UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: ZIMMER NEXGEN KNEE IMPLANT PRODUCTS LIABILITY LITIGATION	)	**MDL No. 2272**
	)	**Master Docket No. 11 C 5468**
BEVERLY GOLDIN,	)	
Plaintiff,	)	
v.	)	**No. 12 C 2048**
ZIMMER, INC.,	)	**Judge Rebecca R. Pallmeyer**
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Plaintiff Beverly Goldin had a total knee replacement (TKR) in 2009. By late 2011, the knee implant—the NexGen Flex knee manufactured by Defendant Zimmer, Inc.—had failed, becoming so loose that Ms. Goldin required a second knee replacement. In this lawsuit, Plaintiff alleges that Defendant Zimmer failed to warn that Plaintiff's excessive weight could cause her knee to fail.

Ms. Goldin's case is one of hundreds that have been assigned to this court as part of a multidistrict litigation proceeding (MDL), in which plaintiffs allege they suffered injury caused by premature loosening of the Zimmer NexGen Flex knee implant. This case is the third to be scheduled for a bellwether trial. The first such case, brought by plaintiff Kathy Batty, resulted in a jury verdict for Defendant. *See Batty v. Zimmer, Inc.*, No. 12 C 6279 [141]. The court granted summary judgment for Zimmer in the second bellwether case, brought by Theodore Joas, and that ruling is now on appeal. *See In re Zimmer Nexgen Knee Implant Prod. Liab. Litig.*, No. 11 C 5468, 2016 WL 6135685 (N.D. Ill. Oct. 21, 2016) [hereinafter "*Joas*"]. Unlike Batty or Joas, Plaintiff in this case does not assert a claim that her NexGen Flex knee implant was defectively designed. Rather, she contends that Defendant failed to provide adequate warnings about the

implant's risk of loosening in patients like her. Specifically, she contends that Defendant did not adequately warn about the device's risk of loosening when implanted in obese patients. She relies in part on the testimony of Dr. Sonny Bal, an orthopedic surgeon, who opines that Defendant's warning labels and instructions were indeed inadequate and that Zimmer's failure to provide proper warnings about the risk of implantation in obese individuals caused Plaintiff's injuries.

Defendant Zimmer has moved to exclude Dr. Bal's testimony [53] under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and has moved for summary judgment [43]. Defendant argues that Dr. Bal is not qualified to offer an opinion about the adequacy of a medical device's warning labels and that his opinions about the adequacy of Defendant's warnings and their role in causing Plaintiff's injury are unreliable. As Dr. Bal is the only expert Plaintiff will call to testify about the adequacy of warnings and causation, Zimmer believes that excluding his testimony would entitle it to summary judgment on Plaintiff's failure-to-warn claim. And even if the court allows Dr. Bal to testify, Defendant contends the court should grant summary judgment because, according to Defendant, there is no evidence that inadequate warnings were the cause of Plaintiff's injuries, and the court should find that the NexGen Flex's warning labels are adequate as a matter of law.

For the reasons stated below, the court grants Defendant's motions in part and denies them in part. Contrary to Defendant's contentions, the court concludes that Dr. Bal is sufficiently qualified to offer his opinions in this case and that those opinions are not so unreliable that the jury should not consider them. In addition, the court concludes that there are disputed issues of material fact concerning the adequacy of Defendant's warnings and their role in causing Plaintiff's injury. Those issues should be resolved by a jury.[1] The court does conclude,

[1] Defendant also moved to strike [68] an affidavit from Dr. Bal that Plaintiff attached to her response to Defendant's motion for summary judgment. (*See* Aff. of Dr. Sonny Bal [58-11] (hereinafter "Bal Aff."), Ex. J to Pl.'s Mem. of Pts. and Authorities in Supp. of Pl.'s Opp'n to Summ. J. [58] (hereinafter "Pl.'s Summ. J. Resp.").) Defendant argues that the

however, that certain opinions of Dr. Bal's are not based on sufficient facts or data. In addition, Plaintiff has failed to respond to Defendant's motion for summary judgment regarding certain claims. Thus the court grants Defendant's motions with regard to those counts in Plaintiff's complaint.

BACKGROUND

In May 2009, because of persistent, severe pain in her right knee, Plaintiff visited an orthopedic surgeon named Dr. Russell Windsor. (Expert Rep. of Dr. Thomas E. Baier [45-4] (hereinafter "Baier Rep."), Ex. D to Def.'s Stmt. of Undisputed Material Facts [45] (hereinafter "Def.'s Stmt."), ¶ 1.) As Defendant's expert, orthopedic surgeon Dr. Thomas Baier, observed, by the time of her first visit with Dr. Windsor, Plaintiff had "exhausted all non-surgical options for the treatment of her right knee degenerative arthritis, including attempts at weight loss and use of nonsteroidal anti-inflammatory drugs and hyaluronate injections." (*Id.*) Ms. Goldin was 58 years old at the time of the visit. (Expert Rep. of Dr. Sonny Bal [50-1] (hereinafter "Bal Rep."), Ex. B. to Def.'s Mem. in Supp. of Mot. to Excl. [50] (hereinafter "Def.'s Bal Mem."), 3.) Dr. Windsor testified that patients who, like Plaintiff Goldin, have exhausted non-surgical options and continue to experience persistent pain caused by arthritis are "at a crossroad." (Dep. of Dr. Russell Windsor [45-2] (hereinafter "Windsor Dep."), Ex. B to Def.'s Stmt., 153:19.) "[E]ither they continue to live their life substantially limited, knowing that the arthritis will worsen, or they have the replacement. It's either or. And it's their choice." (*Id.* 153:20–24.)

Plaintiff elected to undergo TKR surgery, which Dr. Windsor performed in August 2009, replacing Plaintiff's native right knee with a Zimmer NexGen Flex implant. (Def.'s Stmt. ¶ 4.)

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affidavit is not a proper Rule 56 affidavit, rebuttal report, or supplemental report, and is not timely as an expert report. The court believes that the resolution of this motion obviates the need to reach a firm resolution of whether Dr. Bal's affidavit should be stricken. The court does not rely on the assertions contained in that affidavit, apart from Dr. Bal's updated qualifications (receipt of his Ph.D.) and his response to a newly cited study in Defendant's motion to exclude his testimony. The court believes that both of these issues are the proper subjects of a Rule 56 affidavit. To the extent Defendant believes it is entitled to additional relief from the alleged improper disclosure, the court will entertain a motion proposing such relief.

As explained in earlier rulings, the NexGen Flex implant is designed to allow TKR patients to bend their knees at greater angles of flexion than they could with "standard" knee implants (including Zimmer's "Standard" version of the NexGen implant). *See In re Zimmer Nexgen Knee Implant Prod. Liab. Litig.*, No. 11 C 5468, 2015 WL 3669933, at *2 (N.D. Ill. June 12, 2015) [hereinafter "*Batty* Opinion"] (describing the NexGen Flex device in greater detail). Dr. Windsor selects his TKR patients' implants based on his own experience with the products and his general experience as a surgeon. (Def.'s Stmt. ¶¶ 55–56.) Plaintiff Goldin herself played no role in the selection of her implant, read no brochures or literature about the NexGen Flex implant before her surgery, and was unaware of the brand of implant she would receive. (*Id.* ¶¶ 57–58.)

