

UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

Tammy ALLEN	:	
Plaintiff,	:	
	:	
v.	:	Case No. 3:04cv642 (PCD)
	:	
MENTOR Corp.,	:	
Defendant.	:	

RULING ON DEFENDANT’S MOTION FOR SUMMARY JUDGMENT

Plaintiff alleges a product liability claim for damages from a breast implant tissue expander pursuant to the Connecticut Product Liability statute, Conn. Gen. Stat. § 52-572m et seq. The case was removed to this court from the Connecticut Superior Court where it was brought, as Defendant properly invoked this Court’s diversity jurisdiction pursuant to 28 U.S.C. § 1441. Defendant now moves for the entry of summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure.

Though Plaintiff has referred to common law claims of negligence, breach of warranty (express and implied), and misrepresentation in her Memorandum in Opposition to Defendant’s Motion for Summary Judgment, this case will nonetheless be treated solely as a products liability case pursuant to Conn. Gen. Stat. §§ 572m and 572n, which establish that cause of action as the exclusive remedy for product defect claims "in lieu of all other claims against product sellers." Gnazzo v. G.D. Searle & Co., No. H-90-381(PCD), 1990 U.S. Dist. LEXIS 19479, at *3 (D. Conn. Nov. 29, 1990); Burkert v. Petrol Plus of Naugatuck, Inc., 216 Conn. 65, 579 A.2d 26 (1990).

Thus, Plaintiff’s burden is to prove that Defendant’s expander was implanted on March 1,

2002 without change and was defective and unreasonably dangerous at the time of sale and caused her injury. Giglio v. Conn. Light & Power Co., 180 Conn 230, 234-35, 429 A.2d 486 (1980).

I. Background

The factual situation is derived from the complaint, Defendant's Local Rule 56(a)1 statement ("SOF") and Plaintiff's memorandum. Defendant correctly notes Plaintiff's failure to file a L.R. 56(a)(2) statement, warranting a finding of the facts set forth in the SOF. It also notes the lack of a designation of Dr. Foster as an expert pursuant to Rule 26(a)(1) of the Federal Rules of Civil Procedure, and the absence of a report compliant with Rule 26(a)(2) . The first failure together with a lack of qualification, Daubert v. Merrill Dow, 509 U.S.579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993), warrant ignoring his opinions, but he does not appear to come within the specific language of subsection (a)(2).

Plaintiff is a female in her early thirties. In 2001 she considered with her doctor and a plastic surgeon a breast augmentation. At that time a decision was made to perform a mastectomy and a two-step reconstruction. The first step involved tissue expanders, a product designed and manufactured by Defendant, implanted by Plaintiff's plastic surgeon. There is no claim that the device at issue leaked before it was implanted. The device was supplied by Defendant in a package with a Product Insert Data Sheet, PIDS, which the surgeon claims he did not see. While he was aware of such material being included with such products, and thus does not deny that such came in the package with the implant as Defendant asserts, he does not describe any effort to look for or read what Defendant claims was in the package containing the implant. Defendant claims, without contradiction, that the PIDS included information of

significance in two respects. First, it warned that the device could leak. Second, it instructed that the device was constructed with an opening (port), magnetically detectable, through which supplementary saline could be injected and which should be used, as injection outside the port risked leakage.

Plaintiff claims that a deflation of the left implant occurred on or about March 21, 2002, an occurrence which is not the basis of her claim of a product defect. To achieve, or maintain, the volume of the implant that was intended, or desired by the Plaintiff, the left implant was injected with supplemental saline on at least three occasions. Neither Plaintiff nor Dr. Foster claim that leakage of saline solution on March 21, 2002 caused any harm to her. Indeed, Dr. Foster testified that it did not. The expander was left in place until May 10, 2002 when both expanders were removed and replaced with intended permanent implants which could then be accommodated in the space created by the expanders.

