UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

RANDY J. AFRICANO

Plaintiff,

v.

ATRIUM MEDICAL CORPORATION,
a Delaware Corporation,

Defendant.

Case No.: 1:17-CV-7238

Honorable Mary M. Rowland

DEFENDANT'S MOTION FOR JUDGMENT AS A MATTER OF LAW PURSUANT TO RULE 50(A) AND MEMORANDUM IN SUPPORT

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Defendant Atrium Medical Corporation ("Atrium") respectfully moves for judgment as a matter of law under Rule 50(a)(1) of the Federal Rules of Civil Procedure.[1] No reasonable jury could find in Plaintiff's favor on any of his claims.

ARGUMENT

I. PLAINTIFF HAS NOT OFFERED LEGALLY SUFFICIENT EVIDENCE THAT HIS MESH WAS NOT STERILE WHEN IT LEFT ATRIUM'S CONTROL

Under Illinois law, a strict products liability claim requires a showing that the "the injury complained of resulted from a condition of the product, that the condition was unreasonably dangerous, and that it existed at the time the product left the manufacturer's control." *Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 335 (Ill. 2008). In order to establish strict liability for a manufacturing defect, a plaintiff must show that the particular unit at issue deviated from the manufacturer's intended design. *See Salerno v. Innovative Surveillance Tech., Inc.*, 932 N.E.2d 101, 108 (Ill. App. Ct. 2010). Here, Plaintiff presented insufficient as a matter of law to create an issue of fact for the jury that the specific mesh implanted in him was unsterile.

On or about December 10, 2013 Plaintiff was implanted with Atrium ProLite mesh from Lot 10883365, which Atrium made on or about March 8 to March 11 2013. (Dkt. 334, Parties' Joint Proposed Pretrial Order at 3 ¶ 6(1).) Lot 10883365 was sterilized by Atrium's sterilization vendor Steris in a process completed on April 2, 2013. (DX184 at 44845; 4A Tr. (Haas) at 648:13-657:7; *see also* Dkt. 334 at 3 ¶ 6(1).) Steris certified that its facilities and services were in compliance with applicable regulations and industry standards. (DX184 at 44845; 4A Tr. (Haas) at 657:8-658:7.)

To support his claim, Plaintiff alleges, *first*, that he experienced an infection. However,

[1] Plaintiff rested his case on October 15, 2021 and will be advising the jury on October 18, 2021. (4B Tr. at 769:10-770:16.)

the mere fact of injury is insufficient to establish defect. *See Schultz v. Hennessy Indus., Inc.*, 584 N.E.2d 235, 241 (Ill. App. Ct. 1991). Moreover, as discussed in Section II below, the evidence does not support Plaintiff's claim that he was infected. In addition, Plaintiff produced no evidence that any person receiving mesh from the same lot as Plaintiff ever complained of infection. The evidence was, in fact, to the contrary. (Ex. A, Videotaped Deposition of Trevor Carlton ("T. Carlton Dep.") at 211:16-21; 4A Tr. (Haas) at 660:1-660:12.) If there had been a problem with sterilization of that lot, one would not expect the problem to be restricted to Plaintiff's mesh.

Second, Plaintiff points to an observation made by an FDA inspector noted in a Form 483 document and a warning letter (PX4 & PX6). Neither establishes that the specific mesh implanted in Plaintiff was unsterile.[2] In observations after an inspection between July 31, 2021 and September 7, 2012, two FDA inspectors indicated their belief that validation of the sterilization process was inadequate because (1) data were not provided that the process challenge device (PCD) simulated worst case conditions, and (2) the model and lot numbers of the PCDs tested were not provided. (PX4 at 48.)[3] A PCD is intended to be the most difficult product to sterilize. If a process can sterilize the PCD, it will also be able to sterilize all other products. (Ex. A, T. Carlton Dep. at 134:3-135:5; 3A Tr. (Talcott) at 394:3-10, 439:18-440:2; 4A Tr. (Haas) at 667:3-9.) Surgical mesh is a relatively simple product to sterilize. (4A Tr. (Haas) at 640:8-641:6.) The FDA did not indicate that any particular product was not sterile, only that the process required more documentation. (Ex. A, T. Carlton Dep. at 136:4-18; 188:1-8; 189:2-14; 4A Tr. (Haas) at 674:4-7.) In addition, the 483 document makes clear that the "inspectional observations . . . [did]

[2] Atrium objected to both documents on hearsay grounds for the reasons stated Atrium's Motion in Limine No. 2 (Dkt. 302), which is incorporated herein by reference. As hearsay, they are not probative and cannot meet Plaintiff's burden of proof.