At the time of surgery, Plaintiff was 61 inches tall and weighed 241 pounds, giving her a body mass index ("BMI") of 45.5. (Def.'s Stmt. ¶ 6.) In general, a BMI between 25 and 30 is considered "overweight," a BMI between 30 to 35 is considered "obese," a BMI of 35 to 40 is considered "morbidly obese," and a BMI over 40 is considered "super obese." (Pl.'s Stmt. of Add'l Material Facts [58-1] (hereinafter "Pl.'s Stmt. Add'l Facts"), Ex. A to Pl.'s Summ. J. Resp. ¶ 1.) The parties agree that at the time of Plaintiff's surgery in 2009, it was well-known within the orthopedic community that heavy and obese patients are at increased risk for implant failure. (Def.'s Stmt. ¶ 41.) It is also undisputed that written materials accompanying Plaintiff's implant included language concerning the risk of implant failure in obese patients. The "package inserts" accompanying the femoral and tibial components of the NexGen Flex that Dr. Windsor implanted in Plaintiff contain a section labeled "**PATIENT COUNSELING INFORMATION**." (*Id.* ¶¶ 15–16.) Among other information, that section includes the statement that "Complications and/or failure of total knee prostheses are more likely to occur in patients with unrealistic functional expectations, heavy patients, physically active patients, and/or with patients that fail to follow through with the require rehabilitation program." (*Id.* ¶¶ 15–16.) The section also states that patients should be instructed about the possibility that the implant or its components

may wear out, fail, or need to be replaced, and that the implant may not last for the rest of the patient's life. (*Id.*) In addition, the surgical technique guide for the implant includes a section labeled "**Patient Selection**," which instructs surgeons that "[i]n determining the appropriateness of this implant for any patient, careful consideration should be given to the following criteria . . . . 6. The patient should not be obese." (*Id.* ¶ 18.)

The parties disagree about whether Dr. Windsor cautioned Plaintiff that her obesity level increased the risk that her implant would fail. Dr. Windsor testified in his deposition that he does explain the risks of TKR surgery to his patients, and discusses, among other things, "mechanical loosening, infection, wear, rough estimates as to the longevity of the implant and how that can be affected by body weight and activity levels." (*Id.* ¶ 48; Windsor Dep. 29: 4–12.) He said he would have had such a conversation with Plaintiff. (Def.'s Stmt. ¶ 48; Windsor Dep. 30:7–9.) Later in the deposition, Dr. Windsor confirmed that for a patient whose BMI is greater than 35, he advises that longevity of the implant is "possibly and probably compromised based on the fact that she is well beyond a normal average weight," and warns that the implant might be "subject to a shorter longevity just because [her] body weight is higher than the norm." (Def.'s Stmt. ¶ 51; Windsor Dep. 78:11–23.) Plaintiff, for her part, denies that Dr. Windsor ever counseled her about the impact her weight could have on the longevity of her implant and never advised her to lose additional weight. (Pl.'s Stmt. Add'l Facts ¶ 6.)

Whether or not Dr. Windsor told Plaintiff prior to her surgery that her elevated BMI placed her at greater risk for premature implant failure, Dr. Windsor's testimony suggests that over the last three to four years (that is, since Plaintiff's 2009 surgery), he has changed the counseling he provides to obese patients, based on newly available general data regarding TKRs in obese patients. (Windsor Dep. 137:1–12, 139:10–14.) Today, Dr. Windsor tells patients who are morbidly obese (BMI greater than 35) or super obese (BMI greater than 40) that "they're at an increased risk of mechanical failure, whether it be loosening, implant breakage, instability, infection." (*Id.* 137:16–22.) He also tells those patients "it's a good idea to

lose weight," but he acknowledges that "practically speaking, they don't" lose weight or they eventually gain back the weight they lose.[2] (*Id.* 138:1–4.) He did not provide this counseling to Plaintiff because, back in 2009, "we didn't see a specific difference."[3] (*Id.* 140:11–16.) In addition, for morbidly obese or super obese patients, Dr. Windsor now adds a stem extension to the implant's tibial component and fully cements it to the bone in order to better anchor the component. (*Id.* 138:9–14.) Defendant asserts that Dr. Windsor has always warned about the increased risk of mechanical failure in morbidly obese and super obese patients and that the only change in Dr. Windsor's counseling is that he now counsels patients about the possibility of adding the stem extension to the tibial component. (Def.'s Resp. to Pl.'s Stmt. Add'l Facts [76] ¶ 12.) In the court's view, Dr. Windsor's testimony may be ambiguous on this point (*see generally* Windsor Dep. 136:17–141:1), but Plaintiff's characterization is a fair one. Asked directly whether the counseling Ms. Goldin would receive from him, were she to have a knee replacement now, "would be different than the counseling she received in 2009," Dr. Windsor responded that his counseling would indeed differ, regardless of what type of implant he used. (*Id.* 144:11–24.)

After Plaintiff's TKR surgery, she suffered from an "insidious onset of pain" over a period of roughly two years. (Pl.'s Stmt. Add'l Facts ¶ 2.) By December 2011, the tibial component of her implant had loosened and collapsed into approximately 25 degrees varus (that is, angled in a way to give her a bowlegged appearance). (*Id.* ¶ 3.) Another orthopedic surgeon, Dr. Joel Buchalter, diagnosed Plaintiff with a "catastrophic failure of right total knee arthroplasty," and he performed a revision surgery on December 15, 2011, removing her implanted components and "massive osteolytic lesions" and replacing the implant with a new

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[2] The court notes that Plaintiff herself lost some 60 pounds in the year prior to her TKR surgery, but gained some of it back by August 2009. (Baier Rep. at 4.)

[3] It is unclear whether Dr. Windsor means that in 2009, the orthopedic community did not see a specific risk difference between the non-obese and the obese, or between the obese and the morbidly obese or super obese.

device. (*Id.* ¶ 4; Operative Report [58-4] at 1.) Although Defendant's expert, Dr. Baier, opines that Plaintiff's injury was caused by multiple factors, including her obesity, continued weight gain, bone loss, component alignment, and uneven cement mantle distribution, it is undisputed that Plaintiff's weight was a primary factor in the failure of her initial TKR. (Def.'s Resp. to Pl.'s Stmt. Add'l Facts ¶ 5.)

