Thaler v Varlotta
2020 NY Slip Op 33062(U)
September 15, 2020
Supreme Court, New York County
Docket Number: 805366/15
Judge: Joan A. Madden

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK: PART 11

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STEVEN THALER and LISA THALER, INDEX NO. 805366/15

Plaintiffs,

-against-

GERARD P. VARLOTTA, D.O. and SPINE SPORTS OCCUPATIONAL REHABILITATION ASSOCIATES, LLC,

Defendants.

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JOAN A. MADDEN, J.:

In this an action for damages for medical malpractice, lack of informed consent and loss of consortium, defendants Gerard P. Varlotta, D.O. and Spine Sports Occupational Rehabilitation Associates, LLC ("Spine Sports") move for summary judgment and plaintiffs oppose.[1] Plaintiffs also cross-move for an order pursuant to CPLR 3042(b) and CPLR 2001, deeming their First Amended Bill of Particulars, dated and served April 1, 2019, amended nunc pro tunc to that date. Defendants oppose plaintiffs' cross-motion, and cross-move to strike the First Amended Bill of Particulars.

On October 9, 2015, defendant Dr. Varlotta administered bilateral L4-L5 and L6-S1 facet joint injections as treatment for plaintiff Steven Thaler's back pain. Based on the affirmation of plaintiffs' expert, Dr. Adam Carinci, plaintiffs allege that Dr. Varlotta departed from the standard of care by not wearing a face mask during the procedure; not using a fresh spinal needle for each

[1]Defendants assert that Spine Sports rendered none of the subject care to Mr. Thaler and plaintiffs' opposition is silent as to defendant Spine Sports The motion is therefore granted, in the absence of opposition, to the extent of awarding summary judgment to defendant Spine Sports, and dismissing the complaint as against such defendant.

of the four facet joint injections; not maintaining sterile technique by not having an assistant, not disinfecting the tops of the medication vials and contaminating the sterile drape over the arm of the fluoroscopy machine; and administering an excessive dose of Kenalog-40 at an improper interval, in contravention of the manufacturer's package insert.[2] Plaintiffs' expert also opines that Dr. Varlotta failed to obtain proper informed consent from Mr. Thaler, by failing advise him that the risk of infection would be increased by administering Kenalog-40 in "far excess" of the manufacturer's instructions, and that facet joint injections are an invasive procedure "normally performed" by a doctor with an assistant to "better ensure that sterile technique is maintained." Plaintiffs' expert opines that as a result of the departures and the lack of informed consent, Mr. Thaler developed a life threatening staph infection in his spine, necessitating multiple spinal surgeries and leaving him partially disabled.

From July 2014 to October 2015, Dr. Varlotta treated Mr. Thaler for back pain and knee pain. On January 16, 2015, Dr. Varlotta administered bilateral L4-5 and L5-SI intra-articular facet joint injections with 40mg of Kenalog-40 injected at each of the four joints using fluoroscopy for guidance. In May and September 2015, Mr. Thaler returned to Dr. Varlotta with complaints of lower back pain and limited range of motion of his lumbar spine. On October 9, 2015, Dr. Varlotta again administered bilateral L4-5 and L5-S1 intra-articular facet joint injections under fluoroscopic guidance with 40mg of Kenalog-40 injected at each of the four facet joints.

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[2]To the extent the complaint or the bills of particulars allege other departures that are not addressed by plaintiffs' expert, those departures are deemed withdrawn and the Court will not address them.

On October 14, 2015, Mr. Thaler advised Dr. Varlotta that his back pain was worsening. On October 16, 2015, Mr. Thaler presented to Syosset Hospital with complaints of dizziness, weakness, cough and nausea, and was discharged the same day with Tylenol and Tamiflu. On October 17, 2015, he presented to Winthrop Medical Affiliates Urgent Care facility complaining of worsening lower back pain, weakness, fever, chills, congestion, loss of appetite, fatigue and body aches. He was transferred by ambulance to the emergency room at Winthrop Hospital, where a CT scan showed a left lumbar epidural abscess in the L4-5 area.

On October 19, 2015, non-party Dr. Jeffrey Brown performed bilateral L4-L5 laminectomies and a left L4-5 medial facetectomy for drainage and debridement of the lumbar spinal epidural abscess. A culture of the spinal abscess tested positive for the bacteria Staphylococcus aureus (staph). On October 23, 2015, Mr. Thaler was discharged with home care services and home antibiotic infusion therapy. When he returned to Winthrop Hospital on November 10, 2015, an MRI of the lumbar spine showed edema surrounding the left L 4-5 facet joint and posterior fluid collection. Dr. Jeffrey Brown subsequently performed three separate procedures to close the fluid leak and Mr. Thaler was discharged on December 7, 2015.