[3] Throughout this memorandum, Atrium refers to production numbers where available.

not represent a final Agency determination regarding [Atrium's] compliance." (PX4 at 48.)[4]

On October 11, 2012, the FDA sent Atrium a warning letter in which the 483 observations were repeated. (PX6 at 695.) Warning letters are not final agency action. (Dkt. 350, Order at 2.)

A May 2013 report, "FDA Sterilization Response Quality Plan," documented Atrium's actions to respond to the FDA's sterilization observation. (*See* 3A Tr. (Talcott) at 413:19-25; *see also id.* at 421:1-2 (explaining that the plan "was summarizing all the work that had been done up to that point"); 4A Tr. (Haas) at 668:16-674:3; DX, 40, 42, 49, 50.) Atrium concluded that "PCD use ***was appropriate*** but not documented. . . . The sterilization cycle was validated and meets the required SAL levels. This confirms that product sterilized under the cycle met requirements. There is no patient impact." (PX5 at 33212 (emphasis added); *see also* 3A Tr. (Talcott) at 414:19-21.) The report identified many studies that were completed by Atrium and its sterilization consultant and noted that the studies confirmed that the V12/iCast PCD (the ***same PCD*** referenced in the 483 observations (PX4 at 48; 3A Tr. (Talcott) at 410:10-14, 426:3-5)) presented a greater challenge to the sterilization process than other devices tested. (PX5 at 33214; 3A Tr. (Talcott) at 416:25-417:15, 440:3-25; 4A Tr. (Haas) at 673:9-674:7.) Atrium also "determined that there [was] no risk to the product in the field, therefore no field action [was] required to recall product." (PX5 at 33215.)

Neither of the FDA documents Plaintiff relies on constitutes a final agency action and, even if they did, the FDA never determined that any product sold by Atrium was not sterile, let alone the lot of mesh that included Plaintiff's mesh. Significantly, the FDA never required Atrium to

[4] Other observations in the 2012 FDA document concerned products other ProLite or issues other than sterilization. (*See* PX4 at 48-50 (1B – Pleuraguide Kit; 2A – C-QUR mesh; 2B – vascular grafts and patches; 3A – C-QUR curing oven; 3B – C-QUR sprayer, 3C – C-QUR thermaform temperature and time).) Plaintiff did not provide either expert or fact witness testimony about these observations.

withdraw any product from the market. (Ex. A, T. Carlton Dep. at 161:21-23; 3A Tr. (Talcott) at 418:6-15, 423:11-17, 427:12-428:2.) The FDA also did not require Atrium to change its sterilization process. (4A Tr. (Haas) at 674:4-11.) In January 2013, the FDA acknowledged receipt of Atrium's response and indicated that it would need to schedule a follow-up inspection. (PX10, T. Carlton Ex. 21.) FDA inspectors performed another inspection of Atrium's facilities on several days between July 9, 2013 and October 1, 2013. (PX15 at 8972.) None of the observations listed in the document generated by the FDA following that inspection concerned validation of the PCD selection. (PX15 at 8972; 3A Tr. (Talcott) at 434:15-436:1.)[5] In an Establishment Inspection Report, the FDA indicated that Atrium's response was adequate. (DX203 at 68307; 4A Tr. (Haas) at 675:4-677:9.)