Plaintiff experienced some movement of the permanent implants which was corrected by surgery on May 31, 2002. This does not appear to be a basis for the claim. In June and July of 2002, Plaintiff sustained a staph infection that Dr. Foster describes not as caused by but related to the left implant deflation, a view of dubious significance in this case. The infection resulted in the removal of both permanent implants to allow the infection to clear. After clearing the infection, new implants, which Defendant manufactured, were placed.

Plaintiff claims the original implant was defective, that there was no warning of the danger of leakage, that the warnings and instructions "which were given and which accompanied the implant were inadequate to provide sufficient notice to the Plaintiff" of the danger, that the product was misrepresented as safe, that the danger from the product was not disclosed, that

Defendant was negligent in manufacturing and distributing a dangerous product and using improper materials in its construction, in breach of both express and implied warranties as to the product's safety. Plaintiff's sole source of information as to Defendant's implant was Dr. Foster. She did not review the PIDS, nor attempt to do so. She was informed of the procedure's risks, including the risk of expander deflation, which in fact occurred. [Pl.'s Mem., Ex. 2 at 52-57, 70.] She understood that after her mastectomies expanders would be implanted, followed by a second surgery for their removal and the placement of permanent implants. While the expanders were in place she understood they would create a pocket for the implants by being filled with saline into a button on the expander which had to be located for the saline injection. [*Id.* at 71-72.] After their removal, the first implants were examined and the left implant was found to have seven needle holes not within the port but on the palpation ring which bordered the port and which were the only leakage sites found.

II. Standard

A party moving for summary judgment must establish that there are no genuine issues of material fact in dispute and that it is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986). "A party opposing a properly brought motion for summary judgment bears the burden of going beyond the pleadings, and 'designating specific facts showing that there is a genuine issue for trial.'" Amnesty Am. v. Town of W. Hartford, 288 F.3d 467, 470 (2d Cir. 2002) (quoting Celotex Corp. v. Catrett, 477 U.S. 317, 324, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986)). In determining whether a genuine issue has been raised, all ambiguities are resolved and all reasonable inferences are drawn against the moving party. United States v. Diebold, Inc., 369

U.S. 654, 655, 82 S. Ct. 993, 8 L. Ed. 2d 176 (1962); Quinn v. Syracuse Model Neighborhood Corp., 613 F.2d 438, 445 (2d Cir. 1980). Summary judgment is proper when reasonable minds could not differ as to the import of evidence. Bryant v. Maffucci, 923 F.2d 979, 982 (2d Cir. 1991). "Conclusory allegations will not suffice to create a genuine issue." Delaware & H.R. Co. v. Conrail, 902 F.2d 174, 178 (2d Cir. 1990). Determinations as to the weight to accord evidence or credibility assessments of witnesses are improper on a motion for summary judgment as such are within the sole province of the jury. Hayes v. N.Y. City Dep't of Corr., 84 F.3d 614, 619 (2d Cir. 1996).

III. Discussion

Defendant supports its motion with material suggestive of the care required to prevent an expander from being delivered for use without assurance that it does not leak and that of the batch which included Plaintiff's implant there were no other complaints. It points out the absence of evidence from Dr. Foster that the product was defective in manufacture or design and that Dr. Foster has no academic or other experience in the field of implant design or manufacture. It further notes that, not having read the PIDS, Dr. Foster does not fault the instructions and warnings therein, including the warning that injections on or outside the palpation ring were subject to leakage. Their propriety was stated to be the case by Defendant's expert, Dr. Migliore. Dr. Foster knew of the need to locate the dome within the palpation ring as the appropriate location into which a needle should be inserted. [See SOF Ex. 1 at 98 (deposition of Dr. Foster).]

Defendant contends there was nothing wrong with the expander and that doctors were informed as to its proper use in the customary fashion, by its PIDS which Dr. Foster usually reads

but did not in Plaintiff's treatment. Dr. Foster now realizes the need to use the port for saline injections and has taken steps which have avoided repetitions of his aberrant aim in Plaintiff's case. He described his initial inflation of the expander after it was implanted, whereby he located the dome, and the port in its center into which the injection was to be made, using a magnetic detector provided by Defendant, a process he had used previously, and which he used in this case. He regarded Defendant's expander as safe, having had no prior problem with it until this case. FDA approval of the expander and Dr. Foster's continued use of it, absent any evidence to the contrary, would support Defendant's reliance on Restatement (Third) of Torts, § 6(c). [See SOF, Ex. 1 at 87.]