On December 18, 2015, plaintiffs commenced the instant action, asserting claims for medical malpractice, lack of informed consent and loss of consortium, based on the facet joint injections administered by Dr. Varlotta on October 9, 2015. Defendants answered and are now moving for summary judgment. Plaintiffs oppose the motion and cross-move for an order deeming their First Amended Bill of Particulars, dated April 1, 2019, amended to that date. In response, defendants cross-move to strike the First Amended Bill of Particulars.

At the outset, the Court addresses the parties' cross-motions seeking relief with respect to plaintiffs' First Amended Bill of Particulars. The record shows that plaintiffs e-filed the Note of Issue on Thursday, March 28, 2015, and four days later on Monday, April 1, 2015, e-filed a First Amended Bill of Particulars.[3] At that time, plaintiffs did not move for leave of court to amend the bill of particulars post-note, and defendants did not object to the amended bill of particulars. On June 26, 2019, defendants filed their summary judgment motion, which included an expert affirmation from Dr. Duarte who relied solely on the allegations in the original bill of particulars.[4] On August 13, 2019, plaintiff filed a cross-motion to deem their amended bill of particulars amended nunc pro tunc as of April 1, 2019, and opposition to defendants' summary judgment motion, which included an expert affirmation from Dr. Carinci, who relied on the allegations in the First Amended Bill of Particulars. In reply, defendants cross-moved to strike the First Amended Bill of Particulars, but also submitted an Further Expert Affirmation from Dr. Duarte and an affidavit from Dr. Varlotta, both responding the new allegations and theories of liability in the amended bill of particulars.

CPLR 3042(b) permits one amendment of the bill of particulars as of right prior to the filing of the note of issue. See Fields v. Lambert Houses Redevelopment Corp, 105 AD3d 668 (1st Dept 2013). Although leave of court is necessary to amend the bill of particulars post-note, leave to amend is "ordinarily freely given absent surprise or prejudice to the defendants."

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[3]While plaintiffs' counsel asserts the amended bill of particulars was e-filed three days later, by the court's calculations, it was four days later and included a weekend.

[4]Plaintiffs' cross-motion incorrectly assumes that defendants based their summary judgment motion on the First Amended Bill of Particulars.

Henchy v. VAS Express Corp, 115 AD3d 478 (1st Dept 2014); accord Alvarado v. Beth Israel Medical Center, 78 AD3d 873 (2nd Dept 2010); Spiegel v. Gingrich, 74 AD3d 425 (1st Dept 2010); Cherebin v. Empress Ambulance Service, Inc, 43 AD3d 364 (1st Dept 2007).

As the excuse for filing the amended bill of particulars four days after filing the note of issue, plaintiffs' counsel explains that his long-standing paralegal suddenly died on February 8, 2019, and as a solo practitioner, he took over her responsibilities, as well as a number of matters related to her death; he had a planned vacation from April 4 to 9, 2019, which required him to meet a number of deadlines beforehand; and at the March 28, 2019, status conference, the Court denied his and defense counsel's request to extend the April 1, 2019 note of issue date, so he immediately prepared and filed the note of issue on March 28, 2019. As the excuse for not objecting to the amended bill of particulars when it was e-filed post-note on April 1, 2019, defendants' counsel explains that they were not aware until plaintiffs' opposition, that the amended bill of particulars was served after the note of issue was filed, as the associate who would have been notified of the NYSCEF filing "left the office" and the new associate, had not yet bee added to the NYSCEF service list.

Under the circumstances presented, given the de minimus four-day delay (which included a weekend) in plaintiffs' counsel filing the amended bill of particulars, the candid admission of defendants' counsel that they were not aware of the amended bill of particulars until plaintiffs opposed their summary judgment motion, and defendants' submission of an additional expert affirmation and an affidavit from Dr. Varlotta specifically addressing the new allegations and theories of liability in the amended bill of particulars, defendants cannot reasonably claim any

prejudice resulting from the delay. Thus, on the authority of case law holding that amendments to the bill of particulars are to be "freely given, absent prejudice or surprise to the defendants," the Court, in the exercise of discretion, grants plaintiffs' cross-motion and denies defendants' cross-motion, and plaintiffs' First Amended Bill of Particulars is deemed properly served and filed nunc pro tunc as of April 1, 2019. Henchy v. VAS Express Corp, supra; see Martino v. Bendo, 93 AD3d 500 (1st Dept 2012).