It is unusual for the FDA to provide a company with a written response indicating that it is satisfied with a company's response. Instead, it simply takes no action. (3A Tr. (Talcott) at 417:19-418:5, 443:10-22.) That is what happened here. As Trevor Carlton (Atrium's former President) and Timothy Talcott (Atrium's Senior Director of Quality and Improvement Programs) testified, Atrium believed that the FDA was satisfied with its response. (Ex. A, T. Carlton Dep. at 137:1-22; 144:4-15; 145:8-146:10; 203:18-204:3; 3A Tr. (Talcott) at 417:19-418:15, 423:11-17, 434:15-436:1.) It is simply inconceivable that the FDA would permit a non-sterile medical device to remain on the market. (3A Tr. (Talcott) at 418:14-15, 423:11-17, 428:17-429:1.) The FDA required only that Atrium supply additional documentation that it had chosen the correct PCD. Atrium confirmed that it had.

[5] The 2013 FDA document contained ***new*** observations about sterility, but those concerned whether the ***shelf life*** for products ***other than ProLite*** had been validated. (PX15 at 8972-73; 4A Tr. (Haas) at 678:6-680:14; *see also* 3A Tr. (Talcott) at 407:2-11 (explaining the difference between ProLite and C-QUR mesh.)

In *Barnett v. Mentor H/S, Inc.*, the court found that similar evidence of defect proffered by a plaintiff was insufficient. There, the plaintiff opposed summary judgment by relying on, *inter alia*, "FDA inspection reports." *See* 133 F. Supp. 2d 507, 511 (N.D. Tex.), *aff'd*, 31 F. App'x 156 (5th Cir. 2001). As the court explained, those materials "discusse[d] generally the deficiencies in [the defendant's] manufacturing, product design, and quality assurance programs, but [did] not focus on or even address the issue of whether a defect existed ***in any of the specific breast implants supplied to [the plaintiff]***." *Id.* (emphasis added). The court found that this evidence "establishe[d] no more than a surmise or suspicion as to the existence of a defect in the implants received by [plaintiff]" and that judgment as a matter of law was warranted because there was "no legally sufficient evidence to support Plaintiff's contention that a defect existed." *Id*. at 511-12.

Further, under Illinois law, expert testimony is required on matters that are beyond the common experience and understanding of the jurors. *See Baltus v. Weaver Div. of Kidde & Co.*, 557 N.E.2d 580, 588-89 (Ill. App. Ct. 1990). In product liability actions, expert testimony on the issue of defect is usually required. *See Piltch v. Ford Motor Co.,* 778 F.3d 628, 632-33 (7th Cir. 2015); *Show v. Ford Motor Co.*, 659 F.3d 584, 587 (7th Cir. 2011). This is true even in a manufacturing defect case, *Piltch*, 778 F.3d at 632-33, or when a plaintiff proceeds under the "consumer-expectations" test, *Show*, 659 F.3d at 587.

Here, the issue is not whether unsterile mesh would be considered defective, but whether the mesh implanted in Plaintiff was not sterile when it left Atrium's control. Even if the former proposition is obvious, the latter is anything but. Issues of process validation and selection of a process challenge device, together with their implications for either a product line or a specific product, are not within the common understanding of a lay jury. Thus, to meet his burden, Plaintiff needed expert testimony. But the only expert called by Plaintiff was Dr. Sylvestre, who was not

offered as an expert on sterilization methods. (Dkt. 300, Stipulation ¶ 11; 2B Tr. (Sylvestre) at 297:3-7, 299:4-7.)[6] Further, Dr. Sylvestre offered no basis to support her opinion that the mesh was the source of any infection. Indeed, she reached this opinion without even reviewing Dr. Phillips's December 10, 2013 operative note. (2B Tr. (Sylvestre) at 292:13-16; 300:4-6.) She simply assumed her own conclusion. (*Id.* at 276:4-7.)

Dr. Sylvestre's assumption that sterility was not breached in the operating room (*id.* at 299:24-300:3) provides no basis for identifying any particular source of infection. If it did, hospitals and surgeons would not routinely warn that infection is a risk of any surgery, as they did in this case. (DX273 at 53-55; 1B Tr. (R. Africano) at 232:18-233:23.) Even the best surgical practice cannot keep out all bacteria from a surgical site. (Ex. B, Videotaped Deposition of Timothy S. Phillips, M.D. ("Phillips Dep.") at 55:25-56:7.) As one example, during surgery, a nurse opens the mesh using a sterile technique, but if the technique is not applied correctly, "the mesh can become contaminated." (*Id.* at 55:15-24.) There are "reams of research" about bacterial infection of a surgical site despite the use of sterile techniques. (*Id.* at 55:25-56:7.) Dr. Phillips testified that he is not qualified to opine on this complex subject (*id.*), and Plaintiff did not present any other expert evidence to rule out bacterial contamination during the operation. Certainly, Dr. Sylvestre did not. She had no basis for ruling in the mesh as a source of infection any more than she could rule out any other equipment used during surgery, including the scalpel, scissors, retractors, syringe and sterile fluid, sutures, needle driver, steri-strips, dressing, gloves, and coats. (2B Tr. (Sylvestre) at 346:5-8, 348:7-360:8.) In fact, she admitted that she had not addressed any