Defendant flags Plaintiff's admission that she received no information nor warranty as to the expander from Defendant and had no knowledge of any advertisements of it. From the deflation and/or the sequence in her treatment which followed including the infection after the permanent implantation and her claims of subsequent symptomatology and correction of their position, Defendant claims there is no evidence of a defect in the expander nor of a causal relation between it and all that followed.

To defeat the motion, Plaintiff's burden is met by offering evidence that shows the existence of a genuine issue of material fact. Amnesty Am. v. town of West Hartford, 288 F.3d at 470 . That burden is not met by reliance on the pleadings or conclusory assertions. Delaware & H. R. Co.v. Conrail, 902 F.2d 174, 178 (2d. Cir. 1990). There is no dispute but that the leakage on which Plaintiff's claim is based came from the seven punctures on the palpation ring which were caused by Dr. Foster's needle insertions. Plaintiff claims that those leakage sites were caused by a defective design and manufacture such that the punctures were not through a

self-sealing material and that Dr. Foster was not warned of the risk of leakage when the needle insertions were placed on, and not within, the palpation ring. There is no evidence, and thus no basis to claim, that any leak point existed at the time of Defendants' sale of the expander.

Defendant, relying on Conn. Gen. Stat. § 52-572p, argues that Dr. Foster modified or altered the expander when he made the seven injections on, and not within, the palpation ring, contrary to Defendant's instruction and expectation and therefore it is not to be held liable for the leakage from the needle holes that he created.

Defendant argues that it has shown that the expander conformed to its design and thus Plaintiff has no valid claim of a manufacturing defect. Plaintiff has not offered evidence that would support a finding that the expander was other than compliant with Defendant's design. Dr. Foster testified that that was not the case. [SOF, Ex. 1 at 11, 191.] Plaintiff relies on Dr. Foster to supply evidence of a defect, but he disclaims a manufacturing defect, characterizing the flaw as a design defect in that the material surrounding the palpation ring was to be self-sealing so that if a needle was inserted outside the ring it would not leak. [*Id.* at 12.] He claims to have learned later that that was not necessarily the case, a fact he would have known if he had read the PIDS.

Plaintiff argues that a manufacturing defect was involved, ignoring the fact that to prove such she had to prove a deviation in the product from the design of the product. She has proven no such deviation. She argues that she has proven a manufacturing defect because the expander leaked from injections into an area that was to be self-sealing. That argument is put forth as an absolute guarantee, yet her memorandum promptly refutes the argument by noting that the PIDS refers to the "self-sealing technology" of the area as "to minimize and/or prevent" (emphasis

added). She further notes the PIDS admonition: "DO NOT ATTEMPT TO INJECT INTO THE AREA AROUND THE DOME, as damage to the device may occur." [Pl.'s Mem. at 8, emphasis in the original.] That language clearly demonstrates that the device was not put forth with an absolute guarantee there would be no leakage and the fact that Dr. Foster made his injections outside the dome, i.e. into or outside the palpation ring from which leakage occurred would not support a finding of a deviation from the design.

Plaintiff asserts an unwarranted conclusion when she puts forth the proposition that "[t]he mere fact that the Plaintiff's expander leaked in the area where the device was incorporated with self-sealing technology, is evidence of a manufacturing defect." [Id. at 9.] There is nothing in the record to suggest that the expander design or description in the PIDS was assuredly self-sealing, in an absolute sense, or was in any manner guaranteed to be absolutely leakproof. Dr. Foster testified that that was not the case. [SOF Ex. 1 at 186.] Indeed, to reduce any risk of ill-aimed injections into or outside the palpation ring, the dome, inside the ring, was equipped with a metal disc and a magnet was provided with the expander, as Dr. Foster testified, so that the dome, through which an injection could properly be made, could be located precisely. That was the procedure Dr. Foster followed in making the original saline injection after the expander was inserted, but was not followed in the subsequent further inflations intended to bring Plaintiff to the desired size. She has not shown any genuine issue of material fact as to such a defect and thus has not demonstrated any genuine issue of material fact as to a manufacturing defect. She cannot, therefore, recover on that basis.