Turning to defendants' summary judgment motion, plaintiffs initially argue the motion is untimely since it was made beyond the 60-day deadline specified in the Court's Preliminary Conference Order. Plaintiffs' argument is without merit. On November 2, 2017, this Court issued a supplemental discovery order extending the deadline for dispositive motions to 90 days after the filing of the Note of Issue. The record shows that defendants' timely filed their summary judgment motion on June 26, 2019, which was within 90 days of March 28, 2019, the day Note of Issue was filed.

A defendant moving for summary judgment in a medical malpractice action must make a prima facie showing of entitlement to judgment as a matter of law by establishing that "in treating the plaintiff, there was no departure from good and accepted medical practice or that any departure was not the proximate cause of the injuries alleged." Roques v. Nobel, 73 AD3d 204, 206 (1st Dept 2010). To satisfy this burden, defendant must present expert opinion testimony that is supported by the facts in the record, addresses the essential allegations in the complaint or the bill of particulars, and is detailed, specific and factual in nature. See id; Joyner–Pack v. Sykes, 54 AD3d 727, 729 (2nd Dept 2008). Expert opinion must be based on facts in the record or facts personally known to the expert, and the opinion of defendant's expert should specify "in what

way" the patient's treatment was proper and "elucidate the standard of care." Ocasio-Gary v. Lawrence Hospital, 69 AD3d 403, 404 (1st Dept 2010). Defendant's expert opinion must "explain 'what defendant did and why.'" Id (quoting Wasserman v. Carella, 307 AD2d 225, 226 [1st Dept 2003]).

To avert summary judgment, plaintiff must "submit an affidavit from a medical doctor attesting that the defendant departed from accepted medical practice and that the departure was the proximate cause of the injuries alleged." Roques v. Nobel, supra at 207. Plaintiff's expert must address the specific assertions and opinions of defendant's expert. See Bogin v. Metz, 180 AD3d 404 (1st Dept 2020); Sternberg v. Rugova, 162 AD3d 456 (1st Dept 2018); Janelle M. v. New York City Health & Hospitals Corp, 148 AD3d 519 (1st Dept 2017), lv app den 32 NY3d 909 (2018). If the parties submit conflicting expert opinions that are adequately supported by the record, summary judgment must be denied. See Frye v. Montefiore Medical Center, 70 AD3d 15 (1st Dept 2009). "Where the expert's ultimate assertions are speculative or unsupported by any evidentiary foundation, however, the opinion should be given no probative force and is insufficient to withstand summary judgment." Diaz v. New York Downtown Hospital, 99 NY2d 542, 544 (2002). "An expert opinion that is contradicted by the record cannot defeat summary judgment." Bartolacci-Meir v. Sassoon, 149 AD3d 567 (1st Dept 2017).

In support of the motion, defendants submit two expert affirmations from Dr. Robert A. Duarte, who is board certified in psychiatry and neurology, pain medicine and headache medicine, and an affidavit from Dr. Varlotta.[5] Dr. Duarte reviewed the pleadings, the original

[5]As noted above, Dr. Duarte provided an expert affirmation with the original motion papers, and after it became clear from plaintiffs' opposition that they had filed an amended bill of particulars with new allegations and theories of liability, defendants responded with a Further

and amended bills of particulars, the depositions, the affirmation of plaintiffs' expert Dr. Carinci, and medical records including Dr. Varlotta's records and the records of Syosset and Winthrop hospitals. Dr. Duarte opines that Dr. Varlotta administered the facet joint injections in accord with accepted standards of care; Mr. Thaler's infection was not caused by any departure by Dr. Varlotta from proper standards of care; and infection is a known risk of any injection, even when facet joint injections are administered properly with sterile technique, as was done here.

