UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

DINA M. ROBLES BUSH	CIVIL ACTION
VERSUS	NO. 11-1654
THORATEC CORPORATION, ET AL.	SECTION "L" (3)

FINDINGS OF FACT & CONCLUSIONS OF LAW

I. PROCEDURAL HISTORY

Plaintiff Diana Robles Bush ("Mrs. Bush") brings this case on behalf of her deceased husband, Pete Bush ("Mr. Bush"). Mr. Bush was a recipient of the Thoratec HeartMate II left ventricular assist system ("LVAS"), a surgically implanted heart pump manufactured by now-dismissed Defendant Thoratec Corporation ("Thoratec"). It was implanted by the Hunter Holmes McGuire VA Medical Center ("McGuire"), a facility operated by Defendant United States, and Mr. Bush received follow-up care at both McGuire and at Tulane University Medical Center and Clinic ("Tulane"), a facility operated by Defendant University Healthcare System, L.L.C., which has also been dismissed.

Mrs. Bush originally filed suit in Civil District Court for the Parish of Orleans against Thoratec and Tulane. On July 14, 2011, Thoratec removed to this Court, and on October 24, 2011, the Court denied Mrs. Bush's motion to remand and granted Tulane's motion to dismiss on the basis that Mrs. Bush had not proceeded through a medical review panel with respect to her claims against Tulane. (Rec. Doc. 40).

On November 29, 2011, the Court granted Thoratec's motion to dismiss Mrs. Bush's claims on the grounds of preemption pursuant to 21 U.S.C. § 360k(a) and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2007). (Rec. Doc. 41). However, the Court granted Mrs. Bush's motion for

leave to amend her complaint so that she could attempt to state a nonpreempted claim. Mrs. Bush filed an amended complaint (Rec. Doc. 44) and then sought and received leave to file a second amended complaint (Rec. Doc. 68).

In her second amended complaint, Mrs. Bush articulated three potentially parallel state law claims. She argued that because the Food and Drug Administration ("FDA") had no requirements for recall communications, warning requirements under state law were therefore consistent with federal law; or alternatively that Thoratec failed to comply with 21 C.F.R. § 7.49, which provides guidelines for recall notices; or alternatively that Thoratec violated federal regulations either by failing to include adequate notice and instructions in its correction letter, or by failing to identify the design defect in the percutaneous lead and by failing to take appropriate corrective action. However, Mrs. Bush later abandoned all but one theory: that Thoratec violated 21 C.F.R. § 7.49 by failing to include suggested content in its urgent medical device correction letter (the "correction letter"), and that a violation of federal law also violated Thoratec's duty to warn under Louisiana law.

Thoratec then moved to dismiss the second amended complaint because it was precluded by the express preemption clause of the Medical Device Amendments to the Food, Drug, and Cosmetics Act. 21 U.S.C. § 360k(a). (Rec. Doc. 74). In denying its motion, the Court reasoned that Thoratec's arguments were enshrouded in fact. (Rec. Doc. 89).

On July 27, 2012, Mrs. Bush requested leave to further amend her complaint, this time adding claims against the United States. (Rec. Doc. 90). The Court granted Mrs. Bush's request (Rec. Doc. 91), and her third amended complaint was entered into the record. (Rec. Doc. 92). The third amended complaint was dismissed without prejudice shortly thereafter and immediately re-entered, following the presumed final denial of Mrs. Bush's administrative appeal

in Virginia. (Rec. Docs. 98, 99, 100). All claims against Thoratec were then settled and dismissed on June 28, 2013. Currently, the only remaining claims are those against McGuire under the Federal Tort Claims Act ("FTCA"). Specifically, Mrs. Bush alleges:

> Dr. Gundars Katlaps, Lisa Martin and other employees of McGuire failed to properly monitor [the] LVAS, failed to properly instruct the Bushes on how to monitor the percutaneous lead of [the] LVAS for damage, failed to provide proper notice to the Bushes regarding the defects of the . . . LVAS, failed to render proper medical care to him at the time of his medical emergency on May 4, 2010, and committed other acts of negligence and medical malpractice . . . .

(Rec. Doc. 100 at 14).

On August 14, 2013, McGuire filed a motion for summary judgment (Rec. Doc. 120) and then on August 16, 2013, it filed motion *in liminie* to strike Mrs. Bush's expert witness (Rec. Doc. 121). Both were denied on September 30, 2013. (Rec. Doc. 170).

This matter came on for trial before the Court without a jury. After considering the testimony of the witnesses, the exhibits admitted into evidence, and the memoranda submitted by the parties, the Court now makes the following findings of fact and conclusions of law, pursuant to Federal Rule of Civil Procedure 52. To the extent that a finding of fact constitutes a conclusion of law, the Court adopts it as such; to the extent that a conclusion of law constitutes a finding of fact, the Court also adopts that as such.

II. FINDINGS OF FACT

Mr. Bush was born on May 5, 1949. After enlisting in the United States Air Force, Mr. Bush served in Vietnam, where he sustained a service-related hearing loss, and appears to have had a difficult transition from military to civilian life. On July 26, 2001, he married Mrs. Bush. The couple resided in Slidell, Louisiana.

Mr. Bush began to experience cardiovascular difficulties and at some point, he began relying on a pacemaker. In mid-2008, his condition deteriorated and he was admitted for inpatient care. On July 29, 2008, he was transferred from a U.S. Department of Veterans Affairs ("VA") facility in Louisiana to the VA's McGuire facility in Virginia. At the time he was admitted, his primary diagnosis was congestive heart failure and other diagnoses included hypertrophic cardiomyopathy, aortic valve stenosis, and chronic obstructive pulmonary disease. He reported shortness of breath even without physical exertion, which was associated with sharp, stabbing chest pain, which also prevented him from sleeping. According to his medical record, he felt as though "the air [was being] sucked out of him." (J. Ex. 15 at 2). Mr. Bush was initially placed in the intensive care unit, but was later transferred to the cardiology unit.

In late-September, the healthcare providers at McGuire determined that, without further action, Mr. Bush would die within several months. They spoke with Mr. and Mrs. Bush about his options, and recommended that he receive a left ventricular assist system ("LVAS"), until he could undergo a heart transplant. The LVAS is equipment that consists of external and implanted components. The implanted portion, referred to as the left ventricular assist device ("LVAD"), includes both the heart pump itself and a percutaneous lead, which carries power and information to and from the pump. The external portion consists of a system controller and display. Ordinarily, the system receives power from an electrical outlet or a set of rechargeable batteries, but in emergencies, another battery could be used to provide power for up to 12 hours.

Thoratec describes the LVAS as follows:

> The LVAD helps your heart pump blood through your body. A small electric motor inside the LVAD drives the pump. The LVAD is placed (implanted) below your heart. It is attached to your heart and the aorta (the large blood vessel that carries blood from your heart to the rest of your body) . . . . Blood from your heart flows

> into the LVAD. Blood is then pumped into the aorta; and, from there, to the rest of your body.
>
> Your heart pump helps your heart by taking over the function of the diseased left ventricle (your heart's primary pumping chamber). The electric motor drives a small rotor (similar to a propeller), which pushes blood into the aorta and out to the body. Your heart pump is designed to restore blood circulation to the body and its primary organs. You may feel the pump working. This is normal.

(J. Ex. 1 at 8).

On September 25, 2008, Dr. Katlaps implanted the LVAD in Mr. Bush. Prior to surgery, Mr. Bush signed a consent form acknowledging that the "[m]echanical failure of the [LVAD] device due to mechanical, electrical, or other intricate parts of the [LVAD] may lead to death." (J. Ex. 15 at 170). Mr. Bush was the first patient at McGuire to begin using this particular LVAS model, and by all accounts, the surgery was a success.

Following the surgery, Dr. Katlaps and Ms. Martin, the LVAD coordinator, met with Mr. and Mrs. Bush almost every day they were in the hospital. Ms. Martin educated Mr. and Mrs. Bush on how to care for the LVAS components and how to recognize and respond to the various alarm lights and sounds.

In her October 1, 2008,[1] note, Ms. Martin stated that she "[b]riefly reviewed" the LVAS with Mr. and Mrs. Bush" and that "[a]s patient progresses, will continue w[ith] daily education . . . ." (*Id.* at 128). In her next note, dated October 9, 2008,[2] she wrote:

> Met w/patient and wife to provide education on [LVAS]. . . .
>
> Began initial education on [LVAS] equipment. Reviewed all components of system including pump, percutaneous lead, system controller, [power base unit], batteries, and battery clips. . . .

