

No. 68513-9-I

Filed July 13, 2012

**IN THE COURT OF APPEALS
OF THE STATE OF WASHINGTON
DIVISION I**

TERRENCE J. MULLAN, et al.,

Plaintiff/Appellants,

v.

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

Defendant/Respondents.

BRIEF OF RESPONDENT ST. JUDE MEDICAL, INC.

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TABLE OF CONTENTS

	<u>Page</u>
I. INTRODUCTION	1
II. ISSUES PRESENTED	3
III. STATEMENT OF THE CASE	4
A. Class III Medical Devices	5
B. Mullan’s Physicians Prescribed and Implanted an Approved Class III Device to Treat Her Serious Heart Condition	6
C. Product Labeling for the Synchrony II Pacemaker Does Not Guarantee Battery Longevity, But Provides Approximations and Recommended Replacement Time	6
D. There Is No Evidence That the Estimate Provided to Mullan Regarding Battery Longevity Conflicted With St. Jude’s Product Labeling for Her Device	8
E. The Estate Presented No Evidence of Mullan’s Cause of Death	9
F. There Is No Evidence of Device Failure	9
G. The Estate Failed to Rebut the Evidence in Its Possession Provided After Mullan’s Death, Which Showed That Her Pacemaker Was Functioning Normally	12
H. The Estate Speculates That Mullan’s Battery Did Not Last as Long as Projected Contrary to Record Evidence	12
I. There Is No Evidence That St. Jude Was Negligent; the Estate’s Expert Faults Nurse Maria Healey	14

TABLE OF CONTENTS

	<u>Page</u>
J. The Estate’s Effort to “Muddy the Water” Lacked Foundation	15
K. Further Testing of Mullan’s Device More Than Three Years After Her Death Would Not Result in Any Meaningful Evidence	15
IV. ARGUMENT	16
A. The Trial Court Properly Granted Summary Judgment	16
1. There Is No Evidence on the Essential Elements of Product Malfunction, Negligence and Causation	17
a. Mullan’s Device Was Working Properly	18
b. There Is No Evidence of Any Wrongdoing by St. Jude	18
c. The Estate Presented No Evidence of Mullan’s Cause of Death	20
d. The Fact of Mullan’s Death Is Not Evidence of Any Wrongdoing by Anyone	21
e. The Estate’s Proffered Expert Opinion That Battery Test Results Are Inconclusive Failed to Raise a Genuine Issue of Material Fact	21
2. The Estate’s Claims Are Preempted	22
a. The MDA’s PMA Process	23
b. Federal Preemption	25

TABLE OF CONTENTS

	<u>Page</u>
c. Product Labeling	28
d. Complaints Based On Misinformation	29
e. Summary Judgment Was Proper Because the Estate Neither Alleged nor Adduced Evidence of a Violation of Any FDA Requirement	32
3. The Estate’s Complaint Against St. Jude Does Not Survive the Learned Intermediary Doctrine as St. Jude Did Not Provide Any Misinformation	35
B. The Trial Court Did Not Abuse Its Discretion When It Denied the Estate’s Request for a Continuance Under CR 56(f)	37
1. The Estate Failed To Comply With CR 56(f)	38
2. The Trial Court Did Not Abuse Its Discretion When It Ruled That the Estate Was Not Entitled to a Continuance to Conduct Further Electrical Testing	39
3. The Trial Court Did Not Abuse Its Discretion When It Denied a Continuance to “Evaluate” Test Results That the Estate Had in Its Possession for Years	43
V. CONCLUSION	44

TABLE OF AUTHORITIES

Page

Cases

<i>Baker v. Medtronic, Inc.</i> , 2002 WL 485013, at *7 (S.D. Ohio 2002)	29, 31, 32, 33
<i>Barney v. St. Jude Medical Center, Inc.</i> , 1993 WL 13015619, at *5 (N.D. Cal. 1993)	28, 29, 32, 33
<i>Buckman v. Plaintiffs' Legal Comm.</i> , 531 U.S. 341, 121 S.Ct. 2012, 148 L.Ed.2d 854 (2001).....	25, 26, 27
<i>Burmeister v. State Farm Ins. Co.</i> , 92 Wn.App. 359, 966 P.2d 921 (1998).....	38
<i>Cipollone v. Liggett Group, Inc.</i> , 505 U.S. 504, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992).....	25
<i>Desabio v. Howmedica Osteonics Corp.</i> , 817 F.Supp.2d 197 (W.D.N.Y. 2011)	31
<i>Discover Bank v. Bridges</i> , 154 Wn. App. 722, 226 P.3d 191 (2010).....	18
<i>Funk v. Stryker Corp.</i> , 631 F.3d 777 (5 th Cir. 2011).....	21, 26, 30
<i>Goodwin v. Bacon</i> , 127 Wn.2d 50, 896 P.2d 673 (1995)	30
<i>Gross v. Stryker Corp.</i> , --- F.Supp.2d ---, 2012 WL 876719, at *2 (W.D. Pa. Mar. 14, 2012)	25, 30, 33
<i>Gross v. Sunding</i> , 139 Wn.App. 54, 161 P.2d 380 (2007)	38
<i>Hewitt v. Hewitt</i> , 78 Wn.App. 447, 896 P.2d 1312 (1995).....	38
<i>Horn v. Thoratec Corp.</i> , 376 F.3d 163 (3rd Cir. 2004)	27
<i>Horowitz v. Stryker Corp.</i> , 613 F. Supp. 2d 271 (E.D.N.Y 2009).....	26
<i>Illaraza v. Medtronic, Inc.</i> , 677 F. Supp. 2d 582 (E.D.N.Y. 2009).....	26
<i>In re Medtronic, Inc. Sprint Fidelis Leads</i> , 592 F. Supp. 2d 1147 (D. Minn. 2009)	26

TABLE OF AUTHORITIES

	<u>Page</u>
<i>Janda v. Brier Realty</i> , 97 Wn.App. 45, 984 P.2d 412 (1999).....	37, 42, 44
<i>Johnson v. Allstate Ins. Co.</i> , 126 Wn.App. 510, 108 P.3d 1273 (2005).....	29
<i>Kennedy v. Medtronic, Inc.</i> , 366 Ill.App.3d 298, 851 N.E.2d 778 (Ill. App.Ct. 2006).....	23
<i>Kruse v. Hemp</i> , 121 Wn.2d 715, 853 P.2d 1373 (1993).....	17
<i>Lake Chelan Shores Homeowners Ass'n v. St. Paul Fire & Marine Ins. Co.</i> 167 Wn.App. 28, 272 P.2d 249 (2011)	38
<i>LaMon v. Butler</i> , 112 Wn.2d 193, 770 P.2d 1027 (1989)	17
<i>Landberg v. Carlson</i> , 108 Wn.App. 749, 33 P.3d 406 (2001).....	38
<i>Lemelle v. Stryker Orthopaedics</i> , 698 F. Supp. 2d 668 (W.D. La. 2010).....	26
<i>Mackey v. Pioneer Nat'l Bank</i> , 867 F.2d 520 (9th Cir.1989).....	38
<i>Martin v. Medtronic, Inc.</i> , 254 F.3d 573 (5th Cir. 2001).....	24, 40
<i>Medtronic Inc. v. Lohr</i> , 518 U.S. 470 (1996)	26, 29
<i>Molsness v. Walla Walla</i> , 84 Wn.App. 393, 928 P.2d 1108 (1996)	37
<i>Morgan v. Aurora Pump Co.</i> , 159 Wn. App. 724, 248 P.3d 1052 (2011).....	17
<i>Parker v. Stryker Corp.</i> , 584 F.Supp.2d 1298 (D.Colo. 2008)	33
<i>Riegel v. Medtronic, Inc.</i> , 552 U.S. 312, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008).....	passim
<i>Riley v. Cordis Corp.</i> , 625 F. Supp. 2d 769 (D. Minn. 2009).....	26, 30
<i>Stengel v. Medtronic, Inc.</i> , 2010 WL 4483970, at *2 (D.Ariz. Nov. 9, 2010).....	31