Dr. Duarte addresses each alleged departure. First, as to the allegation that Dr. Varlotta departed from the standard of care by not wearing a face mask during the procedure, Dr. Duarte points to Dr. Varlotta's affidavit that he was wearing a face mask, as he always does, during Mr. Thaler's procedure. Dr. Duarte further opines, however, that the standard of care does not require use of a face mask for lumbar facet joint injections, and not using a mask is not a departure from accepted standards of care. He opines that the Centers for Disease Control ("CDC") document that plaintiffs rely on, "strongly recommends" but does not mandate that a surgical mask be worn for certain types of "high-risk prolonged" insertions into the spinal canal or subdural space, and that myelograms, lumbar punctures and epidural or spinal anesthesia are specifically mentioned as such high-risk procedures. Dr. Duarte opines that the premise for the CDC's recommendation is that the cerebrospinal fluid within the dura is a medium in which bacteria can grow and possibly cause bacterial meningitis, but with the facet joint injections Dr. Varlotta administered to Mr. Thaler, the injection needle does not enter the spinal canal, but instead is inserted into the facet joints that are created by extension of the bone on the side of

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Expert Affirmation from Dr. Duarte and an affidavit from Dr. Varlotta.

each of the vertebrae (facets) where they meet those of the adjacent vertebrae, and those joints are outside the spinal canal. Dr. Duarte notes that during the October 9, 2015 procedure, Dr. Varlotta took images of the placement of the spinal needles in Mr. Thaler's facet joints, which show that they were properly placed in the joints and are not in the spinal canal or the subdural space.

Second, as to the allegation that Dr. Varlotta departed from the standard of care by failing to use a fresh needle for each of the four facet joint injections, Dr. Duarte points to Dr. Varlotta's affidavit that he used one sterile spinal needle for injections on the right side, and a new sterile needle for injections on the left side; he made only one spinal needle insertion on each side; and he re-oriented the needle from the upper facet joint to the lower adjacent facet joint to inject that joint without withdrawing the spinal needle through the skin. Dr. Duarte opines that is a proper technique that constitutes a single use of each sterile spinal needle, and that a single insertion of a spinal needle into a facet joint and the re-orientation of the needle to an adjacent facet joint without removing the needle from the skin is proper practice.

Third, as to the allegations that Dr. Varlotta departed from the standard of care by failing to maintain sterile technique by not having an assistant, not disinfecting the tops of the medication vials and contaminating the sterile drape over the arm of the fluoroscopy machine, Dr. Duarte opines that the standard of care does not require an assistant for a procedure involving facet joint injections. He opines that the standard of care requires the use and maintenance of sterile technique, and while some physicians giving injections find it easier or more convenient to have an assistant, Dr. Varlotta's technique accomplished this without the need of an assistant.

Pointing to Dr. Varlotta's testimony describing the procedure, Dr. Duarte opines that the fluoroscopy unit he used was activated by a foot pedal, so another person was not needed to operate the unit; Dr. Varlotta positioned the machine's C-arm (a movable arm extending from the fluoroscopy machine that contains the transducer unit that takes the images) on Mr. Thaler's right side for the first right-sided injections; he placed a sterile drape over the "arm" of the machine to ensure that sterile precautions were maintained when he later used his gloved hand to "swing" the C-arm to reposition the transducer on the left side for the left-sided injections; and after positioning the machine on the right side, he prepared the medications and syringes that were laid out on a sterile field on a table that could be wheeled to the side of the fluoroscopy table. Dr. Duarte opines that this method described by Dr. Varlotta, properly maintained a sterile field throughout the procedure.

Dr. Duarte further opines that Dr. Varlotta described the appropriate and proper use of Chloroprep antiseptic solution to cleanse the skin and proper technique to preserve the sterile area. Specifically, Dr. Varlotta used the swab provided to apply the Chloroprep solution to the skin in three concentric circles and allowed the solution to dry before the injections, which is proper skin preparation that is accepted to cleanse the skin of potential bacteria that can cause infection when needles are inserted to deliver pain medication. He opines that while this process reduces infection risk from skin organisms for injection procedures to a medically accepted degree considered to be standard adequate preparation, it does not 100% guarantee that all organisms will be eradicated or that infection cannot occur; but the incidence of infection is less than 1%, as organisms can be present below the skin surface, sometimes in hair follicles, that are not reached by the Chloroprep antiseptic.

Dr. Duarte opines that Dr. Varlotta only touched the needle hubs and syringes, but never the needles themselves, and did not touch the area of cleansed skin though which the injections were made. He opines that Dr. Varlotta's testimony about drawing medication from the medication vials with one gloved hand and one non-gloved hand comports with the standard of care, as Dr. Varlotta testified that he put out 90% alcohol soaked gauze while preparing the syringes, which Dr. Duarte understands to mean that he dabbed the tops of the vials on the alcohol soaked gauze to cleanse them before inserting the needle used to draw medication into a syringe; since needles come in sterile packages, they are not cleansed with alcohol; and the only purpose for putting out 90% alcohol soaked gauze while drawing up medication is for cleansing the vial tops. He notes that his understanding of Dr. Varlotta's testimony is consistent with Dr. Varlotta's affidavit.

