UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

RONALD KRAEMER,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 1:16-cv-01522-JMS-MJD
	)	
UNITED STATES OF AMERICA,	)	
	)	
Defendant.	)	

ORDER

In 2013, Ronald Kraemer had back surgery at a medical center operated by the Department of Veteran's Affairs (the "VA"). In 2016, after exhausting his administrative remedies, Mr. Kraemer brought suit against the VA alleging that the medical care he received was below the standard of care and that the VA did not obtain his informed consent. [Filing No. 1.] As a result, Mr. Kramer alleges that he suffered severe complications which are permanent and irreversible. [Filing No. 1.] Now pending before the Court is the VA's Motion for Summary Judgment. [Filing No. 50.] For the reasons set forth herein, the VA's Motion is **GRANTED**.

I.
STANDARD OF REVIEW

A motion for summary judgment asks the Court to find that a trial is unnecessary because there is no genuine dispute as to any material fact and, instead, the movant is entitled to judgment as a matter of law. See Fed. R. Civ. P. 56(a). As the current version of Rule 56 makes clear, whether a party asserts that a fact is undisputed or genuinely disputed, the party must support the asserted fact by citing to particular parts of the record, including depositions, documents, or affidavits. Fed. R. Civ. P. 56(c)(1)(A). A party can also support a fact by showing that the materials cited do not establish the absence or presence of a genuine dispute or that the adverse

party cannot produce admissible evidence to support the fact. Fed. R. Civ. P. 56(c)(1)(B). Affidavits or declarations must be made on personal knowledge, set out facts that would be admissible in evidence, and show that the affiant is competent to testify on matters stated. Fed. R. Civ. P. 56(c)(4). Failure to properly support a fact in opposition to a movant's factual assertion can result in the movant's fact being considered undisputed, and potentially in the grant of summary judgment. Fed. R. Civ. P. 56(e).

In deciding a motion for summary judgment, the Court need only consider disputed facts that are material to the decision. A disputed fact is material if it might affect the outcome of the suit under the governing law. Hampton v. Ford Motor Co., 561 F.3d 709, 713 (7th Cir. 2009). In other words, while there may be facts that are in dispute, summary judgment is appropriate if those facts are not outcome determinative. Harper v. Vigilant Ins. Co., 433 F.3d 521, 525 (7th Cir. 2005). Fact disputes that are irrelevant to the legal question will not be considered. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

On summary judgment, a party must show the Court what evidence it has that would convince a trier of fact to accept its version of the events. Johnson v. Cambridge Indus., 325 F.3d 892, 901 (7th Cir. 2003). The moving party is entitled to summary judgment if no reasonable fact-finder could return a verdict for the non-moving party. Nelson v. Miller, 570 F.3d 868, 875 (7th Cir. 2009). The Court views the record in the light most favorable to the non-moving party and draws all reasonable inferences in that party's favor. Darst v. Interstate Brands Corp., 512 F.3d 903, 907 (7th Cir. 2008). It cannot weigh evidence or make credibility determinations on summary judgment because those tasks are left to the fact-finder. *O'Leary v. Accretive Health, Inc.*, 657 F.3d 625, 630 (7th Cir. 2011). The Court need only consider the cited materials, Fed. R. Civ. P. 56(c)(3), and the Seventh Circuit Court of Appeals has "repeatedly assured the district courts that

they are not required to scour every inch of the record for evidence that is potentially relevant to the summary judgment motion before them," Johnson, 325 F.3d at 898. Any doubt as to the existence of a genuine issue for trial is resolved against the moving party. Ponsetti v. GE Pension Plan, 614 F.3d 684, 691 (7th Cir. 2010).

II.
BACKGROUND

Many of the background facts of this case are not in dispute. Local Rule 56-1(b) provides that "a party opposing a summary judgment motion" must file a response that includes "a section labeled 'Statement of Material Facts in Dispute' that identifies the potentially determinative facts and factual disputes that the party contends demonstrate a dispute of fact precluding summary judgment." In this case, Mr. Kraemer presents six points that he alleges are material facts in dispute. The Court notes that not all of these points are factual disputes.[1] In addition, not all factual disputes identified by Mr. Kraemer are material to the determination of this case. Any doubt as to the existence of a genuine issue for trial will be resolved against the VA as required by Rule 56 and explained in Ponsetti, 614 F.3d at 691.

A. Treatment Leading up to 2013 Surgery

Mr. Kraemer is a veteran of the United States Navy who has sought medical care at the VA hospital. [Filing No. 50-1 at 6.] In 1999, prior to seeking medical care at the VA, Mr. Kraemer

[1] The following "material fact[] in dispute" is not a factual dispute: "5. The consent form executed by Ron is not entitled to the rebuttable presumption of I.C. §34-18-12-2 because it was a template used by the VA and not a consent designed for the specific surgery," [Filing No. 57 at 14]. This statement is a legal argument and does not constitute a disputed material fact. See Curtis v. Costco Wholesale Corp., 807 F.3d 215, 219 (7th Cir. 2015) (finding that a plaintiff's statement of material facts was "replete with legal arguments, rather than presenting clear, undisputed material facts supported by admissible evidence" and that accepting plaintiff's reasoning "would undermine our established precedent that district courts are not required to wade through improper denials and legal argument in search of a genuinely disputed fact") (quotations omitted).

began to lose feeling in his hands and feet and sought medical care from Dr. Daniel Cooper. [Filing No. 50-1 at 7]. Dr. Cooper performed surgery on Mr. Kraemer, in which he inserted rods, plates, and screws into Mr. Kraemer's neck. [Filing No. 50-1 at 8].

In 2003, Mr. Kraemer had another surgery involving his neck and back, this time performed by Dr. Francesca Tekula at the Richard L. Roudebush VA Medical Center (the "VAMC"). Dr. Tekula performed a cervical fusion on Mr. Kraemer, "which was performed without complication," resulting in a recovery that Mr. Kraemer stated was "pretty good." [Filing No. 50-2 at 1-2; Filing No. 50-1 at 11.]

Between May and September 2008, Mr. Kraemer sought medical treatment for back pain, including an MRI, several office visits, and physical therapy. [Filing No. 50-17; Filing No. 50-18; Filing No. 50-19; Filing No. 50-20; Filing No. 50-21.]

