IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
CHARLOTTESVILLE DIVISION

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| CYNTHIA B. EVANS, | ) | CASE NO. 3:04CV00097 |
| | ) | |
| Plaintiff, | ) | |
| | ) | |
| v. | ) | REPORT AND RECOMMENDATION |
| | ) | |
| MEDTRONIC, INC., | ) | |
| | ) | By: B. WAUGH CRIGLER |
| Defendant, | ) | U.S. MAGISTRATE JUDGE |

Before the court are the defendant's May 16, 2005 motion for summary judgment and the defendant's June 17, 2005 motion to strike two of plaintiff's affidavits submitted in opposition to summary judgment. The motions are before the court under the authority of 28 U.S.C. § 636(b)(1)(B) to render to the presiding court a report setting forth appropriate findings, conclusions and recommendations of law for their disposition. For the reasons that follow the undersigned will recommend that an order enter GRANTING, in part, and DENYING, in part, the defendant's motion for summary judgment; and GRANTING the defendant's motion to strike from the summary judgment record the plaintiff's late-filed affidavits.

**PROCEDURAL HISTORY**

This products liability action arises from a spinal cord injury sustained by plaintiff on November 12, 2003 during a surgical operation at the University of Virginia Medical Center ("the Hospital"). The November 12 surgery was the last in a series of four surgeries through which Jeffrey Elias, M.D., sought to implant in plaintiff's cervical spine and upper abdomen a functional Medtronic electronic spinal cord stimulation system (technically known and referred to as the "Medtronic Itrel 3 Spinal Cord Stimulation System") to ameliorate disabling pain plaintiff

had experienced since she suffered a back injury in 1998. During the November 12 surgery, Dr. Elias discovered that the portion of the Medtronic system implanted in plaintiff's body called a "lead" had been damaged. Thereupon, he explanted (removed) that particular lead, implanted another, larger version and performed a laminectomy, in which he removed part of the plaintiff's vertebrae.

Although Dr. Elias believed the improvised operation had been successful, plaintiff awoke in severe pain and reported substantial immobility in all her extremities. Thereafter, Dr. Elias determined that plaintiff had suffered a spinal cord injury at some point during the procedure. Plaintiff's neurological condition has only slightly improved since. While she has regained some use of her arms and her right leg, she continues to experience unremitting pain in both of her upper extremities and the left side of her body; spasms, hypersensitivity and other abnormal neurological symptoms; bladder and bowel problems; and blurred vision in her left eye.

Plaintiff filed an action against Dr. Elias, alleging battery as the result of his proceeding with the laminectomy without her consent. That action was settled in July, 2004. Plaintiff also filed a products liability action against Medtronic, Inc. ("Medtronic") in the Circuit Court for Albemarle County, which Medtronic removed to federal court. On August 31, 2004, and at the request of the parties, the presiding District Judge entered an order pursuant to FED. R. CIV. P. 41(a) dismissing the case without prejudice to renew upon certain conditions, namely that the plaintiff would reinstitute any action in the United States District Court for the Western District of Virginia, that she would join no additional non-diverse parties, and that she would not seek a trial by jury. *See* Case No. 3:04CV00014 (Moon, J.), Docket # 31.

On December 17, 2004, plaintiff instituted this action against Medtronic. In her

Complaint, she alleges that the percutaneous lead implanted in her body on August 20, 2003 and found damaged on November 12, 2003 (hereafter referred to as "the Lead") was defective and unreasonably dangerous, that defendant breached its implied warranty of merchantability in that the Lead was not reasonably fit for the purpose for which it was intended, and that the defendant was negligent in manufacturing the Lead. Additionally, she alleges that, as a direct and proximate result of the discovery of the damaged and defective Lead, Dr. Elias performed a medically necessary surgery to explant the Lead and replace it with a larger Specify lead, which procedure caused plaintiff's spinal cord injury.

**THE FACTUAL RECORD**

***The Medtronic Itrel 3 Spinal Cord Stimulation System***

The Itrel 3 Spinal Cord Stimulation System ("the System") is a prescription-level medical device designed to assuage chronic pain by electronically blocking the transmission of pain signals from a patient's nerves to the brain. Defendant's Motion for Summary Judgment, Appendix ("Def's App."), Exhibit 28. The System consists of three basic parts: (1) a thin polyurethane insulated lead wire[1] with imbedded stimulating electrodes at its tip; (2) a battery-powered electronic pulse generator; and (3) a lead extension line that connects the lead to the generator.[2] *Id.* Several Medtronic leads are compatible with the Itrel 3 System, but only two of those are relevant to this case. The first is the Model 3487A "PISCES-Quad" percutaneous lead and the second is the Model 3998 "Specify" lead (also called a "surgical" lead).

The primary difference between the percutaneous lead and the surgical lead is the size of

[1] Each lead, when manufactured, is roughly 13 inches long and 0.05 inches in dianmeter.

[2] Lead extensions are manufactured roughly 26 inches long and 0.105 inches in diameter.

their electrode tips. While the electrodes at the tip of a Medtronic percutaneous lead are nothing more than tiny metal bands wrapped around the tightly coiled inner wire, such that the electrode tip is no thicker than the lead itself, the electrodes in a Medtronic surgical lead are imbedded in a paddle shaped tip that is substantially larger than the lead wire. Def's App., Exh. 24-25. Given the smaller size of the percutaneous lead, a surgeon wishing to implant such a lead need only insert the lead wire into the subcutaneous space adjacent to the spine and thread it upward to the location of the vertebrae where stimulation is desired. Def's App., Exh. 32. The implantation of the larger surgical lead, on the other hand, requires the removal of a portion of the target vertebrae through a medical procedure known as a laminectomy. *Id.*

Once installed, both percutaneous and surgical leads operate the same way. Each is connected to an electronic pulse generator (usually implanted in a patient's abdomen) by way of a lead extension line. Def's App., Exh. 26-27. At the end of the lead extension is a two-pronged plug which fits a receptacle in the generator, much like a switch or socket in a home electrical circuit. *Id.* To fasten the lead to the lead extension, the end of the lead must be inserted into a "connector" at the tip of the lead extension and then a series of set-screws must be tightened. Def's App., Exh. 31-32. After the circuit is established, a silicone protective boot is placed over the connector and sutured to prevent bodily fluids from contaminating the connection. Def's App., Exh. 31. The fully operational system looks like a long, wire-thin snake with either a tube- or paddle-shaped head containing stimulating electrodes (depending on the type of lead), an aerodynamic bulge at its mid-section (the connector), and a semi-circular, plug-like tail (the generator).

Since the operational environment of the Itrel 3 system is the spine and abdominal tissue

of the human body, Medtronic sought to minimize its size and maximize its flexibility and durability. Def's App., Exh. 32 and 36. For instance, the insulated wire lead is made from malleable plastic and metallic materials to permit a wide range of patient movement after implantation. However, the lead is somewhat delicate and subject to failure. Def's App., Exh. 32-36. In its technical literature, Medtronic warns surgeons tasked with installing the system not to bend or kink the lead, not to tie a suture directly to the lead, not to force the lead into the epidural space, and not to over-tighten the set-screws in the connector when attaching the lead to the lead extension. Def's App., Exh. 33. The surgeon is instructed to employ only rubber-tipped bayonet forceps to manipulate the lead and is warned to be extremely careful when using sharp instruments around the lead to avoid damage. *Id.* Medtronic's Patient Management Guidelines for Clinicians and the Patient Information Booklet also warns patients with implanted stimulation systems against excessive or repetitive bending, twisting, bouncing and stretching, as such movements may shift the position of the lead and impede proper stimulation or cause damage to the lead itself. Def's App., Exh. 35-36.

***Plaintiff's Pre-Operational Medical History***

In February of 1998 plaintiff sustained an employment-related back injury. Def's App., Exh. 2, Plaintiff's Answers to Interrogatories ("P's Int. Ans.") at 11. Since that time, plaintiff has suffered chronic pain and numbness and has been totally disabled from work. P's Int. Ans. at 3-5. In July of 1998, plaintiff underwent surgery to correct a herniated disc, and then for the next four years she participated in a host of pain management therapies, none of which substantially improved her condition.[3] Def's App., Exh. 9-11. In February of 2003, plaintiff was referred to

[3] Plaintiff was diagnosed with cervical spondylosis, a chronic degenerative condition of the cervical spine. Def's App., Exh. 9.

Dr. Elias, a neurosurgeon at the University of Virginia Medical Center, to explore implantable spinal cord stimulation therapy. Def's App., Exh. 11. At that time, Dr. Elias was very familiar with the Medtronic spinal cord stimulation system and had performed numerous implantation surgeries using Medtronic percutaneous leads. Def's App., Exh. 38, Deposition of William Jeffrey Elias, M.D. ("Elias Dep.") at 45. Subsequent to examination, in April of 2003, Dr. Elias informed plaintiff that she was a suitable candidate for the implantation of the spinal cord stimulation system, and plaintiff elected to pursue this new course of treatment. Def's App., Exh. 11; Elias Dep. at 19-21; Pl's Int. Ans. at 5-6.

***The August and September Surgeries***

Prior to the November 12, 2003 surgery during which she sustained her spinal cord injury, plaintiff underwent three invasive procedures to implant and modify a Medtronic spinal cord stimulation system. On August 20, 2003, Dr. Elias conducted a trial implantation of the subject Lead in plaintiff's spinal column. After inserting the Lead into the epidural space at the C-7 vertebrae and threading it upward to C-2, Dr. Elias attached the tail end of the Lead to a temporary lead extension by way of a connector, tightened the connector set-screws, and then placed a protective silicone boot over the connector and sutured the boot in place. Def.'s App. 12-13; Elias Dep. at 35-36, 38, 158. When plaintiff reported significant pain relief, Dr. Elias decided that the system was working properly. Elias Dep. at 37, 158-160. He then anchored the Lead to the cervical fascia, a layer of connective tissue located over the muscle in the spine, and closed the wound to finish the surgery. *Id.*

On August 27, 2003, and after a successful one-week trial period, plaintiff was readmitted to the Hospital to undergo the surgical implantation of the remaining components of the Itrel 3

system–an electronic generator and a permanent lead extension. Def's App., Exh. 15. In this procedure, Dr. Elias reopened the cervical incision, removed the protective boot over the connector, loosened the connector set-screws, and removed the tail end of the Lead from the temporary connector. Elias Dep. at 163. After explanting the temporary connector and lead extension, Dr. Elias implanted a generator into plaintiff's abdomen and attached it to a permanent lead extension. Def's App. Exh. 15-16. He then inserted the tail end of the Lead into the permanent connector at the tip of the lead extension in precisely the same manner as he had done in the August 20, 2003 surgery. *Id.*; Elias Dep. at 64. Following this surgery, plaintiff reported a fifty percent reduction in pain. Def's App., Exh. 17.