As to the last allegation that Varlotta departed from the standard of care by administering an excessive dose of Kenalog-40 at an improper interval in contravention of the manufacturer's package insert, Dr. Duarte opines the dosage administered by Dr. Varlotta is within accepted standards, and the package insert is only a recommendation by the manufacturer, and does not represent a standard of care. He opines that Dr. Varlotta performed the facet joint injections at an appropriate interval, nearly nine months after the prior facet joint injections in January 2015, and it is appropriate to repeat the injections at much less frequent intervals as clinical circumstances warrant. He opines there is no acknowledged significant increased risk of injection related infection in performing the facet joint injections in this standard way; any reduction of immune response related to steroids is from systemic steroid administration over an extended period of time, not from intermittent local steroid injections in these accepted amounts separated in time,

and particularly given the nine month interval between the January and October 2015 injections. Dr. Duarte states that he is aware that the half life of Kenalog is 18 to 36 hours, and that the half-life of a drug represents the time it takes for its effect to diminish by half, and then again by half, and then again by half and so on until it is gone; in general 5 to 6 half-lives clear drugs from the system; and for ths reason, any "immunosuppresive" effect, if any, claimed by plaintiffs' expert, due to the administration of the Kenalog in January 2015, would have dissipated long before the October 2015 injections.

Based on the foregoing, defendants have made a prima facie showing for entitlement to judgment as a matter of law with respect to the alleged departures, and the burden shifts to plaintiffs to establish the existence of an issue of fact. In support of their opposition, plaintiffs submit the expert affirmation of Dr. Adam Carinci, who is board certified in anesthesiology and pain management. He reviewed the pleadings, the original and amended bills of particulars, the parties' depositions, Dr. Varlotta's medical records, the records of Syosset and Winthrop hospitals, the MRI reports of Mr. Thaler's lumbar spine, and the affirmation of defendants' expert, Dr. Duarte. As determined below, Dr. Carinci's affirmation is insufficient to raise an issue of fact with respect to any of the alleged departures, as his assertions and opinions are not substantiated by facts in the record. See Diaz v. New York Downtown Hospital, supra.

Dr. Carinci asserts that "[a]ccording to Dr. Varlotta's testimony, he was not wearing a face mask when he performed the October 9, 2015 face joint injections on Mr. Thaler." That assertion mischaracterizes Dr. Varlotta's testimony and is directly refuted by evidence in the record. At his deposition, Dr. Varlotta was asked, "what were you wearing when the procedure took place," and he answered, "I was wearing a scrub top and pants and I was wearing a head

apron and a throat guard." Dr. Varlotta was not asked if he was wearing and mask, and there is no affirmative proof that he did not wear a mask. To the contrary, Dr. Varlotta's affidavit clarifies his testimony by stating that the

> answer I gave referred to the items of "clothing" I was wearing throughout that day, which were a scrub top and pants and a lead (not 'head') apron and a throat guard. These are items that I would consider to be what I was "wearing." I was never asked if I used a surgical masking in performing these injections. I used sterile gloves in performing these injections, but did not consider them or identify them as what I was "wearing." Gloves and masks are discarded after use with each patient throughout the day. In fact I do use a surgical mask when performing spine procedures such as this facet joint injection and I used a mask when performing Mr. Thaler's facet joint injection procedure.

Since the transcript of his deposition, shows that Dr. Varlotta was never directly asked the question whether he was wearing a mask during the procedure, the statements in his affidavit do not contradict his earlier testimony, and as such are properly considered as evidence in support of defendants' summary judgment motion. See Botfeld v. Wong, 104 AD3d 433 (1st Dept 2013); Cox v. McCormick Farms, Inc, 144 AD3d 1533 (4th Dept 2016); O'Leary v. Saugerties Central School District, 277 AD2d 662 (3rd Dept 2000). Thus, in view of Dr. Varlotta's affidavit establishing that he was wearing a mask and the absence of evidence to the contrary, the opinion of plaintiff's expert lacks factual support in the record and fails to raise an issue of fact as to this alleged departure.