Defendant argues that Plaintiff's claim of a failure to warn fails because the warning is to be provided to the physician who chooses the treatment and the product and secondly there is no

expert evidence in the record that the warning provided was deficient, citing Vitanza v. Upjohn Co., 48 F. Supp. 2d 124, 127 (D. Conn. 1999); Vitanza v. Upjohn Co., 257 Conn 365, 378-80, 778 A.2d 829 (2001) (on certification from the United States Court of Appeals for the Second Circuit); Desmarais v. Dow Corning Corp., 712 F. Supp. 13, 17 (D. Conn. 1989); Basko v. Sterling Drug, Inc., 416 F.2d 417, 426 (2d Cir. 1969); Doe v. Yale Univ., 252 Conn 641, 686-87, 748 A.2d 834 (2000). Defendant also relies on the PIDS in use at the time the expander was distributed and which fully, three separate times, warns of the need to make any injection within the palpation ring and not on or outside it due to the risk of leakage. [SOF, Ex. 1 at 183-86.] Dr. Foster admits inclusion in packaging of devices such as the expander of material warning as above. It is his practice to review such material for devices he uses. [Id. at 199.] He did not do so in this case and thus cannot say that Defendant's PIDS was not included in the package containing the expander in question nor did he know what information, including warnings, were there provided and thus he cannot say that the warnings in the PIDS were inadequate. [Id. 67-68, 76.] They were FDA approved.

Plaintiff was fully warned of the risk of leakage and/or deflation. It was Dr. Foster's admitted obligation to warn Plaintiff of all risks, [Id. at 83], an obligation Defendant was entitled to assume he would fulfill and which he could not have fulfilled when he failed to inform himself with respect to the expander by reading the PIDS, a source of which he was aware and failed to find and read. There is no evidence in the record to suggest that the PIDS was not included in the expander package. There is no evidence that providing substantively adequate warnings by means of a product package insert, such as the PIDS, was not a proper method by which to inform a doctor who intended to use the product. See 21 C.F.R. § 801.109. Plaintiff's argument

that public policy is contravened by a requirement that an attending doctor be obliged to read a product insert, for which no authority is cited, flies in the face of manufacturers' reliance on the sanctioned learned intermediary doctrine and is without merit. In addition, Dr. Foster knew he was supposed to inject into the ring; he had previously and on eight injections had done so. His failure to do so on seven occasions was not for lack of warning as to the proper place for injections. A manufacturer cannot be found to have provided inadequate warnings when the physician who used the product failed to read the warnings provided. On the basis of the learned intermediary defense, Basko v. Sterling Drug, Inc., 416 F2d 417, 426 (2d Cir. 1969), or the adequacy of the warning provided, Defendant argues there is no genuine issue of material fact.

Plaintiff claims a duty to warn of an inherent risk and that Defendant could be held to have failed in that duty. Her claim is based on Dr. Foster's testimony that he had no office policy with respect to material provided with a product and had not seen the PIDS supplied with the expander in this case. Thus, Plaintiff would have Defendant held responsible not for failing to provide a warning but because Dr. Foster failed to read the warning provided. He makes no claim that the PIDS warning was inadequate, as he couldn't, having failed to read it. Now, having read it, he concedes that it warns that injections should not be made into the palpation ring lest they cause leakage and is not misleading. [Id. at 185.] It does not sanction injections on or outside the palpation ring and warns that the self-sealing technology does not absolutely prevent leakage if the palpation ring is punctured. [Id. at 186.] Nor does he claim that inclusion of the PIDS with the expander is an inadequate means for providing information about the product. He knew the dome was the proper place for the injection and described how he located and marked it for the original injection. [SOF, Ex. 1 at 98.] He further knew that manufacturers did not

commonly communicate warnings directly to physicians, and that literature was included in the packaging of medical devices. [Id. at 81.] In that way warnings about devices are provided directly to physicians. [Id. at 82.] He had used Defendant's expander which he regarded as safe, having used them since 1995 and continues to do so. [Id. at 32, 87.]