Thereafter, plaintiff developed an infection in the tissue surrounding the generator implantation site. On September 24, 2003, she reentered the Hospital to have the generator removed and her surgical wound cleaned. Dr. Elias began the surgery by making an incision over the connector site and cutting the lead extension just below the connector. Def's App., Exh. 19. He then reopened the incision over the generator, removed it and the severed a portion of the lead extension, and irrigated both wounds with bacitracin and saline. *Id.* Having consulted with plaintiff, Dr. Elias elected to leave the Lead in place until the infection healed and a new generator and lead extension could be implanted. Def's App., Exh. 18-19.

On November 3, 2003, Dr. Elias saw plaintiff to check her wound. Def's App., Exh. 20. He noted some drainage near the area of the connector and determined that the wound would not heal completely until the Medtronic system was revised. *Id.* Dr. Elias and plaintiff discussed the prospect of explanting the Lead and connector and starting afresh at a later date, but neither the doctor nor plaintiff preferred this remedial avenue. Instead, it was agreed that Dr. Elias would

implant a new generator at a different site in plaintiff's abdomen and redirect the tail of the Lead to that location. *Id.*; Elias Dep. at 176, 181-182. This was the purpose of the November 12, 2003 surgery.

***The November 12 Surgery***

On November 12, 2003, plaintiff again was admitted to the Hospital under the care of Dr. Elias. Dr. Elias was assisted in the surgery by Adam S. Kanter, M.D., a resident neurosurgeon and Robin J. Hamill-Ruth, M.D., an anesthesiologist with a background in pain management and experience in the implantation of Medtronic spinal cord stimulation systems. Def's App., Exh. 21-22; Deposition of Robin J. Hamill-Ruth ("Hamill-Ruth Dep.") at 9-10. Also present at the surgery for observation purposes were two Medtronic sales representatives, John Mark Fisher and Mark Thompson. Fisher and Thompson remained outside the sterile field about five feet away from the operating table and played no role in the surgery. Deposition of John Mark Fisher ("Fisher Dep.") at 13-14.

As it is that different people often observe the same event differently, there are minor inconsistencies in the accounts of the November 12, 2003 surgery given by the various participants and spectators. Dr. Elias recalled that the resident, Dr. Kanter, commenced the surgery by prepping the patient and opening the cervical incision by which Dr. Elias originally implanted the Lead. Elias Dep. at 180-182. Dr. Elias revealed that he stepped out of the operation room prior to the cervical incision and returned after the incision had been opened. *Id.* at 181-182. Dr. Kanter could not recall whether he performed the cervical incision. Deposition of Adam S. Kanter ("Kanter Dep.") at 25. Fisher specifically recalled Dr. Elias making the cervical incision prior to stepping out of the operating room to answer a telephone call. Fisher

Dep. at 12. Thompson could not remember which doctor opened the cervical incision or when exactly Dr. Elias left the room. Deposition of Mark Thompson ("Thompson Dep.") at 15-16. Everyone agrees, however, that, in the earliest stage of the surgery, Dr. Elias exited the operating room for a brief period. Elias Dep. at 180-184; Fisher Dep. at 12; Thompson Dep. at 16.

It is further undisputed that, during Dr. Elias' absence, Dr. Kanter tugged on the Lead either with his hands or with rubber forceps, or both. Fisher Dep at 15; Thompson Dep. at 17. Fisher recalled that Dr. Kanter pulled on the exposed portion of the Lead with one hand in a repetitive pull and release fashion for some ten to fifteen seconds. Fisher Dep. at 15-16. Thompson remembered Dr. Kanter attempting to pull the lead extension up and out of the flank incision toward plaintiff's head with a pair of forceps. Thompson Dep. at 17. Both Fisher and Dr. Elias specifically recalled that the flank incision was made *after* Dr. Elias reentered the room. Fisher Dep. at 19-20; Elias Dep. at 185. Fisher also related making a comment to Thompson about the danger to the integrity of the Lead posed by Dr. Kanter's tugging. Fisher Dep. at 16-17. Fisher's comment was based upon his experience with leads that had been damaged in the past by tugging or being pulled tight. *Id.*

After Dr. Elias returned to the operating room, he explored the flank incision, likely with the assistance of a magnifying glass, in order to disconnect the Lead from the connector. Def's App., Exh. 21; Elias Dep. at 185-186. When he cut the suture ligatures and pulled the protective boot back from the tail end of the lead, Dr. Elias observed that the Silastic insulation over the coiled wires in the lead had been breached, the coils stretched, and one of the wires broken around the point where the Lead entered the connector. Def's App., Exh. 21; Elias Dep.77-78. At his deposition, Dr. Elias testified that the Lead's insulation was "open down to the wire" but

did not appear to have been cut, torn back, or peeled back. Elias Dep. at 187-188. Dr. Elias opined that the opening in the insulation was more akin to a "split." Elias Dep. at 188. Dr. Elias testified that the damage to the Lead could not have been visible until the protective boot was removed because the boot "would have covered it." Elias Dep. at 187. Of the two Medtronic observers, only Thompson was situated in such a position to view the damaged Lead. From a distance of five feet, he believed the Lead insulation to be frayed, and he could not see the split about which Dr. Elias testified. Thompson Dep. at 20-22; Fisher Dep. at 23. Thompson recalled that the damage was visible even before Dr. Elias removed the protective boot from over the connector. Thompson Dep. at 22.

Dr. Elias determined that the Lead was not salvageable and explanted it from plaintiff's spinal column along with the connector and the remaining portion of the lead extension. Dr. Elias Dep. at 79, 189-91. It is clear from Dr. Elias' testimony that he had three options at this point in the procedure: First, he could revive plaintiff and discuss the medical options available in order to determine her preferred course of further treatment. Elias Dep. at 80; Hamill Ruth Dep. at 34. Second, he could implant another PISCES-Quad percutaneous lead in place of the damaged Lead and proceed with the implantation of the generator and the lead extension, such that at the conclusion of the surgery the stimulation system would be complete. Elias Dep. at 192-193; Hamill-Ruth Dep. at 29. Third, he could implant a "resume" surgical lead or a Specify surgical lead in place of the damaged percutaneous Lead by way of a laminectomy and then proceed with the implantation of the remainder of the stimulation system as planned.[4] Elias Dep. at 80. Dr. Elias elected to proceed with the operation and to implant a Specify surgical lead in place of the

[4] The difference between a resume and a Specify lead is that the resume lead has one channel of electrodes, whereas the Specify lead has two channels.

explanted percutaneous Lead. Def's App., Exh. 21; Elias Dep. at 79-80. In Dr. Elias' view, the advantages of a Specify lead over another percutaneous lead were twofold: (1) the Specify electrode would be easier to place in the same radiographic position as the original percutaneous electrode because fibrosis (scar tissue) had likely formed around the original Lead in the epidural space and could impede the reinsertion of a new percutaneous lead; and (2) the Specify lead would improve the overall coverage of the Medtronic stimulation system, and further diminish plaintiff's pain, because of the larger size of its electrode tip. Elias Dep. at 193-194.

According to Dr. Elias' postoperative report and his independent recollection, the laminectomy and the implantation of the Specify surgical lead above plaintiff's spinal cord proceeded with "much difficulty," due to fibrosis in the epidural space at the location of the original electrode. Def's App., Exh. 21; Elias Dep. at 194-195. After removing some of this scar tissue, Dr. Elias managed to thread the surgical electrode through the epidural space to the same radiographic position as the original percutaneous electrode. Def. App., Exh. 21; Elias Dep. at 83-84. At the conclusion of the surgery, Dr. Elias believed the procedure had been successful. Elias Dep. at 194-195. He did not become aware of plaintiff's postoperative complications until she regained consciousness and complained of severe pain and immobility in her extremities. Elias Dep. at 97-99. He immediately suspected that plaintiff had suffered a spinal cord injury, but this diagnosis was not confirmed until Dr. Elias received the results of a subsequent MRI, which provided "visible evidence of a spinal cord injury." Elias Dep. at 107-112.

***The Aftermath of the November 12 Surgery and Medtronic's Response***

After Dr. Elias explanted the damaged percutaneous Lead from plaintiff's spinal cord, the Lead was discarded and never has been recovered. Elias Dep. at 89, 91; Fisher Dep. at 27-28;

Thompson Dep. at 31. Dr. Elias testified that it is not his policy to save the components of explanted lead systems even though he is aware that Medtronic will not process a warranty claim without the submission of the damaged component. Elias Dep. at 89-90, 172-174. By the same token, Dr. Elias revealed that he would have taken appropriate steps to preserve the Lead had he been aware that plaintiff would make a warranty claim. Elias Dep. at 174.

A question has been raised here concerning whether either one or both of the Medtronic representatives present at the November 12 surgery had an opportunity to retrieve the damaged lead from the waste container, and, if so, whether they had a duty to secure the Lead in order to investigate into the cause of plaintiff's spinal cord injury or as material evidence in potential litigation. *Id.* As a factual matter, it is undisputed that neither Fisher nor Thompson attempted to retrieve the Lead. Fisher admitted that, at the time of the surgery, he did not believe that Medtronic's warranty covered a lost or misplaced lead. Fisher Dep. at 28-30. Fisher stated that he opted not to retrieve the Lead for two reasons: (1) Dr. Elias never suggested that the Lead might be defective, and (2) it was the responsibility of the Hospital or the plaintiff, as owner of the damaged Lead, to preserve it for any future warranty claim. Fisher Dep. at 30-31. Thompson testified that, in his experience as a Medtronic representative, there had been occasions when he had asked physicians to return products to him so that the products could be tested for warranty purposes. Thompson Dep. at 33. However, Thompson denied that he had any responsibility to retrieve the damage Lead for investigative purposes, notwithstanding a Medtronic policy requesting the return of all explanted Medtronic products for disposal. Thompson Dep. at 34-35. In Thompson's view, the damaged Lead was "hospital property still (sic)." Thompson Dep. at 35.

It is clear from the record that both Fisher and Thompson were in the Hospital when they

became aware that plaintiff had suffered postoperative complications. Fisher learned of plaintiff's plight from an anesthesiologist some twenty to thirty minutes after the procedure was completed. Fisher Dep. at 34. The anesthesiologist informed Fisher that plaintiff did not have feeling in her lower extremities. Fisher Dep. at 34-35. Thompson recalled less detail from the day in question but remembered learning of plaintiff's complications "later that day" when he inquired of Dr. Elias about when the doctor wished Thompson to activate the generator. Thompson Dep. at 29. According to Thompson, Dr. Elias responded that he should wait a couple of days because plaintiff was experiencing some problems. *Id.* Upon closer examination of the phrase "later that day," Thompson testified that he learned of plaintiff's complications after her procedure but prior to the next case, which, according to his experience, was likely to have been anywhere from twenty minutes to two hours. Thompson Dep. at 30. The following colloquy then occurred:

> Q. After you found out this lady had some postop complications, did you consider trying to get ahold of that lead?
>
> A. No.
>
> Q. Did Dr. Elias and you have any conversation about maybe it would be a good idea to get the lead?
>
> A. No, not that I remember.
>
> Q. Should you have asked for that lead, sir?
>
> A. Probably.
>
> Q. Why do you said probably?
>
> A. In retrospect, I wish I had.
>
> Q. Why is that?