[1] Ms. Martin created this note 165 days later on March 15, 2009.

[2] Ms. Martin created this note 158 days later on March 15, 2009.

> Reviewed system controller and discussed buttons and lights and their meanings. . . .
>
> Patient and wife eager to learn and ask appropriate questions. They have "Patient Education" handbook for further review and plan to watch the DVD again soon.

(*Id.* at 119).

Although Ms. Martin also provided Mr. and Mrs. Bush with a copy of the 2008 Patient Handbook and an instructional video, she told them that they did not need to review those independently because she had covered the same material with them in person. Mrs. Bush testified that, as a result, she never read the 2008 Patient Handbook all the way through nor watched the video.

Ms. Martin's next note, dated October 16, 2008,[3] stated:

> Met w[ith] patient and wife for continuing education on [LVAS]. Patient and wife have reviewed the DVD several times and have become very knowledgeable about the pump and it's [*sic*] components. . . .
>
> . . . .
>
> I am very impressed with the way both patient and wife have learned so much about the equipment and how their comfort level and confidence has increased from last week. They are eager to learn as much as possible and we have started to discuss plans for discharge!

(*Id.* at 111).

In her next note, dated October 21, 2008,[4] Ms. Martin relates the following:

> Today, I reviewed all alarms and advisories with patient and wife and what their meanings were. Reviewed what to do in each case and who to notify. . . . Also reviewed how to change system controller in event of problem and instructed that they were to notify [Ms. Martin] immediately if this occurred. Patient and wife are learning this information and answer correctly when "quizzed" on different scenarios most of the time.

[3] Ms. Martin created this note 150 days later on March 15, 2009.

[4] Ms. Martin created this note 145 days later on March 15, 2009.

(*Id.* at 109).

With regard to the alarms, Ms. Martin testified that she instructed Mr. and Mrs. Bush that the system controller would indicate any problem with the pump or the power supply. Ms. Martin further emphasized that they should contact the local emergency medical services ("EMS") if the system controller emitted a *continuous* alarm and should contact Ms. Martin if the system controller emitted an *intermittent* alarm. Ms. Martin explained that continuous alarms are emergent or life threatening and that intermittent alarms are not. As Barbara Elias, an LVAD coordinator who testified as a qualified expert witness, explained, "[t]he patient . . . needs to know what's emergent and what is non-emergent." (Tr. at 320).

On October 24, 2008, nearly a month after the implantation, Thoratec sent a correction letter to providers, including Dr. Katlaps. It noted:

> **Description of problem:** Thoratec has become aware that, over time, *wear and fatigue of the percutaneous lead connecting the [LVAS] blood pump with the external [c]ontroller may result in damage that has the potential to interrupt pump function and may require a reoperation to replace the pump*. . . . The need for pump replacement due to percutaneous lead damage has occurred after implant durations ranging from 6 to 38 months . . . . The estimated probability of the need for pump replacement due to percutaneous lead damage is 1.3% at 12 months, 8.5% at 24 months and 11.4% at 36 months.
>
> **Symptoms of problem:** Damage due to wear and fatigue of the percutaneous lead has occurred in both the externalized and implanted portions of the lead. Damage to the electrical conductors within the lead may or may not be preceded by visible damage to the outer layer of the lead. The damage may be evidenced by the following:
>
> *Transient alarms* due to short or open circuits, often associated with movement of the patient or the lead. . . .
>
> . . . .
>
> **Immediate action to be taken:** *You should request any ongoing [LVAS] patients to return to the hospital for inspection of the percutaneous lead.* If you suspect that a [LVAS] patient may have a damaged percutaneous lead, please contact [technical services] for assistance. . . . NOTE: if damage to the electrical

> conductors in the lead is confirmed, the [LVAS] should be replaced as soon as possible.
>
> **Preventative action:** *Please review the instructions for [u]se with all [LVAS] surgeons and ongoing [LVAS] patients.* The attached excerpts . . . are intended to prolong the useful life.
>
> Thoratec will revise the labeling . . . and the informed consent documents . . . to incorporate the updated risk information contained in this letter. . . .
>
> **Acknowledgment:** Please complete and sign the attached [a]cknowledgment [f]orm and fax it to Thoratec . . . .

(J. Ex. 2-B at 1-2 (emphasis added)).

On October 28, 2008, Dr. Katlaps signed and returned the acknowledgment form that was attached to the correction letter. The acknowledgment form provided:

> Please check all boxes below before returning this form [to Thoratec].
>
> [Box 1] I have reviewed the symptoms that may be associated with damage to the percutaneous lead, and re-emphasized the instructions for care with all of my ongoing patients.
>
> [Box 2] I understand the risk information that Thoratec has provided in this notice, and that the labeling for commercially distributed devices and informed consent documents for clinical studies will be revised to reflect this new information from clinical experience. I also agree to carefully review this risk vs. benefit information with prospective patients.
>
> [Box 3] I acknowledge that I have received [the letter] concerning the percutaneous lead for the [LVAS] and that I understand the contents and have communicated the contents to the appropriate personnel. . . .

(J. Ex. 2-C at 1). The letter also contained an enclosure intended for patients.[5]

[5] In part, this noted:

> [I]t is extremely important that you protect your percutaneous lead, especially if you are active. Always keep your percutaneous lead protected and damage-free. Damage to the percutaneous lead, depending on the degree, may cause the pump to stop.
>
> Remember to follow these recommendations:
>
> . . . .
>
> Check your percutaneous lead daily for signs of damage (cuts, holes, tears). If you discover damage to your lead, report it immediately to your hospital contact person.

Between October 24, 2008, and October 28, 2008, none of Dr. Katlaps' notes reference the letter, nor do they indicate that he provided any new information to Mr. and Mrs. Bush. Ms. Martin's only note during this period, dated October 28, 2008,[6] stated:

> Met with patient and wife to review education re[garding LVAS]. Again discussed all aspects of [the power base unit], batteries, and system controller. Reviewed all alarms [*sic*] conditions again, their meaning, and what to do in each situation.

(J. Ex. 15 at 103). Likewise, it did not indicate that she or Dr. Katlaps relayed the new information regarding the potential of a new alarm, namely a transient alarm..

Dr. Katlaps and Ms. Martin have both testified that they made Mr. and Mrs. Bush aware of the contents of the correction letter, but did not provide them with a physical copy. They also testified that they had concluded that the letter added nothing new and that they had already advised Mr. and Mrs. Bush on the nature of each alarm and response required of the patient. As discussed above, there is no mention of the correction letter or the information contained therein within Mr. Bush's medical record.[7] Ms. Martin explained this absence as intentional; she had

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(J. Ex. 2-B at 5).

[6] Ms. Martin created this note 138 days later on March 15, 2009.

[7] Whatever credibility Ms. Martin's notes carry is further compromised by the method by which those notes were recorded. Ms. Martin routinely used a notebook, rather than the available electronic records system, to document her interactions with Mr. and Mrs. Bush. In many instances it was nearly six months or a year before she transferred those notes to McGuire's electronic records system, at which point she destroyed the originals. She testified:

> I think that obviously the closer to the time of the event [a note is entered], the better it is.
>
> . . . .
>
> I just think [entering a note contemporaneously is] probably the appropriate thing to do. Looking back, I wish I'd never used those [note]books. I wish I had put the notes in the record at the time, but I can't change what I did now.

(Tr. at 303). As one text notes:

been trained to exclude references to incident reports and assumed that the letter was analogous. However, she noted that, in retrospect, she should have included a reference to the letter in the notes. Ms. Martin indicated that she never discussed the possibility that Mr. Bush would experience transient alarms, which were symptomatic of percutaneous lead damage.