In early 2012, Mr. Kraemer visited the emergency room complaining of severe low back pain. [Filing No. 50-22 at 1.] He underwent an MRI, which revealed "[m]ultilevel degenerative changes . . . with superimposed disc extrusion causing severe spinal canal stenosis and impingement of the traversing L4 nerve roots in the subarticular recesses." [Filing No. 50-23 at 2.] Shortly thereafter, on February 21, 2012, Mr. Kraemer had surgery at the VA due to a "herniated disc fragment." [Filing No. 50-3 at 1.] During the operation, Mr. Kraemer had a "red rash on [his] chest, abdomen, groin [and] left thigh." [Filing No. 50-4.]

In April 2012, Mr. Kraemer's wife, Kimberly Kraemer, called the VA and reported that her husband was in "terrible pain with his lower back and numbness in his legs" and that he "was not sleeping" and was "in tears daily." [Filing No. 50-25 at 1.]

In April 2013, Mr. Kraemer reported that he had pulled a muscle in his lower back and had back pain "as before his [February 2012] surgery." [Filing No. 50-27 at 1.] He then had an MRI

on his cervical spine, which showed "[r]emote anterior cervical discectomy with interbody and anterior fusion . . . laminectomy and posterior fixation," [Filing No. 50-28 at 3], and an MRI on his lumbar spine, which showed "concern for residual right central disc extrusion," "enhancing scar tissue," and "degenerative disc changes," [Filing No. 50-28 at 6].

In May 2013, Mr. Kraemer called the clinic "frantic" with pain and was advised to go the emergency room if he could not manage his pain at home. [Filing No. 50-5 at 1.] On May 21, 2013, Mr. Kraemer went to the emergency room complaining of worsening back and leg pain and was referred to the neurosurgery clinic. [Filing No. 50-29 at 1.] At the clinic the next day, Mr. Kraemer was given morphine and told to return to the clinic to discuss surgery. [Filing No. 50-6 at 3.] On June 21, 2013, Dr. Shaheryar Ansari examined Mr. Kraemer and scheduled him for discectomy and laminectomy/otomy surgery in July 2013. [Filing No. 50-30 at 1.] After ordering more x-rays, Dr. Neal Patel concluded that Mr. Kraemer needed a fusion surgery, instead of a decompression surgery. [Filing No. 50-30 at 3.] Mr. Kraemer was notified of this change. [Filing No. 50-11 at 16.]

Mr. Kraemer recalls that prior to his surgery in July 2013, he met with neurosurgeons who told him, "[b]asically, I need to go in there and remove that." [Filing No. 50-1 at 29.]

B. 2013 Surgery

1. Discussion with Dr. Patel Prior to Surgery

On July 31, 2013, Mr. Kraemer was admitted to the VAMC for a spinal fusion. [Filing No. 50-39.] Prior to the surgery, Mr. Kraemer and his wife met with Dr. Patel to discuss the procedure. [Filing No. 50-38 at 7; Filing No. 50-11 at 18.] Although there is no dispute that this meeting occurred, the parties give vastly different versions of the events.

Dr. Patel testified as follows:

The morning of surgery, we discussed what he would undergo would be a minimally invasive L3-4 TLIF. . . . We discussed that a surgical option for this would involve decompressing him centrally and involving taking more of the facet joint that would require a fusion based off the fact that this would leave him inherently unstable, which his films have demonstrated.

We discussed that we would have to encounter quite a bit of scar tissue and define the normal ana -- anatomic borders of the bone. We discussed that we could do this through a minimally invasion option; less blood loss, shorter hospital stay, quick immobilization. That this would entail two incisions in his back that would occur. Each would be about -- about four centimeters, along with a small one over his iliac crust. We discussed that we would place -- use a Stealth OR navigation to kind of help guide the placement. With this instrumentation, it's like a 360 x-ray and we would navigate in screws to help stabilize the spine, and that we would drill out all the bone choking his nerves and decompress him centrally, along with a lateral recess and foraminally. We would then address the disk space where he had recurrent herniation.

…

We discussed that the fusion aspect was going to be inhibited due to his extensive smoking history. . . . That we'd use bone morphogenetic protein in an off label use to help facilitate that. This is a synthetic protein that helps the fusion, that we use it commonly in spine surgery through other approaches, and that Richard Fessler at Northwestern uses it extensively in his minimally invasive fusions.

We discussed that the allograft bone, bag of bones that we call MagniFuse may be necessary if we didn't collect enough of his own bone. We discussed that the screws would be placed to help stabilize it, along with rods, and that I would use a lot of local anesthetic to numb it up to minimize his discomfort.· I discussed with him that I didn't anticipate a need for a blood transfusion. The infection rates through a minimally invasive route are lower than through a more open, traditional route. We discussed the hospital stay would be anywhere from around one to three days.

We discussed that the risks of the procedure inherited CSF leak based off the fact that it was a recurrent surgery with reduced scar tissue; that . . . there's a slightly higher risk of a CSF leak, somewhere that approach around five to ten percent. We discussed infection rates any time you put in hardware are higher. . . . But we'd give him pre-operative and post-operative antibiotics, along with washout with antibiotics.

We discussed that the other risks involve pseudarthrosis, meaning that there may not be a fusion despite our best efforts and that smoking cessation would be vital to get a good fusion for him moving forward. We discussed the other risks of using bone morphogenetic protein as it was a synthetic protein include radiculitis or

> ectopic bone formation. We discussed along with the other risk being anesthesia and death.

[Filing No. 50-38 at 7-11.]