TABLE OF AUTHORITIES

	<u>Page</u>
<i>Terhune v. A. H. Robins Co.</i> , 90 Wn.2d 9, 577 P.2d 975 (1978).....	23
<i>Turner v. Kohler</i> , 54 Wn.App. 688, 775 P.2d 474 (1989).....	37
<i>Wolicki-Gables v. Arrow Intern., Inc.</i> , 634 F.3d 1296 (11 th Cir. 2011).....	33
<i>Wutzke v. Schwaegler</i> , 86 Wn.App. 898, 940 P.2d 1386 (1997).....	29
 Statutes	
21 C.F.R. §§ 801.109, 860.7(d)(1)-(e)(1)	28
21 U.S.C. § 360c(a)(1)(C).....	23
21 U.S.C.A. §§ 321(m).....	28, 33
21 U.S.C.A. §§ 321, 801.109, 801.109(d)	28
RCW 7.72.030(1).....	17
 Other Authorities	
14A KARL B. TEGLAND, WASHINGTON PRACTICE: CIVIL PROCEDURE § 25:21 (2d ed. 2009).....	38
Restatement (3rd) of Torts § 6(c).....	26
Restatement 2 nd of Torts § Section 402A	26
 Rules	
21 C.F.R. § 870.3610(b)	5, 23
CR 56	passim
CR 56(f)	passim
FRCP 56(f).....	38

I. INTRODUCTION

Appellants Terrence J. Mullan, Dana Mullan, Matthew Mullan, Michael P. Mullan, and Christopher R. Mullan (collectively, the “Estate”) filed a complaint for wrongful death against, *inter alia*, respondent St. Jude Medical, Inc. (“St. Jude”). The Estate contends that in September 2008, based on information provided by the medical provider of decedent Danna Mullan (“Mullan”), St. Jude estimated that the battery in Mullan’s Synchrony II, Model 2023 pacemaker would last another five to six months. Mullan passed away a month later for an unknown reason, which the Estate’s complaint vaguely attributes to cardiac arrhythmias.

Mullan’s Synchrony II pacemaker was explanted during an autopsy and returned to St. Jude for reliability testing. At the Estate’s request, on August 17, 2009, St. Jude produced the results of its reliability testing and source documentation, which showed that there was no product malfunction. Test results also showed that Mullan’s pacemaker battery was at or near the point where physicians should *consider* elective replacement (“Elective Replacement Indicator” or “ERI”), and was *not* at the later stage where pacemaker functioning becomes unpredictable (“End of Life” or “EOL”). For nearly two years, the Estate did not question of results of the reliability testing or request further testing.

In July 2011, nearly three years after Mullan died, the Estate filed its complaint, which is based on the slimmest of allegations. The Estate alleged no facts in support of its negligence claim against St. Jude. It just alleged that, based on information provided by Mullan's medical provider, St. Jude estimated that her pacemaker battery "would last approximately another six (6) months" and that she died a month later.

In October 2011, St. Jude moved for summary judgment on the Estate's complaint on the following grounds supported in the record:

1. Mullan's pacemaker was functioning normally and providing prescribed low-voltage therapy within appropriate parameters after Mullan's death; there was no evidence of (a) a product malfunction, (b) any wrongdoing by St. Jude, or (c) a causal connection, including whether Mullan's death was preventable by a pacemaker;
2. Mullan's complaint against St. Jude is preempted by the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act ("FDCA") because there is no allegation or evidence that in providing an estimate of battery longevity St. Jude violated any federal requirement governing Mullan's Synchrony II pacemaker; and
3. Mullan's complaint against St. Jude failed as a matter of law under the learned intermediary doctrine because the undisputed facts are that Mullan's pacemaker was at or near ERI at the time of her death,

and therefore St. Jude could not have breached any legal duty to provide information to Mullan's medical providers that caused her death.

After St. Jude's motion was continued, the Estate opposed the motion on its merits. The Estate did not move for a further continuance under CR 56(f) or propound any discovery on St. Jude. However, at the hearing on St. Jude's motion, the Estate both opposed the motion on its merits and requested a further continuance for discovery.

On February 9, 2012, the trial court, the Honorable Donald E. Eaton presiding, granted St. Jude's motion and denied the Estate's *ore tenus* request for a continuance under CR 56(f). The Estate appeals the court's order granting St. Jude's motion for summary judgment.

II. ISSUES PRESENTED

The Estate's appeal from the trial court's order granting summary judgment to St. Jude raises three main issues:

1. Did the trial court properly find that under the undisputed facts of this case the Estate failed to raise a genuine issue of material fact under Washington's learned intermediary doctrine, and therefore St. Jude was entitled to summary judgment on the Estate's complaint?

2. Alternatively, did the trial court properly grant St. Jude's motion for summary judgment (a) because the Estate's claim against St. Jude is expressly preempted under *Riegel v. Medtronic, Inc.*, 552 U.S. 312,

128 S. Ct. 999, 169 L. Ed. 2d 892 (2008), or (b) because there was no evidence on three essential elements of the Estate’s claim: (i) a product malfunction; (ii) wrongdoing by St. Jude; or (iii) causation?

3. Did the trial court abuse its discretion when it denied an *ore tenus* request for a continuance under CR 56(f)?

III. STATEMENT OF THE CASE

Respondent St. Jude Medical, Inc. is the parent corporation of Pacesetter, Inc., a manufacturer of, *inter alia*, implantable pacemakers and cardioverter defibrillators.¹ Pacesetter, Inc. (collectively with St. Jude Medical, Inc. referred to as “St. Jude”) manufactured the Synchrony II, Model 2023 pacemaker implanted in Mullan. [CP 47, 51, 263]

Respondent North Cascade Cardiology is a medical provider. Respondent Andrew Coletti, M.D. provided medical care to Mullan after her pacemaker was implanted. Respondent Maria Healey, R. N. assisted Dr. Coletti in providing medical care to Mullan. [CP 122, 142]

¹ Pacemakers and implantable cardioverter defibrillators (“ICDs”) are implanted in patients with serious heart conditions to treat cardiac arrhythmias, which can take on many different forms, some of which are treatable, some of which are not. Pacemakers and ICDs are prescribed to treat different indications. A pacemaker is designed to deliver only low voltage therapy to help “pace” a patient’s heart. An ICD has the capability to deliver low voltage therapy as well as high voltage shocks to treat a heart that has stopped beating or is beating too fast or behaving erratically and is therefore not pumping or circulating blood. The high voltage shock is used like a “splash of cold water” to help resuscitate the heart or shock it back into rhythm.

A. Class III Medical Devices

Pacemakers and ICDs, like other implantable medical devices, are Class III devices under the MDA to the FDCA due to an unavoidable risk of serious injury in the commercial use of such devices.² Even when all reasonable precautions are undertaken by the manufacturer, there is a risk of failure and a risk of death or serious injury. Accordingly, Congress passed the MDA to, *inter alia*, ensure that (1) Class III devices are highly regulated and approved by the Food and Drug Administration (“FDA”) before their commercial use—thereby reducing the risk of injury when they are used as prescribed; and (2) personal injury litigation would not make the commercial use of Class III devices cost prohibitive—claims are limited to where a manufacturer allegedly deviated from the approved design, manufacturing process, or labeling of a Class III device.³

Pre-market approval (“PMA”) by the FDA does not guarantee that a device will work as expected after being prescribed by a physician, or that the device will prevent death or serious injury. It means that when a manufacture acts in accordance with the approved design, manufacturing process and labeling for a device, the manufacturer is not negligent or

² See 21 C.F.R. § 870.3610(b); *Riegel*, 552 U.S. at 316-17.

³ See *Riegel*, 552 U.S. at 330 (discussing so-called “parallel” claims, *i.e.*, claims based on a violation of a federal safety requirement).

liable for the commercial use of the device. A patient is subject to an approved risk of injury in the commercial use of the device.