Dr. Carinci asserts that "Dr. Varlotta testified as to using a total of two spinal needles for the four facet joint injections he performed on October 9, 2015," which demonstrates that he was "not utilizing a fresh needle for each injection." He opines that a "used needle" can have bacteria from the skin and blood on it, and "by reinserting the same needle, Mr. Thaler was potentially

exposed to staph bacteria adhering to the needle from the prior injection being transferred to his fact joint." Dr. Carinci's opinion lacks factual support in the record. While it is undisputed that Dr. Varlotta testified that he used two spinal needles for the four facet joint injections, he did not testify that he removed and reinserted the same the needles, and his affidavit conclusively refutes Dr. Carinci's assertion that he reinserted the needles. Dr. Varlotta's affidavit provides the following specific information about the technique he used in administering the injections:

> I used two sterile spinal needles for this procedure, one for the right side and one for the left side. One sterile needle was inserted through the skin once for the right sided injections. Then a new sterile needle is inserted once through the skin on the left side for the left sided injections. That same spinal needle inserted once through the skin was first inserted into the upper facet joint on that side for injection and then it was re-oriented to the lower adjacent facet joint for that facet injection without removing it from the skin in-between injecting each facet joint. Then a new spinal needle was used for the left side, and it was inserted once. After injection of the upper facet joint it was re-oriented to the lower joint for injection. It was not removed from the skin in-between. Thus, there was a single insertion of each spinal needle on each side and there were not multiple insertions of either of the spinal needles through the skin. They were used only for Mr. Thaler for this procedure and thus were not "re-used" in any way. I was not asked at my deposition, nor did I state, that the spinal needle on the right side or on the left side was removed and re-inserted through the skin for the second of the two facet joints in each side. Each sterile spinal needle was inserted once and re-oriented without withdrawing it through the skin. This is my standard practice for facet joint injections like Mr. Thaler's and this is the technique I used for all of his fact joint injections including on October 9, 2015.

Once again, Dr. Varlotta's affidavit does not contradict his earlier deposition testimony, so it is properly considered as evidence in support of defendants' summary judgment motion. See Botfeld v. Wong, supra; Cox v. McCormick Farms, Inc, supra; O'Leary v. Saugerties Regional School District, supra. Thus, since the uncontroverted evidence establishes that Dr. Varlotta did not remove and reinsert the spinal needles, Dr. Carinci's opinion is not supported by facts in the record and fails to raise an issue of fact as to this alleged departure.

Although Dr. Carinci opines that the standard for facet joint injection requires a physician to have an assistant for the procedure, he specifically opines that an "assistant could have ensured" that certain "lapses in sterile technique did not take place," which is founded on the standard of care to maintain and employ sterile technique prior to and during the procedure. And, as to those "lapses in sterile technique," Dr. Carinci opines that Dr. Varlotta did not properly disinfect the tops of the medication vials prior to drawing medication from them, and contaminated the sterile drape on the arm of the fluoroscopy machine.

Dr. Carinci's offers only a conclusory and unsupported opinion that Dr. Varlotta failed to properly disinfect the tops of the medication vials. He neither mentions nor addresses Dr. Varlotta's testimony detailing the steps he took in preparing the medication and syringes:

> Then I opened the sterile drape on the table. I then take each individual syringe and needle and open them and place them onto the sterile field. I open the three containers of the medication. I also have a tray with gauze pads that has 90 percent alcohol in it and I then place one glove on in order to then draw the syringe. I have the vials in my left hand which does not have a glove on, a sterile glove, and I pick up the syringe with the needle after dabbing it into the alcohol. I then withdraw the medications into the syringe.

To the extent such testimony may have created an ambiguity as to whether he was "dabbing" the medication vial or the needle on the alcohol soaked gauze, Dr. Varlotta's affidavit d provides the following clarification:

> The answer I gave indicates that I dabbed the vials on the alcohol soaked gauze before inserting the needle to draw the medications into a syringe. When that answer says "I pick up the syringe with the needle after dabbing it onto the alcohol," that references dabbing the top of the vial on the alcohol soaked gauze before inserting the needle. To the extent that anyone would read that to say that the needle rather the vial was dabbled on the alcohol soaked gauze, I do not dab the needle used to draw the medication into the syringe on the alcohol soaked gauze, as that needle comes out of a sterile package.