Ms. Kraemer recalls that Dr. Patel "explained the surgery." [Filing No. 50-11 at 19.] She asked Dr. Patel "if it was going to be the plates, the titanium plate screws and a cadaver bone and he said yes and that's all he said," and that she did not ask Dr. Patel any other questions about surgery because she "felt like [she] had asked what [she] needed and . . . thought [she] understood what he was saying." [Filing No. 50-11 at 20.] Ms. Kraemer also testified as to the following:

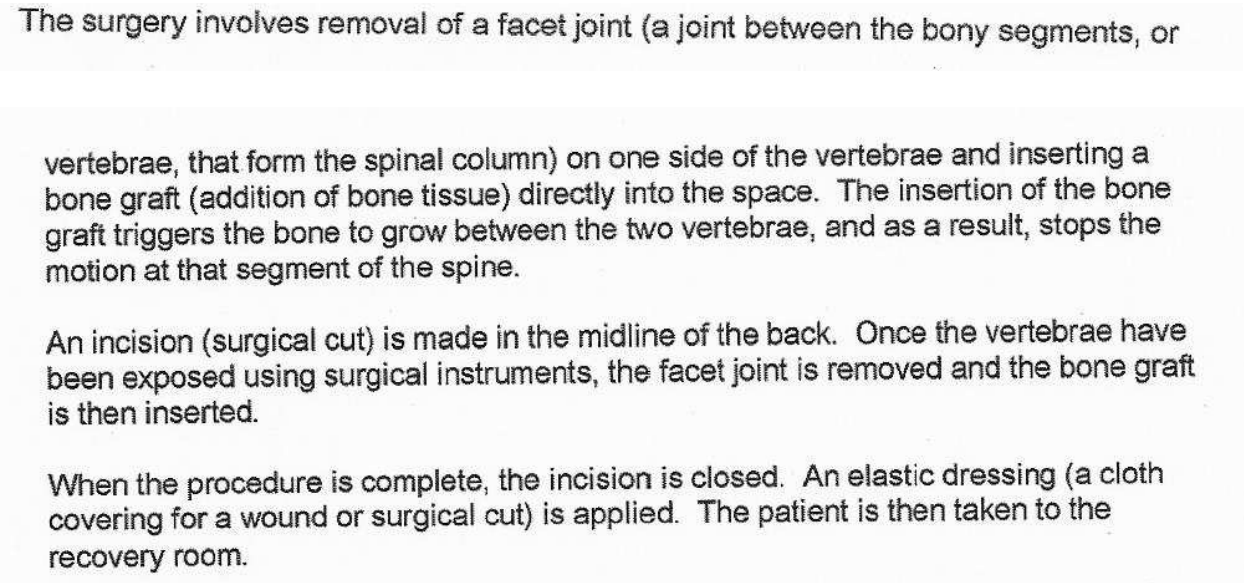
- Dr. Patel didn't say anything about "any graft," [Filing No. 50-11 at 21];
- Dr. Patel did not tell her "he would be using bone morphogenetic protein material in the surgery," [Filing No. 50-11 at 22];
- Dr. Patel did not mention "hives" or "anything resulting in life-threatening hives," [Filing No. 50-11 at 22]; and
- Dr. Patel did not tell her "that he was going to go in through the side," [Filing No. 50-11 at 22].[2]

Mr. Kraemer recalls that they "finally got [him] in" and told him "this is what we're going to have to do." [Filing No. 50-1 at 29.] He states that he had "a serious hearing impairment" and "did not hear much of Dr. Patel's conversation but instead relied on [Ms. Kraemer] to listen to what Dr. Patel said." [Filing No. 57-1 at 1.]

[2] The Court notes that Mr. Kraemer asserts in his brief that Ms. Kraemer testified that "Dr. Patel did not tell the Kraemers . . . that this was an off-label procedure." [Filing No. 57 at 3 (citing Filing No. 50-11 at 22)]. However, the cited portion of Ms. Kraemer's deposition contains no mention of any off-label procedure, and the Court was unable to find such a statement anywhere in the record. As such, this asserted fact does not comply with Local Rule 56-1(e), which requires a party to "support each fact the party asserts in a brief with a citation to a discovery response, a deposition, an affidavit, or other admissible evidence." The Court will, therefore, disregard this asserted fact.

2. The Consent Form

Mr. Kraemer's signature, dated July 31, 2013, appears at the bottom of a form entitled "Consent For Clinical Treatment/Procedure," (the "Consent Form") which details, inter alia, information about the treatment/procedure that Mr. Kraemer was to undergo. [Filing No. 50-7 at 1-6.] The Consent Form provides the following information, in relevant part:

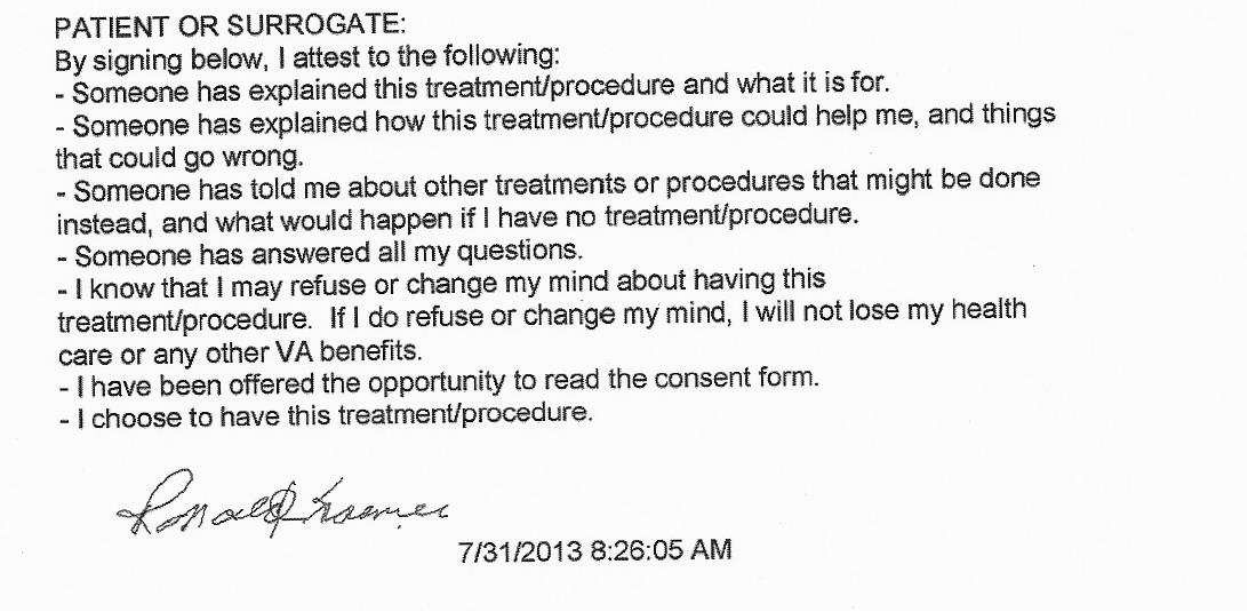


The surgery involves removal of a facet joint (a joint between the bony segments, or vertebrae, that form the spinal column) on one side of the vertebrae and inserting a bone graft (addition of bone tissue) directly into the space. The insertion of the bone graft triggers the bone to grow between the two vertebrae, and as a result, stops the motion at that segment of the spine.