B. Mullan’s Physicians Prescribed and Implanted an Approved Class III Device to Treat Her Serious Heart Condition

Mullan was diagnosed with a congenital heart condition in November 1989. [CP 222] On May 15, 1994, Mullan’s physicians prescribed and implanted a Synchrony II, Model 2023 pacemaker (Serial No. 124814) to treat her heart condition. [CP 223]

The Synchrony II, Model 2023 pacemaker was submitted to the FDA for approval pursuant its rigorous PMA process. On August 19, 1991, the FDA approved the Synchrony II, Model 2023 pacemaker for commercial use in the United States. [CP 47, 51, 57]

C. Product Labeling for the Synchrony II Pacemaker Does Not Guarantee Battery Longevity, But Provides Approximations and Recommended Replacement Time

The User Manual for the Synchrony II, Model 2023 pacemaker, which constitutes product labeling under the FDCA, includes a discussion of battery longevity and recommended replacement time (“RRT”). The RRT for the Synchrony II, Model 2023, which is indicated on the device as Elective Replacement Indicator (ERI), is when the available battery voltage decreases from a maximum capacity of 2.8 volts to approximately 2.4 volts. [CP 47, 83] In contrast, “[e]nd of life (EOL) is defined as the point in time when the device’s pulse amplitude reduces to approximately

50 percent of the programmed value. EOL occurs when the available battery voltage has decreased to 2.2 volts.”⁴ [CP 83]

The User Manual includes multiple charts providing estimated battery longevity based on a wide range of operational conditions experienced by patients and devices. [CP 83] Two charts approximate the mean and estimated ranges of battery longevity based on different programmed settings and normal use conditions. [CP 84] In providing this information to medical care providers, the User Manual expressly disclaims that “RRT precedes EOL by a wide margin of safety, seldom less than three months under normal circumstances,” but “[a]ctual pacemaker longevity is determined by many factors and may be less than, or significantly exceed, any current predication.” [CP 84]

Based on Mullan’s device’s programed settings and measured lead impedances, the User Manual provided two battery longevity approximations applicable to her device: (1) An estimated mean of 13.1 years with a range of 7.7 years (low) and 18.5 years (high); and (2) an

⁴ EOL does not mean that a battery is dead or has no voltage or insufficient voltage for a pacemaker to function and provide therapy as programmed. [CP 226] It means that the device’s battery has drained to the extent that the device becomes unpredictable in terms of its functioning. [CP 47] There is a known, increased risk of product failure. [CP 198-199, 226] Although a device at EOL should be replaced, a patient’s physician must still make a judgment call as to whether a patient is strong enough to undergo replacement surgery and whether the benefits outweigh the risks of surgery.

estimated mean of 11.3 years with a range of 7.1 years (low) and 15.5 years (high). [CP 84, 199, 272] The approximated longevity of her device was more closely reflected by the User Manual's example of devices with a mean of 13.1 years and a high of 18.5 years rather than devices with a mean of 11.3 years and a high of 15.5 years. [CP 272]

D. There Is No Evidence That the Estimate Provided to Mullan Regarding Battery Longevity Conflicted With St. Jude's Product Labeling for Her Device

On September 11, 2008, Mullan's physician, Andrew Coletti, M.D., examined Mullan after Maria Healey, R.N., interrogated her device. [CP 224] Based on information obtained and provided by Nurse Healey, an estimate was provided that Mullan's pacemaker battery had approximately five to six months before Mullan's pacemaker had to be replaced. [CP 142] Arrangements were made to have her pacemaker replaced by the end of the year. [CP 143]

The five to six month estimate provided on September 11, 2008, which projected battery longevity of 14.9 years, did not conflict with or deviate from product labeling for the Synchrony II, Model 2023 pacemaker. Whether the high approximated battery longevity for a device with Mullan's programmed settings and measured lead impedances is 18.5 years, 15.5 years, or somewhere in between, 14.9 years was not inconsistent with product labeling for her device. [CP 272]

E. The Estate Presented No Evidence of Mullan's Cause of Death

On October 12, 2008, Mullan died of unknown causes, vaguely described as cardiac arrhythmias. [CP 3, 276] The Estate had the autopsy report from the San Juan County Coroner's Office, but never provided it to St. Jude. The Estate had nearly three years to investigate the cause of Mullan's death before filing a lawsuit, and provided the autopsy report to its proffered medical expert, Mark J. Seifert, M.D, who had an additional three months to provide testimony as to the cause of death in opposition to St. Jude's motion for summary judgment. Yet, the Estate submitted no evidence as to the cause of Mullan's death. [See CP 220-229] Dr. Seifert did not attach the autopsy report to his declaration, summarize or expound upon the findings, or indicate whether he agrees with them or whether he has a different or an additional opinion as to the cause of death.

Significantly, Dr. Seifert does not opine that the cause of Mullan's death was treatable or preventable by Mullan's pacemaker. [See CP 220-228] Moreover, contrary to the Estate's argument [OB at 3], the fact that Mullan died is not evidence that her pacemaker did not function as programmed, or that anybody was negligent.

F. There Is No Evidence of Device Failure

On October 16, 2008, Mullan's pacemaker was explanted during her autopsy, tested at room temperature by a St. Jude sales representative,

and returned to St. Jude for reliability testing fourteen years and five months (nearly 14.4 years) after it was implanted.⁵ [CP 43-44, 203] St. Jude documented the post-autopsy, out-of-body test results. [CP 294] St. Jude documented in its October 17, 2008 “Field Contact Report” an expressed concern about battery voltage, which was the reason Mullan’s device was being returned for reliability testing: “Device appears to have reached EOL faster than expected.” [CP 94] Similarly, St. Jude documented in its “Product Reporting MDR Review” (or “in-take”) form dated October 22 and 24, 2008, the “Complaint/Reason for Return (RFR)” as “Anticipated Battery Depletion”/“ERI/EOL Margin Short.” [CP 285]

On October 28, 2008, in accordance with FDA regulations, St. Jude conducted reliability testing sixteen days (16) after Mullan died to determine whether there was any evidence of product failure. [CP 48] The analysis of Mullan’s device followed defined steps and procedures [CP 264, 284, 303-304], including (a) preliminary testing and initial assessment of the device memorializing the “as received” measurements downloaded from device memory, and the “as received” measurements

⁵ The results of an out-of-body interrogation are not reflective of actual device performance because the device is tested at a colder room temperature, and not at the in-body temperature of 37°C. The difference in temperature of the device results in a higher reported battery impedance and a lower reported battery voltage than what would be reported if the device was at 37°C, the in-body condition. [CP 268]

obtained from bench testing at 37°C and with a standard 500 ohm load [CP 43, 265-266, 306-309], (b) reprogramming the device to “RTS” (return to standard) settings and measuring device output for further testing, and (c) additional bench testing trying to duplicate device output (i) at RTS settings, (ii) at “as received” settings at 37°C with a standard 500 ohm load (*i.e.*, the “in-body” condition), and (iii) at room temperature without a load (*i.e.*, the out-of-body condition) [CP 43-44, 269-270].

There was no evidence of device failure. [CP 43-44, 48, 93-99, 263-270] Measurements of both the atrial and the ventricular pacing pulse therapy were made in multiple test conditions verifying that Mullan’s pacemaker was functioning properly. [CP 43] The “as received” data from Mullan’s pacemaker and bench testing showed that her device was at or near ERI (2.42 volts). [CP 48, 267-270, 311-316] The results showed that device failure was not the cause of death.⁶ [CP 44, 263]

⁶ At the hearing on St. Jude’s motion, St. Jude walked the trial court through the documents in the Estate’s possession, including the source documentation showing the data downloaded from Mullan’s pacemaker “as received” by St. Jude, as well as “as received” measurements obtained through bench testing. [RT at 8-14] St. Jude directed the court’s attention to the “Measured Data” confirming that the pacemaker was both “sensing” and “pacing” well within parameters. [RT at 14, 17-23]

G. The Estate Failed to Rebut the Evidence in Its Possession Provided After Mullan’s Death, Which Showed That Her Pacemaker Was Functioning Normally

On August 17, 2009, St. Jude sent to the Estate’s counsel, William E. Pierson, Jr., documents that were requested regarding Mullan and her pacemaker, including St. Jude’s Product Analysis Report [CP 278-301], which evidenced that (1) Mullan’s pacemaker was functioning properly—providing prescribed low-voltage therapy well within parameters at the time of her death; and (2) Mullan’s device was at or near ERI. [CP 48, 263, 267-270] In opposing St. Jude’s motion for summary judgment, the Estate’s proffered experts did *not* dispute the evidence in their possession and relied upon by St. Jude that Mullan’s device was functioning normally when she died. Nor did they dispute that her device was at or near ERI (2.42 volts) based on the “as received” data obtained from her device, and the test results St. Jude obtained during reliability testing. Instead the Estate’s proffered experts (a) ignored the evidence of device function entirely and (b) responded by simply questioning, without any foundation or basis in fact, the “reliability” of St. Jude’s data and testing concerning battery voltage. [See CP 201-206, 227-228, 262-276]

H. The Estate Speculates That Mullan’s Battery Did Not Last as Long as Projected Contrary to Record Evidence

The Estate’s complaint alleges that St. Jude did not provide accurate information to Mullan’s medical provider regarding the useful

safe life of her pacemaker. [CP 4] The Estate's case is founded entirely on the supposition that Mullan's device failed to prevent Mullan's death due to unreliable low battery voltage.⁷ [See CP 198-199: "the pacemaker's analog circuitry is assured to become unreliable at (and below) approximately 2.2 volts."; CP 226: "For a pacemaker dependent patient, if the battery voltage drops to an EOL level, the patient runs the risk of dying due to the failure of the pacemaker to function properly."]