A. Because now there's a problem and a question about the lead.

*Id.* at 31-32.

Plaintiff also took the confidential deposition of Vicki L. Schreiber, a medical device reporting specialist for Medtronic, subject to a Protective Order entered by the court on May 24, 2004.[5] Plaintiff's Opposition to Defendant's Motion for Summary Judgment ("P's Opp."), Exh. P. Schreiber's principal duty as a Medtronic employee is to ensure Medtronic's complete compliance with administrative regulations promulgated by the federal Food and Drug Administration ("FDA") to govern, *inter alia*, the handling of medical devices such as the Itrel 3 Spinal Cord Stimulation System. Deposition of Vicki L. Schreiber ("Schreiber Dep.") at 4-5. Schreiber testified that one of the FDA regulations with which Medtronic seeks to comply is codified at 21 C.F.R. § 803. Schreiber Dep. at 9. Section 803 requires a manufacturer of medical devices to report to the FDA within 30 days any incident in which information is available to the manufacturer that reasonably suggests that one of its devices may have cause or contributed to death or serious injury. P's Opp., Exh. Q. As a matter of policy, Medtronic maintains compliance with § 803 by submitting to the FDA what is called a "MedWatch Report." Schreiber Dep. at 9. Medtronic submitted a MedWatch Report in plaintiff's case in which Medtronic implicated the Specify lead, not the damaged percutaneous Lead, in plaintiff's neurological injury. Schreiber Dep. at 9-10, 26. No supplemental MedWatch Report concerning the damaged Lead was ever submitted. Schreiber Dep. at 25-26.

[5] The undersigned is aware of the confidential nature of Ms. Schreiber's deposition and will disclose in this opinion the testimony contained therein only to the extent that such disclosure is necessary to permit a full and fair adjudication of the issues presented by Medtronic's motion for summary judgment. *See* May 24, 2004 Protective Order ¶ 13.

Schreiber also testified that, under applicable FDA regulations, Medtronic has a duty to investigate and determine the cause of serious injuries that involve their medical devices. Schreiber Dep. at 20. Schreiber was then specifically asked whether Medtronic ever requested that the Hospital find and return the damaged Lead. *Id.* She replied in the negative and explained that, in her view, "there was no reason to believe that a serious injury had occurred with that lead." *Id.* Schreiber denied that Medtronic has a duty under FDA regulations to seek the return of a medical device involved in a serious patient injury, instead stating that "[i]t is the responsibility of the user to return it." Schreiber Dep. at 21. According to Schreiber, only when an allegedly damaged or defective product is returned to the company by a user will Medtronic analyze it to determine product quality and reliability. Schreiber Dep. at 29.

***Plaintiff's Expert Evidence***

According to Plaintiff's Identification of Expert Witnesses on Product Defect and Causation, she intends to rely upon the expert testimony of Douglas W. Townsend, PhD, a forensic and metallurgical engineer, on the question of product defect, the expert testimony of Dr. Elias, the neurosurgeon who performed the November 12 surgery, and David C. Urquia, M.D., an orthopedic surgeon, on the questions of causation and medical necessity. Def's App., Exh. 3. Medtronic does not dispute the qualifications of Dr. Elias but does challenge the qualifications of both Drs. Townsend and Urquia, as well as the probative value and admissibility of their opinions. The undersigned will summarize what the record shows of both their qualifications and their opinions, in that order. The undersigned then will set forth Dr. Elias' opinion about causation and medical necessity.

A. <u>Douglas W. Townsend, PhD</u>

*Professional Qualifications*

Dr. Douglas W. Townsend holds three post-secondary degrees in metallurgy and metallurgical engineering, including a master's degree from the Massachusetts Institute of Technology and a doctorate from Queen's University. Def's App., Exh. 46. Dr. Townsend is registered as a professional engineer in Canada and states that his areas of expertise are materials failure analysis, corrosion of metals, weld failures, thermal effects on metals and stress/impact metal failures. *Id.* He testified during his deposition that his specialty is forensic engineering. Deposition of Douglas W. Townsend, PhD ("Townsend Dep.") at 5.

Dr. Townsend has been retained as a forensic engineering expert in over 80 cases in state and federal courts in the United States. Townsend Dep. at 8. Dr. Townsend testified that, as a forensic engineer, he has investigated failures involving, *inter alia*, furniture, vehicles, equipment, heating systems, cooling systems, and building systems, and also biological technologies such as mandible plates, knee joints, bone plates and spinal plates. Townsend Dep. at 10. With specific relevance to this case, Dr. Townsend testified that four years ago he investigated the failure of a spinal stimulator that had a "leak in the sheath." Townsend Dep. at 11.

Dr. Townsend testified that he could not recall any case in which he was retained as an expert but excluded from testifying by the court on grounds that his methodology failed the threshold test set forth in *Daubert v. Merrill Dow Pharmaceuticals*, 509 U.S. 579 (1993). Townsend Dep. at 16. Defense counsel then inquired of Dr. Townsend if he remembered a case from the United States District Court for the District of Maryland called *Linda May Wells v. Ford Motor Company*, in which the judge ruled that the doctor was unqualified to testify as an expert

about the failure of a seat-belt mechanism because his opinion did not meet certain *Daubert* criteria. *Id.* Dr. Townsend recalled the case but did not recall having been excluded from testifying for legal reasons. Townsend Dep. at 17.

When asked by defense counsel, Dr. Townsend testified that he had not received any special educational training or field experience with implantable spinal cord systems. Townsend Dep. at 19. Dr. Townsend admitted that what knowledge he has of the percutaneous Lead at issue in this case he derived directly and exclusively from his review of Medtronic product literature in preparation for this case. Townsend Dep. at 20. However, Dr. Townsend testified that he has extensive experience with the materials out of which the Lead is constructed, namely urethane plastic and iridium metal. *Id.*

*Opinion as to Product Defect*

Dr. Townsend intends to testify that "[t]he lead that was removed from [plaintiff] could not have been damaged according to the descriptions made by the various observers by tugging on it 10 to 12 inches from the connector unless it was defectively manufactured." Def. App., Exh. 45 at 4. Dr. Townsend based his opinion entirely upon (a) the deposition testimony of Dr. Elias, Mark Fisher and Mark Thompson relating to Dr. Kanter's tugging and the damage to the original Lead, and (b) a one-time tensile pull test conducted on an exemplar Medtronic PISCES-Quad percutaneous lead at a laboratory testing facility in Hatfield, Pennsylvania on August 18, 2004. Def. App., Exh. 45. Dr. Townsend gathered that both Thompson and Fisher had observed the resident, Dr. Kanter, tugging on the lead while Dr. Elias was out of the room. *Id.* at 1. He then inferred from the combination of their perspectives that the resident must have been tugging on the lead some 10 to 12 inches from the connector and insulating boot which had yet to be

exposed.[6] *Id.* Since the damaged Lead had not been preserved for inspection, Dr. Townsend attempted to design a test to simulate the forces he thought Dr. Kanter likely applied to the lead during the medical procedure. *Id.* at 2. Dr. Townsend employed a tensile pull test by which he sought to determine "the type and extent of damage that could possibly occur to an exemplar lead if that lead were pulled away from the connector." *Id.*

The tensile test was fairly simple. Dr. Townsend placed the tip of the exemplar lead provided by Medtronic in the upper jaw of a Tinius Olsen 10,000 tensile testing machine and the connector end of the lead in the bottom jaw of the machine. *Id.* The jaws initially were separated by a distance of 9 inches. *Id.* During the first pull cycle, the jaws were slowly pulled apart an additional 1.7 inches over a 15-minute period of time. The machine exerted 1.7 pounds of tensile force on the lead, which resulted in the lead stretching by 1 inch without any evidence of breakage. *Id.* During the second pull cycle, the jaws of the machine slowly were pulled apart until they reached a total separation distance of 14.2 inches, with 3.44 pounds of tensile force being exerted on the lead, at which point the polyurethane insulation broke and pulled back about four inches from the connector end. *Id.* at 2-3. In a third pull cycle, the jaws of the machine again were pulled apart until separated 23.7 inches by a maximum pull force of 3 pounds, at which point three of the four coiled wires broke at the base of the connector under the protective boot and unraveled at various lengths. *Id.* at 3. Dr. Townsend summarized the results of the test as follows: First, the exemplar lead's polyurethane insulation did not break until it was stretched to

[6] It is unclear from Dr. Townsend's report whether, in determining this distance, he relied upon Dr. Townsend's testimony that Dr. Kanter tugged at the lead from the flank incision or Fisher's testimony that Dr. Kanter tugged at the lead from the cervical incision. One may hypothesize that Dr. Townsend gave greater weight to Fisher's recollection, since the flank incision was directly over the connector and tugging from that location would have occurred closer to the connector than 10 to 12 inches.

over 150% of its original length, and when it did break, it did not stay in place but retracted "like a fallen down sock." *Id.* Second, the coiled wires of the exemplar lead did not break until they were stretched to 250% of their original length, and when they did break, they exited the boot and stayed in plain view. *Id.* From this tensile pull test, Dr. Townsend concluded:

> The differences in the appearance of the failure of the lead that was reported during [plaintiff's] operation and the observed failure of the exemplar lead are remarkable. It appears that it would not be possible to breach the polyurethane sheath and break only one electrical wire by tugging on the lead some 10 to 12 inches from the connector and only stretch and break one wire under the insulator [read "connector] unless the lead had been defectively manufactured. If Dr. Kantor (sic) had tugged on a properly manufactured lead some 10 to 12 inches from the connector hard enough to break a wire that lead should have been stretched from a length of about 13 inches to a new length of about 27 inches which should have been noticed by all of the several observers. It also appears necessary to break the polyurethane sheath in half and tug it away from the connector before it is possible to tug hard enough on the sheath to break a wire in a properly manufactured lead. It appears to be very difficult to tug on a lead and only break one wire in a properly manufactured lead.

*Id.* at 3-4.

Defense counsel questioned Dr. Townsend extensively about the specifications of the tensile pull test and its sufficiency for determining product defect. In the course of his testimony, Dr. Townsend admitted that the speed of the Tinius Olsen machine was set by the operator but opined that the speed of the machine did not affect the outcome of the test. Townsend Dep. at 50-52. Dr. Townsend acknowledged that if Dr. Kanter tugged on the Lead with a pair of forceps in the direction of plaintiff's head, the lead could have become crimped or compressed at the point of contact with the forceps. Townsend Dep. at 174. Dr. Townsend further admitted that if the Lead was twisted while tugging with forceps, the Lead could have been subjected to a torsion force, a compression force and a tensile force at a given point on the lead. Townsend Dep. at 175. He conceded that he did not duplicate any of those forces in his tensile pull test. *Id.* Dr.

