NOT FOR PUBLICATION

(Doc. Nos. 138, 139, 140, 141, 148, 152)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

MATTHEW AND KORRIN SEAVEY, husband and wife, Plaintiffs,	:	Civil No. 11-2240 (RBK/JS)
v.	:	**OPINION**
GLOBUS MEDICAL, INC., et al. Defendants.	:	

KUGLER, United States District Judge:

This matter comes before the Court on a number of summary judgment motions filed by the parties in this case. Defendants Mark A. Testaiuti, M.D. and Coastal Spine, P.C.[1] have moved for summary judgment on all claims asserted against them. (Doc. No. 138). Globus Medical, Inc. ("Globus") has also moved for summary judgment on all claims against it. (Doc. No. 140). All defendants have also filed a joint motion for summary judgment as to causation (Doc. No. 141), and Matthew Seavey ("Plaintiff")[2] has also moved for partial summary judgment on the issue of causation (Doc. No. 148). Finally, all defendants have moved to

[1] Dr. Testaiuti conducted his practice through Coastal Spine, P.C. Sec. Am. Compl. ¶ 9. Because the Second Amended Complaint contains no independent allegations against Coastal Spine, other than those asserted against it due to its relationship with Dr. Testaiuti, this Opinion at times will refer to Dr. Testaiuti alone, although the claims against him or arguments advanced by him are in actuality those of both Dr. Testaiuti and Coastal Spine.

[2] Korrin Seavey is also named as a plaintiff, but because her claim is limited to a per quod claim, this Opinion refers to Matthew Seavey when using the term "Plaintiff."

preclude the expert testimony of Dr. Jamie Williams, and to strike an affidavit by Dr. Williams (Doc. Nos. 139, 152).

I. INTRODUCTION

This action arises from an ultimately unsuccessful lumbar fusion surgery performed by Dr. Testaiuti on April 22, 2009, wherein he fused one level of Plaintiff's spine. As part of the surgical procedure, Dr. Testaitui inserted a spinal fixation device, the Globus Medical Thoracolumbar Transition Stabilization System ("Transition Device"), attaching it to two levels of Plaintiff's spine. Plaintiff seeks to proceed to trial on product liability claims related to the Transition Device, and on a lack of informed consent claim against Dr. Testaiuti and Coastal Spine.

A. Plaintiff's Relevant Prior Medical History

Plaintiff originally experienced low back pain in 1999, at the age of 26. Globus' Statement of Undisputed Material Facts ("SUMF") ¶ 23. By 2005, Plaintiff reported to his physician that his back symptoms had progressively worsened over the previous two years, and interfered with his work, sleep, daily routine, and recreation. Id. ¶ 41. In April 2006, he was hospitalized for lower back pain, at which time diagnostic tests were performed on Plaintiff's low back. Id. ¶¶ 44-45. An MRI study showed that Plaintiff had a two-level degenerative disc at L4-5 and L5-S1, a large extruded disc fragment at L5-S1, and a disc herniation at L4-5. Id. ¶ 45. That same month, Plaintiff began disability leave from his employment, which lasted for approximately two months. Id. ¶ 47, Pl. Resp. to SUMF ¶ 47. On April 20, 2006, Plaintiff underwent his first lumbar spine surgery, which involved a partial discectomy at L5-S1. SUMF ¶ 51.

Approximately eight months after his discectomy, in November 2006, Plaintiff reported experiencing radiating back pain and spasms which rendered him unable to walk at times. Id. ¶ 53. He continued to receive medical care for his pain symptoms throughout 2007, including chiropractic treatment, osteopathic manipulation, various types of injection therapy, physical therapy, and management of his pain through medication. Id. ¶¶ 55-67. Plaintiff reported during this time period that none of the treatments or medications he received had relieved his pain. Id. ¶ 66. In May 2008, Plaintiff underwent another MRI, which showed significant lumbar pathology, including degenerative disc disease at L4-5 and L5-S1, with foraminal narrowing and encroachment upon the exiting L5 nerve root. Id. ¶ 71. Subsequent to this diagnosis, Plaintiff received treatment at the Pain Institute in New York, which included physical therapy and trigger point injections. Id. ¶ 74. In January 2009, Plaintiff was hospitalized again with complaints of chronic intractable back pain and left leg weakness and pain. Id. ¶ 81. He indicated that the pain had worsened over the few days prior to his hospitalization. Id.

Plaintiff was also hospitalized on a number of occasions for a condition known as Normokalemic Periodic Paralysis, which he was initially diagnosed with in his teenage years. Id. ¶ 29; Schultz Consultation Rpt., Apr. 1, 2010, Globus Mot. Summ. J. Ex. Vol. 3, Ex. 20. He has treated with multiple physicians who are considered experts in treating this condition. Schultz Consultation Rpt., Apr. 1, 2010. At times, Plaintiff's excruciating pain and muscle spasms were attributed by his treating physicians to the Normokalemic Periodic Paralysis diagnosis. Leone Discharge Summary, Apr. 8, 2010, Globus Mot. Summ. J. Ex. Vol. 3, Ex. 20.

B. Treatment and Surgery with Dr. Testaiuti

On April 2, 2009, Plaintiff initially presented for treatment to Dr. Testaiuti at Coastal Spine. Id. ¶ 88. Dr. Testaiuti ordered a discogram, and discussed surgical options with Plaintiff,

as Plaintiff's most recent MRI showed a complete collapse at L5-S1 with listhesis. Id. ¶ 90. The surgical options included a fusion of L5-S1, and either a dynamic stabilization or a fusion at L4-5, depending on the results from the discogram. Id. The discogram demonstrated that Plaintiff had pain at the L5-S1 level, but that the L3-4 and L4-5 levels were pain-free. Id. ¶ 93. On April 16, 2009, Plaintiff again met with Dr. Testaiuti and discussed the results of the discogram. Dr. Testaiuti informed Plaintiff of three surgical options. Id. ¶ 96. The options included (1) a two-level fusion of L4-5 and L5-S1; (2) a one-level fusion at L5-S1 with dynamic stabilization at L4-5 with the understanding that a fusion of L4-5 may be necessary at a later date; or (3) a fusion at L5-S1 and a total disc replacement at L4-5. Id. Dr. Testaiuti's report from that visit indicates that Plaintiff decided against the two-level fusion at the time of the visit, but that he wanted to discuss the case with his colleagues. Testaiuti Rpt., Apr. 16, 2009, Pl. Opp'n Ex. 18. However, he did schedule the procedure involving the L5-S1 fusion with dynamic stabilization at L4-5, for the following week. Id. The same day, Plaintiff also signed a form entitled "Consent for Operation and Procedure," authorizing the procedure, and affirming that he had been informed of the benefits and risks, some of which are described in the form. Signed Consent Form, Apr. 16, 2009, Pl. Opp'n Ex. 19. Plaintiff admits to signing the form, but disputes that he actually made an informed decision as to whether to undergo the procedure. Pl. Resp. to SUMF ¶ 98.

On April 22, 2009, Dr. Testaiuti operated on Plaintiff's lumbar spine at the Fellowship Spine Surgery Center in New Jersey. SUMF ¶ 99. The operation was the one scheduled the week before, which involved fusion at L5-S1, and dynamic stabilization without fusion at L4-5. Id. ¶ 98. As part of the procedure, the Globus Transition Device was implanted in Plaintiff's lower spine. Id. ¶ 102. The objective of a spinal fusion is to connect adjacent vertebrae in the subject's spine to reduce motion and pain in a diseased or injured segment of the spine. Id. ¶¶ 3,

12. This is accomplished by packing small chips of bone, known as "bone graft," between or alongside the vertebrae that are to be fused. Id. ¶ 12. The premise of fusion is to restrict mobility, and to alleviate spinal pain as a consequence. Id. ¶ 220.[3] Surgeons commonly use spinal fixation devices to provide temporary stability to the bones being fused. Id. ¶¶ 14, 15. The objective of such a device is to improve the chances of a successful fusion of the vertebrae. Id. ¶ 16. Fixation devices generally consist of titanium rods, plates and spacers, which are attached to the vertebrae with screws that run through the pedicles into the vertebrae. Id. ¶ 17. The pedicles are boney arches that connect the front of the vertebral body to the bones around and behind the spinal cord. Id. ¶ 18.