An incision (surgical cut) is made in the midline of the back. Once the vertebrae have been exposed using surgical instruments, the facet joint is removed and the bone graft is then inserted.

When the procedure is complete, the incision is closed. An elastic dressing (a cloth covering for a wound or surgical cut) is applied. The patient is then taken to the recovery room.

[Filing No. 50-7 at 1-2.] In addition, the Consent Form lists several "[k]nown risks and side effects of the treatment/procedure," including but not limited to: "[p]ain, numbness, weakness or scarring where the skin is cut," "[p]aralysis," "[s]troke," and "[d]eath." [Filing No. 50-7 at 1-3.] The Consent Form also contains Dr. Patel's signature, representing that "[a]ll relevant aspects of the treatment . . . have been discussed with the patient." [Filing No. 50-7 at 6.] Finally, the Consent Form contains the following attestation:



PATIENT OR SURROGATE:
By signing below, I attest to the following:
- Someone has explained this treatment/procedure and what it is for.
- Someone has explained how this treatment/procedure could help me, and things that could go wrong.
- Someone has told me about other treatments or procedures that might be done instead, and what would happen if I have no treatment/procedure.
- Someone has answered all my questions.
- I know that I may refuse or change my mind about having this treatment/procedure. If I do refuse or change my mind, I will not lose my health care or any other VA benefits.
- I have been offered the opportunity to read the consent form.
- I choose to have this treatment/procedure.

7/31/2013 8:26:05 AM

[Filing No. 50-7 at 6.]

Mr. Kraemer does not recall "anything about forms" and does not recall reading a consent form. [Filing No. 50-1 at 30.] Ms. Kraemer, however, recalls Mr. Kraemer signing the Consent Form, [Filing No. 50-11 at 22], and Dr. Patel testified that he had Mr. Kraemer sign the Consent Form prior to surgery, and that the Consent Form was a "pre-cut template consent form[]." [Filing No. 50-38 at 11-12.]

C. Post-Operative Care

After the surgery, Mr. Kraemer's pain was resolved and he was kept in the hospital for three to four days. [Filing No. 50-1 at 57.] The second day after his surgery, Mr. Kraemer began experiencing hives on his back. [Filing No. 50-1 at 68.]

On August 8, 2013, Ms. Kraemer called the clinic to report "red welts" on Mr. Kraemer's back. [Filing No. 50-13 at 4.] Later that day, Mr. Kraemer visited the VA walk-in clinic complaining of a "local reaction to tape or drape from surgery" that "r[an] the perimeter of his surgery wound in 2" perimeter – along the tape along a large dressing," and a local reaction on his

face "where the endotracheal tube might have been secured." [Filing No. 50-8 at 1.] He was prescribed topical and oral steroids. [Filing No. 50-8 at 2.]

On August 27, 2013, Mr. Kraemer saw Dr. Patel, at which point he was "doing well," with his leg pain resolved, his back pain improved, and he was able to sleep at night. [Filing No. 50-9 at 1.] Three days later, Ms. Kraemer called the clinic reporting that Mr. Kraemer was breaking out in hives and, although the "cream helps," he needed a refill, which he was subsequently given by Dr. Patel. [Filing No. 50-9 at 1.]

On September 30, 2013, Ms. Kraemer called the clinic reporting that Mr. Kraemer continued breaking out in hives and that his tongue was swelling. [Filing No. 50-31.] On October 4, 2013, Mr. Kraemer saw neurosurgeon Dr. Brandon Lane, who noted that Mr. Kraemer's hives and itching "began only after surgery" and were initially "at the borders of the . . . bandage on his back and on his cheeks where the . . . tube had been taped." [Filing No. 50-10 at 1.] Ms. Kraemer showed Dr. Lane photos of the rash that she had previously taken. [Filing No. 50-10 at 1; Filing No. 50-11 at 33.] At the time, Mr. and Ms. Kraemer were "concerned of neurosurgical instrumentation or bone bag as a source for systemic reactions," which Dr. Lane and attending neurosurgeon Dr. Henry Feuer deemed "unlikely." [Filing No. 50-10 at 1.]

On October 9, 2013, Mr. Kraemer saw his primary care physician for an annual visit, during which Dr. Melody Drake noted that it was "still not clear why" Mr. Kraemer had "ongoing hives since surgery." [Filing No. 50-14 at 1.] Dr. Drake also noted the following:

> Considerable time spent explaining to pt and wife:
> 1) that there are times with cause for URTICARIA is not ID'ed, causes can include, but not limited to food, meds (even food/meds pt has been on for a long time), stress, environmental triggers, and even little known triggers (such as sunlight)
> 2) At times --> Idiopathic urticaria - is a possible final dx - with tx directed to control of sx.
> 3)NS had indicated they were going to consult DERM, but as that consult has not been submitted, PCP will order Telederm today to initiate consult

[Filing No. 50-14 at 4; see also Filing No. 50-11 at 38.]

On October 10, 2013, Mr. Kraemer had an appointment with Dr. Jeffrey Travers, a dermatologist who recommended that Mr. Kraemer "avoid tape products. . . [and] not take medrol dose pack [because] systemic steroids can worsen hives." [Filing No. 50-32.] On October 17, 2013, Mr. Kraemer had a punch biopsy performed by dermatologist Dr. Mouhammad Aouthmany under the supervision of Dr. Jeffrey Travers, in order to determine if "there was inflammation and destruction of the blood vessels." [Filing No. 50-33; Filing No. 50-42 at 7-9.] On October 31, 2013, Mr. Kraemer returned to Dr. Aouthmany, who noted "Urticaria, improving with possible angioedema" with "currently unclear etiology (possibilities include post op antibiotic, vs the hardware placed into patient for the laminectomy)." [Filing No. 50-34 at 2.] On December 19, 2013, Mr. Kraemer returned to Dr. Travers, who noted that Mr. Kraemer's chronic urticaria test, which was performed in October, was weakly positive but hard to interpret, so Dr. Travers repeated the test. [Filing No. 50-35 at 1.]