In contrast, Mrs. Bush asserts that she and Mr. Bush were never made aware of the correction letter or the information it contained. This appears to be the credible account. First, Dr. Katlaps Ms. Martin have made it abundantly clear that Mrs. Bush was incredibly attentive to her husband's treatment and receptive to the information they had provided. Second, Mr. Bush's medical records, which are often incredibly detailed, do not reference the letter or indicate that its contents were communicated to Mr. and Mrs. Bush. Last, even if the records had referenced it, all of Ms. Martin's notes regarding the instruction she provided to Mr. and Mrs. Bush were entered months after the fact, raising questions as to their accuracy. Nor is it believable that Dr. Katlaps or Ms. Martin provided the information at a later date. It is the Court's impression, from the testimony, that both Dr. Katlaps and Ms. Martin concluded that the correction letter added nothing new to the information they had already provided to Mr. and Mrs. Bush and that their only obligation was to re-emphasize the information they had previously imparted, including advising of them of the significance of the continuous and intermittent alarms and what to do when each type of alarm occurred. The credible testimony and evidence supports the conclusion that Mr. and Mrs. Bush were never made aware that the LVAS was capable of emitting an additional alarm, namely a transient alarm, which required immediate action. This is significant

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> By the time a malpractice action comes to trial memories may have dimmed as to what actually occurred at the time negligence is alleged to have taken place, leaving the medical record as the most telling evidence . . . .

BARRY R. FURROW, ET AL., HEALTH LAW 295 (6th ed. 2008).

because a transient alarm is a non-continuous alarm but nevertheless emergent, life threatening, and requires immediate action—characteristics Mr. and Mrs. Bush were told only attached to continuous alarms.

Ms. Martin's next note, dated October 31, 2008,[8] indicated that Mr. Bush was discharged to a residential facility. He remained there, often visiting McGuire daily, until he returned to Slidell, Louisiana, on December 12, 2008. His post-discharge care was handled jointly by McGuire, Tulane, and the Slidell facilities. His primary care physician was in Louisiana, however Ms. Martin remained Mr. Bush's primary contact with regard to the LVAS.

On the night of May 3, 2010, Mr. and Mrs. Bush were asleep when they heard the LVAS emit a sound, which Mrs. Bush described as "a little beep, light beep." (Tr. at 176). Mr. and Mrs. Bush then checked "everything," but were unable to find any malfunction. Mr. Bush, who felt fine, returned to sleep. The following morning they heard the same sound and, again, they checked everything and, once again, found nothing. Mr. Bush continued to feel fine. Mr. and Mrs. Bush then changed the controller, and heard another noise. However, the LVAS was not displaying any visual or auditory alarms. Mr. Bush then switched to battery power. Although everything appeared to be normal, the alarms concerned Mrs. Bush enough that at approximately 8:00 a.m. on May 4, 2010, she called Ms. Martin in Virginia from her home in Louisiana . She was unable to reach Ms. Martin, who was assisting with a surgery, and instead spoke with Mary Compton, Ms. Martin's administrative assistant. According to Ms. Compton, Mrs. Bush expressly stated that she had heard a noise coming from the LVAS which she had never heard before and that Mr. Bush was experiencing intermittent alarms or beeps." (Rec. Doc. 173). Mrs. Bush explained that she wanted to speak with Ms. Martin about the noise and alarms, but noted

[8] Ms. Martin created this note contemporaneously.

that Mr. Bush was doing well and it was not an emergency. Ms. Compton informed Mrs. Bush that Ms. Martin was in surgery and was not available.

At 4:00 p.m., Ms. Martin was out of surgery and Ms. Compton relayed the message. Several minutes later, Ms. Martin called Mrs. Bush back from her car. Their conversation lasted about 30 minutes. Mrs. Bush explained what had happened over the past day. Mrs. Bush wanted Ms. Martin to hear the noise, so she transfered Mr. Bush off of battery power and changed the controller to see if she could replicate it. When she changed the controller, the noise returned and Mr. Bush indicated that he was dizzy. Mrs. Bush told Ms. Martin that it was indicating a "low flow" alarm. Ms. Martin instructed Mrs. Bush to put Mr. Bush back onto battery power and, after doing so, Mr. Bush indicated that he began to feel fine once more. Ms. Martin told Mrs. Bush to keep him on battery power until she could determine the cause of the problem. Mrs. Bush testified that Mrs. Martin told her that they should only be concerned if the LVAS emitted an auditory and visual alarm, and if so, Mr. Bush should be taken to the hospital immediately.

Ms. Martin testified the alarms Mrs. Bush described "didn't make any sense":

> Well, because the way she described the alarms didn't fit with what I knew to be the alarms. Because each alarm has a very specific light and sound associated with it, and they also have changes in the numbers. Because when they're attached to their power module, there are numbers that come up there. So whenever anybody calls and says they've heard an alarm, there's a very specific checklist I go through in my head to ask them, you know, what lights did you see, what did it sound like, what do you feel like, and what the numbers are. And [Mrs. Bush] told me the numbers were all good. And so what they told me didn't add up at all, and I—it didn't seem—it didn't make sense.

(Tr. at 86). Even though the alarms were unusual and inconsistent with the designed alarms, she did not instruct Mrs. Bush to call EMS. Instead, Ms. Martin decided to contact Thoratec and get back to Mrs. Bush.

Less than 30 minutes after Ms. Martin and Mrs. Bush had spoken, and while Ms. Martin was on the telephone with a representative of Thoratec, Mr. Bush collapsed. Mrs. Bush testified that after he collapsed, she was unable to hear the sound of the LVAS functioning. She immediately called EMS, who transported Mr. Bush to a hospital, where he was pronounced dead at 6:58 p.m. According to his autopsy, he experienced "sudden cardiac death." (J. Ex. 4 at 1).

The LVAS components were analyzed by Thoratec after Mr. Bush's death. It was discovered that the implanted portion of the percutaneous lead had frayed interior wires, which likely made contact with one another. The system controller that Mr. Bush was using at the time of his death had shorted completely, and Ms. Martin was unable to retrieve any data from it. The other system controller, which Mr. Bush had recently used, did have salvageable data, although it has not been properly authenticated. Following Mr. Bush's death, Ms. Martin stated that Mrs. Bush had done everything exactly as she should have. However, Ms. Martin later testified that her opinion had changed when she learned that a Thoratec log indicated that there were multiple alarms, including a continuous "red heart" alarms, that "somebody should have told me about." (Tr. at 93). The testimony and evidence reveal that the log files, and other materials prepared as part of Thoratec's investigation, are not entirely reliable because there appears to have been confusion about which controller Mr. Bush was using at which times and also because the malfunction of the LVAS may have unpredictably altered its behavior. (*See id.*).

III. CONCLUSIONS OF LAW

A. FTCA Choice of Law

Mrs. Bush's complaint alleges tortious conduct by McGuire, which is owned, operated, and controlled by the United States, and is brought pursuant to the FTCA. As a general matter,

the United States is immune to suits brought by individuals except where it has explicitly waived its immunity by statute. *In re FEMA Trailer Formaldehyde Prods. Liab. Litig.,* 668 F.3d 281, 287 (5th Cir. 2012). The FTCA creates such a waiver, and "provides the sole basis of recovery for tort claims against the United States." *Id.* (citing 28 U.S.C. § 2671, § 1346). Specifically, the statute provides:

> [T]he district courts . . . shall have exclusive jurisdiction of civil actions on claims against the United States, for money damages [for] personal injury or death caused by the negligent or wrongful act or omission of any employee of the [United States] while acting within the scope of his office or employment, under circumstances *where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred*.

28 U.S.C. § 1346(b)(1) (emphasis added). As is the case with all waivers of sovereign immunity, the language of the FTCA is to be "narrowly construed in favor of the United States." *In re FEMA Trailer Formaldehyde Prods. Liab. Litig.*, 668 F.3d at 287.

The FTCA "requires application of the whole law of the [s]tate where the act or omission occurred," including that state's choice of law rules. *See Richards v. United States*, 369 U.S. 1, 11 (1962); *Guillory v. United States*, 699 F.2d 781, 784 (5th Cir.1983). It is therefore possible that a state's choice of law rules may require application of yet another state's substantive law.

Accordingly, it is necessary to determine where the alleged torts occurred in order to apply the appropriate choice of law provisions. In the context of claims brought under the FTCA, a tort occurs in the place of the act or omission, not the place of the resulting injury. *Richards*, 369 U.S. at 9-10.As the United States Supreme Court has noted:

> In the [FTCA] Congress has expressly stated that the [United States]'s liability is to be determined by the application of a particular law, the law of the place where the act or omission occurred, and we must, of course, start with the assumption that the

> legislative purpose is expressed by the ordinary meaning of the words used. We believe that it would be difficult to conceive of any more precise language Congress could have used to command application of the law of the place where the negligence occurred than the words it did employ in the [FTCA]. Thus we first reject the alternative . . . . The legislative materials cited to us . . . not only lack probative force in a judicial sense, but they are completely unpersuasive to support the argument that Congress intended the words "act or omission" to refer to the place where the negligence had its operative effect. The ease of application inherent in the rule urged . . . lends a certain attractiveness, but we are bound to operate within the framework of the words chosen by Congress and not to question the wisdom of the latter in the process of construction. We conclude that Congress has, in the [FTCA], enacted a rule which requires federal courts, in multistate tort actions, to look in the first instance to the law of the place where the acts of negligence took place.