Dynamic stabilization involves the application of a fixation device classified as "semi-rigid" to a level adjacent to the level being fused. Id. ¶¶ 233-34. A dynamic fusion procedure is designed to combine the technique of traditional fusion with the use of flexible materials, so that the construct provides both the stability needed for fusion as well as a more natural position of the vertebral bodies during bending, while fusion develops. Id. ¶ 239. Thus, some of the motion in the spine is preserved while the vertebrae fuse. Id. ¶ 240. While there is some debate in the medical community as to the efficacy of dynamic stabilization, it has been accepted in the medical field for decades and is a widely accepted treatment that is taught in major teaching hospitals in this country. Id. ¶¶ 240, 243; Finn Dep. 386-88. Semi-rigid devices have been used

[3] Plaintiff disputes a number of facts set forth in Globus' Statement of Undisputed Material Facts as "not relevant" or "incomplete." See, e.g., Pl. Resp. to SUMF ¶¶ 12, 220, 222. Because these are not permissible responses under the local rules, the Court deems as admitted any statement that is disputed by Plaintiff on grounds of relevance or completeness only. See L. Civ. R. 56.1; Durkin v. Wabash Nat'l, Civ. No. 10-2013, 2013 WL 1314744 (D.N.J. Mar. 28, 2013) (deeming as admitted facts that are disputed as not relevant, as "arguments as to the force of those facts belong[] in the brief."). Similarly, statements objected to as "opinion of Defendant's expert" without reference to anything in the record to support a dispute of fact are deemed admitted. The facts relevant to this Opinion set forth by Globus that are deemed as admitted for these reasons are those in paragraphs 9, 12, 145, 220, 222, 233, 234, 254, 262, 265, and 269-73 of Globus' SUMF. The Court also notes that Globus fails to support some of its statements by citations to the record, and the Court therefore does not deem any of these statements as admitted. See SUMF ¶¶ 19, 47, 111.

as both a fusion and non-fusion device since the 1990's in Europe, and since the early 2000's in the United States. SUMF ¶ 254.

Prior to Plaintiff's surgery, Dr. Testaiuti had used several dynamic stabilization devices that were not manufactured by Globus. Id. ¶ 249. He attended lectures by doctors who were utilizing the dynamic stabilization technique with a semi-rigid fixation device in their practices, with the disclaimer made by those doctors that such use was "off-label." Id. ¶ 248. Subsequently, Dr. Testaiuti began using dynamic stabilization with semi-rigid devices in a manner not approved by the FDA in 2007 or 2008. Id. ¶ 252.

Approximately one month after the surgery, Plaintiff reported to Dr. Testaiuti that his low back pain had considerably improved and his radiating symptoms had resolved. Id. ¶ 105. Dr. Testaiuti reported that Plaintiff had "good early postsurgical results" at that time. Id. ¶ 104. Once Plaintiff began physical therapy in June 2009, he suffered from low back tightness that increased on the day of and the day following his physical therapy appointments. Id. ¶ 113. In August 2009, Plaintiff returned to his employment. Id. ¶ 122. By November, 2009, Dr. Testaiuti noted that although complete fusion had not occurred, Plaintiff was "feeling well with regards to his low back," and had "significant symptom improvement." Id. ¶ 130.

However, later in November 2009, Plaintiff sought treatment with a pain management physician, reporting that the April 2009 surgery had not resolved his lower back issues. Id. ¶ 134. In December 2009, Plaintiff had a trial spinal cord stimulator implanted, and then removed. Id. ¶ 135. In February 2010, Plaintiff had his last office visit with Dr. Testaiuti. Id. ¶ 136. Although the report for that visit indicates that Plaintiff continued to enjoy some improvement of his back pain and relief of his radicular pain, it indicates that Dr. Testaiuti asked Plaintiff "to

continue to explore other options regarding pain relief." Id. ¶137; Testaiuti Letter, Feb. 2, 2010, Pl. Opp'n Ex. 22.

C. Background of the Transition Device

The Transition Device that Dr. Testaiuti implanted in Plaintiff is a prescription medical fixation device, consisting of a rod, a spacer with cord, a metallic plate, and six pedicle screws. SUMF ¶ 1. The device was designed and sold by Globus, which manufactures spinal fixation devices used by surgeons to provide temporary stability to bones while promoting fusion. Id. ¶ 14. The Transition Device was approved for marketing by the United States Food and Drug Administration ("FDA") in February 2009, as a spinal fixation device to be used as an "adjunct to fusion." Id. ¶ 9. The FDA regulates the marketing and sale of medical devices pursuant to the Medical Device Amendment of 1976 ("MDA"). Id. ¶ 260. The clearance obtained by Globus for the Transition Device was known as a "510(k) clearance." Id. ¶ 262. This clearance is governed by Section 510(k) of the Federal Food, Drug, and Cosmetic Act, and requires that a manufacturer show that a device is "substantially equivalent" to an existing FDA-approved device. Id. ¶¶ 262-63.

The 510(k) clearance did not permit Globus to market the Transition Device for use as a dynamic fusion device. Id. ¶ 265. The approval letter indicated that "there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling . . . ." Id. The FDA required that a warning be included in the labeling of the device, which read as follows:

> The safety and effectiveness of this device has not been established for the intended use of spinal stabilization without fusion. This device is only intended to be used when fusion with autogenous bone graft is being performed at all instrumented levels.

Id. Globus included the warning in the package insert, product brochure, surgical technique guide, and animation for the Transition Device. Id. ¶ 270. Thus, Dr. Testaiuti's decision to use to the device to stabilize Plaintiff's L4-5 vertebrae without fusing at that level was a use not evaluated or approved by the FDA, or an "off label" use of the device. Id. ¶ 269.

D. Subsequent Back Treatment and Surgeries

In February 2010, Plaintiff underwent a subsequent surgical procedure with a neurologist at the University of Pennsylvania, which involved the implantation of a permanent spinal cord stimulator. Id. ¶ 140. The hardware from the April 2009 surgery was still intact at that time. Finn Dep. 443. On March 29, 2010, approximately one year after the surgery performed by Dr. Testaiuti, Plaintiff was hospitalized for four days for intractable back pain and muscle spasms. SUMF ¶ 141. At the time of that hospitalization, diagnostic studies indicated that Plaintiff's hardware was still intact. Id. ¶ 142; see also Finn Dep. 464. Later in April 2010, Plaintiff was hospitalized again with similar complaints of back pain and muscle spasms. SUMF ¶ 143. Throughout the remainder of 2010, Plaintiff continued to treat with various medical professionals with complaints of back pain, muscle spasms, and radiating pain. Id. ¶¶ 145-56.

On January 18, 2011, a diagnostic test first indicated a problem with the Transition Device. On that date, an X-ray report taken of Plaintiff's spine at the University of Colorado Medical Center found a fracture of the right L4 pedicle screw. Id. ¶ 157. On January 26, 2011, Plaintiff was first evaluated by Dr. Michael Finn, a Neurosurgeon at the University of Colorado School of Medicine, for complaints of low back and radiating pain into his legs. Id. ¶ 158, Pl. Resp. to SUMF ¶ 158. Dr. Finn's impression was that the pain was likely from L5-S1 non-union. SUMF ¶ 159. Ultimately, Dr. Finn operated on Plaintiff on April 7, 2011, which involved a removal of the Transition Device and the insertion of other instrumentation. Id. ¶

166. Dr. Finn revised the L5-S1 fusion and fused Plaintiffs L4 and L5 vertebrae as part of the April 7, 2011 surgical procedure. Finn Report 7. Plaintiff's pain was relieved for a time following his surgery, but within a few months his back pain and muscle spasms returned. SUMF ¶ 169.