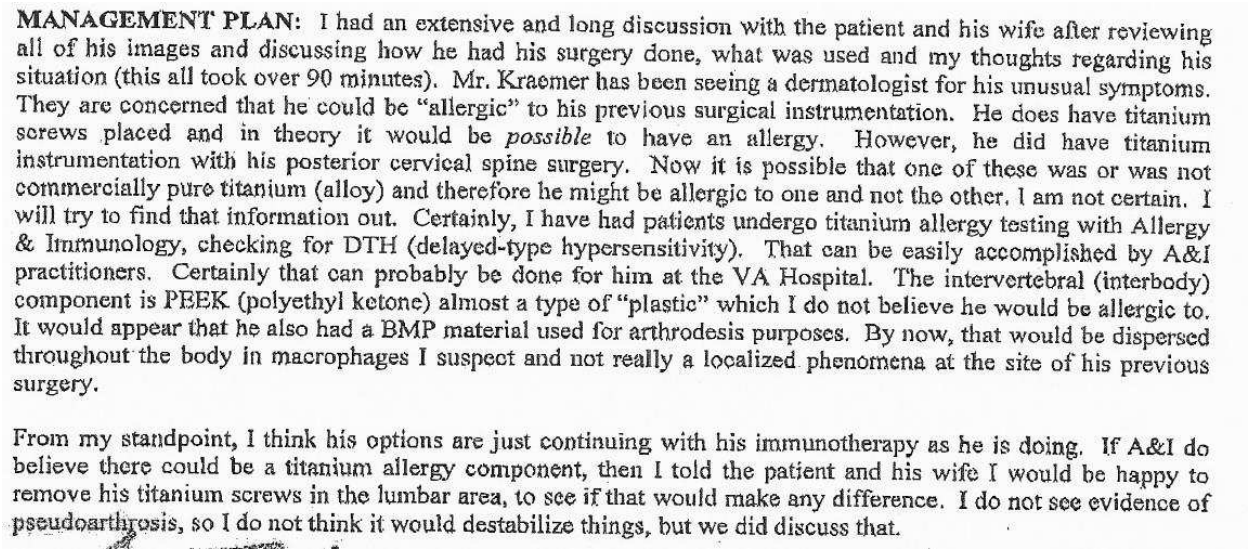
On February 11, 2014, Mr. Kraemer returned to Dr. Travers and indicated that he had an appointment with a neurosurgeon to see about having the graft from his surgery removed. [Filing No. 50-36.] Dr. Travers testified that he:

> thought it was a very reasonable thing to send him back to neurosurgery, because [Mr. Kraemer] was totally convinced, and I could understand why he was totally convinced, that this was due to what was done to him, because he had -- he didn't have hives before he went into surgery, then he has had this problem ever since.· So in his mind, . . . this is what caused it. However, I -- there is no precedent for thinking that something like this could actually be due to -- we don't -- this is just a big lapse in our knowledge base.

[Filing No. 50-42 at 29-30.]

On February 28, 2014, Mr. Kraemer had an appointment with neurosurgery resident Dr. Todd Vogel, who noted that graft removal would be "major surgery" with the risk of numerous

complications. [Filing No. 50-37 at 1.] In May 2014, Mr. Kraemer got a second opinion from neurosurgeon Dr. Thomas Reilly, who opined as follows:



MANAGEMENT PLAN: I had an extensive and long discussion with the patient and his wife after reviewing all of his images and discussing how he had his surgery done, what was used and my thoughts regarding his situation (this all took over 90 minutes). Mr. Kraemer has been seeing a dermatologist for his unusual symptoms. They are concerned that he could be "allergic" to his previous surgical instrumentation. He does have titanium screws placed and in theory it would be *possible* to have an allergy. However, he did have titanium instrumentation with his posterior cervical spine surgery. Now it is possible that one of these was or was not commercially pure titanium (alloy) and therefore he might be allergic to one and not the other. I am not certain. I will try to find that information out. Certainly, I have had patients undergo titanium allergy testing with Allergy & Immunology, checking for DTH (delayed-type hypersensitivity). That can be easily accomplished by A&I practitioners. Certainly that can probably be done for him at the VA Hospital. The intervertebral (interbody) component is PEEK (polyethyl ketone) almost a type of "plastic" which I do not believe he would be allergic to. It would appear that he also had a BMP material used for arthrodesis purposes. By now, that would be dispersed throughout the body in macrophages I suspect and not really a localized phenomena at the site of his previous surgery.

From my standpoint, I think his options are just continuing with his immunotherapy as he is doing. If A&I do believe there could be a titanium allergy component, then I told the patient and his wife I would be happy to remove his titanium screws in the lumbar area, to see if that would make any difference. I do not see evidence of pseudoarthrosis, so I do not think it would destabilize things, but we did discuss that.

[Filing No. 50-15.]

D. Mr. Kraemer's Claim against the VA

Mr. Kraemer submitted a Notice of Tort Claim to the VA on July 6, 2015. [Filing No. 8 at 4.] The VA administratively denied Mr. Kraemer's tort claim on December 30, 2015. [Filing No. 8 at 4.] On June 21, 2016, Mr. Kraemer filed suit in this Court alleging that "Dr. Patel and the VA did not obtain informed consent" to perform the July 2013 surgery on him and that they did not "fully advise him that the procedure was not authorized by the FDA and Medtronic, which was also below the standard of care." [Filing No. 1 at 2.] Mr. Kramer further alleges that the VA "was also negligent in failing to advise [him] of the risks and complications of the INFUSE Bone graft and the use of the BMP-2 bone morphogenetic protein material." [Filing No. 1 at 2.] On January 9, 2018, the VA filed a Motion for Summary Judgment, which is now ripe for the Court's review. [Filing No. 50.]

