

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

DINA M. ROBLES BUSH

VERSUS

THORATEC CORPORATION, ET AL.

CIVIL ACTION

NO. 11-1654

SECTION "L" (3)

ORDER & REASONS

The Court has pending before it several motions by Defendant United States, who operates Hunter Holmes McGuire VA Medical Center ("McGuire"). The first is a motion for summary judgment (Rec. Doc. 120), and the second is a motion in limine to strike an expert witness called by Plaintiff Diana Robles Bush ("Mrs. Bush") and, consequently, for summary judgment (Rec. Doc. 121). The Court has reviewed the briefs and the applicable law, and it now issues this order.

I. BACKGROUND

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 the now-dismissed Defendant Thoratec Corporation ("Thoratec"). It was implanted by McGuire, a facility operated by 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 in light of the Supreme Court's opinion construing that express preemption provision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2007). (Rec. Doc. 41). However, the Court granted Mrs. Bush's leave to amend her complaint so that she could attempt to state a nonpreempted claim. Plaintiff 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, 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).

II. PRESENT MOTIONS

McGuire now moves for summary judgment (Rec. Doc. 120) and to strike Mrs. Bush's expert witness and, consequently, for summary judgment (Rec. Doc. 121). First, McGuire moves for summary judgment on the basis that Mrs. Bush failed to satisfy the "expert certification of merit requirement" for medical malpractice actions brought under Virginia law. (Rec. Doc. 120). Mrs. Bush responds that the claims are not governed by Virginia law because the injuries occurred in Louisiana and, even if they were, Virginia law does not require an expert to establish

a standard of care where the duty owed was ministerial in nature. (Rec. Doc. 127). McGuire replies that Virginia law applies, that professional judgment was involved, that the exception to Virginia's expert certification of merit requirement does not apply to this case. (Rec. Doc. 131-2). Mrs. Bush responds further, arguing that the duty was created when McGuire's employees signed the acknowledgment attached to the correction letter. (Rec. Doc. 133-2). Recently, Mrs. Bush filed another memorandum arguing that because McGuire is "not licensed by the Commonwealth of Virginia," it fails to meet a threshold requirement of Virginia's medical malpractice statute. (Rec. Doc. 160-2 at 1). McGuire replies that both Dr. Gundars Katlaps and registered nurse Lisa Martin are licensed under Virginia law. (Rec. Doc. 165).

Second, McGuire moves to strike Mrs. Bush's expert witness, Ruhi Arslanoglu, because Arslanoglu is not a physician or nurse, and because he does not satisfy the "knowledge" or "active clinical practice" requirements for experts testifying in medical malpractice actions under Virginia law. (Rec. Doc. 121). If the motion to strike is granted, McGuire further moves for summary judgment on the basis that Mrs. Bush will be unable to prove the elements for medical malpractice. (*Id.*). Mrs. Bush again responds that the duty owed to her husband was merely ministerial in nature and did not involve the exercise of professional judgment. (Rec. Doc. 128). Mrs. Bush further asserts that McGuire's own expert witness has stated in a deposition that there was no prevailing standard of care at the time. (Rec. Doc. 134-2; *see also* Rec. Doc. 159-1). McGuire, in turn, argues that Mrs. Bush has misunderstood the expert witness' statement and that a general standard of care applied, even if there was no specific standard of care with regard to the LVAS correction letter. (Rec. Doc. 140-2).

III. UNCONTESTED FACTS

Mr. Bush was admitted to McGuire, which is located in Richmond, Virginia, on July 29, 2008. At the time, he was suffering from end-stage heart disease, including coronary artery disease, nonischemic cardiomyopathy, and critical aortic valve stenosis, and he had been living with a cardioverter-defibrillator and a pacemaker. Prior to his admission, he had undergone cardiac catheterization.

On September 25, 2008, the providers at McGuire surgically implanted an LVAS into Mr. Bush. The device consisted of a heart pump, a system controller, and a percutaneous lead connecting the pump to the controller. Because the percutaneous lead ran from the internal heart pump to the external controller unit, it had both an external portion that can be visually examined for damage and an internal portion that cannot. Mr. Bush was the first patient at McGuire to receive this particular LVAS model.