Plaintiff's most recent surgical procedure that is detailed in the record is the implantation of a Baclofen pump to treat his chronic pain and spasticity. Id. ¶¶ 179-80. This procedure was performed in June 2012. Id. ¶ 180. In November 2012, Plaintiff was again hospitalized for three days due to back pain. Id. ¶ 182. In early 2013, Dr. Finn indicated that Plaintiff continued to suffer from pain "of uncertain etiology." Id. ¶ 186.

On April 20, 2011, Plaintiff filed his complaint, invoking this Court's diversity jurisdiction under 28 U.S.C. § 1332, as Plaintiff is a citizen of Colorado, and the defendants in this matter are citizens of New Jersey and Pennsylvania. Pursuant to an Opinion and Order dated January 26, 2012, this Court denied a motion filed by Globus to dismiss Plaintiff's Express Warranty claims against it. The instant motions followed.

II. LEGAL STANDARD

The court should grant a motion for summary judgment when the moving party "shows that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). An issue is "material" to the dispute if it could alter the outcome, and a dispute of a material fact is "genuine" if "a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986); Matsushida Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986) ("Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no 'genuine issue for trial.'") (quoting First Nat'l Bank of Arizona v. Cities Serv. Co.,

391 U.S. 253, 289 (1968)). In deciding whether there is any genuine issue for trial, the court is not to weigh evidence or decide issues of fact. Anderson, 477 U.S. at 248. Because fact and credibility determinations are for the jury, the non-moving party's evidence is to be believed and ambiguities construed in its favor. Id. at 255; Matsushida, 475 U.S. at 587.

Although the movant bears the burden of demonstrating that there is no genuine issue of material fact, the non-movant likewise must present more than mere allegations or denials to successfully oppose summary judgment. Anderson, 477 U.S. at 256. The nonmoving party must at least present probative evidence from which the jury might return a verdict in his favor. Id. at 257. The movant is entitled to summary judgment where the non-moving party fails to "make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

III. DISCUSSION

A. Product Liability Claims Against Globus

In his Second Amended Complaint, Plaintiff asserts a product liability action against Globus. Product liability actions under New Jersey law are governed by the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 to -11 ("PLA"), and the three permissible theories of liability under the PLA are design defects, manufacturing defects, and inadequate warning defects. N.J.S.A. 2A:58C-2; see also Zaza v. Marquess and Nell, Inc., 144 N.J. 34, 49 (1996) (citing Feldman v. Lederle Labs., 97 N.J. 429, 449 (1984)).[4] In the operative complaint, Plaintiff

[4] The parties assume that New Jersey law governs, and, indeed, it is the substantive law of New Jersey that the Court applies here. Federal courts sitting in diversity "determine which state's substantive law applies by applying the choice-of-law rules of the jurisdiction in which the court sits." Garcia v. Plaza Oldsmobile LTD., 421 F.3d 216, 219 (3d Cir. 2005) (citing Klaxon Co. v. Stentor Elec. Mfg. Co., 313 U.S. 487, 496 (1941)). New Jersey follows the Restatement (Second) of the Conflict of Laws, which indicates that a matter is governed by the law of the state with the "most significant relationship" to the issue before the court. P.V. v. Camp Jaycee, 197 N.J. 132, 141 (2008). Here, the parties point to no state other than New Jersey whose laws would potentially apply to this matter.

asserts a products liability claim based upon all three theories. Plaintiff has now indicated, however, that he does not oppose summary judgment on the manufacturing defect theory. See Pl. Opp'n at 5.[5] Thus, the Court focuses on the product liability claims based upon allegedly inadequate warnings and a design defect.

1. Failure to Warn

Plaintiff asserts that Globus' warnings about the use of the Transition Device were legally insufficient. The sufficiency of warnings is governed by the PLA, which provides that a warning is adequate if it

> is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician. If the warning or instruction given in connection with a drug or device . . . has been approved or prescribed by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. § 301 et seq. or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. § 201 et seq., a rebuttable presumption shall arise that the warning or instruction is adequate . . . .

N.J.S.A. 2A:58C-4.

When a "failure to warn claim implicates the label of or information provided with a medical device, the prospect of preemption of the state law PLA claim arises." Cornett v. Johnson & Johnson, 211 N.J. 362, 387 (2012) (citing Kemp v. Medtronic, Inc., 231 F.3d 216, 236-37 (6th Cir. 2000)). Here, the Transition Device underwent a federal regulatory evaluation

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Although Plaintiff is a citizen of Colorado, he resided in New Jersey at the time of the surgical procedure that is the subject matter of this case, and the surgical procedure was performed in Mount Laurel, New Jersey. The Court, therefore, applies New Jersey law, as that state bears the most significant relationship to the issues now before it.

[5] When the Court refers to the Plaintiff's Opposition Brief in this part of this Opinion, unless otherwise indicated, it is referring to Plaintiff's brief in opposition to Globus' summary judgment motion. (ECF Doc. No. 144). In Part III.B of this Opinion, when referring to Plaintiff's Opposition Brief, the Court refers to his brief in opposition to the motion of Dr. Testaiuti and Coastal Spine (ECF Doc. No. 146).

process, which ultimately resulted in the FDA's grant of permission for Globus to place the device on the market, provided that a warning prescribed by the FDA was given. The approval includes the label and other instructions that are included with a device that the FDA permits to proceed into the marketplace. See id.

The New Jersey legislature recognized the role of federal regulation of drugs and medical devices by including in the PLA a rebuttable presumption that labelling is adequate when a manufacturer includes a warning that complies with FDA requirements. N.J.S.A. 2A:58C-4. Here, Plaintiff does not dispute that the FDA approved the warnings that appeared in the labelling accompanying the Transition Device. Rather, Plaintiff argues that the presumption that the warning is adequate can be rebutted in this case.

During the FDA approval process, the FDA found that "there is a reasonable likelihood that [the Transition Device] will be used for an intended use not identified in the proposed labeling and that such use could cause harm." FDA Letter of Feb. 20, 2009, Def. Opp'n Ex. 1. Plaintiff documents communications and negotiations between Globus and the FDA, which ultimately resulted in a label incorporating the warning approved by the FDA. See Pl. Opp'n at 8-13. The ultimate resolution was that the FDA required that Globus include a warning with the device's labeling, indicating that it was only intended to be used when fusion is "performed at all instrumented levels." FDA Letter of Feb. 20, 2009. Consequently, the materials accompanying the Transition System included the FDA-approved warning that the device was only intended for use accompanying fusion at all instrumented levels. It also warned of the risks of screw breakage, hardware failure, and non-union. See SUMF ¶¶ 271-73.

Despite including the FDA-approved warning labels, Plaintiff argues that the Globus sales representative who provided the device to Dr. Testaiuti, Christopher Felix, knew that the

device would be applied to two levels of Plaintiff's spine, although only one level was to be fused. Pl. Opp'n at 17. Such an application would be contrary to the FDA's warning as to the intended use. While he does not point to direct evidence of such knowledge, Plaintiff argues that such an inference can be drawn because Felix did not act to warn Dr. Testaiuti about the off-label use or dissuade him from using the Transition Device in such a manner, although Felix was present in the operating room for at least part of the surgical procedure.[6] He suggests that Globus quietly encouraged doctors to use the Transition Device off-label, calling it a "wink - don't ask, don't tell" method. Id.

Plaintiff further argues that the diagrams in the Surgical Technique Guide show application of the Transition Device to an unfused segment of a spine. Although Plaintiff cites nothing in the record to support this argument about the diagrams, the Court observes that Plaintiff's engineering expert, Jamie Williams, Ph.D, testified in her deposition that an illustration in the Surgical Technique Guide "doesn't show the device being used at a level that is fused." Williams Dep. 257-258.[7] Additionally, Plaintiff argues that data Globus provided to the FDA was "insufficient." See Pl. Opp'n at 10. He asserts that these facts are enough to rebut the

[6] The Court observes that Felix testified at his deposition that he did not believe he knew at any time up to and including the date of the procedure what type of surgery Dr. Testaiuti planned to perform using the Transition Device. See Felix Dep. 76. Specifically, he testified that he did not know whether Dr. Testaiuti intended to fuse L4-5 or not, and that although he is generally in the operating room for part of a procedure, he typically leaves after the Globus device is attached, prior to the point where a surgeon usually inserts bone graft for a fusion procedure. Id. at 156-58.