The record demonstrates no problem using Defendant's expanders prior to Plaintiff's incident, [Id. at 37], leading to the possibility that he fully knew where to make injections and hit the port in all cases until Plaintiff's. In either instance, his missed aim in her case cannot be attributed to a lack of warning but either to carelessness or a pure accident in failing to hit the port as he intended. [Id. at 187.] That intention belies reliance on an absolute self-sealing function of the ring and the material around the port but rather suggests an awareness of the presence, purpose, and need to use the port as the place to inject. Nonetheless, he faults the lack of a warning he claims not to have received by reason of his failure to read what was readily available to him. Plaintiff cites no authority for the proposition that Defendant, having made available a warning not shown to fail to warn of the condition with which the doctor finds fault, should be held liable not for failure to provide a warning but for the failure of the doctor to read the warning he now heeds.

Apart from the question of Dr. Foster's credibility, which is not here determined, Plaintiff argues that Defendant could be held liable for Dr. Foster's alleged failure to receive a warning which Defendant provided and which allegedly failed to reach the doctor because he failed to read it. He knew of the port on the expander; he took pains to locate it and used it at his original injection after implantation and for eight supplemental injections in Plaintiff's case, and presumably in the prior cases when the expander was used without mishap. His failure to locate

it for seven of Plaintiff's subsequent injections cannot be attributed to a lack of a warning shown to have been available if he had only read it, for nothing he has laid on Defendant led, induced, or permitted him indiscriminately to make injections other than within the port. To sustain Plaintiff's claim would hold Defendant liable for Dr. Foster's ill-aimed injections which resulted not from a failure to warn him to use the port but from his injection of saline without carefully locating the port, the presence and purpose of which he was aware. [SOF, Ex. 1 at 233-34.] The record does not suggest he had any basis to rely on preclusion of a risk of leakage, if the port was not used, from anything communicated by Defendant whose only communication was to the contrary.

Plaintiff's claim that adequate warnings would have altered Dr. Foster's conduct in her case is unfounded because there is nothing to suggest that the warnings Defendant included in the PIDS were inadequate nor that their quality affected his conduct since he did not read them. What would have avoided the missed injection placements was for Dr. Foster to have read the warnings provided and conducted himself accordingly. There is no genuine issue of material fact as to Defendant's obligation to warn when warnings, not shown to be inadequate in content, of a risk of leakage from exactly what Dr. Foster did, i.e., by injecting into the palpation ring, were given but were not heeded because he failed to read them.

There is no evidence in the record contrary to that offered by Defendant which supports the propriety of the expander design. Thus, Plaintiff has offered nothing from a source with expertise in the field of design of such products. The product is not shown to be latently defective and thus expertise in support of the claim is required to demonstrate a defect. Lisella v. Ford Motor Co., No. 3:97CV2001, 1999 U.S. Dist. LEXIS 23321, at * 7, (D. Conn. Oct. 26, 1999).

Medical products "properly prepared, and accompanied by proper directions and warning [are] not defective, nor . . . unreasonably dangerous." Restatement (Second) of Torts § 402A, comment k; Basko v. Sterling Drug, Inc., 416 F. 2d 417, 425-28 (2d Cir. 1969).