III.
DISCUSSION

The Court notes at the outset that Mr. Kraemer brought his claim pursuant to the Federal Tort Claims Act ("FTCA"). FTCA claims are determined "in accordance with the law of the place where the act or omission occurred," 28 U.S.C. § 1346, which in this case is Indiana. In addition, the Seventh Circuit has held that "state law governing expert testimony in medical malpractice cases is applicable to malpractice suits under the [FTCA]." Gipson v. United States, 631 F.3d 448, 452 (7th Cir. 2011). As such, Indiana law – including Indiana law concerning expert testimony – applies to Mr. Kraemer's FTCA claim against the VA. See Martin v. United States, 654 F. App'x 235, 238 (7th Cir. 2016) (citations omitted).

The VA structures its arguments in support of summary judgment consistent with the straightforward elements for medical malpractice negligence, which in Indiana are "(1) that the physician owed a duty to the plaintiff; (2) that the physician breached that duty; and (3) that the breach proximately caused the plaintiff's injuries." *Siner v. Kindred Hosp. Ltd. P'ship*, 51 N.E.3d 1184, 1187 (Ind. 2016) (quoting Mayhue v. Sparkman, 653 N.E.2d 1384, 1386 (Ind. 1995)). However, the parties' arguments require the Court to go beyond the general elements of negligence because they implicate a related but separate concept – informed consent.

In 2009, the Indiana Supreme Court adopted a five part test for informed consent, stating that:

> To succeed on a lack of informed consent action, the plaintiff must prove "(1) nondisclosure of required information; (2) actual damage . . . (3) resulting from the risks of which the patient was not informed; (4) cause in fact, which is to say that the plaintiff would have rejected the medical treatment if she had known the risk; and (5) that reasonable persons, if properly informed, would have rejected the proposed treatment.

Spar v. Cha, 907 N.E.2d 974, 979-80 (Ind. 2009). Since Spar, Indiana Courts have struggled to adapt rules that were enunciated in the context of the traditional elements of negligence to this five-part test. The Indiana Court of Appeals recently noted that "[t]he law in Indiana regarding informed consent is not entirely clear," observing that, on one hand, "[w]hat is clear is that 'physicians have a duty to disclose to their patients information material to a proposed course of treatment.'" Perez v. Hu, 87 N.E.3d 1130, 1134 (Ind. Ct. App. 2017) (quoting Spar, 907 N.E.2d at 984 and citing Bader v. Johnson, 732 N.E.2d 1212, 1217 (Ind. 2000)). "What is less clear is precisely what the elements of an informed consent claim are, and to what extent expert testimony is required to prove such a claim." Id. at 1135.

The latter observation is directly applicable to the case brought by Mr. Kramer, where the key issue is whether and to what extent Mr. Kraemer must provide expert testimony in support of his informed consent claim. Before turning to that issue, however, the Court will first distinguish the rules governing informed consent claims from those involving medical malpractice in the performance of the procedure.

A. Informed Consent Distinguished from Negligence in Surgical Performance

In its brief in support of summary judgment, the VA scarcely mentions the concept of informed consent, except to note that Dr. Sloan "reviewed Mr. Kraemer's medical records and concluded that Dr. Patel met the standard of care both when he obtained Mr. Kraemer's informed consent to the procedure and when he performed the procedure itself." [Filing No. 51 at 15.] Instead, as previously noted, the VA generally argues that Mr. Kraemer has not met "his burden of proving either breach or causation." [Filing No. 51 at 14.]

In his brief opposing summary judgment, however, Mr. Kraemer discusses informed consent numerous times, alleging that one of the genuine issues of material fact precluding

summary judgment is whether his "chronic autoimmune urticaria was the proximate result of the failure of the VA to obtain informed consent to perform the surgery." [Filing No. 57 at 14.] Mr. Kraemer further argues that "the standard of care requires that a physician provide information to a patient about a contemplated procedure that will permit the patient to make a decision whether or not to have the contemplated procedure." [Filing No. 57 at 15.]

The VA responds to Mr. Kraemer's arguments regarding informed consent by again reiterating that Dr. Sloan testified that Dr. Patel met the standard of care in obtaining Mr. Kraemer's informed consent to the surgery. [Filing No. 58 at 6.]

To some extent, the parties' arguments concerning informed consent conflate that concept with general negligence elements of duty, breach, causation. Accordingly, in order to clarify the claim at issue in Mr. Kramer's case, a brief review of informed consent in Indiana is necessary.

In 2006 in Hamilton v. Ashton, the Indiana Court of Appeals clarified that "[t]he issues of informed consent and negligence in surgical performance, though often intertwined, are two independent issues." 846 N.E.2d 309, 317 (Ind. Ct. App. 2006). The Court of Appeals further stated that informed consent "is separate and apart from the doctor's duty to 'exercise that degree of care, skill, and proficiency exercised by reasonably careful, skillful, and prudent practitioners in the same class to which he belongs, acting under the same or similar circumstances.'" Id. at 317 (quoting Vergara by Vergara v. Doan, 593 N.E.2d 185, 187 (Ind. 1992)), and that it "is possible for a doctor to perform a surgery for which there was no informed consent in a medically appropriate way such that the patient has only a cause of action for the failure to receive informed consent and not also for medical malpractice in the performance of the procedure." Id. at 317.

Hamilton was affirmed on rehearing, with the Court of Appeals noting in Hamilton II that the patient bringing suit in the case:

> fail[ed] to recognize the distinction we have made between the fact of a surgery being performed and the manner in which the surgery is performed. If there is no informed consent, the patient has a claim for the fact of the surgery occurring. Within that larger context, if the techniques used in the surgery were themselves negligent, there may also be an independent claim for the manner in which the surgery is performed.

Hamilton v. Ashton, 850 N.E.2d 466, 467 (Ind. Ct. App. 2006) (emphasis in original); see also Spar v. Cha, 907 N.E.2d at 979 (citing Hamilton, 846 N.E.2d at 317) (in which the Indiana Supreme Court explained that although "[l]ack of informed consent to a harmful touching in medical malpractice cases was traditionally viewed as a battery claim," it is now "a distinct theory of liability.").