[7] The Court notes that expert testimony attacking the illustrations is apparently limited to the one statement by Dr. Williams. There is evidently no testimony from Plaintiff's physician expert, Dr. Finn, indicating that a surgeon might interpret the diagrams as a suggestion that the Transition Device can be used without fusion. Plaintiff also points to no testimony indicating whether the Transition Device is attached to the spine prior to the fusion procedure or afterward. Indeed, according to Felix's testimony, the Transition Device is typically set in place prior to the insertion of bone graft. Felix Dep. 157-58. Thus, while the Court will not attempt to explain the meaning of diagrams in the surgical guide, based upon the record before the Court, it seems that the illustrations Plaintiff is referring to may merely depict the spine after the Transition Device is attached, but prior to the insertion of bone graft. This appears to be suggested by the photographs that Plaintiff refers to. In the Surgical Technique Guide, after the section entitled "Final Tightening," is a section entitled "Bone Graft." Globus Surgical Technique Guide 15-16, Pl. Opp'n Ex. 27. The text in this section indicates in bold, italic type "Autogenous bone graft must be inserted at each instrumented level for fusion." Id. at 16.

presumption set forth in the PLA that when the FDA approves or prescribes a warning given in connection with a medical device, the warning is adequate.

The statutory presumption under the PLA means that when a drug or device manufacturer's warning complies with FDA regulations, such compliance is "compelling, although not absolute, evidence that a manufacturer satisfied its duty to warn about the dangers of its product." Kendall v. Hoffman-LaRoche, Inc., 209 N.J. 173, 195 (2012) (citing Perez v. Wyeth Labs, Inc., 161 N.J. 1, 24 (1999)). The New Jersey Supreme Court indicated in Perez that in order to rebut the presumption, a plaintiff would have to show that the manufacturer engaged in deliberate concealment or nondisclosure of after-acquired knowledge of a harmful effect. Perez, 161 N.J. at 25. The Perez court indicated that absent such a finding, "[f]or all practical purposes . . . compliance with FDA standards should be virtually dispositive of such [failure to warn] claims." Id.

The Appellate Division subsequently distinguished Perez, recognizing "an additional basis for overcoming the presumption of adequacy set forth in the PLA." McDarby v. Merck & Co., Inc., 401 N.J. Super. 10, 63 (App. Div. 2008). The McDarby court found that in the context of a pharmaceutical drug, claims of "economically-driven manipulation of the post-market regulatory process" were sufficient to rebut the presumption and permit a jury to decide whether a warning was adequate.

One New Jersey court thereafter summarized the state of the law as follows:

> Presently, the presumption of an adequate warning based on compliance with FDA regulations will be deemed rebutted only if the following proof is presented: (i) deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects ("Perez/Rowe exception") or (ii) manipulation of the post-market regulatory process ("McDarby exception") . . . . Although plaintiffs may present expert testimony in an attempt to rebut the statutory presumption . . ., the presumption in favor of the adequacy of FDA-approved warnings will not be deemed rebutted unless plaintiff produce the type of evidence identified in Perez, Rowe, or McDarby.

Bailey v. Wyeth, Inc., 424 N.J. Super. 278, 312-13 (Law. Div. 2008). The New Jersey Supreme Court recently agreed that these are the only two methods of rebutting the presumption of an adequate warning. Cornett, 211 N.J. at 388 (indicating that "[t]o overcome this presumption," the plaintiff must show "deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects," or "manipulation of the post-market regulatory process.") No other exceptions to the presumption have been recognized by the New Jersey courts.

Plaintiff has not presented any evidence of deliberate concealment of information from the FDA or nondisclosure of knowledge acquired by Globus after the FDA's initial approval of the device. Insofar as Plaintiff alleges that Plaintiff provided "insufficient" information to the FDA during the review process, that does not rise to the level of deliberate concealment. Nor has Plaintiff suggested that any manipulation of the "post-market regulatory process" has taken place. Plaintiff's argument that an inadequate warning was provided, in fact, relates little to the warning itself. Rather, Plaintiff is arguing that through actions unrelated to the actual warning, such as the conduct of its sales representative, and the illustrations in the Surgical Technique Guide, Globus encouraged the use of the Transition Device in a manner unapproved by the FDA without explicitly saying so.

Plaintiff's argument fails because none of his evidence falls within either of the two defined exceptions to the rebuttable presumption of adequacy. Plaintiff has no evidence that any Globus employees encouraged Dr. Testaiuti to use the Transition Device off-label. At most, he has produced evidence suggesting that Felix may have known that Dr. Testaiuti planned to do so and did not prevent this from occurring. Plaintiff has cited no law indicating that a device manufacturer has any duty to prevent off-label use of its products. The FDA does not regulate the use of medical devices by doctors, and does not purport to control how doctors use a given

device. Blazoski v. Cook, 346 N.J. Super. 256, 272 (App. Div. 2002). Nor can the FDA "intrude upon the practice of medicine," through its regulation of the marketing and sale of medical devices. Id. Thus, it follows that a manufacturer has no affirmative duty to intervene in order to prevent off-label use of its product by a surgeon. Plaintiff's claim that a Globus representative allowed "the misuse of the product through calculated silence" is insufficient to create an issue of material fact for trial as to failure to warn.

Plaintiff has produced no evidence showing that Globus marketed the device for use in an off-label manner, and has cited no law indicating that "calculated silence" that fails to prevent a doctor from using a device off-label, is the equivalent of off-label marketing. Further, even if Globus' representatives had encouraged off-label use of their devices—which has not been demonstrated—this conduct would not support a product defect case for inadequate warning.[8] The same reasoning applies to Plaintiff's allegations about the illustrations in the Surgical Technique Guide. While such action, if true, might be actionable, it would not result in a viable products liability action under a failure to warn theory.

In sum, Plaintiff essentially encourages the Court to adopt a new exception to the presumption that compliance with FDA regulations constitutes adequate warning. Pl. Opp'n at 19. Plaintiff seems to propose that an exception should be created when a device manufacturer takes some action independent of the warning that is inconsistent with the warning. While the Court recognizes that there might be some policy rationale for such an exception, creating new doctrines applicable to a state statute is not the role of a federal court sitting in diversity. The Court must follow the New Jersey PLA statutory scheme and the judicial interpretation of that

[8] This is not to suggest that no recourse would exist against a device manufacturer if it marketed its devices for purposes unapproved by the FDA. The consequences for a manufacturer engaging in such conduct would presumably include, but not necessarily be limited to, an FDA enforcement action. See Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 349-50 (2001).

scheme unless and until the New Jersey legislature changes the statute, or the New Jersey Supreme Court adopts a new theory for rebutting the presumption of adequacy. See, e.g., Travelers Ins. Co. v. Carpenter, 411 F.3d 323, 329 (2d Cir. 2005) (the role of "a federal court sitting in diversity is not to adopt innovative theories that may distort established state law."); Orson, Inc. v. Miramax Film Corp., 79 F.3d 1358, 1373 n.15 (3d Cir. 1996) (a federal court exercising diversity jurisdiction "must apply the substantive law as decided by the highest court of the state whose law governs the action.").

The FDA clearly engaged in a deliberative process with Globus prior to approving the warning labels that would ultimately accompany the Transition Device. Any flaws in the FDA's regulatory process are the responsibility of the executive branch to correct.[9] The New Jersey Legislature can also change the rebuttable presumption standard if it wishes to do so, or the New Jersey Supreme Court can adopt additional exceptions to the presumption of adequacy. However, in light of the law as it now stands, Plaintiff has not produced evidence sufficient to hurdle the presumption of adequacy accompanying warning labels approved by the FDA.