Id.; *see, e.g.*, *Ins. Co. of Pa. v. United States*, 590 F. Supp. 435, 442 (S.D. Miss. 1984) (holding that where acts or omissions of an out-of-state tortfeasor caused an in-state injury, the law of tortfeasor's state must be applied).

Here, it is apparent that the allegedly negligent acts or omissions occurred in Virginia. Mr. Bush's LVAS device was implanted in Virginia and much of his recovery occurred in Virginia. Dr. Katlaps received the correction letter and signed the acknowledgment in Virginia, and he and Ms. Martin allegedly failed to inform Mr. Bush of the new information contained in the correction letter during his recovery in Virginia. Although providers in Louisiana and Virginia shared the responsibility for Mr. Bush's care after he returned to Louisiana, Mrs. Bush has previously asserted that the Louisiana providers were never made aware of the correction letter. Further, Mrs. Bush indicates that Ms. Martin "continued to provide close and continuing care to [Mr.] Bush in Louisiana up to and including the day he died." (Rec. Doc. 127-11 at 2). The fact that Mrs. Bush only called Ms. Martin, and not the providers in Louisiana, on the day of Mr. Bush's death implies that she considered Ms. Martin primarily responsible for Mr. Bush's

care. In sum, Mrs. Bush's understanding of the facts does not controvert McGuire's assertion that the alleged acts and omissions all occurred in Virginia, even though the resulting injury to Mr. Bush was in Louisiana.

B. Virginia Choice of Law

Having concluded that the incident occurred in Virginia, it is necessary to apply that state's choice of law provisions to determine which substantive and procedural laws apply. The place-of-the-wrong standard is the "settled rule in Virginia" when resolving conflicts arising in multistate tort actions. *Jones v. R.S. Jones & Assocs., Inc.*, 431 S.E.2d 33, 34 (Va. 1993) (internal quotation marks omitted). Pursuant to this rule, the claims are governed by the substantive law of the forum where the torts occurred and the procedural law of the forum where the action was brought. *Id.* As discussed above, the acts or omissions here took place in Virginia, and accordingly, the substantive law of Virginia is applicable. Because this action was brought in federal court in Louisiana, federal procedural law governs.

C. Virginia Medical Malpractice Act

The Virginia Medical Malpractice Act ("VMMA") provides relief for "any tort action or breach of contract action for personal injuries or wrongful death, based on health care or professional services rendered, or which should have been rendered, by a health care provider, to a patient." VA. CODE ANN. § 8.01-581.1. By its plain language, the statute broadly includes any claims sounding in tort or contract. Thus, all of Mrs. Bush's claims are within the substantive scope of the VMMA.

It is also necessary to determine whether the parties meet the VMMA's criteria. The statute states that any "person . . . licensed by [Virginia] to provide health care or professional services as a physician [or] registered nurse" is considered a health care provider, as is "any

corporation . . . or other entity" if it "employs or engages" such a person and if the corporation or other entity also "engages in health care services." VA. CODE ANN. § 8.01-581.1. Here, evidence in the record indicates that Dr. Katlaps and Ms. Martin were licensed by Virginia to provide health care or professional services as a physician and as a registered nurse, respectively. (Rec. Docs. 165-1, 165-2). With regard to McGuire itself, Mrs. Bush specifically asserts that "as a federal facility, [it] is not licensed by the Commonwealth of Virginia" and it thus falls outside the VMMA's reach. (Rec. Doc. 160-2 at 1). However, the plain language of the VMMA states that "a corporation . . . or any other entity, except a state-operated facility, which employs or engages a licensed health care provider and which primarily renders health care services" is itself a health care provider. VA. CODE ANN. § 8.01-581.1. Thus, McGuire, while not licensed by Virginia itself, is considered a health care provider under the VMMA both because it employs or engages health care providers licensed by Virginia, including Dr. Katlaps and Ms. Martin, and also because it primarily renders health care services.[9] For these reasons, the VMMA also covers the relationships that existed between Mr. Bush and Dr. Katlaps, Ms. Martin, and McGuire, and applies to the extent it is substantive.

D. Malpractice

The VMMA defines "malpractice" as "any tort action . . . for personal injuries or wrongful death, based on health care or professional services rendered, or which should have been rendered, by a health care provider, to a patient." VA. CODE ANN. § 8.01-581.1. "In medical malpractice cases, as in other negligence actions, the plaintiff must establish not only that the defendant violated the applicable standard of care, and was therefore negligent, he must also

[9] The fact that a state-operated facility would be excluded is of no moment, because the FTCA provides "that the federal government shall be liable for tort claims 'in the same manner and *to the same extent as a private individual under like circumstances*.'" *Lucas v. United States*, 807 F.2d 414, 417 (5th Cir. 1986) (citing 28 U.S.C. § 2674).

sustain the burden of showing that the negligent acts constituted a proximate cause of the injury or death." *Brown v. Koulizakis*, 331 S.E.2d 440, 446 (Va. 1985).

Under the VMMA, "expert testimony is ordinarily necessary to establish the appropriate standard of care, to establish a deviation from the standard, and to establish that such a deviation was the proximate cause of the claimed damages."[10] *Raines v. Lutz*, 341 S.E.2d 194, 196 (Va. 1986). The reason for this requirement is that "[i]ssues involving medical malpractice often fall beyond the realm of common knowledge and experience of a lay jury." *Beverly Enterprises-Virginia, Inc. v. Nichols*, 441 S.E.2d 1, 3 (Va. 1994). "Therefore, in most instances, expert testimony is required to assist [that] jury." *Id*.

As a general matter, "whether a witness is qualified to testify as an expert is largely within the sound discretion of the trial court." *Lloyd v. Kime*, 654 S.E.2d 563, 569 (Va. 2008) (internal quotation marks omitted). However, for claims brought under the VMMA, "this determination must be made with reference to [the expert qualification requirement]," which establishes standards for experts testifying on the standard of care.[11] *Id*. It states:

> [I]n any action against a physician, . . . nurse, hospital or other health care provider to recover damages alleged to have been caused by medical malpractice where the acts or omissions so complained of are alleged to have occurred in [Virginia], the standard of care by which the acts or omissions are to be judged shall be that degree of skill and diligence practiced by a reasonably prudent practitioner in the field of practice or specialty in [Virginia] and the testimony of an expert witness, otherwise qualified, as to such standard of care, shall be admitted . . . .

VA. CODE ANN. § 8.01-581.20.

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[10] The Court has previously held that Virgina's expert qualification requirement is substantive law that governs this dispute.

[11] It is necessary to note that the expert qualification requirement "addresses only the qualifications of experts to testify on the standard of care and whether the standard of care is breached," it "do[es] not address whether an expert witness is qualified to testify on proximate causation." *Lloyd*, 654 S.E.2d at 571.

While physicians are presumed to know the statewide standard of care in their particular specialties or fields of medicine if they are licensed in Virginia or are licensed in another state and also meet the educational and examination requirements in Virginia, "[i]f neither situation applies, a witness nonetheless may be qualified to testify as to the standard of care if the witness demonstrates sufficient knowledge, skill, or experience to make him competent to testify as an expert on the subject matter at issue." *Lloyd*, 654 S.E.2d at 569 (internal quotation marks omitted). However, "[i]n all cases, to qualify as an expert witness on the standard of care, the witness must have expert knowledge on the standard of care in the defendant's specialty and an active clinical practice in either the defendant's specialty or a related field of medicine within one year of the date of the alleged act or omission forming the basis of the action." *Id.* (internal quotation marks omitted); *see* VA. CODE ANN. § 8.01-581.20. Thus, in most instances, to be eligible to testify as an expert witness, the person must be a medical practitioner with an active clinical practice.

However, there are exceptions to this requirement "in those rare cases in which a health care provider's act or omission is clearly negligent within the common knowledge of laymen." *Raines*, 341 S.E.2d at 196 n.2 (*citing Easterling v. Walton*, 156 S.E.2d 787, 790-91 (Va. 1967)). The Virginia Supreme Court has been careful to note that "[t]he medical malpractice statutes did not supersede the jury system." *Id*. at 197 ("The determination of negligence, proximate cause, and damages remains within the jury's province.").