[6] Atrium renews its Motion to Exclude Certain Opinions and Testimony of Pamela Sylvestre, M.D. (Dkt. 244) and incorporates by reference the arguments and authorities made in its Memorandum of Law (Dkt. 245) and Reply in support thereof (Dkt. 275), as well as its contemporaneously filed Motion to Strike. (Dkt. 384.)

of the items in an operating room that could be a source of infection. (*Id.* at 360:5-8.)

As a result, Plaintiff failed to sustain his burden to prove that the mesh implanted in him was not sterile when it left Atrium's control.

II. PLAINTIFF HAS NOT OFFERED LEGALLY SUFFICIENT EVIDENCE THAT HIS INJURIES WERE PROXIMATELY CAUSED BY ANY CONDITION OF HIS MESH

Plaintiff alleges that he suffered an infection as a result of the Atrium mesh, but he has proffered insufficient evidence that his wound was infected at all, let alone by Atrium mesh. The evidence presented by Plaintiff shows that from the time he was implanted with Atrium mesh on December 10, 2013 (DX272 at 20-21; Dkt. 334 at 3 ¶ 6(1)) to over 2½ years later just before part of the mesh was explanted in July 2016 (Dkt. 66, 3d Am. Compl. ¶ 16), Plaintiff never presented with any clinical signs unique to infection, as opposed to expected responses to surgery such as inflammation. He visited his implanting physician nine days after his surgery and did not have a fever or other clinical signed of infection. (*See* DX272 at 47; Ex. B, Phillips Dep. at 65:16-66:9, 69:11-14; 2B Tr. (Sylvestre) at 300:10-303:17.) While he presented with a mass in the groin area in May 2015, an ultrasound performed a month later identified only a fluid collection consistent with an inflammatory process. (DX273 at 80-82; Ex. B, Phillips Dep. at 70:22-71:18, 72:12-18, 73:22-24, 74:6-8, 74:15-75:13; 2B Tr. (Sylvestre) at 317:5-7.) Plaintiff showed no overt signs of infection, and his clinical findings were consistent with an inflammatory response. (Ex. B, Phillips Dep. at 75:19-76:7; 2B Tr. (Sylvestre) at 310:17-312:24 (conceding that when Plaintiff saw Dr. Phillips on June 11, 2015, there was no sign of systemic infection). On September 18, 2015, Plaintiff complained to Dr. Phillips about pain and a bulge. Dr. Phillips noted that his pain was intermittent and the bulge was consistent with inflammation and scarring around the mesh. (DX272 at 53; 2B Tr. (Sylvestre) at 317:12-17, 321:1-17.) At that time, an MRI identified a seroma, a ***sterile*** fluid collection, as distinct from an abscess, which would be a sign of infection.

(DX275 at 2; Ex. B, Phillips Dep. at 75:14-18, 76:14-19, 82:1-83:22, 99:4-10; Dkt. 66, 3d Am. Compl. ¶ 14.) Significantly, Dr. Sylvestre did not review this MRI (2B Tr. (Sylvestre) at 321:18-25), but conceded that the radiologist diagnosed a seroma, that seromas are a common occurrence following surgery, and that seromas sometimes persist for over a year (*id.* at 323:22-326:5). The MRI results were consistent with Dr. Phillips's clinical observations. (Ex. B, Phillips Dep. at 86:15-21.)