Plaintiff offers the testimony of Dr. Bal to demonstrate (1) that Plaintiff's obesity caused her implant to loosen and fail, and (2) that the written materials accompanying Plaintiff's implant failed to provide adequate warning about the risks of implant failure in morbidly obese patients. Dr. Bal is a board-certified orthopedic surgeon and a professor in the Department of Orthopaedic Surgery at the University of Missouri Health Care in Columbia, Missouri. (Bal Rep. at 1, 3.) Dr. Bal received his medical degree from Cornell University, a master's degree in business administration from Northwestern University, and a law degree from the University of Missouri School of Law. (*Id.* at 1–2.) He has also completed the requirements for a Ph.D. in materials engineering from the Kyoto Institute of Technology in Kyoto, Japan.[4] (Dep. of Dr. Sonny Bal [50-2] (hereinafter "Bal. Dep."), Ex. B to Def.'s Bal Mem., 17:11–14.) Dr. Bal has been performing hip and knee replacements for the past twenty years and usually performs between 150 and 400 knee replacements each year. (Bal Rep. at 2; Bal Dep. 27:8–13.) In addition, he has acted as a paid consultant for hip and knee device manufacturers, including for Defendant, and has assisted in the design of implant components. (Bal Rep. at 2, 30.) As a practicing orthopedic surgeon, Dr. Bal keeps abreast of medical and scientific developments in his field in order to provide optimal care to his patients. (*Id.* at 2.)

To determine the cause of Plaintiff's injury, Dr. Bal reviewed Plaintiff's medical records, certain of Defendant's internal memoranda, scientific studies regarding the performance of NexGen Flex implants, and expert reports and deposition testimony from Drs. Thomas Brown

[4] In his affidavit, Dr. Bal confirms that he has received his Ph.D. in engineering. (Bal Aff. ¶ 2.)

and Joseph Fetto, both of whom testified in the *Batty* trial and whose expert reports the court has discussed previously. (*Id.* at 9–10); *see also Joas*, 2016 WL 6135684, at *3–*6, *8–*14, *17–*18; *Batty* Opinion, 2015 WL 3669933, at *7–*33 (N.D. Ill. June 12, 2015). According to Dr. Bal, Plaintiff's NexGen Flex implant "failed in reasonable medical probability due to an inability of the tibia to support the stress routinely applied at the component/tibia juncture, especially in a patient of [Plaintiff's] weight." (Bal Rep. at 10.) Dr. Bal opines that, in particular, the tibial component of Plaintiff's implant was unable to support the repetitive stresses placed on it during deep knee bending. (*Id.*) He asserts that Plaintiff was encouraged to engage in activities that required bending her knees at high-flexion angles. (*Id.* at 16.)

TKR implants, he explains, usually last for a period of ten to fifteen years or longer. (*Id.* at 11.) According to Dr. Bal, apart from obesity, there are a number of factors that could potentially contribute to premature failure of a knee implant, including trauma, diabetes, vascular conditions, osteoporotic bone, excessive activity, poor surgical technique, malalignment of the implant's components, or poor cementing of the components to the bone. (*Id.*) As Dr. Bal explains in his report, however, nothing in Plaintiff's medical record indicates that any of those non-weight-related factors was a likely cause of Plaintiff's injury. (*Id.*)

Dr. Bal"s report states that scientific and medical literature recognizes a significant difference in the stress placed on a TKR implant when a patient engages in high degrees of flexion. (*Id.* at 14.) Dr. Bal does not specify the literature to which he refers for that proposition, but he does list the studies, articles, and documents he reviewed in forming his opinion. (*Id.* at 17–22.) In his deposition, Dr. Bal clarified that he relied on Dr. Brown's research and opinions for evidence that deep knee bending creates high, localized stress loads on the tibial component of the implant and can result in loosening. (Bal Dep. 118:15–119:12.) This court has previously ruled that Dr. Brown's opinions regarding the causes of tibial loosening are admissible. *See Batty* Opinion, 2015 WL 3669933, at *16–*18. During his deposition, Dr. Bal also discussed peer-reviewed literature that he believes supports the theory that high flexion

leads to failure of the NexGen Flex. (*See* Bal Dep. 48:19–51:7.) Dr. Bal takes Dr. Brown's analysis one step further, reasoning that the extra weight present in an obese patient would place additional stress on the tibial component during deep knee bending. (Bal Rep. at 10.) He notes that the scientific literature supports the proposition that patients with high BMI scores are more likely to suffer from implant failure and that obesity has been considered a factor in implant failure for decades. (*Id.* at 13, 15–16.) Based on this literature, and on his review of the expert reports of Drs. Fetto and Brown, Dr. Bal opines that Defendant had the knowledge, resources, and ability to conduct tests, and to warn, about the NexGen Flex's risks when implanted in morbidly obese patients. (*Id.* at 15–16.)

Had Zimmer provided Dr. Windsor with adequate information and warnings about the risk of implant failure in obese patients, Dr. Bal asserts, Plaintiff would have received enough information (through Dr. Windsor) to decide whether TKR surgery with a NexGen Flex implant was her best option. (*Id.* at 17.) Instead, according to Dr. Bal, Zimmer provided inadequate information to Dr. Windsor and other implanting surgeons. Dr. Bal concedes that the "patient counseling information" section of the implant's package insert notes that complications and failure may be more likely to occur in "heavy patients," but he points out that the label fails to explain "how much more likely the prosthesis is to fail and what constitutes heavy." (*Id.* at 12.) He also recognizes that the implant's surgical technique guide states that "[t]he patient should not be obese," but he notes that that instruction fails to define obesity in terms of BMI. (*Id.*) Dr. Bal's most significant criticism of Defendant's labeling appears to be that there is no mention of weight or obesity in the "contraindications," "warnings," or "precautions" sections of the package insert. In Dr. Bal's experience, he says, most physicians look to those portions of the labeling for information to guide their counseling of patients regarding a particular device's risks and benefits. (*Id.* at 13.) Given the risk of implant failure in obese patients and the fact that Defendant failed to conduct studies to assess or quantify that risk, Dr. Bal believes Defendant's labeling should at least have instructed surgeons that the NexGen Flex was appropriate for use

only in patients who require high-flexion capability, and should have informed surgeons that the company lacked studies about the clinical performance of the device in morbidly obese individuals. (*Id.* at 16.)

Defendant challenges Dr. Bal's qualifications to offer opinions about the adequacy of warning labels or the mechanical causes of Plaintiff's implant failure. Even if the court finds Dr. Bal qualified, Defendant contends that his opinion about the NexGen Flex's label is not based on any methodology, and that the methodology underlying his causation opinion is unsound. Defendant also takes issue with some of the factual assumptions underlying Dr. Bal's analysis—for example, that Zimmer itself or Dr. Windsor encouraged Plaintiff to engage in high-flexion activities or that Plaintiff ever achieved high flexion after receiving her NexGen Flex implant. In response, Plaintiff urges that Dr. Bal's medical, legal, and engineering training, as well as his experience as a surgeon and consultant, amply qualify Dr. Bal to testify in this case. In addition, she contends that Dr. Bal's opinions are based on a reliable foundation, including his experience as a surgeon, careful review of Plaintiff's medical records, and sound application of scientific research and findings to the facts of Plaintiff's case. Regarding Defendant's argument that Dr. Bal relies on inaccurate factual assumptions, Plaintiff responds that, at least with respect to the issue of whether Plaintiff achieved high flexion (that is, greater than 120 degrees), there is sufficient evidence in the record to create a triable question of fact on that issue.