Nearly a month after the implantation, on October 24, 2008, Thoratec sent a correction letter to providers, including Dr. Katlaps, the surgeon who had performed Mr. Bush's operation. The letter regarded a voluntary recall of the device. 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. X-ray images, [c]ontroller log files, and pump waveform data may be used to assess the extent and location of the damage. 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

(Rec. Doc. 128-2 at 1-2). 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. . . .

(Rec. Doc. 128-2 at 3). The letter also contained information directed at patients.¹

Mrs. Bush asserts that she and Mr. Bush were never made aware of the correction letter or the information it contained. The parties do not appear to dispute the fact that Mr. Bush's medical record does not contain any reference to a discussion between him or Mrs. Bush and the providers at McGuire.

Following the operation, Mr. Bush remained in the hospital until October 31, 2008, when he was transferred to a residential facility. He remained there until he was discharged from McGuire and returned to Slidell, Louisiana, on December 12, 2008. His post-discharge care was handled jointly by McGuire, Tulane, and the Slidell Medical Centers: his primary care physician was in Louisiana, and monitoring of the LVAS occurred in both Louisiana and Virginia.

At approximately 8:00 a.m. on May 4, 2010, Mrs. Bush placed a telephone call from her house in Louisiana to Ms. Martin, the registered nurse monitoring Mr. Bush's LVAS at McGuire. She was unable to reach Ms. Martin, who was assisting with a surgery, and instead left a message for her with Mary Compton, another McGuire health care provider. The message

¹ 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.

(Rec. Doc. 128-2 at 5).

indicated that Mr. Bush's LVAS was emitting intermittent alarms. After the surgery, Ms. Martin immediately returned Mrs. Bush's call at approximately 4:00 p.m. that afternoon. Their conversation lasted for about 30 minutes. About 30 minutes after they had spoken, and while Ms. Martin was on the telephone with a representative of Thoratec, Mr. Bush suffered cardiac arrest and died.

IV. LAW AND ANALYSIS

A. Standard of Review

Summary judgment is appropriate if the moving party can show "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). Under Federal Rule of Civil Procedure 56(c), the moving party bears the initial burden of "informing the district court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). When the moving party has met its Rule 56(c) burden, the nonmovant cannot survive a motion for summary judgment by resting on the mere allegations of its pleadings. *See Prejean v. Foster*, 227 F.3d 504, 508 (5th Cir. 2000). "The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 253 (1986). Furthermore, the nonmoving party "cannot avoid summary judgment . . . by merely making 'conclusory allegations' or 'unsubstantiated assertions.'" *Calbillo v. Cavender Oldsmobile, Inc.*, 288 F.3d 721, 725 (5th Cir. 2002) (quoting *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994)). In deciding a summary judgment motion, a court reviews the facts and draws all reasonable inferences in the light most favorable

to the nonmovant. *Id.* at 725. In order to determine whether McGuire is entitled to judgment as a matter of law, the Court must determine which forum's law applies.

B. FTCA Choice of Law

Mrs. Bush's claims allege tortious conduct by the United States and are 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 alleged 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 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 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.

C. 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.

D. 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. While there is no dispute that Mr. Bush was in fact a patient, Mrs. Bush contends that McGuire does not fit the description of a health care provider. 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 is 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.² For these reasons, the VMMA also covers the relationships that existed between Mr. Bush and Dr. Katlaps, Ms. Martin, and McGuire, and applies to extent it is substantive.

² 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).

E. Expert Certification of Merit

McGuire, in its initial motion for summary judgment, asserts that Mrs. Bush's claims should be dismissed on the basis that she did not obtain an expert certification of merit as required by the VMMA. The requirement states:

Every [complaint] in a medical malpractice action, at the time the plaintiff requests service of process upon a defendant, or requests a defendant to accept service of process, shall be deemed a certification that the plaintiff has obtained from an expert witness whom the plaintiff reasonably believes would qualify as an expert witness pursuant to . . . § 8.01-581.20 a written opinion signed by the expert witness that, based upon a reasonable understanding of the facts, the defendant for whom service of process has been requested deviated from the applicable standard of care and the deviation was a proximate cause of the injuries claimed. *This certification is not necessary if the plaintiff, in good faith, alleges a medical malpractice action that asserts a theory of liability where expert testimony is unnecessary because the alleged act of negligence clearly lies within the range of the jury's common knowledge and experience.*