Townsend's explanation was that he did not have "a box full of leads" or "more time" to examine numerous variations of forces. Townsend Dep. at 158-160.

In addition, Dr. Townsend acknowledged that his test pull lasted "over half an hour" in order to allow him time to make observations, while, according to the evidence in the case, Dr. Kanter tugged on the lead for 10 to 15 seconds. Townsend Dep. at 201-202. It was Dr. Townsend's view that a jerking force repeated numerous times would produce the same failure as the steady, consistent tensile force he applied using the Tinius Olsen machine. Townsend Dep. at 204-205. Later in his deposition, however, the following colloquy between defense counsel and Dr. Townsend occurred:

> Q. So assuming no defect you employ a jerking force -- you would get a different result than employing the controlled tensile force that you employed?
>
> A. No. Basically, you don't know what result you're going to get on a jerking force.
>
> Q. Until you test it?
>
> A. Well, the only way to -- if you want to test the jerking force, get Dr. Canter (sic) to start jerking on various leads and see what his results are. You know, the only one person that can replicate the jerking that -- that Dr. Canter was exerting is Dr. Canter.
>
> Q. And, therefore, you did not replicate the jerking force Dr. Canter applied, to state the obvious?
>
> A. No.

Townsend Dep. at 213-214.

Dr. Townsend was also asked to address whether forces *beyond* those involved in the November 12, 2003 surgery could have caused the observed damage to the Lead. Specifically, he was asked whether forces in the human body–compressive, torsional, or bending–could have

caused the damage. Dr. Townsend could not rule out those other causes without an opportunity to "examine the specific evidence," namely, the failed Lead. Townsend Dep. at 87-89. Again defense counsel pursued the inquiry as follows:

> Q. So, are you telling me that you can't eliminate the possibility that forces applied to the lead between 8/20 and 11/12 caused the alleged damage? You can't eliminate those possibilities?
>
> A. Based on a reasonable engineering opinion, which is more certain than less certain, that is less certain.
>
> Q. And that means you cannot eliminate alternative causes between 8/20 and 11/12 to a reasonable degree of engineering certainty?
>
> A. Not without evidence to show that possibility. Now, there's no evidence at all; therefore, there's no evidence to indicate any possibility other than a manufacturing defect.

Townsend Dep. at 115-116.

In the end, Dr. Townsend was asked repeatedly whether he could specify when and how the damage to the Lead occurred. He finally replied: "I can't give you a time or date." Townsend Dep. at 248. When then asked, "Do you know what caused the damage?" Dr. Townsend responded: "Absent the opportunity to examine the evidence, no." *Id.*

B. David C. Urquia, M.D.

*Professional Qualifications*

David C. Urquia, M.D., is a 1983 graduate of the University of Virginia Medical School who did his internship and residency in general and thoracic surgery at Duke University. Def's App., Exh. 48. Dr. Urquia is board certified in orthopedic surgery and is licensed to practice in North Carolina and Virginia. *Id.* He practices medicine at the West End Orthopedic Clinic in Richmond, Virginia and teaches classes in orthopedic surgery at the Medical College of Virginia.

*Id.* Since 2000, Dr. Urquia has been retained as an expert witness in at least 114 cases. Deposition of Dr. David C. Urquia ("Urquia Dep.") at 12.

Dr. Urquia testified that the only formal exposure he has had to a spinal cord stimulation system was at a medical conference in the late 1990s in which a physician gave a presentation of implantable neurostimulators. Urquia Dep. at 10-11. Dr. Urquia admitted that he has never implanted a neurostimulation system such as Medtronic Itrel 3 System, nor has he specifically consulted any patient about the implantation of such a system. Urquia Dep. at 12-13. Moreover, Dr. Urquia conceded that he is unaware whether a laminectomy procedure is required to implant a percutaneous or a surgical lead in the cervical area of the spine. Urquia Dep. at 15-16. By the same token, Dr. Urquia stated that, prior to reviewing the Medtronic product literature, he possessed some basic knowledge of the trial and permanent implantation procedures for spinal cord stimulation systems. Urquia Dep. at 14-15.

*Opinion as to Causation and Medical Necessity*

Based on his review of plaintiff's medical records, Dr. Urquia opined that: (1) "[t]he surgery that was performed on 11/12/03 was the direct cause of [plaintiff's] spinal cord injury[,]" and (2) "there was reasonable medical necessity to perform the surgery in question," that is, the "lead change." Def's App., Exh. 47. The following exchanges relating to causation took place between defense counsel and Dr. Urquia during his deposition:

> Q. You said [plaintiff's partial cord injury] occurred in the surgery. What happened in the surgery which caused the damage?
>
> A. I don't think anybody knows exactly what happened. All I can say or probably anybody can say is that sometime between the start of the operation and when the patient woke up some type of neurological damage occurred, but probably no one can know exactly when in the surgery it happened.

Q. Dr. Elias testified that in his opinion it occurred during the laminectomy procedure.

A. Okay.

Q. Would you agree or disagree with that?

A. That is possible. Again, my answer stands. I don't think anybody can know with absolute certainty, with reasonable medical certainty exactly when and how the injury occurred. The laminectomy, part of the procedure would be considered the most invasive part of that operation. It certainly is -- it's a logical conclusion, but I don't know when the injury actually occurred.

. . . .

Q. Could putting a patient to sleep cause this type of injury?

A. People have had injuries to their spinal cord being put to sleep under general anesthesia.

Q. So in short, you have absolutely no idea how this injury occurred?

A. I can only give you speculation. I can run through a differential list of possibilities but I cannot tell you with any reasonable degree of medical probability exactly what event produced the spinal cord injury, or maybe there was more than one event – maybe more than one event during the surgery that could have produced it.

. . . .

Q. Was it unlikely that the injury occurred before the percutaneous lead was removed before the laminectomy began?

A. That is possible.

Q. Is it unlikely?

A. I don't know. I can't give you an idea of the relative certainty of any of the possibilities. I couldn't put a percentage of (sic) it to say whether it's likely or unlikely. All I can say is that is one possibility.

Urquia Dep. at 46-49.

In addition, it was Dr. Urquia's view that a medically necessary treatment is "a treatment

or procedure that if withheld would more than likely lead to a failure of treatment [for a] particular patient . . . [I]n other words, the patient's clinical course would suffer in some way if that particular treatment or procedure was withheld." Urquia Dep. at 18-19. On the other hand, he opined that an "elective procedure," that is, a non-emergency procedure, "can be considered medically necessary or not," depending on whether "the patient would have . . . some deterioration in their final outcome" if the course of treatment at issue was not pursued. Urquia Dep. at 19, 24. Upon further inquiry, Dr. Urquia conceded that he had never received any education or training about the meaning of the term "medical necessity" and was aware of no course that teaches specific legal definitions of the term to practicing orthopedic or spinal surgeons. Urquia Dep. at 17. Dr. Urquia stated that his definition of medical necessity derived from his experience as "a practicing physician that has had more than [his] fair share of interactions with medical/legal situations." *Id.*

The doctor then applied this working definition of "medical necessity" and "elective procedure" to the case at hand. He acknowledged that each of the procedures performed by Dr. Elias in the course of plaintiff's spinal cord stimulation treatment were "elective." Urquia Dep. at 25-26. However, when asked by defense counsel whether he agreed with Dr. Elias's view that the November 12 implantation of the surgical lead in place of the damaged percutaneous Lead was elective and thus *not* medically necessary, Dr. Urquia attempted to distinguish his view of medical necessity from that of Dr. Elias, essentially disagreeing with Dr. Elias' more absolute distinction between elective and medically necessary procedures. Urquia Dep. at 27-28. In response to a later hypothetical question posed in an effort to clarify the doctor's view of medical necessity when multiple options are available to achieve essentially the same result for the

patient, the following colloquy occurred:

> Q. Let me ask you this question: Say the neurosurgeon was to perform implant surgery and had the option to use a percutaneous lead or a specified lead. Okay? He could choose either and there were different medical reasons, pros and cons for using either one. Would you say that use of the percutaneous lead in that scenario was medically necessary?
>
> A. Yes. I think if the standard of care for implanting these devices, standard technique as recognized by neurosurgeons around the country, that placement of a percutaneous lead was proper technique for this procedure, then, yes, it would be considered medically necessary.
>
> Q. And if the same doctor, for other legitimate reasons, opted on the specified lead, you would say use of the specified lead was medically necessary?
>
> A. Yes, sir.
>
> Q. So that's how you would define medically necessary?
>
> A. Right. I don't think "medically necessary" refers to the device or which lead he chooses. I mean, I think the term "medically necessary" is the process. It's the process of producing this clinical result. And if the doctor has the choice of several different devices to achieve that result, then that would fall into the definition of medical necessity.

Urquia Dep. at 32-33.

*Supplemental Opinion as to Causation Submitted by Affidavit*

In opposition to Medtronic's motion for summary judgment, plaintiff submitted a supplemental affidavit from Dr. Urquia dated June 9, 2005. In that affidavit Dr. Urquia acknowledges his prior testimony relating to his inability to say when and how the injury occurred," yet he declares after further reflection and review of plaintiff's medical record that he is able to offer a clearer opinion on the etiology, or medical cause, of plaintiff's spinal cord injury. P's Opp. Ex. R at 2. In is his more recent and apparently more informed view Dr. Urquia stated that "within a reasonable degree of medical probability that, in light of the difficulty that

Dr. Elias admittedly experienced in his placement of the surgical stimulating lead in [plaintiff's] cervical spine due to the presence of a surprising amount of scar tissue, her spinal cord injury occurred during either the performance of the cervical laminectomy, the explantation of the percutaneous lead or in the implantation of the surgical lead." *Id.* at 2-3.

C. Dr. Elias, M.D.

*Opinion as to Causation and Medical Necessity*

Dr. Elias opined that plaintiff's spinal cord injury was not caused by the removal/explantation of the damaged percutaneous Lead. Elias Dep. at 193. Instead, he believed that plaintiff's injury was "a contusion from the [replacement] electrode." Elias Dep. at 107-108. It is unclear, however, whether a contusion from the replacement electrode was his exclusive view of causation. Dr. Elias went on to say that he "was also concerned with other etiologies, including ischemia,[7] things like that." Elias Dep. at 108. When plaintiff's counsel pursued the inquiry with the question: "Did you rule out the others, other than spinal cord contusion?" Dr. Elias gave no direct answer. *Id.* Again he was asked: "And that spinal cord injury continued at this point in time, at least believed was caused by a contusion during the 11-12 surgery?" Elias Dep. at 112. His response was: "Ischemia, contusion. I ruled blood clot out." *Id.*

Dr. Elias also testified that the implantation of the surgical lead was not medically necessary:

> Q. You testified on direct that the implantation of the percutaneous lead was an elective surgery; is that correct?
>
> A. That's true.

[7] Ischemia can be described as inadequate blood flow to a part of the body, caused by constriction or blockage of the blood vessels supplying it. *See* Oxford Reference: Concise Medical Dictionary (1990, 3rd ed.), Oxford University Press: Market House Books.

