medical is premised on the allegation that St. Jude Medical had a legal duty to provide accurate information to Ms. Mullan's *health care providers* regarding the remaining life of her pacemaker.

St. Jude Medical contends that, under the learned intermediary doctrine, St. Jude Medical is not liable to the Estate under any circumstances for failing to provide Ms. Mullan's health care providers with accurate information about her pacemaker. The trial court eagerly accepted this contention without citation to any legal authority.

Washington law does allow an injured patient to sue St. Jude Medical for failing to properly provide accurate information to the injured patient's health care providers. *Terhune v. A.H. Robins*, 90 Wn.2d 9, 15, 577 P.2d 975 (1978). If St. Jude Medical breached that duty to Ms. Mullan's health care providers and that proximately resulted in Ms. Mullan's death, then the Estate possesses a cause of action against St. Jude Medical for this breach. *Id.*

In the *Terhune* decision, the Washington State Supreme Court specifically cited *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. 375, 386-87, 528 P.2d 522 (1974), in support of its decision. In the *McEwen* decision, the Oregon Supreme Court held that although a manufacturer's legal duty to provide

accurate information runs only to health care providers, manufacturers remain directly liable to the patient for a breach of this legal duty owed to the health care provider. This is consistent with the nature of the duty itself: to insure the best information is provided by the manufacturer to the one who will actually be administering the care. Yet that doesn't mean that the manufacturer is thereby insulated from liability if the manufacturer breaches this duty. A breach of this duty does not lead to physical injury to the health care provider; the breach injures the patient. That is why a manufacturer owes a legal duty to the health care provider but is liable to the patient for the breach of that duty.

In *Estate of LaMontagne v. Bristol-Myers Squibb*, 127 Wn.App. 325, 111 P.3d 857 (2005), this Court implicitly held that a deceased patient could sue a drug manufacturer for failure to provide a medical practitioner with accurate information. The plaintiff sued defendant drug manufacturer for failure to warn *her doctors* of the risks associated with the drug involved. *Id.*, 127 Wn.App. at 342. In opposing the defendant drug manufacturer's motion for summary judgment, the plaintiff introduced expert testimony from two doctors that the drug manufacturer failed to properly warn plaintiff's treating physicians. *Id.*, 127 Wn.App. at 345-46. In the *Estate of LaMontagne* decision, this Court

dismissed plaintiff's action for failure to show the manufacturer provided the medical practitioner with inaccurate information, not because the deceased was precluded from suing the manufacturer as a matter of law for breaching the manufacturer's legal duty to provide accurate information to health care providers. *Id.*, 127 Wn.App. at 352.

The trial court below that since St. Jude Medical owed a duty to communicate accurate information about Ms. Mullan's pacemaker only to her health care providers, presumably so Ms. Mullan's health care providers could properly treat Ms. Mullan, St. Jude Medical could not be liable to the Estate even if its failure to provide accurate information to Ms. Mullan's health care providers ultimately killed Ms. Mullan. This holding effectively destroyed any legal remedy Ms. Mullan might have against St. Jude Medical for St. Jude Medical's providing inaccurate information to her health care providers and was contrary to the holding in the *Terhune* and *McEwen* decisions cited to above.

Consequently, this Court should reverse the trial court's decision dismissing the Estate's wrongful death lawsuit on the grounds it was precluded by the learned intermediary doctrine.

D. Plaintiffs Presented Sufficient Facts To State A Claim Against North Cascade Cardiology For Violation Of RCW 7.70.030(2).

The trial court below held that the undisputed facts material to the Estate's claims against North Cascade Cardiology failed to state a claim under RCW 7.70.0303(2) as a matter of law. The trial court once again failed to explain this conclusion by citation to either the statute itself or applicable case authority construing this statute. As demonstrated below, this conclusion was a manifest abuse of the trial court's discretion, both literally and figuratively.

Both the Estate and North Cascade Cardiology agree the controlling legal authority applicable to the issue presented to the trial court was this court's decision in *Hansen v. Virginia Mason Medical Center*, 113 Wn.App. 199, 53 P.3d 60 (2002). In the *Hansen* decision, this Court held that the legislature codified the common law action for breach of contract a patient possessed against his or her health care provider at common law when it passed the 1976 Health Care Provider Act, RCW 7.70 *et seq.* *Id.*, 113 Wn.App. at 204.

In the *Hansen* decision, this court held RCW 7.70.030(2) provides a contract cause of action when a medical practitioner expressly undertakes or commits to obtain certain results or cure through a procedure or course of treatment. *Id.*, 113 Wn.App. at

208. In the *Hansen* decision, the court held that the practitioner had to promise to obtain a specific result or cure through a course of treatment or a procedure. *Id.*, 113 Wn.App. at 206

In this case, by North Cascade Cardiology's own account:

1. Defendant, Dr. Andrew Coletti, was not competent to determine if the battery for Dana Mullan's pacemaker needed to be replaced. [CP 107]

2. Dr. Coletti therefore referred Ms. Mullan to Nurse Maria Healey for an examination of her pacemaker. [CP 107]

3. Nurse Healey examined Ms. Mullan's pacemaker, noted a declining battery status, but "satisfactory function of the pacemaker." [CP 142]

4. Nurse Healey spoke with an unidentified representative of St. Jude Medical who indicated that the battery for Ms. Mullan's pacemaker would last another five to six months. [CP 142,, 146]

5. Nurse Healey telephoned Ms. Mullan on or about September 12, 2008, told her the battery for her pacemaker would last another 5-6 months, and understood Ms. Mullan would try and arrange to have the battery for her pacemaker replaced by the end of the year. [142-143, 148]

6. Ms. Mullan died one month later.

Under the facts set forth by North Cascade Cardiology in support of their own motion, the Estate is able to establish that North Cascade Cardiology violated RCW 7.70.030(2).