In its Opening Brief, the Estate proffers the analogy that the battery in Mullan's device was akin to "a car battery [that] may be working, but may not be strong enough to start the car's engine." [OB at 26]. The Estate's argument, which is not supported by any evidence, **assumes multiple things**, including: (1) that Mullan's device failed to provide the prescribed low-voltage therapy, when the evidence is to the contrary; (2) that Mullan's pacemaker was at EOL (2.2 volts) when she died, *not* ERI (2.4 volts), which is contrary to the evidence; (3) that Mullan's heart needed low-voltage therapy, *not* high voltage therapy, which her pacemaker could not provide; (4) that low or high voltage therapy would

⁷ The Estate's engineering expert, Louis F. Bilancia, P.E., opines that the manufacturer of the Wilson Greatbatch model 8077 lithium-iodide battery used by all the major pacemaker manufacturers, including St. Jude, provides an estimated battery longevity of 10-12 years based on its own internal "shelf life," and that "a pacemaker with a useful safe life of 5 years or less is not a competitive product and a device with a useful safe life of 12 years or more is extraordinary." [CP 199]

have “start[ed] the car’s engine”; and (5) that surgery would have been successful, been undertaken in time had a different estimate been given, and prevented Mullan’s death, the cause of which is unknown.

I. There Is No Evidence That St. Jude Was Negligent; the Estate’s Expert Faults Nurse Maria Healey

In opposing St. Jude’s motion for summary judgment, the Estate’s experts did not fault St. Jude for providing a five to six months estimate of battery longevity. Rather, the Estate’s medical expert faulted Nurse Healey for providing St. Jude with allegedly erroneous information. [CP 224-227: “In my opinion, the information Nurse Healey provided St. Jude Medical on September 11, 2008 resulted in a forecast that the battery for Ms. Mullan’s pacemaker could last another five to six months”] The Estate’s engineering expert, however, could not opine on whether the information provided by Nurse Healey resulted in an erroneous estimate. He testified to having Nurse Healey’s declaration [CP 198, 200] and knowing how to perform the industry standard calculation [CP 201], but he did *not* opine that St. Jude provided an erroneous estimate based on the information provided. He did not even opine that, in hindsight, a five to six month estimate was erroneous. Rather, he opined that more information allegedly is needed to determine whether the device was at ERI or EOL at the time of Mullan’s death. [See CP 202-206]

J. The Estate’s Effort to “Muddy the Water” Lacked Foundation

St. Jude’s reply in support of its motion for summary judgment plainly showed why each one of the Estate’s efforts to poke holes in St. Jude’s Product Analysis Report lacked foundation and ignored the record evidence in the Estate’s possession. [CP 249-252] It remained undisputed that Mullan’s pacemaker was functioning properly, and was at or near ERI (*not* EOL) at the time of her death. [CP 43-44, 48, 93-99, 262-276]

K. Further Testing of Mullan’s Device More Than Three Years After Her Death Would Not Result in Any Meaningful Evidence

The Estate opposed St. Jude’s motion on the merits and did not move for a continuance under CR 56(f). [See CP 175-194] The Estate asked for a CR 56(f) continuance for the first time at the hearing on St. Jude’s motion. [CP 341] In support, the Estate argued that it wanted more time to conduct further testing on Mullan’s explanted device. [CP 342] However, the Estate, including its proffered experts, provided no evidence that anything meaningful would be obtained. As St. Jude pointed out, further testing: (1) would *not* evidence the cause of death, *i.e.*, whether it was treatable or preventable by a pacemaker (or ICD); (2) would *not* evidence whether Mullan’s device, three years earlier, was pacing/sensing within the prescribed parameters; (3) would *not* evidence whether the alleged estimate provided in September 2008 conflicted with or deviated

from product labeling; and (4) would *not* evidence whether Mullan's device was at ERI or EOL at the time of her death. [CP 248-259]

St. Jude's expert explained why further testing on Mullan's pacemaker at this point in time would not be meaningful. Even if the sealed container is opened and Mullan's device were tested today, and the battery was not entirely depleted or otherwise in need of replacement and did not fail during further testing due to low battery voltage, the performance of her device three years after the incident would *not* be probative of its performance at the time of Mullan's death, three years earlier. The "as received" measurements and results of confirmatory bench testing sixteen days after Mullan's death would remain the only probative evidence of device function and battery voltage at the material time of Mullan's death. [CP 275-276]

In short, in opposing St. Jude's motion, the Estate's possessed all the material evidence concerning device function and battery voltage. In filing this appeal, the Estate just ignores the uncontroverted evidence that device failure was not the cause of Mullan's death. [CP 263, 276]

IV. ARGUMENT

A. The Trial Court Properly Granted Summary Judgment

This Court reviews a summary judgment order *de novo*, performing the same inquiry as the trial court and considering the facts

submitted and all reasonable inferences from those facts in the light most favorable to the nonmoving party. *Kruse v. Hemp*, 121 Wn.2d 715, 722, 853 P.2d 1373 (1993). This Court can affirm the trial court's judgment “upon any theory established by the pleadings and supported by the proof, even if the trial court did not consider it.” *LaMon v. Butler*, 112 Wn.2d 193, 200-201, 770 P.2d 1027 (1989).

1. There Is No Evidence on the Essential Elements of Product Malfunction, Negligence and Causation

The trial court properly granted summary judgment on the Estate’s complaint against St. Jude. Regardless of legal theory, the Estate failed to present evidence on three essential elements: (a) a product malfunction; (b) wrongdoing by St. Jude; and (c) causation. *See Morgan v. Aurora Pump Co.*, 159 Wn. App. 724, 729, 248 P.3d 1052 (2011) (“[T]he plaintiff in a product liability or negligence action bears the burden to establish a causal connection between the injury, the product and the manufacturer of that product.”) (*citing* RCW 7.72.030(1) (“A product manufacturer is subject to liability to a claimant if the claimant’s harm was proximately caused by the negligence of the manufacturer in that the product was not reasonably safe as designed or not reasonably safe because adequate warnings or instructions were not provided.”)).

a. Mullan's Device Was Working Properly

In moving for summary judgment, St. Jude met its burden of proof that Mullan's device was functioning properly after her death during reliability testing. [CP 43-44, 48, 93-99] It was not a cause of death. [CP 44] Her device was sensing, capturing and pacing as programmed, well within parameters. [CP 43-44, 48, 93-99]

The Estate's experts did not dispute or rebut St. Jude's showing as to device function. They had Mullan's medical records; they testified as to her diagnosis, including her pacemaker dependent status; they did not deny that they knew the amount of low-voltage therapy Mullan's physicians believed she needed to sustain her heart rhythms; and they did not deny that Mullan's device was sensing and capturing her heart rhythms and was still providing more therapy than her physicians believed was necessary to pace her heart. Accordingly, St. Jude was entitled to summary judgment. *Discover Bank v. Bridges*, 154 Wn. App. 722, 727, 226 P.3d 191 (2010) (alleged facts and argument "unsupported by evidence" are insufficient to survive summary judgment).

b. There Is No Evidence of Any Wrongdoing by St. Jude

The Estate's contention that the battery in Mullan's pacemaker was low, and therefore she was allegedly facing an undue "risk" of device

failure, failed to raise a genuine issue of material fact for a second reason:

The Estate presented no evidence of any wrongdoing by St. Jude.

The Estate's experts did not render an opinion that St. Jude was negligent because Mullan's device did not prevent her death or work properly one month after it was interrogated by Nurse Healey. Rather, Dr. Siefert faulted Nurse Healey for providing St. Jude with misinformation. [CP 224-227] The Estate's engineering expert, however, did not opine that the fax sent by Nurse Healey resulted in an erroneous estimate of battery longevity. Rather, lacking any evidence that the estimate provided by St. Jude was erroneous, he resorted to vague, unsupported criticisms of St. Jude's reliability testing, claiming that it somehow is not "scientifically reliable." [See CP 202-206]

St. Jude was entitled to summary judgment because the Estate's experts did not opine that, based on the September 2008 interrogation of Mullan's device and the information available to St. Jude, St. Jude knew, or should have known, and therefore should have informed Mullan's medical provider, that the battery in her device was already at EOL (not at or near ERI). The Estate's experts had access to Mullan's medical records, which included the entire history of her device interrogations. Unlike St. Jude, the Estate's experts had evidence of both Mullan's pacemaker's historical consumption rate, and her device's September

2008 interrogation results. Therefore, not only did the Estate's experts have the information necessary to perform an industry standard battery longevity calculation, they could have corroborated their estimate with historical consumption rates. They did neither in opposing St. Jude's motion for summary judgment.

c. The Estate Presented No Evidence of Mullan's Cause of Death

St. Jude was entitled to summary judgment for a third reason: The Estate presented no evidence of Mullan's cause of death, another essential element of her claim.