VA. CODE ANN. § 8.01-20.1 (emphasis added). It further provides:

Upon written request of any defendant, the plaintiff shall, within 10 business days after receipt of such request, provide the defendant with a certification form that affirms that the plaintiff had obtained the necessary certifying expert opinion at the time service was requested or affirms that the plaintiff did not need to obtain a certifying expert witness opinion. . . . If the plaintiff did not obtain a necessary certifying expert opinion at the time the plaintiff requested service of process on a defendant as required under this section, *the court shall impose sanctions according to the provisions of § 8.01-271.1 and may dismiss the case with prejudice.*

VA. CODE ANN. § 8.01-20.1 (emphasis added).

Whether the expert certification of merit requirement bars Mrs. Bush's claim necessitates a two-step analysis. First, because it is a requirement imposed by Virginia law, it is only applicable here if it is substantive in nature. Second, if it is applicable, its operation only

precludes Mrs. Bush's claims "if alleged act[s] of negligence clearly [are not] within the range of the jury's common knowledge and experience." VA. CODE ANN. § 8.01-20.1.

1. Substantive or Procedural

First, the Court must determine whether the expert certification of merit requirement is substantive and therefore applicable here. As addressed above, Virginia's choice of law rules require this Court to apply Virginia substantive law and federal procedural law. In classifying the requirement at issue, it is necessary to evaluate this delineation as it is drawn by both Virginia and federal courts.

The Virginia Supreme Court has stated that a "[s]ubstantive [rule is] included within that part of the law dealing with creation of duties, rights, and obligations, as opposed to [a] procedural or remedial [rule], which prescribes methods of obtaining redress or enforcement of rights." *Shiflet v. Eller*, 319 S.E.2d 750, 754 (Va. 1984). The United States Supreme Court has drawn a nearly identical distinction, indicating that a procedural rule, unlike a substantive rule, "relates merely to 'the manner and means by which a right to recover . . . is enforced.'" *Mississippi Pub. Corp. v. Murphree*, 326 U.S. 438, 445-46 (1946) (quoting *Guar. Trust Co. of N.Y. v. York*, 326 U.S. 99, 109 (1945)). "The test must be whether a rule really regulates procedure, [that is,] the judicial process for enforcing rights and duties recognized by substantive law and for justly administering remedy and redress for disregard or infraction of them." *Hanna v. Plumer*, 380 U.S. 460, 464 (1965) (internal quotation marks omitted).

However, a rule must not be considered substantive merely because procedural rules "may and often do affect the rights of litigants." *Miss. Pub. Corp.*, 326 U.S. at 445; see *Hanna*, 380 U.S. at 468. For instance, in *Hanna v. Plumer*, the United States Supreme Court held that even if the application of state procedural rule would have a "marked effect" on the outcome of a

case *in media res*, that alone was not enough to make the rule substantive, especially if earlier application of the rule would have had “scant, if any, relevance” to the outcome. *Id.* at 469. The United States Supreme Court has indicated that rules related to service of process are generally procedural, rather than substantive. “[I]n actions arising under federal law, . . . the manner and timing of serving process are generally nonjurisdictional matters of ‘procedure’ controlled by the Federal Rules.” *Henderson*, 517 U.S. at 656 (noting that Federal Rule of Civil Procedure 4 is procedural); *see Hanna*, 380 U.S. at 464 (Rule 4(d)(1) is procedural); *Mississippi Pub. Corp.* 326 U.S. at 445 (Rule 4(f) is procedural). Although the expert certification of merit requirement is entangled with service of process requirements, it is not necessary to determine whether it is a component of the service of process requirement itself.³

Having considered the distinction drawn between substantive and procedural rules, it is necessary to consider how other courts have classified Virginia’s expert certification of merit requirement. The United States Court of Appeals for the Fifth Circuit has not construed the requirement, thus there is no binding authority that addresses the nature of Virginia’s requirement. Instead, other federal courts provide guidance. The United States Court of Appeals for the Fourth Circuit has in a single, unpublished opinion. It applied the requirement without determining that it was substantive. *Keitz v. Unnamed Sponsors of Cocaine Research Study*, 510 F. App’x 254, 256 (4th Cir. 2013). Despite the scarcity of appeals decisions, the requirement has