Since these statements clarify and do not contradict Dr. Varlotta's prior testimony, they are properly considered as evidence in support of defendants' motion to show that Dr. Varlotta dabbed the tops of the medication vials, and not the needles, on 90% alcohol soaked gauze. See Cuevas v. Baruti Construction Corp, 164 AD3d 447 (1st Dept 2018). Even though Dr. Varlotta's testimony may have been ambiguous, it was clearly relevant to the issue of whether the medication vials were properly disinfected. Notably, in his original affirmation, defendants' expert, Dr. Duarte, specifically refers to Dr. Varlotta's testimony about using 90% alcohol soaked gauze, and opines that the method described by Dr. Varlotta for preparing the medications and syringes properly created and maintained s sterile field throughout the procedure. Dr. Carinci, however, neither mentions Dr. Varlotta's testimony nor addresses Dr. Duarte's opinion, and fails to offer any opinion of his own as to the "proper method" for cleansing or disinfecting the vials, and whether the use of 90% alcohol soaked gauze satisfies the standard of care for disinfecting the tops of medication vials and maintaining sterile conditions. Thus, Dr. Carinci's conclusory and unsupported opinion fails to raise an issue of fact as to this alleged departure.

Dr. Carinci likewise fails to address Dr. Duarte's opinion that the standard of care does not require an assistant for facet joint injections, but only that sterile technique be employed and maintained, and even if some physicians find it easier or more convenient to have an assistant, Dr. Varlotta's technique "clearly accomplishes this without the need for an assistant." Dr. Duarte bases his opinion on Dr. Varlotta's testimony that he used a fluoroscopy machine activated with a foot pedal, so he could operate the machine by himself; and after positioning the machine on Mr. Thaler's right side, he placed a sterile drape over the arm of the machine to ensure that sterile precautions were maintained when he later used his gloved hand to reposition

the arm of the machine on the left side. Without support in the record, Dr. Carinci simply opines that the sterile drape was "subject to contamination" when Dr. Varlotta was "handling needles that had punctured the patient's skin while grasping the c-arm on multiple occasions." That opinion, however, is speculative and fails to refute Dr. Duarte's opinion that Dr. Varlotta only touched the needle hubs and syringes, but never the needles themselves, and did not touch the area of cleansed skin through which the injections were made. Thus, Dr. Carinci's conclusory and unsupported opinions fail to raise an issue of fact with respect to these alleged departures.

As the last departure, Dr. Carinci improperly relies on the information contained in the manufacturer's package insert for Kenalog-40 to establish the standard of care. Quoting the sections of the package insert entitled "Infections," "Precautions" and "Dosage," Dr. Carinci opines that Dr. Varlotta departed from accepted medical practice by administering an excessive amount of Kenalog-40 "in disregard of the drug's warnings and dosage instructions" in the manufacturer's package insert; and , that "[i]in accordance with the standard of care, facet joint injections of corticosteriods [e.g. Kenalog-40] must be performed in strict adherence to the manufacturer's instructions with respect to the composition of the solution to be injected, the quantity per injection and the intervals between injections."

It is undisputed that at his deposition, Dr. Thaler acknowledged that he injected 40 mg of Kenalog in each of four facet joints for a total of 160 mg, and that such amount exceeded the dosage amount in the manufacturer's package insert. It is well settled law, however, that the information contained in a drug manufacturer's package insert is only a recommendation, and by itself does not constitute the standard of care. See Spensieri v. Lasky, 94 NY2d 231 (1999).

Moreover, Dr. Carinci fails to address Dr. Duarte's opinion that the dosages administered by Dr. Varlotta are within accepted standards; the package insert is only a recommendation by the manufacturer, and does not represent a standard of care; and Dr. Varlotta administered the facet joint injections at an appropriate interval, nearly nine months after the prior facet joint injections in January 2015, and it is appropriate to repeat the injections at much less frequent intervals as clinical circumstances warrant. Thus, Dr. Carinci's unsupported opinion fails to raise an issue of fact as to this alleged departure.

Finally, as to the lack of informed consent claim, a defendant moving for summary must make a prima facie showing that plaintiff was informed of any reasonably foreseeable risks, benefits and alternatives of the treatment rendered. See Public Health Law §2805–d (1)]; Smith v. Cattani, 2 AD3d 259, 260 (1st Dept 2003). "The mere fact that plaintiff signed a consent form does not establish the defendants' prima facie entitlement to judgment as a matter of law." Godel v. Goldstein, 155 AD3d 939 (2nd Dept 2017) (quoting Schussheim v. Barazani, 136 AD3d 787 [2nd Dept 2016]). Once defendant's burden is satisfied, plaintiff must show that defendant doctor failed to fully apprise him or her of a the reasonably foreseeable risks, benefits and alternatives of the procedure that a reasonable practitioner would have disclosed, and that a reasonably prudent person in plaintiff's position, fully informed, would have opted against the procedure. See Orphan v. Pilnik, 15 NY3d 907 (2010) [citing Public Health Law §§ 2805–d (1), (3)]. "Expert medical testimony is required to prove the insufficiency of the information disclosed to the plaintiff." Id at 908; see Katz v. Sen, 111 AD3d 438 (1st Dept 2013).