No medical device manufacturer can guarantee that a patient will not succumb to her medical condition; can guarantee the performance of a device; or can guarantee that the patient will not suffer an unforeseen cause of death. Here, the Estate did not present the autopsy report and its medical expert did not opine as to the cause of Mullan's death. There is no evidence that Mullan's pacemaker could even treat the suspected cause of her death; that a different type of device could have prevented her death; or that such a device could have been implanted in time had an allegedly accurate estimate of battery longevity been provided to Mullan. Her cause of death remains unknown. [CP 276] Accordingly, St. Jude is entitled to summary judgment for this reason as well.

d. The Fact of Mullan’s Death Is Not Evidence of Any Wrongdoing by Anyone

The Estate did not invoke the doctrine of *res ipsa loquitur* below, or in its opening brief. Yet, its argument is akin to an unfounded claim that because Mullan died when she had a pacemaker implanted, the pacemaker had to be defective or fail to work due to negligence of somebody. The doctrine of *res ipsa loquitur* has been rejected in medical device cases, especially in cases involving serious medical conditions and Class III medical devices. *See, e.g., Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011) (rejecting use of *res ipsa loquitur* to establish “causal connection” between medical device and personal injury).

e. The Estate’s Proffered Expert Opinion That Battery Test Results Are Inconclusive Failed to Raise a Genuine Issue of Material Fact

The Estate’s opposition to summary judgment was based almost entirely on its proffered expert opinion that no reasonable scientific conclusion as to battery voltage could be drawn from the evidence within the Estate’s possession. [OB at 11, 18] The Estate’s proffered expert opinion failed to raise a genuine issue of material fact for multiple reasons. First, the evidence in the Estate’s possession—both as to device function and battery voltage—was more than sufficient to meet St. Jude’s burden in moving for summary judgment. Second, the Estate’s proffered opinion did not address, let alone rebut, St. Jude’s evidence that Mullan’s device

was functioning normally when it was returned to St. Jude for reliability testing. Third, the Estate's proffered opinion as to battery voltage lacked foundation. The proffered criticisms of St. Jude's reliability testing had no basis in fact, and simply ignored record evidence. [See CP 264-276] Fourth, the Estate's proffered opinion that the record evidence is "inconclusive" was insufficient to carry the Estate's burden of proof in opposing summary judgment in any event. Even if believed, it did not support that, more likely than not, Mullan's battery was at EOL, *not* ERI. Fifth, the Estate's proffered opinion did not address the issue of MDA preemption, which remained an alternative ground for summary judgment. Sixth, neither of the Estate's experts faulted St. Jude for the alleged estimate, or opined that the alleged estimate was even erroneous based on the September 2008 interrogation results. Finally, the Estate's failure to submit any evidence as to the actual cause of Mullan's death remained fatal to the Estate's claims against St. Jude.

2. The Estate's Claims Are Preempted

The Estate's complaint against St. Jude is based on an allegation that St. Jude did not accurately estimate the useful safe life of Mullan's pacemaker. [CP 4] Under Washington's learned intermediary doctrine, St. Jude did not owe any legal duty to Mullan to provide information or medical care, but there could be a duty to warn physicians about the risks

attendant with the use of a medical device. *See Terhune v. A. H. Robins Co.*, 90 Wn.2d 9, 14, 577 P.2d 975, 978 (1978) (granting judgment for manufacturer because duty to warn runs to physician and not to patient); *Kennedy v. Medtronic, Inc.*, 366 Ill.App.3d 298, 304, 851 N.E.2d 778 (Ill. App.Ct. 2006) (granting summary judgment because manufacturer did not owe duty to decedent that would support negligence claim).

With respect to Class III medical devices approved by the FDA through the FDCA's rigorous PMA process, the legal duty to provide information to medical providers is defined by federal law. Under the U.S. Supreme Court's recent decision in *Riegel*, no claim for breach of such a duty is stated or can be maintained if the claim falls within the approved labeling and disclaimers for such a device.

a. The MDA's PMA Process

The FDA classifies Mullan's Synchrony II, Model 2023 pacemaker as a Class III device and subjects such devices to the highest and most exacting level of regulation, so as to ensure that they do not reach the market until the FDA is satisfied that they are reasonably safe and effective.⁸ *See* 21 C.F.R. § 870.3610(b); *Riegel*, 552 U.S. at 317

⁸ Before Class III devices may be commercially used in the market, the MDA require manufacturers to obtain pre-market approval from the FDA, with certain exceptions not applicable here. *See* 21 U.S.C. § 360c(a)(1)(C). After reviewing the comprehensive data set forth in a PMA application, which includes the results

(“The devices receiving the most federal oversight are those in Class III, which include . . . pacemaker[s]”); *Martin v. Medtronic, Inc.*, 254 F.3d 573, 576 (5th Cir. 2001) (“A pacemaker is classified as a ‘Class III’ medical device. As such, it must undergo an indisputably thorough, rigorous, and costly premarket review (some 1,200 FDA man-hours at hundreds of thousands of dollars in cost) by the FDA.”).

After a device is approved, the manufacture is prohibited from making any change to the design, manufacturing process or labeling of a device that might affect its safety or efficacy without obtaining further FDA approval. *Riegel*, 552 U.S. at 319. The FDA audits Class III device manufacturers to ensure compliance with their PMA requirements, and issues “483” citations and warning letters for alleged violations, and brings administrative proceedings to enforce federal requirements. *See Buckman v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 349 fn. 4, 121 S.Ct.

of years of clinical testing, the specific device design, its components and materials, the manufacturing methods, testing protocols and quality assurance procedures, and *all proposed labeling and warnings*, the FDA will approve the device for market distribution *if, but only if*, the FDA is satisfied that the device—including its design, manufacturing process, and labeling—is reasonably safe and effective for its intended use. *See* 21 U.S.C. § 360e(d)(2). PMA is based on the FDA’s determination after reviewing all of the materials submitted that the device is reasonably safe and effective. *See* 21 U.S.C. § 360e(c)(1); *Riegel*, 552 U.S. 317-18; *Riley v. Cordis Corporation*, 625 F. Supp. 2d 769, 774 (D. Minn. 2009).

2012, 148 L.Ed.2d 854 (2001); *Gross v. Stryker Corp.*, --- F.Supp.2d ---, 2012 WL 876719, at *2 (W.D. Pa. Mar. 14, 2012).

Mullan’s pacemaker model went through the FDA’s rigorous PMA process and received FDA approval. [CP 47, 51, 57] Thus, the FDA-approved labeling, including product warnings, relating to her device govern the Estate’s complaint against St. Jude.

b. Federal Preemption

Under Article VI, Clause 2 of the United States Constitution, known as the Supremacy Clause, any “state law that conflicts with federal law is ‘without effect.’” *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992) (citation omitted). For Class III medical devices, Congress enacted an express preemption clause, which provides:

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

- (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
- (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

As explained in *Riegel*, 21 U.S.C. § 360k(a) expressly preempts any state law requirement or obligation that would be different from or in addition to those imposed by the FDA under the MDA. *See Riegel*, 552

U.S. at 323-24 (“In *Medtronic Inc. v. Lohr*, 518 U.S. 470 (1996), five Justices concluded that common-law causes of action . . . do impose “requirement[s]” and would be pre-empted We adhere to that view.”) (internal citations omitted). The only claims that survive preemption are so-called “parallel” claims, *i.e.*, state law claims that are based on a violation of a federal safety requirement.⁹ *Id.* at 1011; *Buckman*, 531 U.S. at 353-53 (discussing “parallel” claims).