Q. Implantation of the specified lead was, likewise, an elective surgery, is that correct?

A. Yes, that's true.

Q. And elective as opposed to what; a medically-necessary surgery?

A. Yeah, or emergency.

. . . .

Q. And is it fair to say that using the terminology we talked about earlier, making the decision to implant a Specify lead was not medically necessary at that point?

A. Yes.

Q. And my question was confusing. You're saying yes, it was not medically necessary?

A. That's true.

Elias Dep. at 151-152, 193.

*Supplemental Opinion as to Medical Necessity Submitted by Affidavit*

With Dr. Urquia, Dr. Elias supplemented his discovery testimony on medical necessity with an affidavit dated March 16, 2005. After recapitulating the course of plaintiff's treatment prior to the November 12 surgery, he concluded the following:

> Implantation of [plaintiff's] percutaneous lead in August 2003 and implantation of her Specify cervical lead in November 2003 were elective surgeries. Neither of these procedures was an emergency surgery. To the extent that "medically necessary surgery" is considered synonymous with "emergency surgery," neither of these procedures were medically necessary. However, each of these surgeries was a procedure that a reasonably prudent neurosurgeon would have offered as a reasonable and acceptable method of treatment for [plaintiff's] pain and, based on that standard, each of these procedures was medically necessary.

P's Opp., Exh. S at 3.

**SUMMARY JUDGMENT STANDARD**

Summary judgment is proper only "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact . . . ." FED. R. CIV. P. 56©. In deciding summary judgment "the evidence of the nonmoving party is to be believed and all justifiable inferences must be drawn in its favor." *American Legion Post 7 v. City of Durham*, 239 F.3d 601, 605 (4th Cir. 2001). A "mere scintilla" of proof, however, will not prevent entry of summary judgment. *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 251 (1986); *Retail Services, Inc. v. Freebies Publishing*, 364 F.3d 535, 542 (4th Cir. 2004). The question is "not whether there is literally no evidence, but whether there is any upon which a jury could properly proceed to find a verdict for the party producing it, upon whom the onus of proof is imposed" *Anderson*, 477 U.S. at 251.

**CONTENTIONS OF THE PARTIES**

***Defendant's Arguments in Favor of Summary Judgment***

Medtronic moves for summary judgment on the grounds that plaintiff has put forth insufficient evidence to make out a *prima facie* case of either product defect or proximate causation. With respect to product defect, Medtronic first establishes the legal standard for proof of manufacturing defect under theories of implied warranty of merchantability and negligence. Under *Logan v. Montgomery Ward & Co.*, 216 Va. 425 (1975), in order to prevail under either theory, a plaintiff must show "(1) that the goods were unreasonably dangerous either for the use to which they would ordinarily be put or for some other reasonably foreseeable purpose, and (2) that the unreasonably dangerous condition existed when the goods left the defendant's hands." 216 Va. at 428. To prove negligence, a plaintiff also must demonstrate that the product defect resulted from the manufacturer's failure to exercise "due care" in the manufacturing process.

*Chestnut v. Ford Motor Co.*, 445 F.2d 967, 969 (4th Cir. 1971).

Second, Medtronic sets forth plaintiff's burden of proof under Virginia law for establishing product defect when the allegedly defective product has been lost, destroyed or repaired prior to litigation. "[I]n order to prove defect, a plaintiff who cannot produce or identify the specific item which he claims is responsible for his injuries must present evidence tending to negate *all* reasonable alternative explanations of his injuries." *Lemons v. Ryder Truck Rental, Inc.*, 906 F.Supp. 328, 332 (W.D. Va. 1995)(emphasis added); *accord Wilder v. Toyota Motor Sales, U.S.A., Inc.*, 23 Fed. Appx. 155, 157 (4th Cir. Dec. 17, 2001)(unpublished opinion); *Bolling v. Montgomery Ward & Co.*, 930 F.Supp. 234, 238 (W.D. Va. 1996). Medtronic asserts that this heightened burden of proof applies even when the plaintiff is not at fault for the disappearance of direct evidence of defect. *See Bolling*, 930 F.Supp. at 238.

The damaged percutaneous Lead at issue here was discarded by the Hospital's medical staff on November 12, 2003 and never recovered. Accordingly, Medtronic asserts that, even construing the record in a light most favorable to plaintiff's case, she quite simply has failed to put forward and cannot advance sufficient evidence to negate any, let alone *every*, reasonable alternative explanation for the failure of that Lead other than product defect. Medtronic contends that, absent product defect, the Lead could have weakened and failed from ordinary use during the three months it was implanted in plaintiff's body. In the same way, the Lead could have been damaged during any of the August or September surgeries–that is, when it was initially implanted by Dr. Elias on August 20, 2003, when it was hooked up to the lead extension and the original generator on August 27, 2003, or when the generator and part of the lead extension were removed on September 24, 2003 due to infection in the surrounding tissue. Finally, the Lead

could have been, and most likely was, damaged by Dr. Kanter's ten to fifteen second tugging exercise which took place during Dr. Elias' absence from the operating room. In Medtronic's view, plaintiff's failure to rebut these possible explanations with positive evidence entitles it to judgment as a matter of law.

In addition, Medtronic proposes three reasons why plaintiff's circumstantial expert evidence of product defect (i.e. the testimony of Dr. Townsend that Dr. Kanter's tugging could not have caused the damage to the Lead absent product defect) is inadmissible, and thus is insufficient to avert summary judgment. First, Medtronic argues that Dr. Townsend is unqualified under Fed. R. Evid. 702 to testify about the failure of a Medtronic spinal cord system because he lacks independent experience with such systems. Second, citing *Featherall v. Firestone Tire and Rubber Co.*, 219 Va. 949 (1979), Medtronic contends that the reconstructive test supporting Dr. Townsend's opinion was not conducted under conditions substantially similar to the conditions of the November 12 surgery, and as such, his opinion must be excluded. Third, Medtronic argues that Dr. Townsend's methodology and resulting opinion are unreliable under the standard set forth in *Daubert,* 509 U.S. at 579 and *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999), because Dr. Townsend (a) conducted the single pull tensile test without a written protocol, (b) based his test conditions on imprecise deposition testimony about Dr. Kanter's tugging, and (c) did not attempt to reproduce the test to assure the propriety of his results.

With respect to causation, Medtronic contends that, even if plaintiff were to prove a defect in the damaged percutaneous Lead, she has failed to present evidence demonstrating that the defect proximately caused her spinal cord injury. Medtronic cites *Banks v. City of Richmond*,

232 Va. 130 (1986) as setting forth the standard for determining proximate cause under Virginia law: "'The proximate cause of an event is that act or omission which, in natural and continuous sequence, unbroken by an efficient intervening cause, produces the event, and without which that event would not have occurred.'" 232 Va. at 135 (quoting *Beale v. Jones*, 210 Va. 519, 522 (1970)). Said another way, a person (or corporate entity) is liable only for the natural and foreseeable consequences of his (its) negligence. *Id.* In addition, under Virginia law "in a products liability action, proof of causation must ordinarily be supported by expert testimony because of the complexity of the causation facts." *McCauley v. Purdue Pharm. L.P.*, 331 F.Supp.2d 449, 464 (W.D. Va. 2004).

Medtronic argues that plaintiff's expert evidence on the issue of causation is at best equivocal and cannot support a reasonable inference of proximate cause. Medtronic attacks plaintiff's expert evidence on two fronts. First, Medtronic argues that neither Dr. Elias nor Dr. Urquia can state with a reasonable degree of medical certainty that plaintiff's spinal cord injury occurred *after* Dr. Elias discovered and determined to replace the damaged Lead. Since it is undisputed in the record that the damaged Lead *itself* did not cause plaintiff's injury, Medtronic believes that the uncertainty of Drs. Elias and Urquia concerning the etiology, or medical cause, of plaintiff's injury is dispositive. Second, Medtronic contends that, even if a jury could somehow reasonably infer from the testimony of plaintiff's experts that her injury occurred after the discovery of the damaged Lead, the decision of Dr. Elias to proceed with the implantation of the surgical lead by way of laminectomy was not medically necessary and therefore constitutes a superseding cause, which breaks the chain of causation as a matter of law. On this latter point, Medtronic asks the court to consider the similar case of *Porter v. Pfizer Hosp. Products Group,*

*Inc.*, 783 F.Supp. 1466 (D. Me. 1992), in which the court entered judgment against the plaintiff because it found that the doctor's decision to replace plaintiff's damaged and allegedly defective artificial hip with a different and inferior model constituted a "clear supervening cause" of his injuries.

Finally, and almost as an addendum to its voluminous arguments regarding product defect and proximate cause, Medtronic articulates two additional reasons why the court should grant summary judgment against plaintiff. First, Medtronic argues that plaintiff has failed to advance any evidence showing that Medtronic did not exercise ordinary care during the manufacturing process which produced the damaged percutaneous Lead. Thus, under the standard set forth in *Chestnut v. Ford Motor Co.*, plaintiff's negligence claim cannot survive as a matter of law. Second, Medtronic contends that plaintiff's warranty claims must fail because Medtronic's Limited Warranty of the damaged Lead disclaimed all implied warranties and conditioned coverage upon the return of the alleged damaged Lead.

***Plaintiff's Arguments in Opposition to Summary Judgment***

With respect to product defect, plaintiff replies to Medtronic's argument that Dr. Townsend's testimony is inadmissible under the *Featherall* standard by arguing that an exact replication of the actual event of Dr. Kanter's tugging is experimentally impossible, given that (a) the Lead was attached to a live human body when it was likely damaged, and (b) the record does not contain a precise description of the act of tugging from which to assess the appropriate forces to incorporate into any reconstructive experiment. Plaintiff contends that Dr. Townsend's tensile pull test fairly approximated the most obvious force that Dr. Kanter put on the lead, a straight-line tensile force, and demonstrated that such a force would not cause the type and extent of

damage to a properly manufactured percutaneous lead that Dr. Elias observed on November 12, 2003.

Plaintiff argues, moreover, that its evidence of defect would have been much more substantial if either or both of Medtronic's representatives present at the November 12 surgery had retrieved the damaged Lead from UVA's medical staff after it was discarded. Plaintiff argues that the record is clear that both Fisher and Thompson saw the damage to the Lead in the operating room before it was removed from plaintiff's spine and were present in the Hospital when they learned of plaintiff's severe postoperative complications. Plaintiff argues that both Fisher and Thompson were trained to respond in accordance with Medtronic's duties to the FDA under 21 C.F.R. § 803.50 to report and investigate any incident of serious injury or death involving one of Medtronic's devices, and that their inaction on November 12 constitutes a spoliation of material evidence under *Vodusek v. Bayliner Marine Corp.*, 71 F.3d 148 (4th Cir. 1995) and *Wolfe v. Virginia Birth-Related Neurological Injury Compensation Program*, 40 Va. App. 565 (2003). Plaintiff preemptively argues that Medtronic may not defend against her charge of spoliation by claiming that Fisher and Thompson reasonably believed the Lead had been damaged by Dr. Kanter's tugging and therefore were under no obligation to attempt to retrieve the Lead. In plaintiff's estimation, the legal duty imposed upon Medtronic and its agents to preserve the Lead is absolute and not subject to the prerogative of Fisher and Thompson. Plaintiff, therefore, asks the court to impose upon the defendant, by legal sanction, an inference of product defect sufficient to defeat summary judgment.