There are a number of instances where, pursuant to this exception, qualified expert testimony in medical malpractice cases has not been required. For example, in *Jefferson Hospital, Inc.* v. *Van Lear*, a patient fell and broke his hip while trying to locate a bathroom after the floor nurse failed to respond to a call light that had been plainly visible to her for 20 to 30

minutes. 41 S.E.2d 441, 442-43 (Va. 1947). There, the Virginia Supreme Court recognized that expert testimony was not necessary because the hospital employees "were, of course, aware of the physical condition of [the patient, t]hey knew the nature of his operation and disabilities[, t]hey knew, or should have known, that a delay in answering his call for a nurse or an orderly . . . might induce him to get out of bed and attempt to wait on himself." *Id* at 443.

In *Beverly Enterprises-Virginia, Inc. v. Nichols*, a patient choked after she attempted to eat food that a provider left without offering assistance. 441 S.E.2d at 3. There, the Virginia Supreme Court again concluded that it was possible to find "negligence without the necessity of expert testimony on the appropriate standard of care," because the provider "was aware of [the patient's] mental and physical condition [and] that she was unable to feed herself and had two prior serious choking incidents." *Id.* "Certainly, a jury does not need expert testimony to ascertain whether the defendant was negligent because its employees failed to assist [the patient] under these circumstances." *Id*.

Likewise, in *Nichols v. Kaiser Found. Health Plan of Mid-Atlantic States, Inc.*, a patient became seriously ill after she was given the wrong medicine. The Virginia Supreme Court upheld the trial court's conclusion that "expert testimony was unnecessary because a jury could understand, without the aid of such testimony, that dispensing wrong medication is a breach of a pharmacist's standard of care." 514 S.E.2d 608, 609 (Va. 1999). It reasoned:

> Here, plaintiff did not present expert testimony in the strict sense of that term, that is, a witness was not formally qualified who responded to hypothetical questions. Nevertheless, there was abundant opinion testimony from plaintiff's treating physicians, particularly [the patient's doctor].
>
> Consequently, the case reduces to whether there was sufficient evidence, comprised of medical opinion and lay testimony, to present a jury question on causation. We answer that query in the affirmative; testimony from a 'pure' expert witness was unnecessary.

Id. at 612.

In yet another case, *Coston v. Bio-Medical Applications of Va., Inc.*, a patient was injured after she was placed in a defective chair by an employee who knew the chair was broken. 654 S.E.2d 560, 563 (Va. 2008). The Virginia Supreme Court reasoned that "[c]ertainly, the issue whether the [employees] acts or omissions in this case constitute medical negligence is within a jury's common knowledge and experience and, therefore, expert testimony is not necessary. *Id.*

Because Mrs. Bush did not present the testimony of a qualified doctor or nurse with regard to the elements of medical malpractice—the applicable standard of care, whether that standard of care had been breached, and whether the alleged breach was the proximate cause of the alleged injury[12]—each of these elements must be within the common knowledge and experience of a layperson. Mrs. Bush has alleged that Dr. Katlaps and Ms. Martin are negligent both for their decision to withhold the new information contained in the correction letter and that Ms. Martin is negligent for not instructing Mr. Bush to seek immediate medical attention on the day of his death.

[12] At trial, McGuire moved for judgment as a matter of law, pursuant to Federal Rule of Civil Procedure 52(c). In doing so, it noted that the Virginia Supreme Court has held that "[t]o recover against a physician for failure to provide . . . information [about a proposed medical treatment or procedure], the patient generally is required to establish by expert testimony whether and to what extent any information should have been disclosed." *Tashman v. Gibbs*, 556 S.E.2d 772, 777 (2002). For instance, in *Tashman v. Gibbs*, a physician failed to disclose the risks of a particular procedure, the physician's inexperience in performing that procedure, and the available alternatives to that procedure. *Id.* at 778. There, the Virginia Supreme Court held that the patient was required to establish the standard of care through expert testimony. *Id.* Here, the circumstances are distinguished. The correction letter's information on the transient alarms was not intended to inform Mr. Bush's decision to give or withhold consent for his *doctor* to proceed, instead it was intended to inform Mr. and Mrs. Bush's decision as to how *they* should proceed. After hearing argument at trial, the Court denied the motion, in part noting that the common knowledge exception to the expert testimony requirement may apply or, if the exception did not apply, that the expert testimony could be provided by McGuire. The Court further concludes that, because summary disclosures were not provided for Dr. Katlaps and Ms. Martin, they are only capable of providing fact testimony, not expert testimony, under the provisions of Federal Rule of Civil Procedure 26.

1. Standard of Care

It is necessary to determine whether the standard of care required that Dr. Katlaps and Ms. Martin relay the correction letter or its contents to Mr. and Mrs. Bush or required Ms. Martin to instruct Mr. and Mrs. Bush to seek immediate medical attention on May 4, 2010. As mentioned previously, the Virginia Supreme Court has held that "the standard of care in a medical malpractice action [is] that degree of skill and diligence exercised by a reasonably prudent practitioner in the same field of practice or specialty in Virginia." *Tashman v. Gibbs*, 556 S.E.2d 772, 777 (Va. 2002). Likewise, the VMMA requires:

> [I]n any action against a physician, . . . nurse, hospital or other health care provider to recover damages alleged to have been caused by medical malpractice . . . , the standard of care by which the acts or omissions are to be judged shall be that degree of skill and diligence practiced by a reasonably prudent practitioner in the field of practice or specialty in [Virginia] . . . .

VA. CODE. ANN. § 8.01-581.20(a). A provider is not the "insurer of [a] diagnosis and treatment . . . ." *Brown*, 331 S.E.2d at 445.

In determining the applicable standard of care, the testimony of a qualified expert witness may assist in the determination, but it is not itself dispositive. Despite the necessity of qualified expert testimony on the standard of care in most instances, "[t]he determination of negligence, proximate cause, and damages remains within the [fact finder]'s province." *Raines*, 341 S.E.2d at 197. "[A]ny issue as to the standard of care to be applied shall be determined by the [fact finder]." VA. CODE. ANN. § 8.01-581.20(b). Although an expert must ordinarily testify as to the "degree of skill and diligence practiced by a *reasonably prudent* practitioner," VA. CODE. ANN. § 8.01-581.20(a) (emphasis added), it is the fact finder—not the expert—who establishes the standard of care, provided their determination is "based upon evidence and not upon speculation." *Raines*, 341 S.E.2d at 197. As Justice Oliver Wendell Holmes noted: "What usually

is done may be evidence of what ought to be done, but what ought to be done is fixed by a standard of *reasonable prudence*, whether it usually is complied with or not." *Tex. & P. Ry. Co. v. Behymer*, 189 U.S. 468, 470 (1903) (emphasis added). Judge Learned Hand elaborated:

> [I]n most cases *reasonable prudence* is in fact common prudence; but strictly it is never its measure; a whole calling may have unduly lagged in the adoption of new and available devices. It never may set its own tests, however persuasive be its usages. Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission.

T.J. Hooper, 60 F.2d 737, 740 (2d Cir. 1932).

With regard to the correction letter, it is necessary to determine whether the standard of care required that Dr. Katlaps and Ms. Bush relay its contents to Mr. and Mrs. Bush. Mrs. Bush has not offered the testimony of a qualified expert witness. Thus, as a threshold matter, it is necessary to decide whether the contents of the letter can be understood by a layperson.

In making this determination, it is useful to consider the letter itself. The letter, which was intended for healthcare providers, contains language that is not incomprehensible to a layperson (that is, someone other than a licensed doctor or nurse).[13] In fact, it was authored by an

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[13] Presumably, a layperson includes anyone who is a "practitioner in the field of practice or specialty" of the alleged tortfeasor. VA. CODE. ANN. § 8.01-581.2(a). Provided, of course, that such a person is also among those listed as healthcare providers by the VMMA:

> [A] person, corporation, facility or institution licensed by this Commonwealth to provide health care or professional services as a physician or hospital, dentist, pharmacist, registered nurse or licensed practical nurse or a person who holds a multistate privilege to practice such nursing under the Nurse Licensure Compact, optometrist, podiatrist, chiropractor, physical therapist, physical therapy assistant, clinical psychologist, clinical social worker, professional counselor, licensed marriage and family therapist, licensed dental hygienist, health maintenance organization, or emergency medical care attendant or technician who provides services on a fee basis . . . .