The federal regulatory scheme understands that Class III devices such as Mullan’s pacemaker are unavoidably dangerous products that cannot be flawlessly manufactured and that, despite all reasonable precautions, a percentage of them will fail or not perform as expected.¹⁰ FDA approval reflects a risk-reward determination that would not be available under a fifty-state regulatory regime. To protect consumers from faulty products and manufacturers from excessive litigation, Congress

⁹ District courts routinely dismiss cases under *Riegel* that are not based on a finding or allegation by the FDA of a failure to comply with a federal (PMA) requirement. *See, e.g., Lemelle v. Stryker Orthopaedics*, 698 F. Supp. 2d 668, 678 (W.D. La. 2010); *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 588-89 (E.D.N.Y. 2009); *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769 (D. Minn. 2009); *Funk v. Stryker Corp.*, 673 F. Supp. 2d 522, 532 (S.D. Tex. 2009); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 278-79 (E.D.N.Y. 2009); *In re Medtronic, Inc. Sprint Fidelis Leads*, 592 F. Supp. 2d 1147, 1157 (D. Minn. 2009).

¹⁰ Prior to the MDA, pacemakers were regulated by the laws of fifty different states and viewed as unavoidably unsafe, prescription devices. *See* Restatement (3rd) of Torts § 6(c); Restatement 2nd of Torts § Section 402A, cmt. k.

promulgated the MDA, imposed a comprehensive set of federal regulatory standards and requirements on the production and distribution of Class III devices, and preempted all state-law claims that seek to or would impose different or additional state law standards or requirements on manufacturers of PMA devices. 21 U.S.C. § 360k(a); *Buckman*, 531 U.S. at 350 (“complying with the FDA’s detailed regulatory regime in the shadow of 50 States’ tort regimes [would] dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the FDCA and the MDA.”).

The FDA has “unequivocally expressed the opinion that state common law claims . . . against a PMA-approved device are preempted.” *Horn v. Thoratec Corp*, 376 F.3d 163, 171 (3rd Cir. 2004). They threaten the statutory framework for the regulation of Class III devices, including the flow of information to medical providers. State actions are not characterized by centralized expert evaluation of device regulatory issues. Instead, they encourage, and in fact require, lay judges and juries to second-guess the risks and benefits of a device or information to the intended population—the central role of the FDA—sometimes on behalf of a single individual or group of individuals. That individualized redetermination of risks and benefits can result in decisions—including damage awards—that create pressure on manufacturers to stop providing

information within the parameters of approved labeling, or to provide information that FDA has neither approved, nor found to be scientifically required. This situation can harm the public health by stifling the flow of beneficial information or by encouraging the use of “defensive labeling.” *Id.* at 178 (citing FDA *Amicus Curiae* Letter Br., at 24-25).

c. Product Labeling

The FDCA broadly defines “labeling” to include “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.” 21 U.S.C.A. §§ 321(m). As previously stated, the FDA requires manufacturers to include proposed medical device labeling and warnings as part of the PMA process. *See* 21 C.F.R. §§ 801.109, 860.7(d)(1)-(e)(1). Because medical devices such as pacemakers are available only by prescription, the FDA requires that *all* directions, information and warnings be directed to medical providers, and not patients. 21 U.S.C.A. §§ 321, 801.109, 801.109(d). Such information and disclosures take the form of a “User Manual” (aka a “Technical Manual” or “Physician’s Manual”) which accompanies the device. *Id.*; *Barney v. St. Jude Medical Center, Inc.*, 1993 WL 13015619, at *5 (N.D. Cal. 1993); *Baker v. Medtronic, Inc.*,

2002 WL 485013, at *7 (S.D. Ohio 2002).¹¹ As a condition for receiving pre-market approval, manufacturers are required to submit labeling “of which the Physician’s Manual is a part” to the FDA for review and approval. *Barney*, 1993 WL 13015619, at *5. The substantive content of the proposed labeling must include information regarding indications, effects, routes, methods of administration, any relevant hazards, contraindications, side effects, and precautions. *Id.*

d. Complaints Based On Misinformation

The Supreme Court has affirmed that the MDA broadly preempt common law claims challenging the safety of a PMA device, including the distribution, labeling, marketing, or sale of such a device. *See Riegel*, 552 U.S. at 312.¹² In *Riegel*, the plaintiffs brought suit against a manufacturer

¹¹ St. Jude directs the Court to *Barney* and *Baker*, not for their precedential value, but for their factually analogous situations under the Supreme Court’s more recent decision in *Riegel*. While St. Jude does not ask the Court to base its decision on these unpublished decisions, in recognition of *Johnson v. Allstate Ins. Co.*, 126 Wn.App. 510, 519, 108 P.3d 1273 (2005), these cases illustrate and follow other citable decisions in this area.

¹² Before *Riegel*, one panel of the Washington State Court of Appeal held that strict liability claims related to medical devices were not preempted under *Medtronic v. Lohr*, 518 U.S. 470, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996), because strict liability laws were of “general application” and were not directed specifically at medical devices. *Wutzke v. Schwaegler*, 86 Wn.App. 898, 904, 909, 940 P.2d 1386 (1997). At the time there was a split among federal and state courts regarding whether *Lohr* left open the possibility of state product liability tort laws surviving the MDA. *See Riegel v. Medtronic, Inc.*, 451 F.3d 104, 117 & n.16 (2nd Cir. 2006) (discussing split and citing *Wutzke* as representing one side of it). The *Wutzke* line of cases was overruled by the Supreme Court in *Riegel*,

of a PMA device, a catheter, after the catheter ruptured in an artery during heart surgery. The plaintiffs alleged that the catheter was dangerous and unsafe because it was designed, manufactured or labeled in a manner that violated New York law. The Supreme Court held that the MDA preempted plaintiffs' common law claims, which challenged everything relating to the design, testing, inspection, distribution, labeling, marketing, and sale of the catheter, because the FDA had approved those things. *Id.* at 320-21. The Supreme Court deferred to the district court's interpretation of the complaint that plaintiffs' claims were seeking to impose liability on the defendant even if it had complied "with the relevant federal requirements." *Id.* at 330.

Under *Riegel*, claims challenging the information provided to a medical provider concerning the safety or efficacy of a device, including its expected performance, may no longer be based on common law duties. Rather, they must be based on a violation of, failure to comply with, or a deviation from approved labeling, a so-called "parallel" claim. *See Riley*, 625 F. Supp. 2d at 777; *Gross*, 2012 WL 876719, at *30; *Funk*, 673 F.Supp.2d at 524-32, *aff'd* 631 F.3d 777; *Desabio v. Howmedica*

which is binding precedent under the Supremacy Clause. *See Goodwin v. Bacon*, 127 Wn.2d 50, 58-61, 896 P.2d 673 (1995).

Osteonics Corp., 817 F.Supp.2d 197, 202-03 (W.D.N.Y. 2011); *Stengel v. Medtronic, Inc.*, 2010 WL 4483970, at *2 (D.Ariz. Nov. 9, 2010).

For example, in *Baker* the plaintiff sued when the battery on her infusion pump stopped prematurely, thereby causing injury. *Id.* at *2. The plaintiff claimed that a Medtronic technician had made an “express representation that [the pump] would continue to function for 30 days after the low battery alarm sounded. Instead, the device only worked for 15 days.” *Id.* The plaintiff did not directly challenge the adequacy of the product labeling by claiming that she was unaware of the possibility that the device could cease to function due to battery depletion. *Id.* Instead, the plaintiff argued that the representations made by the technician that the battery life would continue for 30 days constituted “off label representations,” which were not approved by the FDA and therefore, fell outside the scope of preemption. *Id.* The *Baker* court disagreed, finding that, “because the representation was not in conflict nor did it vary from the FDA approved warnings,” there was no “off label representation” and the case fell within the scope of preemption. *Id.* The claim that the representation of thirty days was false because the battery lasted only fifteen days was likewise preempted. The *Baker* court held:

The FDA approved literature delivered with the SynchroMed pump provides statistical values for a physician to utilize in estimating the life of the pump in the

presence of a low battery alarm. The literature provides that 66% of users would fall within the standard error life expectancy curve, which amounts to a period of 30 to 80 days of pump effectiveness, and 33% would fall outside that range. Dr. Rea was aware of these statistics. Moreover, the representations made by Medtronic technicians as to the 30 day life expectancy *were consistent with the statistical literature approved by the FDA.*

Baker, 2002 WL 485013, at *8 (emphasis added). Thus, because the representative's statements of battery longevity were consistent with the labeling for the device, the Court held that "to allow a state cause of action for inadequate warnings would impose different requirements or requirements in addition to those required by federal regulations. . . . Since the FDA considered and approved the aforementioned warning with respect to battery life of the SynchroMed pump, Plaintiff's state law claim for failure to warn is preempted by the MDA." *Id.*; *Barney*, 1993 WL 13015619 at *3 (physician's manual in use at time of plaintiff's valve replacement controlled negligence claim).

e. Summary Judgment Was Proper Because the Estate Neither Alleged nor Adduced Evidence of a Violation of Any FDA Requirement

The Supreme Court in *Riegel* placed the burden of pleading and proving a federal violation on plaintiffs in cases involving a PMA

device.¹³ Accordingly, the Estate bore the burden of pleading a viable “parallel” claim in connection with St. Jude’s alleged five to six month estimate of battery longevity, and proving that St. Jude’s estimate deviated from or conflicted with approved product labeling. *See Baker*, 2002 WL 485013, at *8; *Barney*, 1993 WL 13015619 at *3; *see also Wolicki-Gables v. Arrow Intern., Inc.*, 634 F.3d 1296, 1301-02 (11th Cir. 2011); *Gross*, 2012 WL 876719, at *20-22; *Parker v. Stryker Corp.*, 584 F.Supp.2d 1298, 1301-03 (D.Colo. 2008).