On July 27, 2016, Plaintiff went to the emergency room. (DX274 at 97-99; 2B Tr. (Sylvestre) at 326:7-11.) In the 2½ years between his implant surgery and emergency room visit, no health care practitioner treated Plaintiff for an infection other than a respiratory infection. (2B Tr. (Sylvestre) at 327:3-8.) When he presented at the emergency room, Plaintiff did not have a fever, abnormal white blood cell count, or any other signs of systemic infection. (DX274 at 97-99; 2B Tr. (Sylvestre) at 327:20-328:24.) A CT scan did not show enlarged lymph nodes in the abdomen or pelvic region. (2B Tr. (Sylvestre) at 328:25-329:16.) Dr. Holmstrom performed an incision and drainage procedure following the CT scan and a gram stain did not show the presence of bacteria or white blood cells on the fluid removed. (*Id.* at 330:17-334:19.) On July 29, 2016, Dr. Alexander Nagle drained the seroma and removed that part of the ProLite mesh that was not embedded in surrounding tissue. (Dkt. 66, 3d Am. Compl. ¶ 16; 2B Tr. (Sylvestre) at 334:20-24.) Dr. Nagle noted that only the unincorporated mesh was removed. Incorporated mesh was left intact. (DX280 at 3-4; 2B Tr. (Sylvestre) at 334:25-335:5.) The mesh was not cultured. (2B Tr. (Sylvestre) at 336:5-7, 339:24-340:4.) Dr. Sylvestre conceded that, if a surgeon suspected infection, the typical practice would be to send the excised material to be cultured. (*Id.* at 340:5:17.) Both before and after the surgery, the mesh was never tested for the presence of bacteria. (*Id.*at 340:23-341:1.) Likewise, no fluid or debris from the surgery was cultured for

bacteria. (*Id.* at 341:2-9.) Post-operative notes indicate that the mesh left in place was well incorporated, uninfected, and that the Plaintiff was doing well. (DX274 at 12-13.) When Plaintiff was seen by Dr. Phillips in August 2016, his wound was healing well and showed no signs of infection. (DX265 at 78; Ex. B, Phillips Dep. at 87:11-22, 89:12-90:2, 90:6-11; 2B Tr. (Sylvestre) at 341:10-23.) Similarly, when Plaintiff was seen by Dr. Nagle in August 2016, he was recovering well with no signs of infection. (2B Tr. (Sylvestre) at 342:3-343:24.)

Dr. Sylvestre's testimony is insufficient to meet Plaintiff's burden for several reasons. Dr. Sylvestre is a pathologist, with no training in surgery. (*Id.* at 285:11-25.) She is not board certified in internal medicine and never completed a residency in internal medicine. (*Id.* at 288:2-6.) She never completed a fellowship in infectious diseases. (*Id.* at 288:7-9.) As a pathologist, Dr. Sylvestre evaluates human tissue and spends her days reviewing specimens under a microscope. (*Id.* at 288:17-23.) In this case, however, she was not called upon to use these skills. She never reviewed any pathology specimens, never looked at any tissue samples, and never used a microscope. (*Id.* at 288:24-299:4.) That's because there are no lab results that support a finding of infection.[7] While Dr. Sylvestre attempted to explain away the negative results found by Dr. Holmstrom (*id.* at 355:14-357:11), that does not change the fact that the results do not provide ***affirmative*** support for Dr. Sylvestre's opinion. And it is Plaintiff—not Atrium—who has the burden of proof.

Dr. Sylvestre also failed to consider or offer any explanation for the complete absence of other clinical findings that might otherwise suggest an infection. In over 2½ years, Plaintiff never

[7] A culture following the incision and drainage grew staphylococcus lugdunensis, but Dr. Sylvestre conceded that this organism could be found on human skin and did not opine that it was the source of infection. (2B Tr. (Sylvestre) at 359:1-362:22.) It was noted on the report as "a small amount consistent with contamination or colonization"; the report otherwise found that there were no bacteria growing from the fluid sample. (*See* DX274 at 114-116.)