Should the court bar Dr. Bal's testimony, Defendant notes, Plaintiff's case would lack any expert support, and Plaintiff's case could not survive a summary judgment motion. But even if the court admits Dr. Bal's expert opinion, Defendant argues, summary judgment is warranted, because the warnings accompanying Plaintiff's implant were adequate as a matter of law and because Plaintiff lacks sufficient evidence to prove that a different warning would have prevented her injury. Plaintiff responds that the record contains sufficient evidence to allow the jury to determine whether Defendant's warning was adequate and whether an inadequate warning can be considered the cause of Plaintiff's injury. The court discusses the admissibility

of Dr. Bal's testimony before addressing the parties' summary judgment arguments.

DISCUSSION

I. Dr. Bal's Expert Testimony

Rule 702 of the Federal Rule of Evidence sets out the circumstances under which a witness may testify as an expert:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
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> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
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> (b) the testimony is based on sufficient facts or data;
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> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Under *Daubert*, the district court plays the role of gatekeeper and is responsible for determining whether the witness satisfies the Rule 702 factors—that is, whether the expert is qualified, whether the expert's methodology is reliable, and whether the testimony is relevant and will assist the trier of fact. *Myers v. Illinois Central R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010).

To determine whether an expert is qualified, the court "compar[es] the area in which the witness has superior knowledge, skill, experience, or education with the subject matter of the witness's testimony." *Gayton v. McCoy*, 593 F.3d 610, 616 (7th Cir. 2010). In determining whether the expert's proposed testimony is reliable, the district court must assess whether the reasoning or methodology underlying the expert's opinions is valid and whether that reasoning or methodology properly can be applied to the facts in issue. *Daubert*, 509 U.S. at 592–93. The focus of that inquiry "must be solely on principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at 595. The soundness of the facts underpinning the expert's analysis and the correctness of the conclusions he reaches based on that analysis "are factual matters to be determined by the trier of fact, or, where appropriate, on summary

judgment." *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000). Thus, an expert's opinion may be admissible even if his testimony is "shaky." *Daubert*, 509 U.S. at 596. The traditional and appropriate means of attacking challenged expert testimony is "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof . . . ." *Id.*

A. Dr. Bal's Qualifications to Assess the Adequacy of Defendant's Warnings

Defendant contends that Dr. Bal is unqualified to offer an opinion about the adequacy of Defendant's warnings and instructions. Dr. Bal lacks the training and experience to offer such an opinion, Defendant argues, because he has not received formal education or training in medical device labeling, has never presented or published on the topic, and has never drafted a warning for a medical device. In addition, Defendant notes, Dr. Bal admitted that he does not know "one way or the other" whether the NexGen Flex device's label violated any FDA regulations and does not consider himself a "warnings expert." (Bal Dep. 15:24–16:2, 16: 21–22.)

The court is not persuaded that these concerns render Dr. Bal unqualified to offer opinions about Defendant's warnings. To determine whether Dr. Bal is a qualified expert, the court must compare "the area in which [Dr. Bal] has superior knowledge, skill, experience, or education with the subject matter of [his] testimony." *Gayton*, 593 F.3d at 616. Dr. Bal will not be testifying about whether Defendant's warnings complied with FDA regulations or about the process of drafting medical device labels. The inquiry into the adequacy of a medical device's warnings is to be made "[a]lways bearing in mind that the warning is to be read and understood *by physicians*, not laypersons, [and] the factors to be considered in resolving this question include whether the warning is accurate, clear, consistent on its face, and whether it portrays with sufficient intensity the risk[s] involved." *Martin v. Hacker*, 83 N.Y.2d 1, 10, 628 N.E.2d 1308, 1312 (1993) (emphasis added). Thus the subject matter about which Dr. Bal will be testifying—how doctors would read and understand Zimmer's warning and whether the warning

would sufficiently portray the device's risks *to them*—maps directly onto an area in which he has superior knowledge and experience. As an orthopedic surgeon who has implanted medical devices in thousands of patients over many years, Dr. Bal "need[s] to be aware of [device warnings] and understand them and apply them to actual surgery when [he] execute[s] operative procedures on patients." (Bal Dep. 16:23–17:2.) Dr. Bal is clearly qualified to assess whether a device's labeling and instructions would provide adequate warnings to orthopedic surgeons like himself.

B. Reliability of Dr. Bal's Opinions about the Adequacy of Defendant's Warnings

Defendant nevertheless urges the court to exclude Dr. Bal's opinions about the adequacy of the NexGen Flex's warning labels because the opinions are not based on a reliable methodology. Indeed, according to Defendant, Dr. Bal's opinions are not based on any methodology at all; Defendant notes that Dr. Bal cites to no authority or accepted standards for appropriate warnings or labeling and does not propose any specific language that Defendant should have used in its warning. In addition, Defendant argues that Dr. Bal's opinions about the adequacy of Defendant's warnings are not based on a reliable method because they are contradicted by his own testimony, the testimony of Dr. Windsor, and the evidence in the record.

Dr. Bal's proposed testimony concerning the adequacy of Defendant's warning is, as noted, based primarily on his experience as an orthopedic surgeon. Testimony based primarily on an expert's experience may be admissible even if there is no "scientific" method underlying the expert's opinions. Nonscientific expert testimony in particular fields may not "easily admit of rigorous testing and application." *Lee v. Carthage College*, 714 F.3d 516, 525 (7th Cir. 2013). In a discussion of nonscientific expert testimony, the Advisory Committee note to the 2000 Amendments to Rule 702 offers the example of a law enforcement agent who testifies about the use of code words in a drug transaction. *See* FED. R. EVID. 702 (Advisory Committee Notes to 2000 Amendments). In such a case, the "principle" underlying the agent's testimony is that

participants in drug transactions regularly use code words to conceal the nature of their activities. *Id.* The "method" the agent uses is "the application of extensive experience to analyze the meaning of the conversations." *Id.* "So long as the principles and methods are reliable and applied reliably to the facts of the case, this type of testimony should be admitted." *Id.* In this case, Dr. Bal is a trained and certified orthopedic surgeon and is, himself, a professor of orthopedic surgery. In his own medical practice, he reads medical device labels, which are "directed at [him] as a professional," and he uses and applies them when operating on patients. (Bal Dep. 16:23–17:2.) Dr. Bal's opinion is based on his "application of extensive experience" and insight into how doctors read and understand warning labels. He relies on that experience and insight to explain how doctors might interpret the labeling accompanying the NexGen Flex. This method provides an adequate basis for reliable expert testimony.