Plaintiff's failure to warn claim would also fail on an independent ground. In the case of certain prescription drugs and medical devices, a manufacturer satisfies its duty to warn by providing the prescribing physician with information about the dangers of the drug or device. See Grobelny v. Baxter Healthcare Corp., 341 F. App'x 803, 806 (3d Cir. 2009) (citing Niemiera v. Schneider, 114 N.J. 550 (1989)). This is known as the "learned intermediary" doctrine, which

[9] For example, Plaintiff has asserted that he was not warned that the device did not undergo certain tests. Seavey Aff. ¶ 10. However, Plaintiff describes a process where the FDA engaged Globus and requested that additional testing be done on the Transition Device prior to its being marketed. See Pl. Opp'n 8-10. The FDA ultimately viewed the testing done on the Transition Device and/or a predicate device as adequate, as it approved the marketing of the device pursuant to its 510(k) approval process, provided that certain warnings were included. Plaintiff does not suggest that Globus misled the FDA. Thus, the Court must decline Plaintiff's invitation to question the adequacy of the testing process, as it is not this Court's place to challenge the adequacy of the FDA's regulatory process in a warning context, particularly in light of the New Jersey Legislature's decision to enact the presumption of adequacy standard.

was codified in N.J.S.A. 2A:58C-4. Id. The key issue in determining whether the learned intermediary doctrine applies is whether a drug or device is directly marketed to consumers. Perez, 161 N.J. at 19. The record indicates that the Transition Device was marketed to surgeons, and not directly the ultimate recipients of the device such as Plaintiff, and Plaintiff does not challenge the application of the learned intermediary doctrine here. See Pl. Opp'n at 20.

When the learned intermediary doctrine applies, a drug or medical device manufacturer fulfills its duty to warn the ultimate user of its product when it provides a physician with an adequate warning about any dangerous propensities that product may have. Banner v. Hoffman-LaRoche, Inc., 383 N.J. Super. 364, 375-76 (App. Div. 2006); Niemiera v. Schneider, 114 N.J. 550, 559 (1989). Thus, due to the application of the learned intermediary doctrine, Globus' duty was to warn Dr. Testaiuti of the dangers of the device, and not to warn Plaintiff directly.

Globus clearly satisfied this duty. Dr. Testaiuti testified that he knew prior to the surgery that the device was only approved by the FDA for use with fusion and bone graft at all levels the device was applied to, and he knew the underlying risks associated with using the device without fusion at all levels. Testaiuti Dep. 184-85. He nonetheless felt it was safe to use the device without fusion at all levels, and testified that he believed that other surgeons around the country also felt such off-label use was safe. Id. His decision was based upon his medical judgment and experience, as well as the result of a discussion with Plaintiff, according to Dr. Testaiuti's testimony. Id. at 113-118. He testified that his decision was based upon Plaintiff's individual condition and needs, and because he knew that the FDA does not prohibit a surgeon's use of any device off-label, he concluded that such a course was the best possible treatment for his patient. Id. at 264-65, 279. Dr. Testaiuti also testified that Globus did not promote the "off-label" use of its device. Id. at 263-64.

Thus, Globus thus can, and did, satisfy its duty to warn the surgeon prescribing the device, and cannot be held liable for failing to prevent Dr. Testaiuti from using the device in an off-label fashion. There is no dispute of fact as to whether Dr. Testaiuti was adequately informed and warned about the risks of using the device without fusion at all instrumented levels. Where the learned intermediary doctrine applies, it is the duty of the learned intermediary to provide the ultimate consumer of the product with information about the dangers or side effects of the product. Niemiera, 114 N.J. at 562. The concept of warning by the intermediary thus "will blend in this context with the concept of informed consent," which will be discussed in part III.B. Id. Summary judgment must be granted in Globus' favor on the failure to warn product liability claim.

2. Design Defect

Plaintiff has also asserted a product liability claim based upon an alleged design defect in the Transition Device. Globus argues that it should be granted summary judgment on this claim because Plaintiff has not set forth any evidence indicating that an alternative safe design exists. Plaintiff states in response that he is not required to show a feasible alternative design. Pl. Opp'n at 21.

Under the PLA, a manufacturer or seller is not liable if "a practical and technically feasible alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of the product" was not available at the time when the product in question left the manufacturer's control. N.J.S.A. 2A:58C-3.[10] It is

[10] According to the statute, the alternative design requirement does not apply if the court finds, based on clear and convincing evidence, that (1) "[t]he product is egregiously unsafe or ultra-hazardous" and (2) an ordinary user of the product "cannot reasonably be expected to have knowledge of the product's risks" or it poses a risk of serious injury to persons other than the consumer, and (3) "[t]he product has little or no usefulness." N.J.S.A. 2A:58C-3 (emphasis added). Plaintiff does not argue that this exception applies, and it seems clear that the exception would not apply, for one reason, because the Transition Device quite clearly has some "usefulness."

established law in New Jersey that such an alternative design is part of a Plaintiff's prima facie case when asserting a claim in products liability premised upon a design defect. Nelson v. Biogen Idec Inc., Civ. No. 12-7317, 2013 WL 1700918, at *1 (D.N.J. Apr. 19, 2013) (citing Cavanaugh v. Skil Corp., 164 N.J. 1, 5 (2000)); Smith v. Keller Ladder Co., 275 N.J. Super. 280, 284 (App. Div. 1994). The New Jersey Supreme Court has indicated that it is the plaintiff who must show the reasonableness and feasibility of the alternative design. Cavanaugh, 164 N.J. at 6-7. The feasible alternative design requirement has been applied within this District in the context of a design defect claim related to a medical device under the PLA. See Jones v. Synthes USA Sales, LLC, Civ. No. 08-2060, 2010 WL 3311840, at *10 (D.N.J. Aug. 19, 2010) (granting summary judgment for the defendant, a medical device manufacturer, where the plaintiff did not "present any feasible or practical alternative design theories to support their defect-design product liability action").

A plaintiff can satisfy this element of a product liability claim through expert testimony. See Rocco v. N.J. Transit Rail Operations, Inc., 330 N.J. Super. 320 (App. Div. 2000) ("an expert opinion is ordinarily relied upon to establish a reasonable alternative design"). The expert must show that the alternative design was available at the time of the product's manufacture, and that it was practical and feasible. N.J.S.A. 2A:58C-3. Plaintiff's only expert who appears qualified to give an opinion about an alternative design is his engineering expert, Dr. Williams. However, Dr. Williams did not propose an alternative design in her report. See Williams Report, Pl. Opp'n Ex. 3. In her deposition, Dr. Williams could not point to anything that she would change to correct the alleged defective design of the Transition Device, other than it being "too flexible." Williams Dep. 280-82. Also she indicated that Globus should have performed additional testing on the Transition Device, she had not performed any of the tests herself. Id. at

280. Plaintiff has also submitted an affidavit from Dr. Williams indicating that "[t]he only 'alternative safe design' would have been the Revere (rigid) system. There is no other 'alternative safe design' that is in use, or that has been approved or cleared by the FDA, because all attempts at a stand-alone device (used without fusion) have been rejected by the FDA." Williams Aff. ¶ 41. While Defendants have moved to strike Dr. Williams' affidavit, it is not necessary to decide whether her affidavit is admissible.[11]

Even considering the affidavit, Plaintiff has not established the existence of an alternative safe design. It is insufficient to merely recite that such an alternative design exists. Rather, a plaintiff must demonstrate the reasonableness and feasibility of the alternative design. Cavanaugh, 164 N.J. at 5-7. Plaintiff points to nothing in the record, not even Dr. Williams' affidavit, indicating that any alternative design is reasonable or feasible, or why such an alternatively designed product would have prevented the harm to Plaintiff. See, e.g., Diluzio-Gulino v. Daimler Chrysler Corp., 385 N.J. Super. 434, 441 (App. Div. 2006) ("Expert testimony in conclusionary terms is insufficient to meet that burden."); Ortiz v. Yale Materials Handling Corp., Civ. No. 03-3657, 2005 WL 2044923, at *6 (D.N.J. Aug. 24, 2005) ("an expert must have 'good grounds' for his opinion, and in the case of alternative designs, testing is crucial.") (citing Dhillon v. Crown Controls Corp., 269 F.3d 865, 870 (7th Cir. 2001)).