had a fever, never had nausea, never had elevated white blood cells, never had enlarged lymph nodes, never had redness at the surgical sight, and never had a recurrence of his hernia. When he complained of pain and a mass 2½ years after surgery, an ultrasound and MRI were both consistent with a non-infectious process, such as inflammation or a seroma. *See supra* at 7-8. Not only did Dr. Sylvestre fail to offer an explanation for any of these findings, she considered medical records and deposition testimony cherry-picked for her by Plaintiff's counsel (2B Tr. (Sylvestre) at 290:13-16), ignoring many others. (*See id.* at 291:16-18 (Phillips deposition), 292:13-16 (December 10, 2013 operative note), 293:23-294:1 (December 19, 2013 note), 294:2-7 (January 20, 2014 note), 294:8-10 (September 18, 2015 note), 294:11-295:17 (September 28, 2015 MRI), 295:18-21 (Courtney, emergency room physician, deposition), 296:3-10 (records after fall 2016). Dr. Sylvestre also did not review the complaint in this action (*id.* at 296:11-13), where Plaintiff admits that he had a seroma, and did not ever examine Plaintiff (*id.* at 289:11-14).

In fact, Dr. Sylvestre's opinion that Plaintiff experienced an infection is based on little more than reading Dr. Nagle's operative report. (*Id.* at 279:7-12.) However, to reach her opinion, she had to disregard Dr. Nagle's sworn deposition testimony (*id.* 278:23-279:6, 280:4-16), as well as another reference in the operative note where he indicated the patient had a hematoma (DX280 at 3; 2B Tr. (Sylvestre) at 338:18-339:1-21). Further, in the absence of any clinical findings to support her opinion, Dr. Sylvestre made certain assumptions that were beyond her expertise, such as how long a hematoma or seroma might last (*id.* at 277:16-278:3, 324:1-326:5) or whether only part of mesh could remain infected for a 2½ year period (*id.* at 336:21-337:24). Due to her lack of clinical expertise, she also could not exclude alternative causes for a hematoma, such as abdominal pressure from snowmobiling and coughing (*id.* 307:21-24, 309:13-310:16), or the risks of infection from an open procedure (*id.* at 345:1-346:4), or another piece of equipment being the

source of any alleged infection (i*d.* at 360:5-8).

In short, Dr. Sylvestre's opinion is circular. She assumed her conclusion. She can point to no signs, symptoms, or lab results to support her opinion. She relies on a highly selective review of the medical records and deposition testimony and disregards the deposition testimony of the surgeon who explanted the mesh.

Accordingly, judgment should be granted in Atrium's favor for two independent reasons. First, Atrium renews its argument that Plaintiff has judicially admitted that the fluid collection he experienced was a sterile seroma and not an infected abscess.[8] Second, medical causation must be established by expert testimony. *See O'Keefe v. Greenwald*, 574 N.E.2d 136, 142 (Ill. App. Ct. 1991). For the reasons discussed above, Dr. Sylvestre's testimony was insufficient to meet Plaintiff's burden.

III. PLAINTIFF HAS NOT OFFERED LEGALLY SUFFICIENT EVIDENCE OF HIS FAILURE-TO-WARN CLAIM

"When a plaintiff attempts to prove that a drug manufacturer failed to adequately warn, he must first demonstrate that there was a duty to warn." *N. Tr. Co. v. Upjohn Co.*, 572 N.E.2d 1030, 1037 (Ill. App. Ct. 1991). A manufacturer has a duty to warn of any unreasonably dangerous condition of the product and to instruct the user on the proper use of the product. *See Salerno*, 932 N.E.2d at 109-10; *see also Baltus*, 557 N.E.2d at 588 (duty to warn of latent defect or a dangerous propensity of which a user would normally be unaware). In cases involving prescription drugs and medical devices, the duty runs to the learned intermediary; there is no duty to warn the patient directly. *See, e.g.*, *Hansen v. Baxter Healthcare Corp.*, 723 N.E.2d 302, 311 (Ill. App. Ct. 1999), *aff'd*, 764 N.E.2d 35 (Ill. 2002); *N. Tr. Co.*, 572 N.E.2d at 1037. In addition, any defective

[8] Atrium incorporates by reference the arguments and authorities cited in its Memorandum of Law Regarding Judicial Admissions (Dkt. 337).

condition or dangerous propensity must be one of which the manufacturer knows or should know, even in strict liability cases. *See Woodill v. Parke Davis & Co.*, 402 N.E.2d 194, 198 (Ill. 1980); *N. Tr. Co.*, 572 N.E.2d at 1037; *In re Depakote*, 2015 WL 4776093, at *3 (S.D. Ill. Feb. 14, 2015).