Contrary to Defendant's suggestion, Dr. Bal does provide testimony about what Defendant's label should have said, with the caveat that the *specific* language would depend on what Defendant knew at the time it released the product. According to Dr. Bal, Defendant should have informed surgeons about its knowledge of the implant's risks when used by obese patients. If Defendant had not yet tested the performance of the device in obese patients, he says Defendant should have let implanting surgeons know about the lack of performance data for use in such patients. (*Id.* 64:2–6.) And if Defendant had tested and found an increased incidence of implant failure in patients with high BMIs, he says, the label should have included that information. (*Id.* 64:6–9.)

As Defendant interprets those opinions, they are contradicted by undisputed facts in the record, by Dr. Bal's own testimony, and by the testimony of Dr. Windsor. Defendant points out, for example, that although Dr. Bal opined that the terms "heavy" and "obese" are vague, Dr. Bal himself testified that the term "heavy," which can be found in the patient guide on his website, means "[p]atients that are outside of the normal body range, BMIs over 30" (*id.* 69:8–11); he agreed that Plaintiff was "heavy" (*id.* 36:24–37:1); and he testified that "obese" means

"[g]enerally a BMI over 30 with morbid obesity starting with BMI over 40." (*Id.* 25:8–12.) In addition, Defendant notes that Dr. Windsor understood Plaintiff to be heavy and obese. (Windsor Dep. 140:4–10, 195:5–7.) Defendant also highlights purportedly inconsistent testimony from Dr. Bal about whether statements in a surgical technique guide can be considered a warning (*compare* Bal Dep. 16:9–16 (surgical technique guide is "part of the instructions that are given to me and representations made by the implant manufacturer as to the proper techniques, indications, contraindications, precautions, and cautions attending to implanting the device") *with id.* 102:13–17 ("I don't think that [section of the surgical technique guide is] a warning. It says patient selection."). And Defendant insists that the references to heavy and obese patients in the NexGen Flex device's package insert and surgical technique guide defeat Dr. Bal's assertion that Defendant's labels and instructions failed to warn about the implant's risks in obese patients.

Again, the court is not persuaded that these purported inaccuracies and inconsistencies render Dr. Bal's opinion inadmissible. As an initial matter, the court is not certain that Dr. Bal's testimony has been inconsistent or contrary to the factual record. Dr. Bal can recognize that "heavy" and "obese" are terms with settled meanings but nevertheless assert that the way those terms were used in Defendant's labeling and instruction was vague. Specifically, Dr. Bal asserts that the risk of implant failure is particularly grave for patients who are very heavy and very obese—that is, individuals with BMIs over 35 or over 40. Thus, references to risks for "heavy" and "obese" patients may be too vague to communicate that the most serious risks are for morbidly obese or super obese patients. In addition, the package insert indicates an increased risk of implant failure for both "heavy" patients and "physically active" patients. Given that a large number of candidates for knee implants are likely to be either heavy or physically active, it is not unreasonable or inconsistent for Dr. Bal to conclude that Defendant's failure to differentiate very obese patients from other patients (by explaining "how much more likely the prosthesis is to fail" in very obese patients) rendered the term "heavy" vague. (Bal Rep. at 12.)

Nor does the court share Zimmer's conclusion that Dr. Bal has been inconsistent in his testimony regarding the presence of warnings in the surgical technique guide. It is possible for him to say, consistently, that a surgical technique guide contains instructions and warnings for how a surgeon should *conduct an operation* but that the "patient selection" section of a surgical technique is not the appropriate medium to warn about which patients should or should not receive an implant at all. Finally, the text of the package insert and the surgical technique guide do not defeat Dr. Bal's assertion that Defendant's labeling materials lack an adequate warning about obesity. Dr. Bal contends that the location of, and context surrounding, the purported "warnings" were such that an orthopedic surgeon would not understand those statements to be warnings at all. Dr. Bal may, of course, be mistaken on all these matters. But it is not the court's role to judge the correctness of a proffered expert's conclusions. *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000). And even if Dr. Bal's testimony contains inconsistencies—either internal inconsistencies or inconsistencies with other evidence in the record—"such inconsistencies go to the weight of the evidence and not its admissibility." *In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig.*, No. 3:09-MD-02100-DRH, 2011 WL 6302889, at *9 (S.D. Ill. Dec. 16, 2011).

Defendant also argues that Dr. Bal's opinion about the vagueness of the terms "heavy" and "obese" is not relevant in this case because there is no dispute that Plaintiff would qualify as heavy and obese at the time of her TKR surgery. As explained above, however, the point is not necessarily that "heavy" and "obese" are vague words in general or that it is unclear whether Plaintiff was heavy or obese at the time of her surgery. Rather, Dr. Bal's theory is that a very obese individual like Plaintiff faced a particularly high risk of implant failure, about which Defendant failed to provide adequate warning. Again, Dr. Bal's position may not be correct, but cross-examination and the presentation of contrary evidence are the more appropriate tools to combat a potentially inaccurate conclusion.

C. Reliability of Dr. Bal's Obesity/High Flexion Opinion

Defendant treats Dr. Bal's causation opinion as two having two components: (1) his opinion that Plaintiff's implant loosened because her obesity placed undue strain on the implant when she engaged in high-flexion activities and (2) his opinion that no alternative cause other than her obesity caused the implant to loosen. Zimmer contends both components of the causation opinion are flawed.

Regarding Dr. Bal's so-called "first" causation opinion, one of Defendant's criticisms is that Dr. Bal incorrectly assumes, without evidence, that Plaintiff "was encouraged to engage in high flexion activities increasing her risk unnecessarily." (Bal Rep. at 16.) Defendant is correct that there is no evidence in the record that either Defendant or Dr. Windsor encouraged Plaintiff to engage in high-flexion activities. The court is aware that Defendant designed the NexGen Flex to allow patients to achieve high flexion and that its marketing materials may have encouraged patients to attempt high-flexion activities. But Plaintiff in this case did not testify that she received such encouragement, Dr. Windsor did not testify that he provided such encouragement, and Plaintiff admits that she did not see any brochures or literature or packaging about the implant she would receive and did not even know the name Zimmer or what type of implant she had received until after her revision surgery. (Dep. of Beverly Goldin [50-7], Ex. G to Def.'s Bal Mem., 144:23–145:4, 242:14–25.) Thus, the court would not permit Dr. Bal to testify that Plaintiff was encouraged to engage in high-flexion activities; such testimony is not based on sufficient facts or data. FED. R. EVID. 702(b). As the court understands Plaintiff's theory, however, evidence that she was encouraged to achieve high flexion is not necessary for her case. Instead, her failure-to-warn theory requires her only to show that Defendant (and Dr. Windsor, acting on Defendant's guidance) failed to warn her about risks, regardless of whether or not Zimmer encouraged her to engage in risky behavior.