VA. CODE. ANN. § 8.01-581.1. Further, *Black's Law Dictionary* defines "layman" as "[a] person who is not a member of a profession or an expert on a particular subject. "

engineering-technician-turned-director-of regulatory-affairs at Thoratec with a bachelor's degree in biological science, who himself was a layperson (it had also been approved by a vice president, who also appears to be a layperson). The letter's author confirmed that its intended audience was healthcare providers (including, doctors, nurses, and laypersons), and explained that Thoratec also intended for those providers to communicate its contents to patients. In sum, it was written by a layperson and its contents were intended to be transmitted to laypersons. This means that, even if its content were too complex to be understood by a layperson without specialized knowledge, it could be explained by a layperson with such specialized knowledge. Thus, to the extent the new information contained in the correction letter is relevant to whether a doctor or a nurse had a duty to relay that information, such a determination is plainly within the common knowledge and experience of a layperson.

Dr. Matthias Loebe, McGuire's qualified expert witness, testified that "[t]he standard of care would require to alert the patient and his caregivers to seek support when they have recurrent alarms; and, in particular, seek—and if these alarms do not go away, to seek support in an institution that is close by." (Tr. at 360). He also indicated that it was incredibly important that patients had been properly educated on how to react to various alarms, but it was not necessary that they understand the underlying causes of those alarms. Of the alarms, Ms. Elias explained that it was necessary for both patients and healthcare providers to "know what's emergent and what is non-emergent." (Tr. at 320).

Prior to receiving the correction letter, doctors and nurses were only provided information about continuous and intermittent alarms. Within this context, the question is

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Layman, BLACK'S LAW DICT. (9th ed. 2009). Accordingly, under the specific circumstances here, a layperson is anyone who is not a doctor or a nurse.

whether the so-called transient alarm, discussed by the correction letter, constituted a new type of alarm, separate and distinct from the continuous and intermittent alarms. As a preliminary matter, it is useful to consider the plain meaning of each of these terms. The term "continuous" means something that is uninterrupted.[14] In contrast, the term "intermittent" means something that is not continuous, but comes and goes.[15] Patients were trained that continuous alarms were emergent—requiring them to immediately contact EMS—and that intermittent alarms were non-emergent—requiring them to call their healthcare provider. It is within this context that Mr. and Mrs. Bush responded to the alarms they recognized prior to Mr. Bush's death. The correction letter referenced neither continuous nor intermittent alarms, instead describing "[t]ransient alarms due to short or open circuits, often associated with movement of the patient or the lead" symptomatic of a problem "that has the potential to interrupt pump function and may require a[n] operation to replace the pump." (J. Ex. 2-B at 1-2). Like the term "intermittent," the term "transient" means something that also comes and goes.[16] Ruhi Arslanoglu, a biomechanical engineer, noted that continuous and intermittent alarms were "designed to be present when the device is functioning properly" whereas a transient alarm is "caused by the unexpected, unforeseen damage [and] it is not necessarily predictable . . . how [it] would present itself." (Tr.

[14] These terms appear to have consistent meanings both in their common and medical usage. For instance, *Merriam-Webster* defines “continuous“ as “marked by uninterrupted extension in space, time, or sequence.“ *Continuous*, MERRIAM-WEBSTER, http://www.merriam-webster.com/dictionary/constant. Likewise, *Stedman‘s Medical Dictionary* defines “continued“ as “continuous; without intermission . . . “ *Continuous*, STEDMAN‘S MED. DICT. (27th ed. 2000).

[15] As for the term “intermittent,“ *Merriam-Webster* defines it as “coming and going at intervals “ and “not continuous.“ *Intermittent*, MERRIAM-WEBSTER, http://www.merriam-webster.com/dictionary/intermittent. Similarly, *Stedman‘s Medical Dictionary* defines it as “[m]arked by intervals of complete quietude between two periods of activity.“ *Intermittent*, STEDMAN‘S MED. DICT. (27th ed. 2000).

[16] *Merriam-Webster* defines “transient“ as “passing especially quickly into and out of existence.“ *Transient*, MERRIAM-WEBSTER, http://www.merriam-webster.com/dictionary/transient. *Steadman‘s Medical Dictionary* defines it as “[s]hort-lived; passing; not permanent; said of a disease or an attack.“ *Transient*, STEDMAN‘S MED. DICT. (27th ed. 2000).

at 155). Although a transient alarm is like an intermittent alarm because it is one that comes and goes, it is unlike an intermittent alarm because it requires immediate action.

As noted above, Dr. Loebe and Ms. Elias testified that the standard of care required a healthcare provider to supply information about the nature of each type of alarm. Despite this, they concluded that Dr. Katlaps and Ms. Martin did not breach the standard of care by not providing information about a new type of alarm. This is inconsistent with the requirement that the healthcare provider provide information about each alarm. Such an inconsistency defies logic and Dr. Loebe's and Ms. Mratin's detailed testimony regarding the standard of care itself, and it hampers the credibility of their determination that the standard of care had not been breached by Dr. Katlaps and Ms. Martin. The credible testimony and evidence supports the conclusion that the standard of care in this case required that a doctor or nurse provide information about all alarms to their patients.

Had Dr. Katlaps and Ms. Martin provided the information contained within the correction letter, Mr. and Mrs. Bush would have been able to determine the meaning of the transient alarms they experienced and react themselves. However, this information was not communicated to them and they were not able to respond appropriately on their own. Instead, they were only able to describe the LVAS' behavior to Ms. Martin, forcing her to do what they might have done themselves had they been properly informed.

2. Breach

Having established that the standard of care required a doctor or nurse to educate the patient about all alarms and also that a nurse recognize and respond appropriately to those alarms, it is necessary to determine whether that standard was breached by either Dr. Katlaps or Ms. Martin. With regard to the correction letter, Mrs. Bush alleges that Dr. Katlaps and Ms.

Martin did not provide the information it contained and thus breached the standard of care. Dr. Katlaps noted that he reviewed the symptoms of the percutaneous lead problem. He also conceded that the correction letter "did not tell us anything new [and] there was no new concept described in that notice and no new additional action necessary beyond what it describe[d]." (Katlaps Tr. at 59-60). He stated that he did speak with Mr. Bush about the correction letter, but he was vague regarding what he said, and there is nothing to indicate that he mentioned anything about a transient alarm:

> I do not have a vivid detailed recollection of exactly specifically what we discussed. I do remember that we had a conversation that there is a notice . . . . [I said] the most important thing, if there are any alarms on the device, he needs to notify a proper provider. Again, that's depending on what the alarm.
>
> . . . .
>
> *There are alarms on the device that he needs to act appropriately according to his previous training.* That has been—we have tried to drive this message home again and again and again. Different things can happen to the device. Different things can happen to you. Different things can happen, you know, in the interface between you and the device. One of the reasons why the alarms are there is so that you can let us know if there is something wrong. . . .

(Katlaps Tr. at 62-63 (emphasis added)). It is apparent that Dr. Katlaps did not believe the correction letter contained information that would change the way Mr. and Mrs. Bush responded to certain alarms, nor is there any indication in the medical record that he discussed the existence or nature of transient alarms.

Ms. Martin had a similar mindset. Although she understood the difference between a transient alarm, which irregularly stops and starts, and an intermittent alarm, which has regular "short little inter-beeps every second or every four seconds," (Tr. at 56), she did not appear to have drawn this distinction for Mr. and Mrs. Bush after she received the correction letter:

> We told [Mr. and Mrs. Bush] that we would be monitoring for the alarms that we were aware of, yes, but not any mention of—I never ever have used the word "transient" in any discussion with anybody related to the [LVAS].
>
> . . . .
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> [I do not think it is not important to use that term], I just think it makes it confusing for everybody when you say another word. I mean, we knew alarms were bad. So—but, no, intermittent alarms are not life-threatening; continuous alarms are life-threatening. Intermittent alarms can progress to continuous alarms. So to add "transient," I don't think that—I mean, that confuses me, honestly.

(Tr. at 59-60).

As discussed in detail above, McGuire's qualified expert witnesses, Dr. Loebe and Ms. Elias, both testified that the standard of care would require a doctor or nurse to educate a patient on how to react to all alarms. The evidence and testimony demonstrates that Dr. Katlaps and Ms. Martin did not discuss with Mr. and Mrs. Bush potential of a transient alarm or that this new type of alarm required immediate action. Thus, they breached the standard of care.