Thus, the duty to warn can arise in two situations: (1) where the manufacturer knows or has reason to know of a defective condition of the product or (2) where the product is not defective but has propensities that require adequate instructions for its proper use. As an example of the latter category, several drugs may have the side effect of raising a patient's blood pressure. Such drugs are not defective and may be commonly prescribed, but they require adequate instructions for use. Here, it is undisputed that the Instructions for Use warned as follows:

> Complications that may occur with the use of any surgical mesh include, but are not limited to inflammation, infection or mechanical disruption of the tissue and/or mesh material, possible adhesions when placed in direct contract with the viscera (intestines).

(JX1 at 25957.) To challenge the adequacy of this warning, Plaintiff was required to present expert testimony. *See Hernandez v. Schering Corp.*, 958 N.E.2d 447, 455 (Ill. App. Ct. 2011); *Sosnowski v. Wright Med. Tech., Inc.*, 2012 WL 1030485, at *7 (N.D. Ill. Mar. 27, 2012); *Peterson v. Wright Med. Tech., Inc.*, 2014 WL 12539635, at *6 (C.D. Ill. Feb. 13, 2014). He did not.

Instead, Plaintiff attempted to allege a failure-to-warn claim in the former category. That is, Plaintiff alleges that the mesh he received was not sterile, creating a duty to warn on Atrium's part. Under this theory, his failure to warn claim is not independent of his manufacturing defect claim. Thus, if Plaintiff cannot prove that his mesh was defectively manufactured, *i.e.*, unsterile, then his failure to warn claim also fails. *See Salerno*, 932 N.E.2d at 110 (plaintiff's failure-to-warn claim failed with waiver of his defective design claim); *Bensenberg v. FCA US LLC*, 2020 WL 7029885, at *10 (C.D. Ill. Nov. 30, 2020) (plaintiff's failure to warn claim failed when there was no evidence that a car's airbag or seatbelts were defective).

Plaintiff's allegation that Atrium should have warned of the FDA's 483 observations or that it had received a warning letter does not save his failure-to-warn claim. Initially, as noted above, neither constitutes a final agency determination. Regardless, there is no legal duty to warn of communications with the FDA; rather, the manufacturer has a duty to warn of ***defective conditions*** of the product of which it knows or should know. At best, evidence of the FDA communications are relevant only to the issue of Atrium's knowledge. As discussed above, the FDA never found that any Atrium product was not sterile. Instead, it required only additional documentation that Atrium's selection of a PCD was properly validated. In addition, the testimony from Atrium employees shows that Atrium believed the FDA had accepted the re-validation and that there was not an issue with sterilization itself. Atrium also determined that there no patient impact from the validation issue raised by the FDA. And because the FDA was satisfied with Atrium's response months before Plaintiff's implant surgery, the 2012 483 document and warning letter are irrelevant to Plaintiff's failure to warn claim. *See supra* at 3-4.

Further, the FDA communications in and of themselves cannot meet Plaintiff's burden to show that Atrium was on notice of a product defect. Once again, expert testimony was required. For example, in *Northern Trust Co. v. Upjohn Co.*, an Illinois appellate court held that whether case reports were sufficient to establish a drug manufacturer's knowledge of an association between the drug and cardiac arrest "was a complex question which required expert testimony." 572 N.E.2d at 1037. The court also held that evidence of federal regulations could not meet the plaintiff's burden to show actual or constructive knowledge on the part of the manufacturer without expert testimony. *See id.* at 1040. Here, the FDA's communications concern matters that are outside the experience of an average jury. Plaintiff asks the jury to make various inferential leaps from the documents, but he does so without any expert testimony. Because expert testimony was

required, judgment should be entered in Atrium's favor. *Cf. N. Tr. Co.*, 572 N.E.2d at 1039-40 (holding that directed verdict should have been entered for defendant).