Here, Plaintiff does not argue that he satisfied the alternative design requirement, and understandably so, for it is clear that he has not. Nor does he recognize the existence of showing an alternative design as part of a prima facie design defect claim. Pl. Opp'n at 21. But this does not lessen its applicability in connection with Globus' motion for summary judgment. Plaintiff

[11] The Court scheduled a hearing pursuant to Daubert v. Merrell Dow Pharms, Inc., 509 U.S. 579 (1993), with the expectation that Dr. Williams would testify, due to the Defendants' motions to preclude her proposed expert testimony and to strike her affidavit. In a letter dated February 10, 2014, Plaintiff waived his right to have a Daubert hearing. See ECF Doc. No. 170.

cites N.J.S.A. 2A:58C-3 in its entirety, and then summarily states that "the Plaintiff in this case is not required to prove a technically feasible alternative design." Pl. Opp'n at 21. It is unclear what portion of the statute Plaintiff believes supports the idea that he is not required to show an alternative design. In arguing that "[t]he defect in this case is that the device was never intended for the use to which Dr. Testaiuti put it in Matt Seavey," Plaintiff seems to blend his argument that an alternative design is not part of his prima facie case with his argument that Dr. Testaiuti used the device incorrectly.[12] Pl. Opp'n at 21-22. Plaintiff misunderstands the theory of design defect liability, which is concerned with "whether the manufacturer acted in a reasonably prudent manner in designing and fabricating a product." Zaza, 144 N.J. at 50.

The design defect claim is therefore easily resolved, as the New Jersey Supreme Court has indicated that N.J.S.A. 2A:58C-3 "does not alter the plaintiff's burden to show defendant's failure to follow a reasonable alternative design." Cavanaugh, 164 N.J. at 7. In a diversity case, this Court must follow the holdings of the New Jersey Supreme Court. Because Plaintiff has not shown a reasonable alternative design to the Transition Device, as required under New Jersey law, summary judgment must be granted in Globus' favor on the design defect product liability claim.

B. Claims Against Dr. Testaiuti

Plaintiff initially asserted four claims against Dr. Testaiuti. The first claim is for negligence as a result of an alleged breach of the standard of care when operating on Plaintiff. The second asserts lack of informed consent. The third claim is an action under New Jersey's products liability statute. Finally, the fourth relates to breach of express warranty. Because

[12] In a sense, the argument that the product was defectively designed because Dr. Testaiuti used it incorrectly appears to be an attempt to pursue what is in reality a medical malpractice claim under the guise of a design defect claim. As indicated in the next section, Plaintiff has stated that he has abandoned his medical malpractice claim asserting a breach of the standard of care by Dr. Testaiuti.

Plaintiff has indicated that he does not oppose summary judgment on the medical negligence claim, or the breach of express warranty claim, see Pl. Opp'n at 5-6, 16, the Court need only analyze the informed consent and product liability claims against Dr. Testaiuti.

1. Informed Consent

In his lack of informed consent claim, Plaintiff argues that Dr. Testaiuti did not provide Plaintiff with the information that a reasonable person in Plaintiff's position would want to know about the risks and benefits of the installation of the Transition Device as Dr. Testaiuti intended to utilize it. He alleges that Dr. Testaiuti did not fully inform him as to alternative methods of treatment, and that Dr. Testaiuti did not inform him of the FDA status of the device. Seavey Aff. ¶¶ 14, 22. Dr. Testaiuti asserts that he discussed Plaintiff's surgical options in detail with Plaintiff, including the option to have a one-level or two-level fusion. Testaiuti Dep. 93-94. He indicates that Plaintiff chose to have only one level fused, and that he told Plaintiff about the Transition Device, including its approval by the FDA for use as a fusion device only. Id. at 94. Dr. Testaiuti indicates that he told Plaintiff that he would use the device "in an off-label manner not to fuse that segment of L4-5 but to just stabilize it." Id. Dr. Testaiuti testified that he explained this to Plaintiff by telling him that "it would be used . . . by not fusing in an area that it was FDA approved to be used as fusion in." Id. at 100. He indicates that he also told Plaintiff that there was a risk that he might need an additional surgery such as a fusion or disc replacement at L4-5 in the future. Id. at 94-97. He also indicated that he told Plaintiff about the risks associated with the surgery, including hardware failure and the failure of the surgery to resolve his symptoms. Id. at 97-98. For the purposes of this motion, the Court must resolve all factual disputes and draw all inferences related to what Dr. Testaiuti told Plaintiff prior to the surgery in Plaintiff's favor, as the nonmoving party. Thus, in deciding this motion, the Court

assumes that Dr. Testaiuti did not tell Plaintiff of the "off-label" use of the Transition Device and did not fully describe alternative options to the surgery that was actually performed.

An action for lack of informed consent involves "the nondisclosure of medical information." Blazoski v. Cook, 346 N.J. Super. 256, 270 (App. Div. 2002). A plaintiff must prove four elements to prevail in an informed consent case. He must show that:

> (1) the physician failed to comply with the [reasonably-prudent-patient] standard for disclosure; (2) the undisclosed risk occurred and harmed the plaintiff; (3) a reasonable person under the circumstances would not have consented and submitted to the operation or surgical procedure had he or she been so informed; and (4) the operation or surgical procedure was a proximate cause of plaintiff's injuries.

Howard v. Univ of Med. & Dentistry of N.J., 172 N.J. 537, 549 (2002) (citations and emphasis omitted).

With respect to the informed consent allegations in this case, the Court first observes that when a surgeon uses a medical device in an "off-label" manner, a failure to disclose that information to the patient is, alone, insufficient to support a claim that the physician failed to meet the applicable disclosure standard. A physician must disclose "all material information that a 'prudent patient' might find significant for a determination whether to undergo the proposed therapy." Blazoski, 346 N.J. Super. at 267 (citing Niemiera, 114 N.J. at 562). However, "the FDA regulatory status 'do[es] not speak directly to the medical issues surrounding a particular surgery.'" Id. at 271 (quoting Southard v. Temple Univ. Hosp., 781 A.2d 101, 107 (Pa. 2001)). This is the case because the FDA's "concern is to regulate the marketing and labelling of medical devices, not to intrude upon the practice of medicine or redefine the doctrine of informed consent." Id. at 272. Doctors may "use medical devices for off-label purposes that are not FDA approved, provided that the FDA has approved the device for some other purpose." Id.

Thus, the law is established in New Jersey that the fact that a device is being used in a manner unapproved by the FDA does not fall under the umbrella of information that a "prudent patient" would find significant. Doctors routinely use devices for purposes that are not approved by the FDA. Blazoski, 346 N.J. Super. at 269 ("health care providers often employ medical devices for an 'off label' use"). The statutory scheme that allows the FDA to regulate medical devices indicates that "[n]othing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient . . . within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396. Although the "manufacturers may not themselves promote such uses, it is not unlawful for doctors to employ or prescribe medical products for 'unapproved' uses. Indeed, the FDA claims that it has long recognized the important role that some unapproved uses may play in the practice of medicine." Washington Legal Found. v. Kessler, 880 F. Supp. 26, 28 n.1 (D.D.C. 1995) (internal citations omitted). To the extent that Plaintiff attempts to characterize Dr. Testaiuti's use of the product as a "rejected" use that is somehow distinct from "an innocent 'off-label'" use, his argument fails. See Pl. Opp'n at 1. It is clear from the applicable law that the FDA cannot, and does not attempt to, prevent the use of an approved device in an unapproved or "rejected" manner by a physician. Plaintiff cites no law in support of the distinction that he wishes to draw between off-label use that is "innocent" and off-label use that is not.