Finally, with respect to causation, plaintiff argues that, under Virginia law, the defective Lead need not be the sole cause of plaintiff's spinal cord injury. Rather, it is sufficient that the

defendant's action contributed to the final result or set in motion other agencies which in turn produced or contributed to the final result. *See Von Roy v. Whitescarver*, 197 Va. 384, 393 (1955). Plaintiff contends that Dr. Elias' discovery of the damaged Lead and subsequent determination to remove it and implant a new surgical lead were both events set in motion by a defect in the Lead, which led to plaintiff's injury, not superseding events which broke the chain of causation as a matter of law. *See* Virginia Model Jury Instructions Civil Instruction No. 5.010 (VMJI)("[a] superseding cause breaks the chain of events so that the defendant's original negligent act is not a proximate cause of the plaintiff's injury.").

In addition, plaintiff defends Dr. Urquia's testimony as to both causation and the medical necessity of the laminectomy and implantation of the surgical lead. With respect to the etiology of plaintiff's spinal cord injury, plaintiff contends, first, that Dr. Urquia stated in his deposition that her injury occurred between the beginning and the end of the November 12 surgery, and, second, that the doctor's recently executed affidavit clarifies, but does not contradict, that testimony, such that his opinion as to the cause of plaintiff's injury is now obvious. Plaintiff also contends that Dr. Urquia's testimony concerning the medical necessity of the laminectomy and implantation of the surgical lead is an unmistakable part of the record and is corroborated by testimony from Dr. Hamill-Ruth who indicated that, given the possibility of scar tissue buildup, the replacement of a percutaneous lead with another of like kind "can be technically very, very difficult, and requires -- or it is safer to do the open procedure." Dep. of Hamill-Ruth at 33.

***Medtronic's Argument Rebutting Plaintiff's Charge of Spoliation***

In its reply brief, Medtronic again questions the legal sufficiency of plaintiff's evidence of product defect and causation and then goes on to respond to plaintiff's allegations of spoliation.

On the latter point, Medtronic contends that it had no duty under the FDA regulations to retrieve the Lead, only to report to the FDA any incident of serious injury or death involving one of its devices. Moreover, Medtronic reminds the court that plaintiff has never asserted that the original Lead caused her injury but has rather that the laminectomy and implantation of the surgical lead damaged her spinal cord. Thus, in Medtronic's view, the FDA regulations imposed no duty whatsoever with respect to the original Lead, only with respect to the surgical lead, which duty Medtronic satisfied. Finally, Medtronic contends that during and after the November 12 surgery the Lead remained the property of plaintiff and the Hospital, such that Medtronic neither had a duty to retrieve the Lead itself nor a right to demand that the Hospital return the Lead to its care.

**FINDINGS, CONCLUSIONS AND RECOMMENDATIONS OF LAW**

Under either a negligence theory or a warranty theory, a plaintiff must show: "'(1) that the goods were unreasonably dangerous either for the use to which they would ordinarily be put or for some other reasonably foreseeable purpose, and (2) that the unreasonably dangerous condition existed when the goods left the defendant's hands.'" *Garrett v. IR Witzer Co.*, 258 Va. 264, 267-68 (1999) (quoting *Logan v. Montgomery Ward & Co., Inc.*, 216 Va. 425, 428 (1975)). In addition, to sustain a negligence claim, a plaintiff must also show that the product defect resulted from the defendant's failure to exercise "due care." *Chestnut*, 445 F.2d at 969.

This case presents two questions concerning product defect and a third concerning proximate cause. The questions are: (1) whether Dr. Townsend's opinion is admissible to prove that the damaged Lead was dangerously defective at the time it left Medtronic's hands; (2) if this evidence is excluded, whether plaintiff is entitled to an inference of product defect because Medtronic failed to preserve the damaged Lead as material evidence in a potential litigation; and

(3) whether the testimony of Drs. Elias and Urquia is sufficient to establish a *prima facie* case of causation concerning plaintiff's spinal cord injury and the medical necessity for the subsequent laminectomy and implantation of the surgical lead. The undersigned will address these issues seriatim. Then, the undersigned will address whether plaintiff has put forth evidence sufficient to establish a *prima facie* case of negligent manufacture and, finally, whether Medtronic expressly disclaimed implied warranties including that of merchantability in the Limited Warranty provided with the Lead.

## I. *Dr. Townsend's Tensile Test and the* Featherall *Standard* [8]

The undersigned recognizes that, in *Featherall*, the Virginia Supreme Court for the courts of the Commonwealth addressed the admissibility of an experimental test designed to reproduce a failure of an allegedly defective product. The court held that "[t]he results of experiments are not admissible in evidence unless the tests were made under conditions which were the same or substantially similar in essential particulars to those existing at the time of the accident." 219 Va. at 959 (citing *Habes v. Madigan*, 213 Va. 485, 487 (1973); *Richards v. Commonwealth*, 107 Va. 881, 893 (1908)). The court then applied this standard to exclude from evidence the results of an

[8] As an initial matter, Medtronic argues that Dr. Townsend is not qualified to testify as an expert with respect to spinal cord implantation systems because of his historical lack of experience with such systems. The undersigned, however, believes Dr. Townsend is qualified. *See* The Factual Record at 14-15. An expert witness need only possess "knowledge, skill, experience, training, or education," which will assist the trier of fact in understanding the evidence or determining a fact in issue in a case. FED. R. EVID. 702. Dr. Townsend is a professional forensic engineer with a PhD in metallurgy and extensive practical experience. For the past seventeen years, he has investigated failures of engineering systems. Although it is true that Dr. Townsend is not a biomedical engineer and has never investigated the physical failure of a spinal cord stimulation system, he is familiar with the components of such a system both as a matter of general knowledge and by review of Medtronic's product literature. In the undersigned's view, he qualifies as an expert in forensic engineering.

experimental test designed to replicate the conditions under which a syrup tank in a soda fountain machine ruptured under high pressure, ejecting its lid into the air with explosive force and injurious consequences. The court reasoned that neither of two experiments submitted by the plaintiff as evidence of product defect was substantially similar to the actual event. In the case of the first experiment, the test lid was immersed in cola syrup during testing when the actual lid, prior to the accident, had been subjected to cleansing solution for some time. In the case of the second experiment, a 1/32 inch difference existed between the test lid and the actual lid, which, the expert testified, "could affect the separation" of the lid from the syrup tank. *Featherall*, 219 Va. at 365.

By referring to *Featherall*, the undersigned has not failed to consider that questions of admissibility in diversity cases ordinarily are procedural and are controlled by the Federal Rules of Evidence or any other federal statutory or decisional authorities addressing the admissibility of evidence in the federal courts. The exception lies where the evidence offered for admission constitutes an essential element of a state law claim in a diversity action, in which case state law authority controls. The importance of *Featherall*, therefore, does not lie in its controlling effect on a decision here. Rather, the questions here are whether the tests or experiments performed in this products liability case are sufficiently similar to the events giving rise to the action as to make them relevant and material for consideration by the trier of fact, or whether, even if relevant, the probative value thereof is outweighed by any prejudicial effect. FED. R. EVID. 401-403

Here, Dr. Townsend's test, namely a single tensile pull test on an exemplar percutaneous lead, ostensibly was designed to replicate the physical effect of Dr. Kanter's tugging on the

alleged damaged Lead manufactured by Medtronic. Dr. Townsend formulated the test parameters and procedure for the test knowing the description given Dr. Kanter's actions by Fisher and Thompson, the two Medtronic representatives present at the November 12 surgery. Dr. Townsend then compared the results of his experiment to the deposition testimony of Dr. Elias who inspected the original Lead under magnification at the time the damage was discovered. Dr. Townsend's tensile pull experiment took place in a laboratory setting and employed an industry-standard tensile testing machine, the Tinius Olsen 10,000.

In the undersigned's view, Dr. Townsend's reasoning and experimental methodology are both "scientifically valid" and pass muster for *Daubert* purposes. However, the circumstances under which Dr. Townsend conducted his experiment differ in a number of ways from those under which the evidence shows Dr. Kanter tugged on the original Lead on November 12, 2003 as to raise a question of substantial similarity, thus the relevance and prejudice of permitting the trier of fact to consider this evidence.

First, and as conceded by Dr. Townsend, tugging a wire-shaped object attached to an immovable base, either with hands or with forceps, may subject the object to more than one type of force at the point of attachment. Dr. Townsend, himself, admitted that the original Lead could have experienced bending, torsion, crimping and/or compression forces along with a tensile force (pulling) at any one point in the Lead, since the evidence is that Dr. Kanter tugged the Lead toward plaintiff's head as Thompson described. Dr. Townsend further admitted that, while his tensile test subjected the exemplar lead to a single tensile force along a straight line for many minutes, the actual sequence of tugging included both pull and release, at an unknown cycle speed, over a period of ten to fifteen seconds. He attempted to excuse facial discrepancies

between the experiment and the actual events as described in the evidence by citing the high cost of an exemplar lead, the significant time required to conduct multiple experiments with a variety of incident forces, the need to observe the process of deformation and destruction of the Lead, and, though a bit tongue-in-cheek, the unavailability of a cadaver containing an implanted lead upon which Dr. Kanter might reenact his operative procedures for experimental purposes. Townsend Dep. at 200-203, 209.

Most certainly Dr. Townsend encountered legitimate practical difficulties impeding his efforts to reproduce the conditions of the November 12 surgery in an experimental environment. After all, the law does not require experimental exactitude, for the presence of some variables between the test or experiment and the conditions giving rise to the cause of action may not affect the relevance or trustworthiness of the experiment. Yet here, Dr. Townsend acknowledged that a number of factors likely could have altered his test results, namely (a) conceivable forces other than tensile force to which the original Lead may have been subjected at the lead/connector interface at the time of failure, including bending, compression, crimping, and torsion; (b) the pull and release sequence Kantor's tugging; and (c) the abbreviated time over which Dr. Kanter tugged at the original Lead. Just as the diameter of the syrup tank lid and the liquid present in the tank were essential conditions of the explosion at issue in *Featherall*, the type, tempo and duration of force are essential to the act of tugging at issue here.[9]

[9] Medtronic also argues that the tensile pull test was not substantially similar to the actual event because Dr. Townsend did not (a) suture the lead to the connector like Dr. Elias, (b) position the upper clamp of the Tinius Olsen machine over the lead end of the connector in a manner approximating the surgical stress, or attempt to recreate conditions surrounding around the exemplar lead that existed during surgery, such as elevated temperature and acidity from body fluids and friction from bones and ligaments in the spine. Def's Motion for Summary Judgment at 33-34. It is the undersigned's considered view that these dissimilarities would impact the weight to be given Dr. Townsend's evidence rather than its admissibility.