Mrs. Bush has also alleged that Ms. Martin breached the standard of care by not recognizing and appropriately responding to the transient alarms described on the day of Mr. Bush's death. Ms. Martin's own testimony indicates that she did not recognize the existence of the transient alarms described by the correction letter, nor did she instruct Mr. and Mrs. Bush to seek immediate medical attention. Accordingly, she breached the standard of care in this instance, as well.

Before turning to the question of causation, it is necessary to address McGuire's assertion that Mr. and Mrs. Bush were contributory negligent because they did not timely and accurately describe the alarms Mr. Bush had experienced. "Contributory negligence is an affirmative defense that is based on the objective standard of whether a plaintiff failed to act as a reasonable person would have acted for his own safety under the circumstances." *Sawyer v. Comerci*, 563

S.E.2d 748, 752 (Va. 2002). "[I]n order for contributory negligence to bar a plaintiff's recovery in a medical negligence action, the plaintiff's negligence must be concurrent with the defendant's negligence." *Id.* "A defendant who relies upon the defense of contributory negligence must prove that the plaintiff deviated from a standard of care and that the deviation was a proximate cause of damages." *Id.* at 753.The defendant has the burden of proving its existence by a preponderance of the evidence. *Id.* at 752. It is generally a question of fact, not law. *Id.* In this case, there are two areas where it is suggested that contributory negligence is present: first, in Mrs. Bush's failure to report the alarms recorded on the log and, second, in her failure to accurately describe the alarms which she communicated to Ms. Martin. Each is discussed in turn.

As noted previously, Mrs. Bush's account of the alarms Mr. Bush experienced appears to be credible. Ms. Martin's account differs, but she bases that mainly on statements she received from Thoratec, not her own experience. Further, the results of Thoratec's investigation are not conclusive with regard to what alarms occurred and when they occured, especially given the mechanical and electrical damage to the device. As Dr. Arslanoglu's testimony demonstrated, the transient alarms occurred as a result of a malfunction in the alarm mechanism itself; they were unplanned, unexpected, and unpredictable symptoms of underlying damage. Mr. and Mrs. Bush were observed by Dr. Katlaps and Ms. Martin to be incredibly vigilant with regard to Mr. Bush's care, and it defies logic to think that they would have purposefully neglected to inform Dr. Katlaps or Ms. Martin of any emergent alarm the device had issued. Even if McGuire had demonstrated that they were negligent by concealing these alarms, that negligence does not meet the concurrency requirement of Virginia law. Accordingly, the Court concludes that Mr. and Mrs. Bush were not negligent.

3. Causation

Next, it is necessary to determine whether Dr. Katlaps' or Ms. Martin's breach of the standard of care was the proximate cause of Mr. Bush's death. In Virginia, it is "simply [necessary] to prove that the particular time and manner of the patient's death resulted from the defendant's negligence," not "that the patient would have recovered perfect health, or survived indefinitely in the absence of the negligence." *Blondel v. Hays*, 403 S.E.2d 340, 344 (Va. 1991).

Here, had Mr. and Mrs. Bush been armed with the information contained in the correction letter, it is unlikely that Mr. Bush would have spent May 4, 2010, running errands or moving around his yard after experiencing irregular alarms the previous night and that morning. Instead, he and Mrs. Bush would have recognized the possibility that the alarms were caused by underlying damage to the percutaneous lead and understood that, if that was what was causing the alarms, the damage could be exacerbated by additional movement. As Dr. Katlaps and Ms. Martin testified, Mr. and Mrs. Bush were incredibly receptive to the information they had provided and attentive to Mr. Bush's care. Therefore, it is more likely than not that they would have recognized the alarms as a symptom of percutaneous lead damage and been proactive in their response. Ms. Martin testified that she had provided Mr. and Mrs. Bush with several methods of contacting her or, if she was unavailable, someone else at McGuire. She also instructed that they page—rather than call—her in an emergency. Had they been aware of the significance of the transient alarms, it is more likely than not that they would have followed her instructions and paged her. If she had not responded, they would have sought immediate medical attention. They also would have been able to limit Mr. Bush's movement and prevent any further damage. Likewise, had Ms. Martin recognized the alarms as a possible consequence of

percutaneous lead damage, she could have instructed Mr. Bush to limit his movement and seek immediate medical attention.

Although it is impossible to predict exactly what would have occurred, Mr. Bush would more likely than not have been in a hospital—perhaps even one with a VAD center—at the time he collapsed on May 4, 2010. This is so whether or not the transient alarms were symptomatic of the percutaneous lead damage or some other problem with the LVAS. It is not clear that being in a hospital would have resulted in Mr. Bush's long-term survival, but it is likely, if not certain, that his life would have been prolonged. (If the transient alarms were symptomatic of percutaneous lead damage, which it appears that they were, Mr. Bush may have lived minutes, hours, days, or weeks longer simply by limiting his movement, even without immediate medical attention.)

However, the conclusion that Mr. Bush would have lived longer depends on a finding that his death was the result of the LVAS' failure. This is a question of medical causation. As the Virginia Supreme Court has noted, "the question of causation of a human injury is a component part of a diagnosis, which in turn is part of the practice of medicine." *Combs v. Norfolk & W. Ry. Co.*, 507 S.E.2d 355, 358 (Va. 1998). There are instances where laypersons may be treated as qualified expert witnesses regarding causation, however in this instance causation is closely tied to a diagnosis. Here, both Dr. Loebe and Dr. Katlaps have addressed this issue.

Dr. Loebe testified that Mr. Bush's death was not a result of the LVAS' failure. Instead, he stated that the LVAS had not replaced the function of Mr. Bush's heart, that the malfunction of the LVAS "is usually not [a] fatal event for the patient," and that "patients do not die when the [LVAS] suddenly stops." (Tr. at 359, 367). Instead, he indicated that the proximate cause of Mr. Bush's death was his underlying heart disease, not any failure of the LVAS. Put differently, the

progression of Mr. Bush's heart disease was an intervening event severing the causal relationship between the device's failure and Mr. Bush's death. However, his is not the only testimony on this point.

Despite its intended purpose of assisting his heart—not replacing it—Dr. Katlaps, Mr. Bush's treating physician, testified that the LVAS had been keeping Mr. Bush alive. He estimated that without it, he would only have remained alive for days or weeks, but that with it he would live at least a year. Unlike Dr. Loebe, he concluded that Mr. Bush's heart disease had progressed to the point where his heart was unable to function without the LVAS. Thus, any failure of the device would result in Mr. Bush's death. He discussed Mr. Bush's life expectancy with the device:

> That would be quite—you know, that would be really an estimate. As you understand, there is no way to know . . . . But there are some criteria that can help us make that estimate more accurate, like [the] patient's age . . . . Mr. Bush was already in his early sixties and comorbidities. [Mr.] Bush had had two entries into his chest. You know, his surgery was more invasive than, than some others. [Mr.] Bush had, they called it history of terminal vascular disease, chronic obstruction pulmonary disease, COPD. He had recorded a history of a set of vascular accidents.
>
> Taking all that into account, his life expectancy was limited for many reasons, which were not—which had nothing to do with [the] LVAD. . . . And we knew based on the experience of, of ours and other centers at that time . . . the statistical analysis, you know, one year, two year, three year survival on those devices.
>
> . . . .
>
> [His life expectancy at the time of his death was m]aybe, maybe, maybe one, two or three years.

(Katlaps Tr. at 67-69).

Having weighed the testimony of Dr. Loebe and that of Dr. Katlaps, it appears that Dr. Katlaps' conclusions are a better and more credible fit with the other testimony and evidence. Although it is not impossible that Mr. Bush's natural heart would have stopped at the moment it

did—even if the LVAS had continued to function properly—the timing seems too great a coincidence. Further, Dr. Katlaps was intimately familiar with Mr. Bush's condition, having implanted the device and served as his doctor—albeit remotely—for a number of years. In contrast, Dr. Loebe reached his determination on the basis of what he had read, relying in part on the medical record that had been prepared by Dr. Katlaps and Ms. Martin. Accordingly, the testimony and evidence establishes that Mr. Bush died as a direct and proximate consequence of the device's failure. Therefore, but for Dr. Katlaps' and Ms. Martin's breach of the standard of care, Mr. Bush's life would have been extended by some measure.