Plaintiff argues that Blazoski does not mean that a court should grant summary judgment for a physician on a claim that the physician did not disclose the off-label use of a device. He highlights that Blazoski involved a plaintiff's appeal of the trial court's refusal to issue a directed verdict for the plaintiff on the issue of the physician's failure to disclose the FDA status of a device, and that the informed consent question went to the jury in Blazoski. He focuses on the

section of the opinion that states "[u]nderstandably, in this case the trial court permitted the jury to consider whether the FDA status was material to a prudent patient's decision to undergo the spinal fusion procedure. By its verdict, the jury obviously concluded that it was not." Blazoski, 346 N.J. Super. at 274. Plaintiff argues that this section means that a jury should always decide whether a prudent patient would want to know about the FDA status of a device.

This Court does not read Blazoski to mean that a jury must decide each time whether a reasonable patient would want to a physician to disclose that he intends to use a device for a non-FDA-approved purpose. The plaintiff in that case underwent a spinal fusion surgery in which the surgeon affixed a device to the lumbar spine by using screws that were approved by the FDA for another use, but had not been approved for use in lumbar fusion surgery. Id. at 266-67. The device later had to be removed due to pain that the plaintiff experienced, and it was discovered that a locking nut had come off one of the screws, which caused motion in the fixation device. Id. at 263. The New Jersey Appellate Division in that case "reject[ed] plaintiffs' argument that the FDA's Class III classification was medical information concerning a material risk." Id. at 272. It recognized that "physicians have the right, exercising reasonable medical judgment, to use medical devices for off-label purposes that are not FDA approved, provided that the FDA has approved the device for some other purpose." Id. (citing Staudt v. Froedtert Mem'l Lutheran Hosp., 580 N.W. 2d 361, 362-63 (Wis. Ct. App. 1998)). The court also recognized and followed the majority of jurisdictions that limit informed consent claims to medical information and do not allow them to extend to actions related to nondisclosure of a device's regulatory status. See id. at 269-70 (citing Southard; Klein v. Biscup, 673 N.E. 2d 225, 231 (Ohio App. 1996)).

Plaintiff also seeks to distinguish Blazoski on the basis that the screws at issue in Blazoski were "experimental," while the Transition Device in this case is, he claims,

"specifically prohibited by the FDA for safety purposes." Pl. Opp'n at 14. The screws at issue in Blazoski had been approved at the time by the FDA for experimental use by "a few hospitals across the country" in the pedicles of the lumbar spine. Blazoski, 346 N.J. Super. at 263. Plaintiff seeks to distinguish the Transition Device on that basis, since it was not FDA-approved for use without fusion anywhere. However, this was not the basis for the court's holding in Blazoski. In its discussion of whether a physician must obtain informed consent for off-label use of a device, the court did not once mention the experimental approval of the device at issue there. See id. at 267-73. The device in Blazoski was unapproved by the FDA for general off-label use, just as the Transition Device is here.

Plaintiff has also not shown that the FDA makes any distinction between experimental and prohibited devices with respect to the general marketplace for a device. The FDA can only regulate the marketing and labelling of devices. Id. at 272. It cannot regulate what physicians do with the devices with respect to their patients. Id. Plaintiff has cited nothing indicating that the FDA indicated anywhere that physicians were "prohibited" from using the device for any purpose. On the contrary, Plaintiff's own expert indicates that surgeons sometimes use dynamic stabilization devices without fusion although this is not an FDA-approved use. Finn Report 10; Finn Dep. 532, 539, 572-73. The record reflects that the FDA either gives its approval for a device manufacturer to market a device for a particular purpose or it does not. If it does not issue approval, the manufacturer may not market the device for the unapproved purpose. The FDA Clearance letter that Plaintiff cites in support of the device supposedly being "specifically rejected" for use without fusion does not indicate any such rejections with respect to physicians. See Pl. Resp. SUMF ¶ 255; FDA Letter, Feb. 20, 2009, Pl. Opp'n Ex. 1. It merely indicates that "[t]he safety and effectiveness of this device has not been established for the intended use of

spinal stabilization without fusion," and that such use "could cause harm." Id. Thus, Globus here could not market the Transition Device for application without fusion, just as the screw manufacturer in Blazoski could not have marketed the screws for the off-label use that the doctor made of them.

This does not, however, end the inquiry. If the risks underlying the FDA's decision as to regulatory status are material, they must be disclosed. Plaintiff asserts that Dr. Testaiuti did not inform him that "he did not know the complications and adverse events associated with dynamic stabilization without fusion." See Seavey Aff. ¶ 17. Plaintiff also alleges that he was not informed of a lack of studies about use of the Transition device without fusion, and that using the device at a non-fused level might jeopardize the fusion. Id. ¶¶ 15, 16, 18. He also indicates that he was not informed of the risk that his pain symptoms would not resolve if the device failed, that fusing L4-5 would have "eliminate[d] the risk of failure of the device," and that the specific use of the device increased the risk of requiring a fusion at L4-5 at a later time. Id. ¶¶ 21-23.

In order to show that an undisclosed risk existed, a plaintiff must show, through expert testimony, that the physician should have been aware of the risk, and that the risk was recognized in the medical community. Febus v. Barot, 260 N.J. Super. 322, 327 (App. Div. 1992). In Febus, the trial court granted summary judgment to the defendants in a medical malpractice case. Id. at 323-24. The plaintiff did not produce any expert reports during discovery, and appealed, arguing that none were necessary to prove a lack of informed consent claim. Id. at 326. The appeals court indicated that, under New Jersey law, no expert is required to "prove that an undisclosed risk would have been material to the patient's consent." Id. at 327. However, the Febus court indicated that "proof of a risk recognized by the professional community must come from a qualified expert," and upheld the defense summary judgment verdict because the plaintiff

had not produced an expert report or testimony indicating that the scarring the plaintiff complained of was a recognized risk in the medical community attendant to the surgery she underwent. Id. at 328. "Without such [expert] proof, a jury issue concerning the doctor's liability for failure to disclose that risk would not arise." Id. (quoting Calabrese v. Trenton State College, 162 N.J. Super. 145, 156 (App. Div. 1978)).

Subsequent courts have required expert testimony to establish a lack of informed consent claim under New Jersey law. See Chamberlain v. Giampapa, 210 F.3d 154, 161-62 (3d Cir. 2000) (indicating that expert testimony is required under New Jersey law to "establish that the risk cited was one that the defendant should have been aware of because it was known to the medical community at the time. . . . [P]roof of a risk recognized by the professional community must come from a qualified expert"); Mulholland v. Thomas Jefferson Univ. Hosp., Civ. No. 09-4322, 2011 WL 3425282, at *4 (D.N.J. Aug. 4, 2011) (expert testimony is required to explain what the risks are, that they are known to the medical community, and to what extent a physician performing the same procedure as the defendant should be aware of the risks); Posta v. Chung-Loy, 306 N.J. Super. 182, 204 (App. Div. 1997) ("[a] jury may not speculate in an area where laypersons could not be expected to have sufficient knowledge or experience.").

Plaintiff points to no expert testimony indicating that any of the risks asserted in his affidavit or elsewhere were recognized within the medical community or were risks that a physician implanting a stabilization device should have been aware of. Instead, Plaintiff argues that he need not produce expert testimony to survive summary judgment. See Pl. Opp'n at 8-9. Plaintiff cites Largey v. Rothman, 110 N.J. 204 (1988), for the proposition that whether an undisclosed risk is material to a prudent patient is a jury question that requires no expert testimony. However, Dr. Testaiuti admits that whether the risk is material requires no expert

testimony. See Testaiuti Mot. Summ. J. 13. The cases he relies on, which are discussed above, cite Largey and indicate that it did not obviate the requirement that expert testimony be produced to show that (1) the defendant physician should have been aware of the risk, and (2) it was recognized in the medical community. See, e.g., Febus, 260 N.J. Super. at 328 ("Largey . . . did not alter the rule of Calabrese that proof of a risk recognized by the professional community must come from a qualified expert."); Mulholland, 2011 WL 3425282, at *4 (rejecting an argument by the plaintiffs based upon Largey that no expert testimony was required at all in an informed consent case).