North Cascade Cardiology telephoned Ms. Mullan on September 12, 2008 and told her (the promise) that the battery for her pacemaker would last another five to six months (the specific result), and put her on a course of treatment that involved checking the condition of her pacemaker's battery once a month to maintain the pacemaker's proper operation. Before the first month had elapsed, Ms. Mullan died.

At oral argument, North Cascade Cardiology claimed that simply telling Ms. Mullan the battery for her pacemaker would last another 5-6 months did not constitute an "express promise" to Ms. Mullan. Rather, North Cascade Cardiology was merely serving as a messenger in relaying certain information regarding her pacemaker from St. Jude Medical. [RP p. 100, lines 1-2].

A "promise" is defined by WPI 301.02 as follows:

A promise is an expression that justifies the person to whom it is made in reasonably believing that a commitment has been made that something specific will happen or not happen in the future. A promise may be expressed orally, in writing, or by conduct.

Telling Ms. Mullan her pacemaker would last another 5-6 months doesn't get any more of a promise under WPI 301.02.

Telling Ms. Mullan the battery for her pacemaker would last another 5-6 months was an expression that justified Ms. Mullan in believing that something specific would happen in the future, *i.e.* the battery for her pacemaker, upon which she relied upon to stay alive, would last another 5-6 months. This promise was buttressed by a specific course of treatment to check the condition of her pacemaker telephonically on a monthly basis to insure the battery for the pacemaker indeed did last another 5-6 months. These facts, coupled with the fact that Ms. Mullan died within a month of her first visit to North Cascade Cardiology, more than amply demonstrate a violation of RCW 7.70.030(2) by North Cascade Cardiology in this lawsuit.

A violation of RCW 7.70.030(2) does not require introduction of expert testimony, only evidence of a promise and breach of that promise. *Hansen v. Virginia Mason Medical Center*, 113 Wn.App. at 208. Under the current set of undisputed facts placed before this Court by North Cascade Cardiology, if the Court accepts the Estate's legal argument set out above, it is the Estate, not North Cascade Cardiology, who are entitled to judgment as a matter of law for violation of RCW 7.70.030(2) at trial.

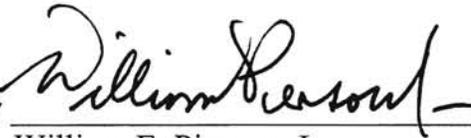
IV. CONCLUSION

The trial court abused its discretion in failing to grant the Estate's request for a CR 56(f) continuance. The trial court erred as a matter of law in holding the Estate's claims against St. Jude Medical were barred by the learned intermediary doctrine. The Estate presented sufficient facts to state a claim against North Cascade Cardiology for violation of RCW 7.70.030(2).

A reasonably prudent and disinterested observer would conclude the Estate did not obtain a fair, impartial, and neutral review of all the evidence put before the trial court which should convince this Court to reverse the trial court's ruling on February 9, 2012 in its entirety, and allow the Estate to return to the commencement of pretrial discovery in this lawsuit.

RESPECTFULLY SUBMITTED this 18th day of June, 2012.

LAW OFFICE OF
WILLIAM E. PIERSON, JR. | PC

By 

William E. Pierson, Jr.
WSBA No. 13619

Attorneys for Appellants
TERRENCE J. MULLAN, et al.

CERTIFICATE OF SERVICE

The undersigned certifies that on this day he caused to be served in the manner noted below, a copy of the document to which this certificate is attached, on the following counsel of record:

Defendants
NORTH CASCADE
CARDIOLOGY PLLC
ANDREW COLETTI
MARIA HEALEY

Bruce W. Megard, Jr.
BENNETT BIGELOW &
LEEDOM, P.S.
1700 Seventh Avenue, Suite 1900
Seattle, WA 98101

- via U.S. Mail
- via hand delivery
- via e-mail
- via facsimile

Defendant
ST. JUDE MEDICAL,
INC.

Jeffrey M. Thomas
Susannah C. Carr
GORDON TILDEN
THOMAS & CARDELL
LLP
1001 Fourth Avenue,
Suite 4000
Seattle, WA 98154

- via U.S. Mail
- via hand delivery
- via e-mail
- via facsimile

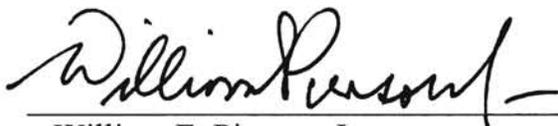
Mary H. Spillane
WILLIAMS KASTNER &
GIBBS PLLC
601 Union Street, Suite 4100
Seattle, WA 98101-2380

James A. Gale
FELDMAN GALE P.A.
One Biscayne Tower, 30th
Floor
2 South Biscayne Blvd.
Miami, FL 33131

via U.S. Mail
 via hand delivery
 via e-mail
 via facsimile

via U.S. Mail
 via hand delivery
 via e-mail
 via facsimile

DATED this 18th day of June, 2012.



William E. Pierson, Jr.