E. Damages

1. Amount

Having concluded that Mr. Bush's death would not have occurred but for Dr. Katlaps' and Ms. Martin's breach of the applicable standard of care, it is necessary to consider damages. Under Virginia law, a court "may award such damages as to it may seem fair and just." VA. CODE ANN. § 8.01-52. The following types of damages are permitted:

> 1. Sorrow, mental anguish, and solace which may include society, companionship, comfort, guidance, kindly offices and advice of the decedent;
> 2. Compensation for reasonably expected loss of (i) income of the decedent and (ii) services, protection, care and assistance provided by the decedent;
> 3. Expenses for the care, treatment and hospitalization of the decedent incident to the injury resulting in death;
> 4. Reasonable funeral expenses; and
> 5. Punitive damages may be recovered for willful or wanton conduct, or such recklessness as evinces a conscious disregard for the safety of others.

Id. Prior to reaching a determination as to damages, it is relevant to consider the awards made in other instances where medical malpractice has resulted in death. Of course, prior awards are not dispositive since each case is dependent on its own unique facts, but prior awards for similar

damages are instructive. A survey of these awards demonstrates that general damages—that is, those for sorrow, mental anguish, and solace—are usually between $150,000.00 and $950,000.00 for each survivor and specific damages vary. *See, e.g.*, *Estate of Robertson v. Perry*, 2013 WL 7139777 (Va. Cir. Ct. 2013) (awarding $50.466.80 in medical expenses, $10,316.85 in funeral expenses, and $216,822.27 to each survivor of an 89-year-old patient); *Estate of Willever v. Williams*, 2012 WL 4503122 (Va. Cir. Ct. 2012) (awarding $438,000.00 in medical expenses and $390,500.00 to each survivor of a 73-year-old patient); *Estate of Madison v. Chesapeake Anesthesiologists*, 2011 WL 7163456 (Va. Cir. Ct. 2011) (awarding $425,000.00 to the spouse and $125,000.00 to each child of a patient); *Estate of Lopez v. Galumbeck*, 2010 WL 5517655 (Va. Cir. Ct. 2010) (awarding $975,000.00 to the spouse and $243,750.00 to each child of a 36-year-old patient); *Estate of Budnick v. Barry v. Walter*, 2009 WL 5171892 (Va. Cir. Ct. 2009) (awarding $46,997.56 for medical expenses, $2,675.00 for funeral expenses, and $2,200,000.00 to the survivor of a patient); *Estate of Browder v. Gamache*, 2009 WL 1912388 (Vir. Cir. Ct. 2009) (awarding $211,953.29 for medical expenses, $785,000.00 for economic loss, and $6,500,000.00 to the survivor of a patient); *Cumbee v. Nicholson*, 2007 WL 4755239 (Va. Cir. Ct. 2007) (awarding $56,163.29 in medical expenses, $10,512.38 in funeral expenses, and $140,000.00 to each of survivor of a patient); *Estate of Butler v. Mid-Atlantic Permanente Med. Grp., P.C.*, 2003 WL 22111034 (Va. Cir. Ct. 2003) (awarding $950,000.00, approximately $161,615.00 to $368,614.00 of which was for loss of income, to the survivor of a 53-year-old patient with a life expectancy of 15 to 20 years); *Estate of Fadle v. Mueller*, 1998 WL 1757227 (Va. Cir. Ct. 1998) (awarding $724,000.00 to the survivor of a 63-year-old patient). Additionally,

there does not appear to have been any award for punitive damages in such a case in the past decade.[18]

Here, Mrs. Bush seeks $665,000.00 plus interest in general damages, $195,000.00 in punitive damages, and $184,307 in special damages. In support of her claim for sorrow, mental anguish, and solace, Mrs. Bush testified that, after Mr. Bush's death, she was hospitalized for depression and experienced weight loss, isolationism, and insomnia. She was treated for approximately four days. Her medical records indicate that she was billed $11,967.74 for that hospitalization. (J. Ex. 5 at 1-4). Mrs. Bush appears to have suffered significantly as a result of Mr. Bush's untimely death and the Court concludes that damages for sorrow, mental anguish, and solace of $200,000.00 are fair and just.

With regard to damages for reasonably expected loss of income or services, the credible evidence indicates that Mr. Bush would have been able to live an additional two years had the LVAS continued to function properly. Accordingly, the Court adopts the conclusions of Mrs. Bush's expert witness, who calculates Mrs. Bush's damages for reasonably expected loss of income or services for that period as $23,535.00.

With regard to the expenses for care, treatment, and hospitalization as well as funeral expenses, the Court notes that the parties stipulated that Mrs. Bush is not entitled to any reimbursement because these expenses have been or will be paid by the United States.

[18] Mrs. Bush additionally seeks damages "for [Mr. Bush's] physical and mental pain and suffering that he endured in suffering a fatal heart attack and dying, and his loss of enjoyment of life." (Rec. Doc. 100 at 17). Under Virginia law, which is controlling in this matter, a plaintiff may not seek damages for a decedent's pain and suffering. *See Jappell v. Arlington Health Found.*, No. 97–9631, 1998 WL 34174587, at *4 (Va. Cir. Ct. Dec. 2, 1998) ("[T]he fact that the [legislature] included the decedent's hospital and funeral expenses among the damages permitted under the Wrongful Death Act and made no mention of the decedent's pain and suffering during such hospitalization implies that such omission was intentional." (citing VA. CODE ANN. § 8.01-52)). Further, even if such damages were available, there is no testimony or evidence to support an award here.

With regard to punitive damages, the testimony and evidence do not justify or support an award. Under Virginia law, "negligence which is so willful or wanton as to evince a conscious disregard of the rights of others, as well as malicious conduct, will support an award of punitive damages in a personal injury case." *Booth v. Robertson*, 374 S.E.2d 1, 3 (Va. 1988); *see Doe v. Isaacs*, 579 S.E.2d 174, 176 (Va. 2003). Here, Dr. Katlaps and Ms. Martin were negligent in failing to provide information about the new type of alarm and Ms. Martin was negligent in failing to recognize the immediate nature of the situation on the day of Mr. Bush's death. The testimony and evidence clearly demonstrates that Dr. Katlaps and Ms. Martin did what they thought was best for Mr. Bush—that it did not coincide with what the standard of care required is unfortunate but does not suggest malice or a wilful or wanton disregard of Mr. Bush's rights. At all points, they acted carefully, thoughtfully, and diligently. For instance, Dr. Katlaps and Ms. Martin did not merely neglect to tell Mr. and Mrs. Bush about the transient alarms; instead they made a decision not to tell them after having read and discussed the correction letter. Similarly, Ms. Martin did not merely dismiss Mrs. Bush on the day of Mr. Bush's death; rather she immediately called Thoratec and attempted to determine the problem. It is abundantly clear that Dr. Katlaps and Ms. Martin genuinely cared for Mr. and Mrs. Bush.

2. Distribution

Having determined the aggregate amount of damages, it is necessary to decide whether they must be reduced because of a prior settlement. With regard to FTCA claims, state law dictates how a settlement before trial will impact the distribution of damages after trial. *See Gill v. United States*, 429 F.2d 1072, 1078 (5th Cir. 1970). Under Virginia law, "[w]hen a release . . . is given in good faith to one of two or more persons liable for . . . wrongful death," that release does not "discharge any other person from liability[,] but any amount recovered

against the other person or any one of them shall be reduced . . . in the amount of the consideration paid for [the release]." VA. CODE ANN. § 8.01-35.1(a); *see Fairfax Hosp. Sys., Inc. v. Nevitt*, 457 S.E.2d 10, 14 (Va. 1995). Here, Mr. Bush suffered but one wrongful death, which Mrs. Bush alleges was caused by the United States and other now-dismissed parties, thus any damages will be reduced by the amount of consideration paid for the prior settlement. (*See* Rec. Doc. 188).

IV. SUMMARY

On the basis of the above findings of fact and conclusions of law, the Court finds that Mrs. Bush has not sustained any injury due to the negligence of the United States or its employees, Dr. Katlaps and Ms. Martin. Accordingly, **IT IS ORDERED** that the United States pay Mrs. Bush $200,000.00 for sorrow, mental anguish, and solace and pay $23,535.00 in compensation for reasonably expected loss of income of the decedent and services, protection, care and assistance provided by the decedent, with a credit for the amount of consideration paid for the prior settlement. (*See* Rec. Doc. 188).

New Orleans, Louisiana, this 1st day of April, 2014.

UNITED STATES DISTRICT JUDGE