Plaintiff also cites Adamski v. Moss, 271 N.J. Super. 513 (App. Div. 1994), and argues that knowledge of a risk in the medical community can be established through a defendant or by use of medical literature. However, Adamski affirmed the entry of summary judgment for a defendant physician, finding that "[t]he judge correctly determined that plaintiff was required to produce proof, usually through expert testimony, concerning the appropriate standard of care in this medical malpractice case." Id. at 518. The Appellate Division agreed that in some cases, a jury could conclude that a duty of care had been breached in a medical malpractice case without expert testimony. Id. However, it indicated that in the case before the court "[i]n view of her separate claims of negligence in the manner in which defendant performed the operation and in defendant's failure to obtain her informed consent, plaintiff is required to establish the standard of care in either or both of these areas." Id. With respect to the informed consent claim, the Appellate Division held that the plaintiff could not satisfy this requirement through medical and legal textbooks. Id. at 519. The court indicated that such learned treatises could only be called to the attention of an expert witness on direct examination or cross-examination. Id. Because the plaintiff had no right to appropriate the testimony of the defendant's expert witness, or to

compel her adversary's expert to testify, the informed consent claim failed. Id. at 520. The court also rejected the plaintiff's suggestion that she could meet her burden through examination of the defendant physician himself, indicating that plaintiff would have had to qualify the treatises during discovery if she wanted to rely upon them for the purposes of summary judgment. Id.

Here, Plaintiff's informed consent claim fails for the same reason as the plaintiff's claim in Adamski. He has produced no expert testimony to describe a risk recognized in the medical community that Dr. Testaiuti was aware of or should have been aware of, and that Plaintiff indicates was not disclosed to him.[13] His vague reference to meeting this burden through medical literature or through the defendant fails for the exact same reason that the plaintiff's argument failed in Adamski. See Pl. Opp'n at 9. Plaintiff has not explained what medical literature he would rely upon to defeat summary judgment. This notwithstanding, medical literature can only be introduced through an expert witness, and Plaintiff has pointed to no medical literature introduced during discovery that satisfies his burden. He has produced no expert that has relied on any medical literature, and would have had to introduce medical literature through Dr. Testaiuti's deposition testimony if he was to establish the informed consent standard of care that way.[14]

2. Product Liability Claims Against Dr. Testaiuti

Plaintiff also seeks to advance a product liability claim against Dr. Testaiuti. This claim is governed by New Jersey statute, which provides:

> In any product liability action against a health care provider for harm allegedly caused by a medical device that was manufactured or designed in a defective

[13] The Court attempted to schedule a Daubert hearing wherein Plaintiff's expert medical witness, Dr. Finn, would testify prior to the instant motions being decided in this matter. This was in light of the admissibility of Dr. Finn's expert conclusions being challenged by Defendants. However, pursuant to a letter from Plaintiff's counsel to the Court dated February 10, 2014, Plaintiff waived his right to a Daubert hearing with respect to Dr. Finn. See ECF Doc. No. 170.

[14] The Court has reviewed the exhibit list from Dr. Testaiuti's deposition, and it does not appear that any medical literature was marked as an exhibit during his testimony. See Testaiuti Dep., Exhibit List.

> manner, or for harm caused by a failure to warn of a danger related to the use of a medical device, the provider shall not be liable unless: (1) the provider has exercised some significant control over the design, manufacture, packaging or labeling of the medical device relative to the alleged defect in the device which caused the injury, death or damage; or (2) the provider knew or should have known of the defect in the medical device which caused the injury, death or damage, or the plaintiff can affirmatively demonstrate that the provider was in possession of facts from which a reasonable person would conclude that the provider had or should have had knowledge of the alleged defect in the medical device which caused the injury, death or damage; or (3) the provider created the defect in the medical device which caused the injury, death or damage.

N.J.S.A. 2A:58C-11.

This statute codified existing New Jersey common law precedent, which held that because physicians perform an important function in society, as a policy matter they should not be held strictly liable in product liability actions unless they had control over the design, manufacturing, packaging, or labeling of the product, created the defect, or knew or should have known of the product defect. See Johnson v. Mountainside Hosp., 239 N.J. Super. 312, 322-23 (App. Div. 1990); Feldman v. Lederle Labs., 97 N.J. 429, 442 (1984); Brody v. Overlook Hosp., 66 N.J. 448, 450 (1975).

Plaintiff has pointed to no evidence in the record that Dr. Testaiuti had any involvement in the design, manufacture, packaging or labeling of the Transition Device. Nor has he demonstrated that Dr. Testaiuti knew or should have known of any defect involving the Transition Device. Further, there is certainly no evidence in the record indicating that Dr. Testaiuti created any defect in the device. Plaintiff has cited no cases under New Jersey law where a medical provider was held to be liable under N.J.S.A. 2A:58C-11 under similar facts, or under any facts at all. Rather, Plaintiff returns to his argument that the FDA "prohibited" the utilization of the Transition Device that Dr. Testaiuti employed, in that he used the device without fusion at all levels where the device was attached. See Pl. Opp'n 15-16. He argues this

is sufficient to satisfy the second scenario contemplated by the statute, and that the defects that Dr. Testaiuti knew of or should have known of involved a lack of studies and testing, the FDA limitation on marketing the device for use without fusion, and that the device would jeopardize fusion and fail in the event fusion was not successful. Pl. Opp'n 15-16. After listing a number of alleged defects in the product that primarily relate to off-label use, Plaintiff summarily states that they are defects that Dr. Testaiuti knew of or should have known of, without further explanation. Pl. Opp'n 16.

Aside from the reality that the FDA cannot "prohibit" off-label use of a device, as discussed in the previous part of this section, Plaintiff's argument fails because it does not relate to any defect in the product that Dr. Testaiuti allegedly knew of or should have known of. Rather, every alleged defect listed by Plaintiff relates to its use without fusion, as Dr. Testaiuti utilized the Transition Device. Thus, Plaintiff's products liability claim against Dr. Testaiuti constitutes an attempt to shoehorn a medical malpractice or informed consent claim into a products liability cause of action by attempting to characterize off-label use and the risks associated with such use as a "defect." Plaintiff has cited no law, and the Court is aware of none, suggesting that he can use a products liability claim as a second attempt at a negligence claim against a physician, without having to demonstrate the standard of care. To allow such a cause of action to proceed would be to dispense with the expert testimony requirement for both medical negligence and informed consent claims by allowing an analogous claim to proceed in the guise of a product liability cause of action. Further, the PLA is a strict liability statute. Green v. Gen. Motors Corp., 310 N.J. Super. 507, 517 (App. Div. 1998). To allow a product liability claim against a surgeon to proceed past summary judgment based on off-label usage would allow litigants to hold physicians strictly liable for harm resulting from any off-label use

of a device, which would be in contravention of established New Jersey law. Blazoski, 346 N.J. Super. at 270-71. Summary judgment will thus be granted in favor of the medical provider defendants on this claim.

C. Breach of Express Warranty Claims

Plaintiff initially asserted a claim for breach of express warranty against all defendants. However, Plaintiff has now indicated that he does not oppose summary judgment on the manufacturing defect and express warranty claims, and thus summary judgment will be granted for the defendants on these claims. Pl. Opp'n at 20.

D. Per Quod Claim

Because summary judgment is being granted on all of Plaintiff's claims, summary judgment will be entered on Korrin Seavey's per quod claim as well. See Tichenor v. Santillo, 218 N.J. Super. 165, 173 (App. Div. 1987).

IV. CONCLUSION

For the reasons expressed herein, the motion by Dr. Testaiuti and Coastal Spine for summary judgment will be **GRANTED**, and the motion by Globus Medical for summary judgment will be **GRANTED**. The joint defense motion for summary judgment as to causation, Plaintiff's motion for summary judgment as to causation, the joint defense motion to preclude the testimony of Jamie Williams, and the joint defense motion to strike the affidavit of Jamie Williams will be **DIMISSED AS MOOT**. An accompanying Order shall issue.

Dated: 3/11/2014

/s/ Robert B. Kugler
ROBERT B. KUGLER
United States District Judge