Defendant also objects to Dr. Bal's assumption that Plaintiff did achieve high flexion (understood as a flexion angle above 120 degrees); this assumption, Defendant says, has no

basis in fact. Again, the court does not understand Plaintiff's theory to require a showing that she achieved high flexion. There is agreement among the experts in this case that Plaintiff's obesity was a primary factor in the failure of her implant (Def.'s Resp. to Pl.'s Stmt. Add'l Facts ¶ 5), and Dr. Bal's theory is that Defendant (1) had reason to know of or to study the risk that obesity would lead to implant failure generally and (2) failed to warn about that risk or the lack of studies about that risk. That theory does not depend on Plaintiff's having achieved high flexion before her knee implant failed. That is not to say that whether Plaintiff achieved high flexion is irrelevant. On the contrary, to the extent Dr. Bal can also show that Plaintiff did engage in high flexion and that high flexion increased the risk of failure, this could bolster Plaintiff's case by (1) showing that Defendant had even greater reason to conduct studies and to provide warnings and (2) providing a more detailed mechanical account of how Plaintiff's implant failed.

In any event, the court concludes that Dr. Bal's assumption that Plaintiff achieved high flexion does rest on a sufficient factual basis to present the issue to a jury. Zimmer insists that there is no medical record establishing that Plaintiff achieved a range of motion greater than 110 degrees prior to her revision surgery. Dr. Bal assumes that Plaintiff did achieve flexion above 120 degrees (the angle at which Dr. Brown and others consider to be high flexion) because she engaged in activities, like gardening and getting in and out of a bathtub, that require deep knee bending. (Bal Rep. at 10.) He also notes that Plaintiff's medical records show that she reached 125 degrees of flexion soon after her initial surgery, suggesting that she was able to achieve at least that degree of flexion after her initial implantation but prior to her revision. (*See, e.g.*, Bal Dep. 76: 9–21.) Defendant counters that Dr. Bal's assumptions about the flexion required by Plaintiff's pre-revision activities are unfounded because Dr. Bal does not know exactly how Plaintiff gardened or how she entered and exited the bathtub (*id.* 79:22–80:4), and Plaintiff herself testified that she never kneeled down when gardening but rather would stand or stoop down. (Goldin Dep. 155:6–16.) In addition, Defendant, relying upon its experts and a study by Merrill A. Ritter, et al., argues that an orthopedic surgeon cannot draw conclusions about flexion

levels achieved after the initial implant based on the level of flexion achieved after the implant is replaced, because post-revision flexion is so variable. *See, e.g.*, Merrill A. Ritter, et al., *Predicting Range of Motion After Revision Total Knee Arthroplasty*, 19 J. Arthroplasty No. 3, 338 (2004) [hereinafter "*Ritter*"] ("The flexion measurements after revision total knee arthroplasty were 81% more variable than the flexion measurements after primary total knee arthroplasty.").

In his affidavit, Dr. Bal contests Defendant's interpretation of *Ritter*. According to Dr. Bal, the quotation from *Ritter* upon which Defendant relies shows only that there was more *variability* in patients' knee flexion after revision surgery than there was after primary replacement. (Bal Aff. ¶ 10.) But *Ritter* affirms, he contends, that the most important factor affecting post-revision range of motion is the patient's preoperative flexion. (*Id.* (citing *Ritter*, 19 J. Arthroplasty No.3 at 342).) And although Defendant's experts contend that Plaintiff's post-revision high flexion may be the product of mechanical and other changes in her knee, such as loosening of the knee following operation, Dr. Bal responds that Plaintiff was able to achieve 110 degrees of flexion just prior to her revision surgery, at a time when her pain, instability, and malalignment of her knee would have restricted her movement. (*Id.*) Thus, he explains, it is likely that she was able to achieve well over 110 degrees of flexion prior to the collapse of her initial implant, and that her post-implant flexion is consistent with her pre-implant flexion, rather than a result of post-revision mechanical changes. (*Id.*) Without taking a position on whether Dr. Bal is correct that Plaintiff achieved high flexion with her NexGen Flex knee, the court concludes that there is a sufficient factual basis for Dr. Bal to make that assumption. Through cross-examination and presentation of contrary testimony, Defendant will have ample opportunity to test that assumption at trial.

Defendant also contends that even if Plaintiff engaged in high-flexion activities, Dr. Bal has no reliable basis for his opinion that the NexGen Flex is prone to failure in obese individuals who engage in high flexion. Defendant appears to make three points in support of this argument: (1) Dr. Bal's reliance on the engineering opinions of Dr. Brown is misplaced because

testimony about Dr. Brown's theories would be impermissible "parroting" of another expert's opinions and because this court ruled in *Joas* that Dr. Brown's theories did not support a design-defect claim; (2) the literature Dr. Bal cites does not support his conclusion that the NexGen Flex implant is dangerous in obese individuals who engage in high flexion; and (3) Dr. Bal's testimony about the implant's dangers for obese patients engaging in high flexion is unreliable because it is full of inconsistencies.[5]

Regarding Defendant's first argument, the court disagrees that Dr. Bal's reliance on Dr. Brown's prior report and testimony from this case would amount to impermissible "parroting." It is true that "[a] scientist . . . is not permitted to be the mouthpiece of a scientist in a different specialty." *Dura Auto. Sys. of Indiana, Inc. v. CTS Corp.*, 285 F.3d 609, 614 (7th Cir. 2002). But Dr. Bal has a Ph.D. in engineering and is permitted to consult Dr. Brown's materials "to offer an opinion within [Dr. Bal.'s] domain of expertise." *Id.* That is, as an orthopedic surgeon with engineering training, Dr. Bal can explain Dr. Brown's theory of high-flexion loading to the jury while also adding his own opinions about the increased loading caused by obesity, opinions based on his experience and his review of the medical and scientific literature. With regard to the value of Dr. Brown's theory in light of this court's ruling in *Joas*, the court believes that both Defendant and Plaintiff are reading too much into the court's discussion of Dr. Brown's opinion in that case. In *Joas*, the court ruled that Dr. Brown's opinions could not support an argument that the standard version of the NexGen knee was a safer alternative to the NexGen Flex because Dr. Brown acknowledged that the NexGen Flex was the safer knee for individuals who

[5] Defendant also appears to contend that Plaintiff (and, thus, Dr. Bal) should not be permitted to argue that any aspect of the NexGen Flex's design was defective because Plaintiff abandoned her design-defect claim. (*See, e.g.*, Def.'s Bal Mem. at 25–26.) It is not inconsistent, however, for a plaintiff to abandon a claim that would require her to prove that a product's design renders it "inherently dangerous or defective," *Milazzo v. Premium Tech. Servs. Corp.*, 7 A.D.3d 586, 588, 777 N.Y.S.2d 167, 169 (2nd Dep't. 2004), while maintaining that a product's design presents a serious danger when not accompanied by a proper warning, or that the manufacturer has a duty to warn about use of a product in circumstances that have not yet been tested.

engage in high flexion. *Joas*, 2016 WL 6135685, at *17. The court's ruling was made in the specific context of that case, which was governed by Wisconsin law and the requirement to show a safer alternative design to prove a design defect. *Id.* The court did not rule that Dr. Brown's theory was unreliable or that it could not support a different theory of design defect, and thus the court's ruling does not preclude a discussion of Dr. Brown's theory in support of a failure-to-warn claim in this case. Indeed, in *Batty*, the court ruled that Dr. Brown's opinions regarding the risk of tibial loosening caused by high flexion were reliable and admissible. *Batty* Opinion, 2015 WL 3669933, at *16–*18. For reasons discussed below, the court will not allow Plaintiff to argue that an alternative implant would have been more effective for her, and thus the inability of Dr. Brown to support an alternative-design theory has little relevance here.