Based on Dr. Duarte's affirmation, defendants have made a prima facie showing for judgment as a matter of law on the lack of informed consent claim. Dr. Duarte opines that when

Mr. Thaler presented to Dr. Varlotta on October 9, 2015 for the second bilateral L4-5 and L5-Si facet joint injections with the identical dose of Kenalog-40, Dr. Varlotta properly reviewed the risks of the procedure, including infection, bleeding, increased pain, nerve damage, paralysis or death, and Mr. Thaler consented to the procedure, both verbally and in writing. He points to the notes in Dr. Varlotta's operative report that he discussed the procedure, including its risks, with Mr. Thaler and obtained his verbal and written informed consent. Noting that the written consent form signed by Mr. Thaler states that the risks of the procedure include infection, Dr. Duarte opines that bleeding and infection are the two most common risks and complications from a facet joint injection, and even in ideal conditions, infections occur and are a risk of the procedure. He further opines that contrary to the opinions of plaintiffs' expert, Dr. Carinci, there is no accepted evidence that he is aware of establishing that the risk of infection increased with the amount of steroid injected by Dr. Varlotta, so that a different informed consent was warranted or required by the accepted standard of care, beyond that conveyed to Mr. Thaler; and it was not necessary or required that Dr. Varlotta advise patients that other providers use an assistant when giving facet joint injections, and he is not aware of any established accepted evidence of any increased risk or incidence of infection following facet joint injections with the use of an assistant versus not.

In opposition, the opinions of plaintiff's expert, Dr. Carinci, are insufficient to raise an issue of fact. He opines that Dr. Varlotta failed to obtain a proper informed consent from Mr. Thaler by not advising that the risk of infection would be increased by administering Kenalog-40 in "far excess" of the manufacturer's instructions, and that facet joint injections are an invasive procedure "normally performed" by a doctor with an assistant to "better ensure that sterile

technique is maintained." Since this Court has already determined that Dr. Carinci's opinions about he dosage of Kenalog-40 and the use of an assistant, do not represent the standard of care so as to support a medical malpractice claim, the failure to convey such information is not a "departure from what a reasonable practitioner would have disclosed," so as to support a lack of informed consent claim. Orphan v. Pilnik, supra at 908; see Katz v. Sen, supra at 438. Additionally, Dr. Carinci fails to opine that a reasonably prudent person in Mr. Thaler's position, fully informed of such information, would have elected not to undergo the facet joint injections. See Public Health Law §2805-d(1), (3); Orphan v. Pilnik, supra. While plaintiff's testimony may be sufficient to establish the necessary element of what a reasonable person would have done if fully informed, Mr. Thaler merely testified that Dr. Varlotta did not advise him that the risks of the procedure included infection; he did not state that he would have declined the procedure or opted for an alternative, had he been informed of the risk of infection, or any other risk. See e.g. Hugh v. Ofodile, 87 AD3d 508 (1st Dept 2011) (expert testimony not required to show what a reasonable person would have done).

Thus, since plaintiffs have failed to establish an issue of fact as to any of the alleged departures, or the lack of informed consent claim, so as to defeat defendants' motion, defendant Dr. Varlotta is entitled to summary judgment. And as noted above, in the absence of opposition, defendant Spine Sports is also entitled to summary judgment. Given the dismissal of Mr. Thaler's claims, the loss of consortium claim of plaintiff Lisa Thaler, must also be dismissed.

Accordingly, it is

ORDERED that plaintiffs' cross-motion is granted and plaintiffs' First Amended Bill of Particulars is deemed properly served and filed nunc pro tunc as of April 1, 2019; and it is further

ORDERED that defendants' cross-motion to strike plaintiffs' First Amended Bill of Particulars, is denied; and it is further

ORDERED that defendants' motion for summary judgment is granted, and the complaint in its entirety is dismissed as against defendants Gerard P. Varlotta, D.O. and Spine Sports Occupational Rehabilitation Associates, LLC, and the Clerk is directly to enter judgment accordingly.

DATED: September 15, 2020

ENTER:

J.S.C.

HON. JOAN A. MADDEN
J.S.C