³ In at least one instance, the Virginia Supreme Court has held that it is distinguishable from service of process in certain instances. *See Bowman v. Concepcion*, 722 S.E.2d 260, 266 (Va. 2012) (“[T]he effort expended by the plaintiff to obtain the Code § 8.01–20.1 expert opinion does not constitute part of the due diligence effort to obtain service of process on the defendant expressly required under Code § 8.01–275.1.”). *But see Lents v. Vetter*, No. CL–2009–12028, 2010 WL 7375603, at *1–2 (Va. Cir. Ct. Apr. 2, 2010). (“[A]bsent service of process or a request for a formal waiver of service of process, the defendant foregoes its right to request verification of the plaintiff’s expert witness certification.”).

been applied frequently by federal district courts in Virginia, usually without analysis as to whether it is substantive. Instead, many of those cases have relied on the Fourth Circuit's decision in *Starns v. United States*, which held that the VMMA damages cap is substantive. 923 F.2d 34, 37 (4th Cir. 1991), or on a district court's decision in *Parker v. United States*, which broadly interpreted *Starns* as "applying [the *entire*] Virginia Medical Malpractice Act in [an] FTCA action involving federally operated health care providers in Virginia." *Parker v. United States*, 475 F. Supp. 2d 594, 596 (E.D. Va. 2007); see *Winston v. United States*, No. 11-0812, 2013 WL 4829292, (E.D. Va. Sept. 10, 2013); *Johnson v. Kilgore*, No. 11-0416, 2012 WL 3544916, at *7 n.6 (W.D. Va. Aug. 16, 2012); *Bell v. United States*, No. 11-0060, 2011 WL 3734458, at *3 (E.D. Va. Aug. 24, 2011); *White v. Owens*, No. 10-0514, 2011 WL 3652592, at *7 (W.D. Va. Aug. 19, 2011); *Delaney v. Marsh*, No. 08-0465, 2010 WL 1212569, at *3 n.6 (W.D. Va. Mar. 25, 2010); *Smith v. United States*, No. 08-0838, 2010 WL 256595, at *2 (E.D. Va. Jan. 19, 2010); *Moody v. DeJesus*, No. 08-0432, 2009 WL 187682 (W.D. Va. Jan. 23, 2009); *Creekmore v. Maryview Hosp.*, No. 08-0235, 2008 WL 5100110, at *3 (E.D. Va. Dec. 2, 2008); *Moody v. DeJesus*, No. 08-0432, 2008 WL 5082432, at *5 (W.D. Va. Dec. 1, 2008); *Bond v. United States*, No. 08-0324, 2008 WL 4774004, at *3 (E.D. Va. Oct. 27, 2008). In one particularly confusing instance, a district court observed that the "[d]efendant erroneously cites *Starns* . . . as standing for the proposition that an FTCA medical malpractice action is subject to the VMMA expert certification of merit requirement" (because "*Starns* dealt exclusively with the VMMA's . . . damage cap, and did not in any instance refer to . . . the expert certification of merit requirement"), and instead relied on *Parker* as support for the proposition that "[a]n FTCA medical malpractice action is subject to the VMMA expert certification of merit requirement." *Downing v. United States*, No. 07-0466, 2008 WL 816678, at *10 & n.15 (W.D. Va. Mar. 26,

2008) (citing *Parker*, 475 F. Supp. 2d at 596). Another district court applied the expert certification of merit requirement, finding that “the plaintiff’s [medical] negligence claim fails based on *procedural* reasons.” *Keitz v. Virginia*, No. 11-0061, 2011 WL 4737080, at *5 (W.D. Va. Oct. 5, 2011) (emphasis added).

Despite the fact that an analysis of this issue has been largely overlooked by federal courts in Virginia, there are several decisions that aptly suggest “some questions exist as to whether or not the VMMA is procedural or substantive in nature” and indicate that “[o]nly if it is substantive do its provisions bind this Court.” *Kerr v. U.S. Dep’t of Justice*, 07-0422, 2008 WL 3928701, at *3 n.5 (E.D. Va. Aug. 21, 2008) (citing *Sanchez-Angeles v. United States*, No. 07-0596, 2008 WL 2704309, at *5 (W.D.Va. July 10, 2008)). In *Sanchez-Angeles v. United States*, a district court raised the question as to “whether the expert certification [of merit] requirement, a Virginia *procedural* law, should be applied in [a federal] court to bar [VMMA] claims.” 2008 WL 2704309, at *5 (emphasis added). It then summarized the *Erie* doctrine’s instruction that federal courts apply “state substantive law and federal procedural law,” and it indicated that federal courts have extended *Erie* to FTCA actions. *Id.* However, this was dicta and its holding did not decide the issue presented here.