Defendant also argues that the literature upon which Dr. Bal relies does not support the conclusion that the combination of obesity and high-flexion leads to loosening of high-flex implants like the NexGen Flex. But Defendant does not dispute that there is support in the literature for the proposition that high levels of obesity may contribute to premature implant failure. It is thus not an unreasonable leap for Dr. Bal to conclude—based on Dr. Brown's theories and other literature concerning the link between high flexion and implant loosening—that obesity would put even greater stress on an implant during high flexion, and that such stress could lead to premature loosening and failure. Even if the studies Dr. Bal cites do not definitively show that obesity and high flexion combine to cause loosening of the implant Plaintiff used—because, for example, the studies involved knee failure of a different kind, involved a different version of the high-flex implant, or did not specifically analyze the combined effect of obesity and high flexion (Def.'s Bal Mem. at 17–18)—the studies may still support the proposition that high obesity levels can lead to increased rates of failure in implants like Plaintiff's, thus providing a basis for Dr. Bal's conclusion. Defendant might disagree with the

conclusions Dr. Bal draws from those studies, but it is not the court's role at this stage to question the soundness of an expert's conclusions.[6] *See Daubert*, 509 U.S. at 595.

Defendant also points out that Dr. Bal has provided inconsistent opinions about, for example, whether Plaintiff's weight would impact the longevity of her implant, whether it is more difficult to achieve proper implant alignment in obese patients, and whether the NexGen Flex is defectively designed. Dr. Bal may not have been entirely consistent in stating his opinions, but "any such inconsistency does not go to the reliability of [his] methodology, but instead goes to the flaws and ultimately the persuasiveness of [his] opinion[s]," and Defendant may test those opinions during cross-examination. *Hill v. City of Chicago*, No. 06 C 6772, 2011 WL 2461362, at *5 (N.D. Ill. June 20, 2011).

D. Reliability of Dr. Bal's Opinion Excluding Alternative Causes

Defendant argues that Dr. Bal's so-called "second" causation opinion is unreliable because Dr. Bal's exclusion of alternative causes of Plaintiff's injury was not a proper "differential diagnosis." In *Joas*, the court excluded a causation opinion on the grounds that the plaintiff's expert had failed to conduct a proper differential diagnosis, specifically by failing to "rule in" possible causes of the knee failure in that case and by failing to explain his reasons for "ruling out" causes unrelated to the NexGen design. *See Joas*, 2016 WL 6135685, at *7–*14. As an initial matter, the court notes the differences between Dr. Fetto's differential diagnosis in *Joas* and the one Dr. Bal conducts in this case. Prior to *Joas*, the court excluded Dr. Fetto's general causation opinions in *Batty*, and there was little radiographic evidence in *Joas* of the specific cause of the plaintiff's injury. Thus Dr. Fetto's specific causation opinion in *Joas* crucially depended on a proper and systematic exclusion of alternative causes. Unlike in *Joas*, the court has already determined here that Dr. Bal has a sufficient basis for opining about the

[6] Defendant also criticizes the articles Dr. Bal cites because they were published after Plaintiff's surgery, and thus Defendant could not have had notice of their findings. The date of these studies may be important for a summary judgment argument on Defendant's duty to warn, but it is not relevant to the reliability of Dr. Bal's causation opinion.

cause of Plaintiff's injury apart from any differential diagnosis. Indeed, unlike in *Joas*, there is no dispute in this case that Plaintiff's obesity was a primary factor in the failure of her implant. As a result, Dr. Bal's causation opinion does not depend upon the exclusion of alternatives.

In this context, Dr. Bal has provided sufficiently reliable grounds for concluding that each of the alternative causes he considered was not the likely cause of her injury. For example, he explains that Plaintiff's frequent falls were not the likely cause of her injury because they coincided with the onset of pain in her knee and were thus likely caused by (and not the cause of) her device failure. (Bal Rep. at 11.) Her medical records also showed no sign of diabetes, rheumatoid arthritis, seronegative spondyloarthropathy (another type of arthritis), or vascular issues. (*Id.*) And although the record is unclear about whether she had osteoporotic bone, Dr. Bal notes that significant osteoporosis would be unlikely at her age. (*Id.*) His review of her x-rays did not reveal any problems with surgical technique, alignment of components, or cementing, and there was no evidence that Plaintiff engaged in excessive activity. (*Id.*) Thus, Dr. Bal provides adequate reasons for his exclusion of these alternative causes, and his testimony will assist the jury by explaining why he believes those potential alternative causes were likely not the causes of Plaintiff's injury in this case.

E. Propriety of Dr. Bal's Opinions about Regulatory Procedures

Defendant urges the court to exclude Dr. Bal's opinions regarding the regulatory procedure Defendant used to obtain FDA approval. Defendant contends that Dr. Bal is not qualified to offer such testimony, that the testimony lacks any reliable basis or methodology, and that the testimony would mislead the jury. The court ruled previously in *Batty* that "assuming any expert testimony on the [FDA] 510(k) clearance process would have probative value at Ms. Batty's trial (a matter not free from doubt), it is 'substantially outweighed' by the danger of misleading the jury." *In re Zimmer Nexgen Knee Implant Prod. Liab. Litig.*, No. 11 C 5468, 2015 WL 5145546, at *14 (N.D. Ill. Aug. 31, 2015) (citing FED. R. EVID. 403). The court sees no reason to depart from that ruling in this case. The point Plaintiff purportedly intends to establish

through this testimony—that Defendant failed to share information about its product and its testing—is a point that can be made without reference to FDA regulations and procedures.

II. Summary Judgment

A court shall grant summary judgment if the moving party shows that there is "no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). In determining whether there is a genuine dispute of material fact, courts must view the evidence in the light most favorable to the non-moving party, and draw all reasonable inferences in her favor. *Carson v. ALL Erection & Crane Rental Corp.*, 811 F.3d 993, 995 (7th Cir. 2016). Nevertheless, to survive a motion for summary judgment, the non-moving party "must point to specific facts showing that there is a genuine issue for trial; inferences relying on mere speculation or conjecture will not suffice." *Trade Fin. Partners, LLC v. AAR Corp.*, 573 F.3d 401, 407 (7th Cir. 2009).