IV. PLAINTIFF HAS NOT OFFERED LEGALLY SUFFICIENT EVIDENCE THAT ATRIUM'S CONDUCT WAS WANTON, MALICIOUS, OR OPPRESSIVE

New Hampshire does not permit recovery of damages "as a punishment to the defendant or as a warning and example to deter him and others from committing like offenses." *Vratsenes v. N.H. Auto, Inc.*, 289 A.2d 66, 67 (N.H. 1972). While only compensatory damages may be awarded, enhanced compensatory damages may be awarded to "reflect the aggravating circumstances" when the conduct is "wanton, malicious, or oppressive." *Id.* at 68; *accord Figlioli v. R.J. Moreau Cos.*, 866 A.2d 962, 966 (N.H. 2005); *Precourt v. Fairbank Reconstruction Corp.*, 856 F. Supp. 2d 327, 344 (D.N.H. 2012). "[E]nhanced compensatory damages . . . are awarded only in exceptional cases, and not even in every case involving an intentional tort." *Figlioli*, 866 A.2d at 966; *see also DCPB, Inc. v. City of Lebanon*, 957 F.2d 913, 915 (1st Cir. 1992) (observing that enhanced compensatory damages have generally "been reserved for intentional torts committed under exceptionally unsavory circumstances").

Thus, in *Figlioli*, the New Hampshire Supreme Court affirmed summary judgment where the plaintiff introduced evidence that a defendant's employee had been negligent, but nothing more. *See* 866 A.2d at 967. Similarly, the New Hampshire Supreme Court has held that drunk driving, while "deplorable," is not equivalent with the conduct required to support an award of enhanced compensatory damages. *See Johnsen v. Fernald*, 416 A.2d 1367, 1368 (N.H. 1980). As the court explained:

> If we were to agree with the plaintiff and hold that "malice" for the purpose of measuring damages is the intentional doing of a wrongful act, then every intentional tort would give rise to the larger amount of damages. Instead of allowing an award of damages to be based on implied or legal malice we prefer to base such an award only on a showing of actual malice. There must be ***ill will, hatred, hostility, or evil motive*** on the part of the defendant.

Id. (cleaned up, emphasis added); *see also Gelinas v. Mackey*, 465 A.2d 498, 500 (N.H. 1983) ("[T]he act of driving while intoxicated did not constitute 'wanton or malicious' conduct as defined at common law for purposes of enhancing damages.").

Plaintiff has failed to sustain his burden to show that Atrium's conduct was wanton, malicious, or oppressive. Even construed favorably for Plaintiff, the evidence would show no more than: (1) Atrium selected a PCD based on the expert guidance of its sterilization vendor (PX3 at 32603), (2) the FDA questioned whether Atrium had sufficiently validated that the PCD represented the most difficult product to sterilize, (3) Atrium undertook extensive efforts to respond to the FDA and determined that there was no patient impact from the FDA's observations because Atrium had been using an appropriate PCD, (4) in a follow-up inspection, the FDA did not raise any concerns about the PCD, (5) the FDA determined that Atrium's PCD response was adequate, and (6) the FDA never required Atrium to change its sterilization process or withdraw any product from the market. *See supra* Section I. These facts cannot support an award of enhanced compensatory damages. "If the evidence is insufficient, as a matter of law, the jury [should] not be instructed on enhanced compensatory damages." *Precourt*, 856 F. Supp. 2d at 345; *see also DCPB, Inc.*, 957 F.2d at 916 (affirming judgment as a matter of law in favor of defendant on issue of enhanced compensatory damages).

WHEREFORE, for the reasons set forth above, Atrium respectfully asks that the Court grant this motion and enter judgment in its favor as a matter of law.

Dated: October 16, 2021

Respectfully submitted,

/s/ Mark S. Cheffo

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CERTIFICATE OF SERVICE

In accordance with Rule 5.5 of the Local Rules of the United States District Court for the Northern District of Illinois, I hereby certify that a true and correct copy of the foregoing document has this 16th day of October, 2021 been filed been electronically with the Clerk of Court using the CM/ECF system. Notice of these filings will be sent to all counsel of record and parties by operation of the Court's electronic filing system.

/s/ Mark S. Cheffo
Mark S. Cheffo