Although there are no federal courts that have analyzed the nature of Virginia’s expert certification of merit requirement, there are several that have addressed similar provisions in other states. For instance, a similar requirement in Texas requires:

(a) In a health care liability claim, a claimant shall, not later than the 120th day after the date each defendant's original answer is filed, serve on that party or the party's attorney one or more expert reports

(b) If, as to a defendant physician or health care provider, an expert report has not been served within the period specified

. . . the court, on the motion of the affected physician or health care provider, shall, . . . enter an order that:

(1) awards to the affected physician or health care provider reasonable attorney's fees and costs of court incurred by the physician or health care provider; and

(2) dismisses the claim with respect to the physician or health care provider, with prejudice to the refiling of the claim.

TEX. CIV. PRAC. & REM. CODE ANN. § 74.351. As articulated by one court, “[e]very [federal district] court within Texas to consider whether the new [requirement] applies in federal court has held that it does not.” *Mason v. United States*, 486 F. Supp. 2d 621, 625 (W.D. Tex. 2007) (collecting cases). Specifically, it and other district courts reasoned that its application would conflict with many of the Federal Rules of Civil Procedure, including Rule 11’s sanctions for frivolous claims. *Id.*

Considering the delineation between substantive and procedural rules as drawn the Virginia Supreme Court and the United States Supreme Court and also the reasoning of other district courts applying this and similar requirements, this Court concludes that Virginia’s expert certification of merit requirement is procedural, and thus inapplicable. The requirement “does not operate to abridge, enlarge, or modify the rules of decision by which [this Court] will adjudicate [a litigant’s] rights.” *Miss. Pub. Corp.*, 326 U.S. at 445–46. Further, the requirement, which is intended to discourage frivolous claims, does nothing more than replicate substantive elements of a claim under the VMMA.⁴ In order to prove a claim under the VMMA, the law requires proof

⁴ As trial court in Virginia has noted:

There are no annotations of legislative intent . . . nor any court opinions However, a reasonable interpretation of the overall intent of the Statute is to discourage the filing of law suits for nuisance purposes by unscrupulous parties hoping that a settlement can be forced by the mere institution of litigation.

of the applicable standard of care, a deviation from the applicable standard of care, and a causal relationship between that deviation and the injury claimed. *Raines v. Lutz*, 341 S.E.2d 194, 196 (Va. 1986). Likewise, the expert certification of merit must state that a health care provider “deviated from the applicable standard of care and the deviation was a proximate cause of the injuries claimed.” VA. CODE ANN. § 8.01-20.1. Thus, the contents of such a certification have no bearing whatsoever on the decisive adjudication of the matter: with or without such a certification, Mrs. Bush would still be required to prove the elements of her VMMA claims at trial. For these reasons, the Court holds that the expert certification of merit requirement is inapplicable as procedural. Here, the Federal Rules of Civil Procedure govern. Those rules, in contrast to the VMMA, do not require such a certification.

2. Exception

However, even if the Virginia expert certification requirement were substantive and thus applicable here, dismissal would not be appropriate because Mrs. Bush’s claims are likely excepted under the language of the requirement and because dismissal is discretionary. Without addressing whether Mrs. Bush’s claims actually do require expert testimony on the standard of care, the Court concludes that she has, in good faith, “assert[ed] a theory of liability where expert testimony is unnecessary because the alleged act of negligence clearly lies within the range of the jury's common knowledge and experience.” VA. CODE ANN. § 8.01-20.1. Here, McGuire requested that Mrs. Bush provide an expert certification of merit (Rec. Doc. 120-4), and Mrs. Bush responded that “[t]he determination as to whether the McGuire . . . employees followed

Stewart v. Wampler, No. CL05-375, 2006 WL 4535030 (Va. Cir. Ct. Jan. 20, 2006).