At the hearing on St. Jude’s motion for summary judgment the Estate conceded that its complaint against St. Jude was preempted unless it was based on a violation of a federal standard or requirement governing the commercial use of Mullan’s pacemaker:

The Court: So you agree you have to be able to show that [St. Jude] violated a federal standard?

¹³ *See supra* note 9 and cases cited therein. Here, there is no dispute that the Estate’s complaint was challenging the safety or efficacy, including the performance, of a PMA device. [CP 47, 51] Thus, the Estate’s objection to St. Jude’s request for judicial notice that the User Manual for the Synchrony II, Model 2023 pacemaker constitutes approved product labeling missed the point. The Estate did *not* deny that Mullan’s pacemaker was a PMA device or that the User Manual is “labeling” under federal law. *See* 21 U.S.C.A. §§ 321(m); *Baker*, 2002 WL 485013, at *2; *Barney*, 1993 WL 13015619, at *5. The Estate also did not dispute that federal law prohibits Class III device manufacturers from commercially using *unapproved* manuals for PMA devices, as that constitutes product labeling and would violate federal law. The Estate just opposed St. Jude’s request for judicial notice that the User Manual was reviewed by the FDA and approved for commercial use in the United States. [CP 179-180]

Mr. Pierson: Absolutely . . . *Riegel* stands for the proposition that the standard of care in these devices will be set by the FDA, not the states.

[RT 54:18-55:15 (emphasis added)]

The Estate's complaint is preempted because there is no allegation or evidence that St. Jude deviated from or did anything that conflicted with any PMA requirement in providing a five to six month estimate of battery longevity to Mullan's medical care provider. In fact, St. Jude's User Manual clearly states that the estimated useful safe battery life of the Synchrony II, Model 2023 pacemaker was anywhere from 7.1 to 18.5 years, depending on programming, usage and many other factors. St. Jude's estimate of the battery life remaining in Mullan's device placed the projected lifespan of that device well *within* that range. Moreover, the User Manual expressly warns that battery longevity estimates are mere approximations and actual longevity may vary up or down, thereby warning medical providers and disclosing the subject risk of injury:

Since any projections of pacemaker service life are based on accelerated battery test data, these values should be considered only approximations. Actual pacemaker longevity is determined by many factors and may be less than, or significantly exceed, any current predictions.

[CP 84] Because the Estate neither alleged a violation of a federal standard, nor adduced any evidence of a federal violation, it was

undisputed that the Estate was not bringing a “parallel” claim within the meaning of *Riegel*, and summary judgment was appropriate.¹⁴

3. The Estate’s Complaint Against St. Jude Does Not Survive the Learned Intermediary Doctrine as St. Jude Did Not Provide Any Misinformation

While the trial court “did not reach a decision on the issue of judicial notice,” and therefore did not reach federal preemption as a ground for summary judgment, the trial court did hold that “the Motion can be decided on under CR 56. Under the undisputed material facts of this case, Plaintiffs’ claim against St. Jude is barred by the learned intermediary doctrine.” [CP 325] In its Opening Brief, the Estate concocts a “straw man” in an attempt to challenge this holding:

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.

¹⁴ Indeed, the Estate’s argument that Mullan’s device failed to work as expected is precisely the type of claim that is preempted under *Riegel*. The Estate argued below that if Mullan’s device did not perform or last as long as expected, then St. Jude should be liable—even if the projected useful life was consistent with product labeling. The Estate reasoned that there should be no preemption because the calculation St. Jude (or the industry) uses to approximate battery longevity (as referenced by its own expert) is not included in the User Manual. [CP 181, 183] However, there is no such requirement. That would be a different or additional state law requirement—one that the FDA deemed was not necessary, or did not affect or improve the safety or efficacy of the device. Liability could only arise if St. Jude’s estimate deviated from or conflicted with approved labeling, and there is no such allegation or evidence in this case.

[OB at 29] Here, the Estate both misstates the law and St. Jude's position, and ignores the import of the trial court's holding.

To state and maintain a claim for breach of legal duty under Washington's learned intermediary doctrine, as limited by *Riegel* in a case involving a PMA device, the Estate needed to start by pleading and proving two things: (1) that St. Jude deviated from approved labeling in providing a five to six month estimate of battery longevity to Mullan's medical provider; and (2) St. Jude provided Mullan's medical provider with inaccurate information. It was not enough to have a viable legal theory. The Estate needed facts to support its claim. [CP 257-259]

The trial court held that the Estate did not have the facts to survive the learned intermediary doctrine. The trial court twice referenced in its holding that "[u]nder the undisputed facts of this case" St. Jude only owed, and certainly did not breach, a legal duty of care to Mullan's medical providers. [CP 325] This holding is correct.

St. Jude did not provide any inaccurate information to Mullan's physician. The Estate's experts did *not* even opine that St. Jude's five to six month estimate was inaccurate based on the information available to St. Jude. Reliability testing confirmed that, at the time of Mullan's death, her device was at 2.42 volts, *i.e.*, at or near ERI (*not* EOL). [CP 264, 284, 286-287, 311] Therefore, the uncontroverted evidence was that Mullan's

device had more than sufficient battery life to function reliably.

Accordingly, the trial court correctly concluded that St. Jude was entitled to summary judgment under the learned intermediary doctrine.

B. The Trial Court Did Not Abuse Its Discretion When It Denied the Estate's Request for a Continuance Under CR 56(f)

The Estate contends that the trial court abused its discretion when it denied a request for a continuance under CR 56(f). CR 56(f) permits a court to defer a ruling on a summary judgment motion to allow the party opposing summary judgment more time to gather evidence. The party requesting the continuance bears the burden of demonstrating by affidavit: (1) what specific evidence would be established through additional discovery; (2) how it would raise a genuine issue of material fact; and (3) a good reason for the delay in obtaining the desired evidence. *See* CR 56(f) (three requirements must “*appear from the affidavits*”) (emphasis added); *Janda v. Brier Realty*, 97 Wn.App. 45, 54, 984 P.2d 412 (1999) (citing *Turner v. Kohler*, 54 Wn.App. 688, 693, 775 P.2d 474 (1989)).

The denial of a CR 56(f) motion is reviewed for a manifest abuse of discretion. *Id.* (citing *Molsness v. Walla Walla*, 84 Wn.App. 393, 400, 928 P.2d 1108 (1996)). A court abuses its discretion if it bases a decision on “unreasonable or untenable grounds.” *Lake Chelan Shores Homeowners Ass'n v. St. Paul Fire & Marine Ins. Co.* 167 Wn.App. 28, 40, 272

P.2d 249 (2011). A court may deny a CR 56(f) request, and does not abuse its discretion, if *any one* of the three CR 56(f) affidavit requirements for relief has not been satisfied. *Gross v. Sunding*, 139 Wn.App. 54, 68, 161 P.2d 380 (2007). Here, the trial court did not abuse its discretion in denying the Estate’s CR 56(f) request at the hearing on St. Jude’s motion.