In the end, the undersigned is of the view that there are substantial dissimilarities between the subject surgery and Dr. Townsend's tests. Moreover, the reconstructive imprecision demonstrated in this case is not overcome or excused by Dr. Townsend's offer of inadequate financial resources and insufficient time to conduct testing. In other words, Dr. Townsend's single tensile pull test falls short of the standard set in *Featherall*, and it equally fails to provide evidence that is relevant and trustworthy to be considered by the trier of fact in this federal court. Consequently, the undersigned RECOMMENDS that the District Court exclude consideration of Dr. Townsend's expert testimony concerning his test and its results.

## II. *Medtronic's Duty to Preserve Material Evidence and Spoliation*

### A. Medtronic's Duty to Preserve the Lead

Plaintiff's argues that Medtronic had a legal duty to preserve the Lead in conjunction with discharging its duty as a manufacturer of medical devices, under 21 C.F.R. § 803.50, to report any incident of death or serious injury in which one of their devices may have been a contributing cause. [10] However, plaintiff cites no controlling or persuasive authority suggesting that the regulations establishing Medtronic's duty to report also allow for the imposition of a sanctions

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[10] Entitled "Manufacturer Reporting Requirements," 21 C.F.R. § 803.50(a) reads in pertinent part:

> *Reporting Standards*. Device manufacturers are required to report within 30 days whenever the manufacturer receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer . . . [m]ay have caused or contributed to a death or serious injury . . . .

21 C.F.R. § 803.50(b)(2) continues:

> Manufacturers are also responsible for conducting an investigation of each event. evaluating the cause of the event.

for any preserve medical devices from spoliation. The undersigned has found no such prevailing precedent in the Fourth Circuit.[11]

Rather, the Fourth Circuit Court of Appeals has recognized an independent duty to preserve material evidence:

> The duty to preserve material evidence arises not only during litigation but also extends to that period before litigation when a party reasonably should know that the evidence may be relevant to anticipated litigation. If a party cannot fulfill this duty to preserve because he does not own or control the evidence, he still has an obligation to give the opposing party notice of access to the evidence or of the possible destruction of the evidence if the party anticipates litigation involving that evidence.

*Silvestri v. General Motors Corp.*, 271 F.3d 583, 591 (4th Cir. 2001)(internal citations omitted).[12] Therefore, the specific questions this court must answer appear to be 1) whether Medtronic's representatives should have anticipated litigation concerning the damaged Lead; and, if so, 2) whether any obligation to give plaintiff notice of access to the evidence or of the possible destruction of the evidence required them to take steps to retrieve and preserve the Lead after they learned of plaintiff's injury. The undersigned believes that both questions should be

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[11] Medtronic argues that it *did* satisfy the regulatory requirements of 21 C.F.R. § 803.50 when it reported to the FDA an incident of serious injury involving the replacement surgical lead implanted in plaintiff by Dr. Elias on November 12. Medtronic maintains that it had no duty to report anything about the damaged percutaneous Lead because it has never received any information reasonably suggesting that the damaged Lead caused or contributed to plaintiff's spinal cord injury. Furthermore, the record does not disclose whether Medtronic ever conducted an investigation into the event of plaintiff's injury. In any event, it is the undersigned's view that Medtronic's duties to the FDA do not provide a basis for imposing sanctions under the spoliation doctrine.

[12] Plaintiff cites *Wolfe v. Virginia Birth-Related Neurological Injury Comp. Program*, 40 Va. App. 565 (2003), in support of its spoliation theory. Again, the evidentiary effects of any spoliation are governed by federal and not state law. *See Hodge v. Wal-Mart Stores, Inc.*, 360 F.3d 446, 449-50 (4th Cir. 2004). Consequently, *Silvestri v. General Motors Corporation*, 271 F.3d 583, 591 (4th Cir. 2001), set forth the appropriate standard.

answered in the affirmative.

It is undisputed that two Medtronic employees, Fisher and Thompson, attended the November 12, 2003 surgery in their representative capacities on behalf of the defendant. Both Fisher and Thompson admitted that they were present in the operating room on behalf of their employer, thus in furtherance of Medtronic business, albeit ostensibly as observers and not as active participants in the surgical procedure itself. Fisher Dep. at 8; Thompson Dep. at 9. There is no dispute that Thompson observed the damaged Lead before Dr. Elias explanted it from plaintiff's spine. There also is no dispute that, while Fisher did not directly observe any damage to the Lead, he overheard Dr. Elias state that there were "lead fractures;" discuss the damage with the resident, Dr. Kanter; and declare that the Lead was unusable. Fisher Dep. at 22-25. In addition, Fisher and Thompson were present when Dr. Elias both removed the Lead from the plaintiff and undertook to perform the subsequent laminectomy and implantation of a surgical lead. Fisher Dep. at 31; Thompson Dep. at 25-28. After Dr. Elias explanted the damaged Lead, both Fisher and Thompson observed the doctor transfer the Lead to the scrub nurse for disposal, though both disavowed knowledge of what the scrub nurse then did with the Lead. Fisher Dep. at 27-28, 31; Thompson Dep. at 31-32. Between twenty minutes and two hours later, and while both still were in the Hospital, Fisher and Thompson learned of the nature and initial extent of plaintiff's postoperative complications. Both are trained in and understand the value of recapturing a damaged Medtronic product, if only for warranty purposes, but neither made any effort in this case to retrieve, or have Hospital personnel retrieve, the damaged Lead.

The undersigned is of the view that both of Medtronic's employees reasonably should have known that it was likely that the damaged Lead would become the subject of a claim. In

other words, litigation could have been anticipated, the kind that not only could involve the treating physicians, but one involving their company's medical device. Objectively, Fisher and Thompson were in a better position than anyone else associated with plaintiff's surgery to assess the need for preservation of the device, if for no other reason than to protect the interests of their employer when questions arose about the cause of plaintiff's subsequent surgery and resulting injury. Applying *Silvestri*, the undersigned concludes that Fisher and Thompson had a duty, Medronic, to warn plaintiff of the impending destruction of the Lead, even though they did not possess or exert control over the product at the time.[13] Moreover, considering plaintiff's physical status and the imminent threat that the Lead would be discarded, Metronics, by and through its two employees, had a duty to take reasonable steps to preserve the Lead until someone on plaintiff's behalf could intercede. Whether the attempt would have been successful is not the issue. The point is that either Fisher or Thompson, or both, easily could have made inquiry and undertaken efforts to retrieve or preserve the device from disposal.

B. Determining the Appropriate Sanction

The imposition of a sanction for spoliation of evidence is an inherent power of federal courts, though it is one limited to that which is necessary to redress conduct that abuses the judicial process, and the decision to impose such a sanction is governed by federal law. *Silvestri*, 271 F.3d at 590*; Hodge v. Wal-Mart Stores, Inc.*, 360 F.3d 446 (4th Cir.2004) One of those sanctions is to impose an adverse inference against the party having a duty to preserve the

[13]*See Infant C. v. Boy Scouts of America, Inc.*, 239 Va. 572, 578 (1990)("[N]otice to an agent is legally imputed to its principal.")

evidence. *Hodge*, 360 F.3d at 449.[14] Certainly, the evidence in this case cannot support a conclusion that either Fisher or Thompson, or both, acted in bad faith in failing to pursue retrieval or preservation of the Lead. By the same token, the eventual destruction of the Lead has substantially prejudiced the plaintiff. *See* P's Opp. at 8, 12, 14. The undersigned believes that plaintiff is entitled to the benefit of an adverse inference against Metronics on the issue of product defect as the result of its employee's conduct, and so RECOMMENDS its imposition by the presiding District Court.

As a consequence, the inference would have the effect of establishing a *prima facie* case of product defect notwithstanding the absence of expert evidence to that effect. Genuine issues of material fact relating to product defect, therefore, have been presented, and the defendant's motion for summary judgment, to this extent, should be DENIED. It is so RECOMMENDED.

**III. *Proximate Causation***

In order to recover, the plaintiff must produce expert *prima facie* evidence establishing that the defective lead proximately caused or contributed to her spinal injury. *See Banks*, 232 Va. at 135. In Virginia, "'[t]he proximate cause of an event is that act or omission which, in natural and continuous sequence, unbroken by an efficient intervening cause, produces the event, and

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[14] The Fourth Circuit Court of Appeals has made it clear that the severe sanction of dismissal of a claim, defense or case as a whole is justified only when the court can conclude either "(1) that the spoliator's conduct was so egregious [e.g. deliberate or taken in bad faith] as to amount to a forfeiture of his claim, or (2) that the effect of the spoliator's conduct was so prejudicial that it substantially denied the defendant the ability to defend the claim." *Silvestri*, 271 F.3d at 593; s*ee Cole v. Keller Industries, Inc.*, 132 F.3d 1044, 1047 (4th Cir. 1998). A less severe sanction could be drawing an adverse inference against the spoliator upon which a jury could premise judgment absent evidence preponderating to the contrary. *See Hodge*, 360 F.3d at 450; *Hartford Insurance Co. v. American Automatic Sprinkler Sys.*, 201 F.3d 538, 543-44 (4th Cir. 2000); *Vodusek v. Bayliner Marine Corp.*, 71 F.3d 148, 156 (4th Cir. 1995).

without which that event would not have occurred.'" *Id.* (quoting *Beale v. Jones*, 210 Va. 519, 522 (1970)). Proof of proximate cause in a products liability case must be supported by expert testimony. *McCauley v. Purdue Pharmaceuticals L.P.*, 331 F.Supp.2d 449, 464 (W.D. Va. 2004). In this particular case, plaintiff also must produce expert evidence demonstrating a nexus between the alleged defective lead and any medical necessity of the subsequent surgical procedures leading to her injury in order to establish, at the very least, that the lead was a contributing cause for the surgery.

Plaintiff designated two experts to testify as to causation, Dr. Elias, the treating neurosurgeon who performed the November 12, 2003 surgery, and Dr. Urquia, a specially retained expert on spinal surgery.[15] Medtronic has argued strenuously that, when questioned about the cause of plaintiff's injury, neither could identify with any degree of medical certainty the precise time during the November 12 operation when plaintiff's injury occurred. Moreover, Medtronic has pointed out that, at one point, Dr. Elias testified that the laminectomy and implantation of the surgical lead were elective procedures, thus raising questions relating to

[15] As to Dr. Townsend, Medtronic contends, as an initial matter, that Dr. Urquia is unqualified to testify as an expert with respect to causation and medical necessity. The undersigned disagrees. Dr. Urquia is a board certified practitioner and medical school-level professor of orthopedic surgery. His current clinical practice involves both surgical and office clinical, and Dr. Urquia exercises hospital emergency room privileges. Urquia Dep. at 9. Although he has never performed or participated in the surgical implantation of a spinal cord stimulation system, he has extensive general experience with the management of chronic pain and has referred patients to specialists who implant spinal cord stimulation systems. Urquia Dep. at 13. Moreover, he has had some professional exposure to Medtronic's implantable spinal cord stimulation systems and, prior to reviewing Medtronic's product literature in preparation for this case, he had a basic working knowledge of the methodology for surgical implantation of such systems. In the undersigned's view, Dr. Urquia's knowledge, skill, experience, training and education qualify him to testify as to both causation and medical necessity in this case and RECOMMENDS that the presiding court find likewise.

medically necessity and intervening or superceding cause. In Medtronic's view, such equivocation by plaintiff's own experts should result in summary judgment for the defendant on the issue of causation.