As per Dr. Foster, the risk of deflation in expanders is inherent and unavoidable and not shown to be provided against by any manufacturer. He would fault the design, including the material surrounding the port as not absolutely self sealing. He is not shown to have any education, training, or experience in the design of such devices. He has not testified as to any knowledge of materials compatible with use of such devices, the availability of such, nor an absolute seal proof/leak proof quality. He would thus require a design that guaranteed such quality when he knew of no product possessing such a quality. His view was further at odds with his testimony that leakage of saline is not harmful and that deflation, an inevitable risk in such devices, could readily be rectified by simply injecting supplemental saline to regain or maintain the desired volume of the expander. As he is not shown to be qualified to give the opinion evidence on which Plaintiff relies, his testimony does not create a genuine issue of material fact. The mere fact of deflation does not prove a defect.

Lastly Defendant argues that Plaintiff cannot prove the second element of her claim because no evidence has been produced that would permit a finding that injury and damages she alleges occurred were causally related to the deflation which occurred on March 21, 2002. In this respect Defendant cites and relies on the testimony of Dr. Foster, as does Plaintiff. Expert medical testimony is required. Plaintiff claims injuries resulting from the expander deflation of which she was warned, starting with a different permanent implant, emotional upset because of the leakage, a capsular contraction that required adjustment, a staph infection, left side pain and

spasms, headaches, and hair loss. For the different implant she cites Dr. Foster at pages 61-62 and 72, on none of which is there any suggestion by him that the implant used was affected by the leakage from the expander. Indeed, he noted that the permanent implant used, being expandable, was chosen to give Plaintiff the option of expanding it to her desired size. [Id. at 110.] Her emotional reaction to the leakage would not be compensable as she was warned of the risk, per Dr. Foster, and proceeded with no adverse result nor any complaint of side effects or complications. [Id. at 39-40.] After the expander implant she was injected to expand the implant to create the cavity for the final permanent implants. [Id. at 104-05.] After March 21, there was no further surgery until the permanent implantation on May 10. The capsular contraction is not shown to have been caused by the expander leakage, [id. at 125-26], and Defendant's expander was chosen as creative of the better capsule into which the permanent implant could be placed and because of there occurring less problems with capsular contraction. [Id. at 36-37.] Dr. Foster did not know the cause of the migration of the port on the May 10 implant. [Id. at 121.] Capsular contraction is a normal physiological result after an implantation and was found in relation to both implants, not just on the left where the earlier leakage had occurred. It was surgically corrected on both sides. [Id. at 121-23.] The tightness of which she complains was seen as normal following the procedures involved. [Id. at 127.] Dr. Foster could not testify to a causal relation between the expander leakage and the staph infection which occurred, [id. at 137], but said it was related, which he described in terms of the number of surgeries that she had led to the possibility of infection. [Id. at 133-34.] The infection was found on the left and right sides. While he did say they were related in terms of one following the other, the complications that occurred after the left expander deflation "weren't to a reasonable medical certainty caused by

it.” [Id. at 160.] None of Plaintiff’s surgery has been shown to be other than the expectable course of the treatment she subjected herself to from the mastectomy to the final reinsertion of her implants, thus any scarring cannot be, and has not been, shown to be caused by expander leakage. So also her claims of pain, hair loss, nerves, headaches, loss of sleep and appetite, most of which were not mentioned to Dr. Foster, who has not causally connected any of her complaints to the leakage in keeping with the requisite legal standard. Plaintiff suggests that he has related it all but nowhere has he voiced a view of there being proximal causation and thus absent evidence of same, there is no issue of material fact to be presented to the jury.

No genuine issue of material exists when "the record taken as a whole could not lead a rational trier of fact to find for the non-moving party." Matsushita Elec. Indus. Co. v. Zenith radio Corp., 475 U.S. 574, 594, 89 L. Ed. 2d 538, 106 S. Ct. 1348 (1986). All factual inferences from the material supplied are to be viewed in "in the light most favorable to the party opposing the motion." Rodriguez v. City of New York, 72 F.3d 1051, 1060 (2d Cir. 1995). Applying the legal principles on which Defendant’s motion is to be judged, defendant is entitled to summary judgment as a matter of law

Accordingly, Defendant’s motion is granted and the case is dismissed. The Clerk shall close the file.

Dated at New Haven, Connecticut this 31st day of March, 2006.

/s/
Peter C. Dorsey
United States District Judge