[the correction letter's] instructions can be made on common knowledge and ordinary experience and does not require 'standard of care' medical testimony." (Rec. Doc. 120-6 at 2). Considering the facts particular to this case and the applicable substantive law of Virginia, addressed *infra*, the Court has no reason to conclude Mrs. Bush's assertion was made in bad faith.

3. Discretion

Alternatively, dismissal, which is discretionary, is inappropriate in this instance. McGuire argues that the statutory language "shall impose sanctions . . . and may dismiss" should be read to mean that either sanctions or dismissal is *required* as a matter of law when a certification has been requested but not provided. However, the Virginia Supreme Court has indicated that "[s]tatutes in derogation of the common law are to be strictly construed and not to be enlarged in their operation by construction beyond their express terms." *See Isbell v. Commercial Inv. Assocs., Inc.*, 644 S.E.2d 72, 75 (Va. 2007) (internal quotation marks omitted). Given this presumption, the Court does not find McGuire's reading persuasive. As *Black's Law Dictionary* notes, the word "shall" has multiple meanings, including: "has a duty to," "should," "may," "will," or "is entitled to." BLACK'S LAW DICTIONARY (9th ed. 2009). While it is unlikely that "shall" means "may" in this context (the legislature had already used that word in the sentence, presumably to mean something else) it is still not clear that "shall" must mean "has a duty to." In this context, it seems just as likely that it means "should," "will," or "is entitled to." Accordingly, the imposition of sanctions or dismissal is discretionary, and here that discretion cautions against either remedy.⁵

⁵ Under the expert certification of merit requirement, "the option to dismiss the case is clearly left to the court's discretion." *Sanchez-Angeles*, 2008 WL 2704309, at *5 n.6 (W.D. Va. July 10, 2008).

This is not an instance where dismissing the claims would avoid the unnecessary expenditure of resources litigating frivolous claims. On October 11, 2012, Mrs. Bush filed a third amended complaint naming McGuire. (Rec. Doc. 100). After an extension of time to answer was requested and granted (Rec. Docs. 104, 105), McGuire answered the amended complaint on December 21, 2012. McGuire has since participated in telephone status conferences with the Court on February 26, 2013, May 21, 2013, and July 2, 2013. (Rec. Docs. 110, 113, 117). It was only on July 25, 2013, that McGuire sent Mrs. Bush a written request for an expert certification of merit regarding her claim pursuant to the VMMA. (Rec. Doc. 120-4). On August 7, 2013, just over 10 days later, Mrs. Bush responded without any certification, arguing that Virginia law was not applicable to the case or, alternatively, that her failure to provide the certification would be excused. (Rec. Doc. 120-5). McGuire then filed the present motion for summary judgment on the basis that Mrs. Bush's failure to provide the certification was fatal under Virginia law. (Rec. Doc. 120). McGuire set this motion for submission on September 4, 2013, nearly a year after the complaint against it had been filed and merely a month prior to trial. (Rec. Doc. 120-1). Whatever the purpose of the VMMA's expert certification of merit requirement, it does not seem that its operation would stem unnecessary expenditure of resources by McGuire in this instance because the litigation is on the cusp of trial. If Mrs. Bush's claims are meritless, that issue will be resolved adequately in a matter of weeks. Thus, even if the rule were substantive, the Court would not exercise its discretion to dismiss the claims or impose sanctions.⁶

⁶ As discussed below, the Court also concludes that the exception to Virginia's requirement that the standard of care be established via a physician's testimony may apply in this instance, in which case the certification requirement would be abrogated.

F. Expert Qualifications

The issue raised by McGuire's second motion to strike, and consequently, for summary judgment, is whether Mrs. Bush's failure to provide an qualified expert to testify on the standard of care warrants dismissal. The United States Court of Appeals for the Fifth Circuit has held that for claims brought pursuant to the FTCA, "the liability of the United States . . . is governed by [state] negligence principles." *Pesantes v. United States*, 621 F.2d 175, 179 (5th Cir. 1980). In *Pesantes v. United States*, the Fifth Circuit held that for FTCA claims, a district court must apply Louisiana's qualification requirement for standard-of-care experts, "as interpreted by the state's highest court." *Id.* In doing so, it noted that the qualification requirement was substantive, rather than procedural. *Id.* In *Woods v. United States*, an unreported case, the Fifth Circuit further held that a district court had properly granted summary judgment against a plaintiff who failed to provide a standard-of-care expert, as required by Texas law. No. 10-10599, 2011 WL 857007 (5th Cir. Mar. 11, 2011); see *Stewart v. United States*, 293 F. App'x 272 (5th Cir. 2008). Thus, Virginia's expert qualification requirements are applicable here because such requirements are consistently held to be substantive in nature.