Plaintiff, on the other hand, has reminded the court that, for all of Dr. Urquia's inability to pinpoint a precise time plaintiff's injury occurred, he clearly opined that (a) plaintiff sustained her injury at some point during the November 12 surgery, and (b) the laminectomy and surgical lead implantation by Dr. Elias were medically necessary due to the damage to the original Lead and the need to continue plaintiff's treatment plan under the circumstances which then existed. Plaintiff also points out that Dr. Elias specifically opined that plaintiff 's injury was the result of "a contusion from the [replacement] electrode." Elias Dep. at 108. Finally, plaintiff offered Dr. Urquia's explanation of his testimony in a recently filed affidavit as a clarification of, opposed to a change in his testimony concerning the cause of plaintiff's injury. There, Dr. Urquia offers that, "in light of the difficulty that Dr. Elias admittedly experienced in his placement of the surgical stimulating lead in [plaintiff's] cervical spine due to the presence of a surprising amount of scar tissue, her spinal cord injury occurred during either the performance of the cervical laminectomy, the explanation of the percutaneous lead or in the implantation of the surgical lead." Certainly Dr. Urquia's affidavit, which does not appear necessarily inconsistent with his deposition testimony, was offered after the close of discovery, and to that extent, is untimely for summary judgment purposes. However, on balance, the undersigned agrees with plaintiff that the deposition testimony of Drs. Elias and Urquia is sufficient to get the question of causation

before the jury.[16]

In assessing plaintiff's evidence of causation, this court must ask whether a reasonable jury, could conclude, without speculation, surmise or conjecture, that the condition of the Lead caused Dr. Elias to perform a series of unplanned but medically necessary surgical procedures to remove the damaged lead and implant a replacement lead, during which subsequent procedure plaintiff sustained her spinal cord injury. The record discloses at least six instances from which a trier of fact could answer that question in the affirmative, namely: (1) Dr. Urquia's unequivocal testimony that plaintiff's spinal cord injury occurred during the course of the November 12 surgery; (2) Dr. Urquia's testimony that the laminectomy was the most invasive part of the surgery; (3) Dr. Elias' testimony that the implantation of the surgical lead was accomplished with "much difficulty" due to scar tissue in the epidural space; (4) Dr. Urquia's testimony that the laminectomy and implantation of the surgical lead were reasonably medically necessary, and (5) Dr. Elias' testimony that, in his view, plaintiff's injury resulted not from the explanation of the original Lead but rather from a contusion to the spinal cord caused by the replacement electrode implanted during the subsequent surgery.

That does not mean there is other evidence, or the lack thereof, which may lead

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[16] Medtronic argues that Dr. Urquia's affidavit contradicts his deposition testimony and, thus, warrants exclusion from consideration on summary judgment. *See Rohrbough v. Wyeth Lab., Inc.*, 916 F.2d 970, 976 (4th Cir. 1990); *Barwick v. Celotex Corp.*, 736 F.2d 946 (4th Cir. 1984). The undersigned disagrees. The affidavit was submitted at the eleventh-hour and, apparently, for the sole purpose of opposing summary judgment. Plaintiff has not offered any reason why the information in Dr. Urquia's affidavit was not brought out during his deposition. *See Callas v. Trane CAC, Inc.*, 776 F.Supp. 1117, 1119 (W.D. Va. 1990). For summary judgment purposes Dr. Urquia's deposition testimony should stand or fall on its own. Notwithstanding the fact that the affidavit was filed after the close of discovery, it does not necessarily mean that Dr. Urquia should not be barred from explaining to the jury the testimony he already has offered in his pretrial testimony should his veracity be put in issue during trial.

reasonable people to conclude otherwise, for the undersigned cannot determine whether the jury will "connect the dots" precisely in the manner sought by plaintiff. Yet, the reasonable jury could do so.[17]

## IV. *Remaining Issues*

A. Sufficiency of Plaintiff's Evidence of Negligence in Manufacturing

Under Virginia law, a products liability plaintiff asserting negligence in manufacturing must prove "*not only* that the product was dangerously defective at the time that it left the defendant's hands, *but also* that the defect was the result of the defendant's failure to exercise due care." *Chestnut*, 445 F.2d at 969 (emphasis added). In this case, plaintiff alleges that Medtronic negligently manufactured the percutaneous Lead that Dr. Elias explanted during the November 12 surgery. Complaint ¶ 10; P's Opp. at 11. Medtronic argues, however, that "Plaintiff has not offered any expert testimony or other evidence concerning the applicable standard of care to which Medtronic should be held with regard to its manufacturing process, and indeed, has not offered any testimony or evidence concerning how Medtronic deviated from such standard." Def's Motion for Summary Judgment at 49. The undersigned agrees.

Of the three experts proffered by plaintiff in support of her case, Dr. Townsend was designated to address product defect while Drs. Elias and Urquia were designated to address

[17]Along with her memorandum opposing summary judgment, plaintiff submitted a supplemental affidavit from Dr. Elias addressing his view of the term "medical necessity." Dr. Elias certainly testified that the lead replacement surgery on November 12, 2003 was elective, not emergency, and his affidavit does not contradicted that testimony. The affidavit simply acknowledges that there are different definitions of medical necessity in the field of medicine. The one mentioned in his deposition seems to address whether the procedure was a practical necessity; the other addresses whether such procedure was a reasonably prudent and acceptable method of treatment pain. In either or both cases, there is sufficient evidence in this record to establish a *prima facie* case that the alleged defective Lead was the sole or, at least a proximate contributing cause, for plaintiff's subsequent surgery in which her spinal cord was injured.

causation and medical necessity. No expert was designated to address issues relating to negligent manufacturing, and there is no evidence in the record submitted by the parties suggesting that Medtronic was negligent in manufacturing the damaged Lead. Moreover, Dr. Townsend, the forensic engineer, was asked about the manufacturing process, but each time he overtly declined to provide any opinion concerning the plaintiff's negligent manufacturing claim. In fact, when asked whether what he knew of quality control and assurance testing was done by Medtronic in the manufacture of the alleged damaged Lead, Dr. Townsend revealed he knew nothing and added that he had "no idea whether it was even subjected to quality control." Townsend Dep. at 38. Further, in response to questioning about the forces to which the Lead may have been subjected during the manufacturing process, Dr. Townsend stated point blank: "I wasn't there, nor do I have a statement as to how this lead was manufactured . . . . " Townsend Dep. at 133.

Under *Chestnut*, plaintiff has failed to produce evidence showing that the defendant breached the prevailing standard of care while manufacturing the allegedly defective device. Therefore, the undersigned RECOMMENDS that the defendant's motion for summary judgment on this claim be GRANTED and plaintiff's claim for negligence in manufacturing be DISMISSED.

B. Medtronic's Express Disclaimer of Implied Warranties and Consequential Damages

Appearing almost an afterthought, Medtronic asserts that it expressly disclaimed any implied warranty of merchantability concerning the instant Lead in the written Limited Warranty provided with the sale of the Lead. Plaintiff does not address this argument in her opposition to summary judgment. Section C(1) of the Limited Warranty relied on by the defendant provides,

in pertinent part:

> Except as expressly provided by this Limited warranty, MEDTRONIC IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE OR MALFUNCTION OF THE LEAD, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT OR OTHERWISE.

Def's App., Exh. 33, MDTCBE 00152. Section C(2) of the Limited Warranty goes on to provide that the "Limited Warranty is made only to the patient in whom the Lead is implanted," and "AS TO ALL OTHERS" all warranties are expressly disclaimed or confined to the terms of the document. *Id.*

Under Virginia law, a manufacturer may expressly disclaim the implied warranty of merchantability only if the disclaimer (a) mentions merchantability and (b) is conspicuous. VA. CODE § 8.2-316(2). Moreover, a manufacturer may limit or exclude remedies otherwise available to a claimant, except where the limitation or exclusion is unconscionable. VA. CODE §§ 8.2-719(1) and (3). A limitation or exclusion of remedies relating to "consumer goods," i.e. goods used or purchaser for personal, family or household purposes, is considered "prima facie unconscionable." VA. CODE §§8.2-719(3), 8.9A-102(23).

By its own terms, any attempt to disclaim or exclude warranties was directed solely to the "As To All Others" in section C(2) of Medtronic's Limited Warranty, and not to any patient, such as the instant plaintiff. The limitation of remedies set forth in Paragraph C(1) is a limitation on consequential damages in a "consumer goods" case, which cannot be enforced because it is *prima facie* unconscionable, and there is nothing in the record to rebut the *prima facie* unconscionability of this exclusion. *See Martin v. American Medical Systems, Inc.*, 116 F.3d

102, 105 (4th Cir. 1997). Defendant's motion for summary judgment premised on warranty exclusion or remedy limitation should be DENIED, and it is so RECOMMENDED.

***Summary of Recommendations***

For the aforesaid reasons, the undersigned hereby RECOMMENDS that the presiding court enter an order

1. GRANTING Medtronic's motion to exclude Dr. Townsend's testimony on the issue of product defect and its motion to strike/deny consideration of, for summary judgment purposes, plaintiff's late-filed affidavits;

2. GRANT defendant's motion for summary judgment on plaintiff's claim of negligent manufacturing;

3. GRANT plaintiff's motion to impose an adverse inference that the Lead was defective because of defendant's spoliation of the evidence;

4. DENY the balance of Medtronic's motion for summary judgment.

5. Fix a date for the trial of this case.

The Clerk is directed immediately to transmit the record in this case to the presiding United States District Judge. Both sides are reminded that pursuant to Rule 72(b) they are entitled to note objections, if any they may have, to this Report and Recommendation within ten (10) days hereof. Any adjudication of fact or conclusion of law rendered herein by the undersigned not specifically objected to within the period prescribed by law may become conclusive upon the parties. Failure to file specific objections pursuant to 28 U.S.C. § 636(b)(1)(C) as to factual recitations or findings as well as to the conclusions reached by the

undersigned may be construed by any reviewing court as a waiver of such objection.

The Clerk of the Court hereby is directed to send a certified copy of this Report and Recommendation to all counsel of record.

ENTERED: _____

United States Magistrate Judge

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Date