Viewed through this lens, it is apparent that Mr. Kraemer's case implicates informed consent, not medical malpractice in the performance of the procedure. Mr. Kraemer does not argue that Dr. Patel negligently performed the surgery and does not even detail the manner in which Dr. Patel performed the surgery. Instead, Mr. Kraemer argues that he was "unaware of the specific details of the surgical procedure and its risks and complications." [Filing No. 57 at 14.] Accordingly, Mr. Kraemer's only claim in this case sounds in informed consent, and the Court now turns to the parties' arguments concerning the standard of care to which Dr. Patel should be held.

B. The Standard of Care for Informed Consent

The VA contends that none of the treating physicians that Mr. Kraemer disclosed as experts opined that Dr. Patel breached the standard of care. [Filing No. 51 at 14.] The VA argues that, to the contrary, Dr. Sloan's review of Mr. Kraemer's records establishes that Dr. Patel's treatment of Mr. Kraemer fell within the standard of care. [Filing No. 51 at 15 (citing Filing No. 50-40; Filing No. 50-41).]

In his brief in opposition to summary judgment, Mr. Kraemer relies upon Lahr v. United States, 2010 WL 4386547, at *5 (S.D. Ind. Oct. 28, 2010), for the proposition that expert testimony is not always required in order "to determine what a reasonably prudent physician should tell a patient in order to obtain informed consent." [Filing No. 57 at 15.] Mr. Kraemer argues that expert testimony is not required in this case because Dr. Patel used a "pre-cut template" in order to obtain Mr. Kraemer's consent, that Mr. Kraemer could not hear Dr. Patel during the conversation prior to his surgery, and that Dr. Patel could not recall whether Ms. Kraemer was present for this conversation. [Filing No. 57 at 16.]

In its reply brief, the VA argues that Mr. Kraemer's purported genuine issue of material fact that Dr. Patel breached the standard of care because Mr. Kraemer could not hear him is "not genuinely in dispute given Dr. Sloan's expert report concluding that Dr. Patel met the standard of care in obtaining Mr. Kraemer's informed consent." [Filing No. 58 at 2 (citing Filing No. 50-40; Filing No. 50-41).] In addition, the VA argues that Mr. and Ms. Kraemer's lay opinions that Dr. Patel did not explain the surgery "are insufficient to create a genuine issue of material fact, especially in light of Dr. Sloan's unequivocal conclusion that Dr. Patel met the standard of care when he obtained Mr. Kraemer's informed consent prior to the July 2013 surgery." [Filing No. 58 at 2.] Further, the VA distinguishes Lahr from the facts of this case, arguing that expert testimony is not required only where "the breach is so egregious that a layperson can determine that the doctor breached the standard of care." [Filing No. 58 at 5.]

Here again, a brief history of Indiana law on this subject is necessary. In 1992, in Culbertson v. Mernitz, the Indiana Supreme Court compiled an exhaustive summary of "Informed Consent in Indiana Jurisprudence" for the purpose of determining whether "expert medical testimony is required to establish the standard of care of health care providers on the issue of

informed consent." 602 N.E.2d 98, 98-101 (Ind. 1992). The Court ultimately concluded "that expert medical testimony is necessary to establish whether a physician's disclosure of risks comports with what a reasonably prudent physician would have disclosed." Id. at 103.

In the twenty-five years since Culbertson, Indiana courts have reconsidered, but not overruled, its holding. See Perez, 87 N.E.3d at 1136 (reviewing Culbertson and noting that "[i]n later years, our supreme court has seemingly drifted away from the majority holding in Culbertson and toward the dissent's view, although it has never been overruled"). Most relevant to the inquiry here is the Indiana Court of Appeals' 1999 ruling that expert testimony generally is required to determine what a reasonably prudent physician should tell a patient before performing a medical procedure, unless the matter is within a layperson's understanding. Bowman v. Beghin, 713 N.E.2d 913, 916-17 (Ind. Ct. App. 1999). The Bowman court held that a doctor's failure to perform half of the surgery that the patient thought he was undergoing was enough to excuse the patient from presenting expert testimony at trial. Id. at 917. In addition, the Bowman court gave the following example of an instance that would not require expert testimony: "the failure to advise a patient that a surgeon will remove the patient's leg hardly requires expert testimony to establish that the standard of care requires that the physician must tell the patient that such a procedure is to take place" because a "lay person can understand what is required." Id. at 917.

Mr. Kraemer urges this Court to apply the exception to Culbertson set forth in Bowman to his case and find that he need not present expert testimony to establish the standard of care because the matter is within a layperson's understanding. However, the Court is not persuaded that Dr. Patel's failure to advise Mr. Kraemer of the potential risks of urticaria/hives is comparable to the removal of a limb or the failure to perform half of a surgery. Additionally, the Court finds the medical implications of using an INFUSE Bone graft and BMP-2 bone morphogenetic protein

material are outside the scope of a layperson's knowledge. See Boston v. GYN, Ltd., 785 N.E.2d 1187, 1192 (Ind. Ct. App. 2003) (finding that "the medical implications of leaving the Hulka clip in [a patient's] body, whether loose or attached to a fragment of fallopian tube, and the medical risks of searching for it during a surgical procedure are outside the scope of a layperson's knowledge," and that the patient was therefore required to submit expert testimony to establish the applicable standard of care and how it was breached). As such, in order to survive summary judgment, Mr. Kraemer must present expert testimony that a breach of the standard of care occurred, and this he has not done. Accordingly, the VA is entitled to Summary Judgment on Mr. Kraemer's claim.

Although the Court's analysis may stop here, the Court will briefly address Mr. Kraemer's allegation that he was not able to hear Dr. Patel's description of the surgery. Mr. Kraemer presents no authority in support of his argument; however, the Indiana Supreme Court in Culbertson set forth the following relevant discussion:

> [A] physician should not be required to guess or speculate as to what a hypothetical "reasonably prudent patient" would "need to know" in order to make a determination. A physician should only be required to do that which [s]he is trained to do, namely, conduct himself [or herself] as a reasonably prudent physician in taking a history, performing a physical examination, ordering appropriate tests, reaching a diagnosis, prescribing a course of treatment, and in discussing with the patient the medical facts of the proposed procedure, including the risks inherent in either accepting or rejecting the proposed course of treatment. From a physician's viewpoint, [s]he should not be called upon to be a "mind reader" with the ability to peer into the brain of a prudent patient to determine what such patient "needs to know," but should simply be called upon to discuss medical facts and recommendations with the patient as a reasonably prudent physician would.