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." *Raines*, 341 S.E.2d at 196. 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.⁷ *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 this Commonwealth, 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 this Commonwealth 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.

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.” *Id.* (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

⁷ 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.

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.

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 [do] not supersede the jury system.” *Id.* at 197 (“The determination of negligence, proximate cause, and damages remains within the jury's province.”).

There are 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.*

Here, Mrs. Bush alleges that Dr. Katlaps knew or should have known that he needed to communicate the fact that LVAS implanted into Mr. Bush was defective and that Ms. Martin knew or should have known that the transient alarms experienced by Mr. Bush should have

immediately indicated that he needed to be admitted to a hospital. Ruhi Arslanoglu, Mrs. Bush's expert, does not meet the expert qualification requirements to testify as to the standard of care because he is not a physician, nor does it appear that he, as an engineer, meets the clinical practice requirements. This does not, however, bar him from testifying as an expert with regard to causation. While he cannot be struck, the issue is whether Mrs. Bush's failure to provide a qualified expert's testimony on standard of care necessitates summary judgment against her.

The Virginia Supreme Court has not reached the issue of whether a plaintiff's evidence is insufficient as a matter of law without a qualified expert in VMMA claim. However, one state trial court in Virginia has held, "[i]n short, in a medical malpractice case, the mere absence of expert testimony in support of the plaintiff's allegations is not enough to justify summary judgment [because a] further determination must be made as to whether the case is outside the common knowledge and experience of the jury, and thus requires expert testimony." *Keegan v. Kaiser Permanente*, No. 196457, 2002 WL 921255, at *3 (Va. Cir. Ct. Mar. 6, 2002).

Considering this precedent, this Court is not convinced that the alleged lapses of Dr. Katlaps and Ms. Martin require testimony on the standard of care. Mrs. Bush claims that Dr. Katlaps was negligent when he did not relay information from the manufacturer of a defective device to his patient, who was relying on that device's consistent functioning to live. If this is what actually occurred, the only lapse is within the understanding of anyone who has been a patient. Mrs. Bush also claims that Ms. Martin was negligent when she did not recognize the transient alarms for what they were and immediately direct Mr. and Mrs. Bush to a hospital. If so, she had to do nothing more than remember that the correction letter instructed patients experiencing transient alarms in for immediate diagnostic testing, exactly what Mr. and Mrs. Bush would have had to do if they had in fact been provided the letter or the information it

contained. Failing to provide a copy of a letter or read that letter to a patient and failing to remember the consequence of a transient alarm—if that is what occurred—do not seem to fall beyond the realm of common knowledge and experience of a lay jury, never mind a lay judge.

Even if it were necessary in this case for Mrs. Bush to have provided an expert to testify as to the standard of care, it is not clear that her failure to do so is fatal. For instance, the Virginia Supreme Court has indicated that the standard of care was proved by the defendant’s expert witness where the trial court erred in allowing the plaintiff’s witness to testify. *Hinkley v. Koehler*, 606 S.E.2d 803, 808 (Va. 2005). Courts in states with similar requirements have held similarly. *Porter v. Henry Ford Hosp.*, 181 Mich. App. 706, 710, 450 N.W.2d 37, 40 (Mich. Ct. App. 1989) (“A plaintiff in a medical malpractice case is required to use expert testimony to establish the standard of professional care. . . . However, it is not mandatory that he use his own expert to do so. He may establish the standard through defense witnesses.” (citation omitted)).

V. CONCLUSION

For the forgoing reasons, **IT IS ORDERED** that Defendant United States’ motion for summary judgment (Rec. Doc. 120) and motion to strike and for summary judgment (Rec. Doc. 121) are **DENIED. IT IS FURTHER ORDERED** that pursuant to Virginia law, Plaintiff Bush’s expert, Ruhi Arslanoglu, may not testify as to the standard of care.

New Orleans, Louisiana, this 30th day of September, 2013.


UNITED STATES DISTRICT JUDGE