1. The Estate Failed To Comply With CR 56(f)

The Estate did not file a motion for a continuance under CR 56(f) or include such a request in its opposition brief. Rather, the Estate’s CR 56(f) request came by way of (1) a verbal request for a continuance by counsel at the hearing on the summary judgment motion and (2) assorted references in their opposition brief and expert declaration to an alleged need to obtain additional evidence to test or cross-examine the “reliability” of St. Jude’s “reliability testing.” [CR 189, 202; RT 46-59]

The Estate’s failure to follow the requirements of CR 56(f) wholly undermines its claim that the trial court abused its discretion.¹⁵ Indeed, the

¹⁵ See *Burmeister v. State Farm Ins. Co.*, 92 Wn.App. 359, 368, 966 P.2d 921 (1998) (“an oral request for a continuance does not appear to comply with the requirement in CR 56(f) that such a request be made by affidavit”); *Landberg v. Carlson*, 108 Wn.App. 749, 756, 33 P.3d 406 (2001) (“CR 56(f) requires a proper motion supported by affidavit.”); *Hewitt v. Hewitt*, 78 Wn.App. 447, 455, 896 P.2d 1312 (1995) (“Rule 56(f) requires affidavits setting forth particular facts expected from the movant's discovery.”) (quoting *Mackey v. Pioneer Nat'l Bank*, 867 F.2d 520, 523–24 (9th Cir.1989) (interpreting FRCP 56(f)); see also 14A KARL B. TEGLAND, WASHINGTON PRACTICE: CIVIL PROCEDURE § 25:21 (2d ed. 2009) (CR 56(f) “requires the party seeking a continuance to justify

court's denial of CR 56(f) relief was proper, and was certainly not an abuse of discretion, because the Estate did *not* submit a proper motion requesting such relief. Nor did the Estate submit *any* affidavit factually explaining, *inter alia*, how the desired evidence identified by the Estate would raise a genuine issue of material fact, or why it was not obtained sooner. The trial court properly relied upon the Estate's failure to justify its near two-year delay in responding to St. Jude's reliability testing, and St. Jude's evidence that further reliability testing at this juncture, more than three years after the incident, would be meaningless.

2. The Trial Court Did Not Abuse Its Discretion When It Ruled That the Estate Was Not Entitled to a Continuance to Conduct Further Electrical Testing

At the core of the Estate's CR 56(f) argument, here and before the trial court, is its insistence that the Estate needed access to Mullan's actual pacemaker, so that it could test "several reasonable hypotheses" as to the cause of her death. [CR 189; 202] The trial court concluded that this request was not a basis for granting a continuance because the results of any test conducted more than three years after Mullan's death would have no evidentiary value. [CR 325] St. Jude's expert testified that, because of normal depletion of battery charge over time, any testing performed

the request by affidavit, demonstrating good cause for the delay and outlining the evidence sought to be discovered if the continuance is granted.").

now—more than three years after Mullan’s death—“would not produce scientifically reliable data of the battery’s condition *at the material time of Ms. Mullan’s death.*” [CR 276 (emphasis added)]

Moreover, it is nonsense to suggest that a “root cause” analysis should have been done to determine “why” a device failed, when testing showed that the device did *not* fail. [CP 275] The trial court certainly did not abuse its discretion when it concurred that the Estate waited too long after Mullan’s death to seek further evidence as to the condition of Mullan’s pacemaker battery in October 2008. [CP 276]

The Estate argues for the first time that new testing on Mullan’s pacemaker *might* yield meaningful results because the Synchrony II had a projected lifespan of up to 18.5 years, and Mullan’s pacemaker was only 17.6 years old at the time of the hearing on St. Jude’s summary judgment motion. [OB at 23] This belated argument, which is contrary to the Estate’s theory of the case, may be rejected out-of-hand for two reasons. First, it was not presented to the trial court. *See Martin v. Johnson*, 141 Wn.App. 611, 617, 170 P.3d 1198 (2007). Second, it misses the point. St. Jude’s expert’s testimony was *not* that the battery in Mullan’s pacemaker was necessarily “empty” more than three years after her death, but rather that, because of natural battery depletion over time, electrical testing on a battery *today* would not yield scientifically meaningful or reliable

information about its electrical characteristics as of *three years ago*. [CR 276] Accordingly, even if the pacemaker could be “turned on” in 2012, it could not provide the evidence that the Estate seeks, that is, the amount of charge that was remaining in the pacemaker battery as of September 2008. [*Id.*] There is and was nothing “unreasonable” or “untenable” about the trial court’s decision to accept such un rebutted expert testimony.¹⁶

Nevertheless, the Estate objects that, in reaching its conclusion regarding the futility of further testing, the trial court “appeared to completely ignore” the Declaration of Louis Bilancia, PE. [OB at18] This speculation is without merit because Bilancia offered no factual basis to support the competency of such delayed testing, or to excuse the Estate’s delay in seeking such testing, and therefore provided no basis for the trial court to disregard St. Jude’s expert’s testimony, let alone a basis for holding that such reliance was a manifest abuse of discretion.

The Estate further contends that it was entitled to a CR 56(f) continuance to seek more evidence because the evidence before the trial

¹⁶ Indeed, the Estate had ample opportunity to submit affidavits from their experts factually explaining how battery voltage (whether zero, one or two volts) more than three years after the incident *could* produce meaningful results in trying to prove the battery voltage of Mullan’s device at the time of Mullan’s death. They did not do so, let alone try to justify the Estate’s delay in seeking further testing. Faced with uncontroverted expert testimony as to the lack of evidentiary value of the testing that the Estate said it wanted to conduct during a continuance, the trial court was well within its discretion to conclude—as it did—that the Estate had failed to meet its burden under CR 56(f).

court, including the electrical tests performed on Mullan's pacemaker, did not support a "scientifically reliable conclusion" regarding the cause of Mullan's death. [OB at 18-19] This argument is a *non-sequitur*, was *not* presented to the trial court, is *not* supported by any affidavit, and is self-defeating as to the merits of the Estate's complaint.

The Estate had Mullan's autopsy and medical records and chose not to submit them to the trial court. The Estate did not have any of its experts opine as to the cause of Mullan's death, and whether it was treatable or preventable. The purpose of reliability testing is to determine whether there was any evidence of a possible product malfunction, which there was not. Further reliability testing would not evidence whether the cause of Mullan's death was treatable by a pacemaker, or preventable by another device. The Estate would still be speculating as to the cause of Mullan's death even if further testing was conducted. Therefore, the Estate's *belated* argument, which is *not* supported by *any* affidavit, is wholly insufficient to establish an abuse of discretion. *Janda Realty*, 97 Wn.App. at 54 (court does not abuse its discretion in denying CR 56(f) request where requesting party proposes to use the continuance to secure evidence that would not, even if credited, raise a triable issue of fact precluding summary judgment).

3. The Trial Court Did Not Abuse Its Discretion When It Denied a Continuance to “Evaluate” Test Results That the Estate Had in Its Possession for Years

Finally, the trial court acted well within its discretion when it overruled the Estate’s unsupported arguments for a continuance, concluding that the Estate had failed to explain why it could not have obtained relevant information during the *thirty months* between its receipt of St. Jude’s reliability testing in August 2009, and the February 2012 hearing on St. Jude’s summary judgment motion. In fact, the Estate’s expert regarding the type of pacemaker at issue testified that a standard protocol for estimating the remaining charge in Mullan’s pacemaker battery would have been to perform a calculation based on an “annual battery lifetime report” published by the manufacturer of the battery, and the information in Mullan’s medical records. [CR 201]

There is no dispute that the Estate’s expert could have performed this standard calculation. He had full access to Mullan’s medical records, including the data Nurse Healey extracted from Mullan’s pacemaker on September 11, 2008. The Estate did not deny that its expert knew or had access to the battery manufacturer’s “annual report.” Thus, the trial court could reasonably conclude that the Estate failed to meet its burden under CR 56(f) to explain why the Estate’s experts could not have run their own calculations and estimates to attempt to challenge the accuracy of St.

Jude's estimate. *Janda Realty*, 97 Wn.App. at 54 (court does not abuse its discretion in denying CR 56(f) relief if requesting party does not offer adequate explanation for delay in obtaining evidence).

V. CONCLUSION

For the foregoing reasons, the trial court's order granting St. Jude's motion for summary judgment should be affirmed, and St. Jude should be awarded its costs on appeal.

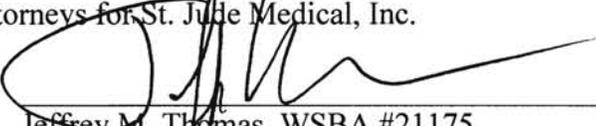
DATED this 18th day of July, 2012.

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