Culbertson, 602 N.E.2d at 103.

Viewing the facts most favorably to Mr. Kraemer, there is no dispute that Mr. Kraemer signed the Consent Form and that Dr. Patel had at least a brief discussion with Mr. Kraemer immediately prior to surgery. It initially bears note that Mr. Kraemer has presented no evidence

that Dr. Patel knew about his hearing problem. But moreover, consistent with Culbertson, Dr. Patel was not required to guess or speculate what Mr. Kraemer subjectively needed to know and, particularly in the absence of any authority to the contrary, Dr. Patel was not required to guess that Mr. Kraemer had a hearing problem that prevented him from hearing the conversation with Dr. Patel immediately prior to surgery. Mr. Kraemer's hearing does not, therefore, affect the Court's analysis of his informed consent claim.

C. Causal Connection in Informed Consent Cases

Having determined that the VA is entitled to summary judgment due to Mr. Kraemer's failure to present expert testimony that a breach of the standard of care occurred, the Court need not consider the parties' other arguments. However, even if Mr. Kramer had presented the requisite evidence of an inadequate disclosure, the VA would still be entitled to summary judgment because Mr. Kramer has not provided expert testimony demonstrating the requisite causal connection.

The VA argues that Mr. Kraemer cannot establish "that the July 31, 2013 surgery caused him to develop urticarial[]." [Filing No. 51 at 15.] Here again, the VA argues that none of Mr. Kraemer's treating physicians opined that the surgery caused the urticaria, including Dr. Travers and Dr. Sloan—each of whom opined the opposite. Dr. Travers explained that "Mr. Kraemer's chronic autoimmune urticaria developed around the same time as his July 2013 surgery," but that he "does not believe that the surgery and the urticaria are related, or that the surgery caused the urticaria," [Filing No. 51 at 16 (citing Filing No. 50-42)], Dr. Patel was unable to link the surgery to the urticarial, [Filing No. 51 at 16 (citing Filing No. 50-39)], and Dr. Sloan concluded that "[t]here is no indication or evidence to support that Mr. Kraemer's hives or were caused by the use of Infuse during his July 31, 2013 surgery," [Filing No. 51 at 16 (citing Filing No. 50-40)].

Mr. Kraemer, however, argues that the following pieces of evidence are sufficient to create a genuine issue of material fact with regard to causation:

- Dr. Travers "testified that: 'I think we have the culprit, a reason why he has his disease,'" [Filing No. 57 at 14 (citing Filing No. 50-42 at 29)]; and
- Dr. Travers "was convinced that there was a temporal relationship between the surgery and the urticaria and that the protein that [Mr. Kraemer's] body is making is triggering his mast cells to form the chronic autoimmune urticarial," [Filing No. 57 at 14 (citing Filing No. 50-42 at 16-17)].

In its response brief, the VA states that "Mr. Kraemer claims that Dr. Travers concluded that the surgery was the cause of Mr. Kraemer's urticaria" but that this is "simply not true" and that "[i]n reality, Dr. Travers testified that he could not connect the surgery to the urticaria." [Filing No. 58 at 3 (citing Filing No. 50-42 at 34 (in which Dr. Travers testified "I can't – I don't feel comfortable making the connection between the two")].

Despite significant evolution in Indiana law regarding informed consent, one principle has remained consistent: expert opinion is generally necessary to establish the causal connection between the inadequate disclosure and the resulting damages. Bunger v. Brooks, 12 N.E.3d 275, 281-82 (Ind. Ct. App. 2014) (citing Bunch v. Tiwari, 711 N.E.2d 844, 850 (Ind. Ct. App. 1999)); see also Perez, 87 N.E.3d at 1137 (whether actual damage was caused as a result of an inadequate disclosure generally is a matter requiring expert opinion").[3]

[3] It should be noted that this aspect of causation is separate and distinct from the second issue discussed in Bowman: "whether a claimant must present expert testimony on the issue of causation where the claim is that he would not have consented to surgery but for the representation by a surgeon that he would perform a specific surgery and did not." 713 N.E.2d at 917. On this point, the Bowman court held that "[a] lay jury is capable, without the benefit of expert opinion, of deciding the truth of [a patient's] claim that he [or she] would not have consented to the surgery but for the misrepresentations of what procedure would be done." Id. at 917. This opinion was

The Court is simply not persuaded that anything in Dr. Travers' deposition establishes a causal connection between the disclosure in this case and the alleged damages. The VA is correct that Dr. Travers explicitly states in his deposition that the literature "doesn't say" that the "morphogenic bone protein material" used in Mr. Kraemer's surgery is the "causative factor." [Filing No. 50-42 at 29.] Dr. Travers further testified that although he believed Mr. Kraemer that his urticaria is "temporally related to" the surgery – meaning "it first came out around the surgery" at the time of his testimony, he did not "feel comfortable making the connection between the two." [Filing No. 50-42 at 34.] Dr. Travers' testimony does not, therefore, qualify as expert testimony in support of the argument that an alleged failure to obtain informed consent caused Mr. Kraemer's damages in this case. Accordingly, the VA is entitled to summary judgment.

IV.
CONCLUSION

Due to Mr. Kraemer's failure to provide expert testimony regarding the standard of care for his informed consent claim and expert testimony establishing the requisite causal connection for the same, the VA is entitled to summary judgment on his claim. As such, the Court need not analyze this case under each element of the five part test for informed consent set forth by Spar, 907 N.E.2d at 979-80. The VA's Motion for Summary Judgment [50] is **GRANTED**. Final judgment shall issue accordingly.

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recently upheld in Perez, 87 N.E.3d at 1137 (holding that "it seems clear" that no expert testimony would be required as to whether a plaintiff would have chosen different treatment if he or she had known of the risk involved with the performed treatment). Therefore, expert testimony would not be required on the issue of whether Mr. Kraemer would have chosen different treatment. Having determined that the VA is entitled to summary judgment for other reasons, however, the Court need not and will not reach this issue.

Date: 4/17/2018

Hon. Jane Magnus-Stinson, Chief Judge
United States District Court
Southern District of Indiana

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