The parties agree that Plaintiff's claims are governed by the substantive law of New York, the state in which she underwent her initial TKR surgery and suffered her injury. Defendant has moved for summary judgment on all of the claims asserted in Plaintiff's complaint. (Def.'s Mot. for Summ. J. [43].) In her response to Defendant's motion, however, Plaintiff offers arguments in support only of claims for failure to warn and for punitive damages. (Pl.'s Summ J. Resp.) Thus the court grants Defendant's motion for summary judgment with respect to Plaintiff's other claims. *See* FED. R. CIV. P. 56(c).

A. Adequacy of Zimmer's Warnings

In New York, the warning for a pharmaceutical or medical device product may be considered adequate as a matter of law if it provides "specific detailed information" on the product's risks. *Martin*, 83 N.Y.2d at 10, 628 N.E.2d at 1312. To determine whether a given warning is legally adequate or presents a factual question for resolution by a jury, a court must consider "not only the meaning and informational content of the language but also its form and manner of expression." *Id.* An adequate warning, as read and understood by the physicians to

which it is directed, should be "accurate, clear, consistent on its face, and [should] portray[] with sufficient intensity the risk involved in taking the drug [or using the device]." *Id.* Defendant insists that the warnings contained in the package insert and surgical technique guide are adequate as a matter of New York law. As Defendant emphasizes, the package insert for the NexGen Flex device implanted in Plaintiff actually does contain a warning about the increased risk of implant failure in heavy and obese patients. Defendant urges that this express warning about the risk that allegedly resulted in Plaintiff's injury entitles Defendant to summary judgment. Dr. Bal's criticism of the language used in, and the presentation of, the warnings accompanying the device do not undermine the adequacy of those warnings, Defendant asserts.

The court disagrees with Defendant that its warning is adequate as a matter of law merely because its labeling materials make reference to the risk of implant failure in heavy and obese patients. Even apart from Dr. Bal's concerns about the adequacy of the terms "heavy" and "obese," there are considerations that "directly affect the adequacy of a warning, including the location and conspicuousness of the warning and the method in which the warning is communicated to the ultimate user." *Figueroa v. Boston Sci. Corp.*, 254 F. Supp. 2d 361, 370 (S.D.N.Y. 2003). As explained, Bal can plausibly argue that the terms "heavy" and "obese" fail to convey the particular risks faced by morbidly obese patients. Viewing his testimony in the light most favorable to Plaintiff, Dr. Windsor appears to concede that morbidly obese patients face an increased risk of mechanical failure and that Defendant did not warn about this increased risk back in 2009 when Plaintiff had her surgery. (Windsor Dep. 137:16–22, 140:11–16.) A physician reading about the risk of implant failure in "heavy" patients might understand that warning to refer to the well-known fact that implants may not last as long in obese patients, but that same physician might not realize, as Dr. Bal contends, that the risk of premature implant failure is particularly great in morbidly obese patients.[7] It is true that Dr. Windsor says

[7] Defendant argues that a warning about risks for heavy or obese patients is sufficient to warn about the risks for *morbidly obese* patients in the same way that a road sign

the particular risks faced by morbidly obese people were not known until *after* Plaintiff's 2009 surgery, and that Dr. Bal relies on studies that post-date Plaintiff's surgery to show that morbidly obese patients face greater risk of implant failure. But a jury could reasonably conclude, as Dr. Bal argues, that Defendant knew that many of its patients were obese and knew that its high-flexion devices might be subject to heavy loading and thus should have studied the effects of the increased loads produced by morbidly obese patients. Indeed, Plaintiff has produced evidence that Defendant knew that approximately 85% of its female patients had a BMI greater than 30. (*See* Dep. of Travis "Jarv" Campbell [58-7], Ex. F to Pl.'s Stmt. Add'l Facts, 165:7–11.) At least, a jury could find that Defendant should have informed physicians that it had not conducted such testing, or find that had Defendant conducted that testing, it would have discovered the increased risks that later studies revealed.[8]

Defendant argues that New York law does not recognize a cause of action for "failure to test" and that there is no legal authority to support the proposition that a manufacturer is charged with advance constructive knowledge of studies that have not been published at the time of manufacture. Defendant is correct that New York does not recognize a stand-alone failure-to-test cause of action; after all, if a product works perfectly, there can be no claim arising from the mere fact that the manufacturer chose not to test it. New York law does, however, confirm that "[a] manufacturer has a duty to warn against latent dangers resulting from

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warning that motorists should not drive around a curve faster than 30 miles per hour is sufficient to warn motorists that they should not drive around the curve at *40 miles per hour*. But to carry the analogy further, the road sign warning may be inadequate, for example, if the risks motorists face at 30 miles per hour and at 40 miles per hour are of different magnitudes. If drivers understand that driving at 30 miles per hour creates only a slight risk that the car will swerve, drivers might take that risk without realizing that driving at 40 miles per hour creates a significantly increased risk that the car will roll over. In the same way, an even greater risk for morbidly obese patients may require a greater, and more particularized, warning.

[8] In this case, the literature referred to by Drs. Windsor and Bal regarding the connection between morbid obesity and implant failure could provide support for the jury's inference about what Defendant's testing, if conducted, would have shown. That distinguishes this case from *Joas*, where Dr. Brown admitted that he had "no way of knowing" what the testing he recommended would have shown. *See Joas*, 2016 WL 6135685, at *3.

foreseeable uses of its product of which it knew or should have known." *In re N.Y. City Asbestos Litig.*, 27 N.Y.3d 765, 788, 59 N.E.3d 458, 470 (2016). And in the products liability context, New York's highest court has included favorable citations to section two of the Third Restatement of Torts. *See id.* at 787, 59 N.E.3d at 469. Comment m to that section states that a "seller bears responsibility to perform reasonable testing prior to marketing a product and to discover risks and risk-avoidance measures that such testing would reveal[, and a] seller is charged with knowledge of what reasonable testing would reveal." Restatement (Third) of Torts: Prod. Liab. § 2 (1998). Thus the court concludes that Plaintiff has adequate legal support to present evidence to the jury that Defendant failed to conduct reasonable testing, which would have revealed risks concerning the implantation of its device in obese patients, and that Defendant failed to warn about that risk and its lack of adequate testing.

In addition to the content of Defendant's labeling, Plaintiff and her expert criticize the manner in which Defendant presented its warning to physicians. Indeed, they assert that the references to heavy patients in the implant's package insert, and to obese patients in the surgical technique guide, do not constitute "warnings" at all. According to Dr. Bal, when determining what information they should provide to patients concerning a device's risks, most physicians look to the portions of the package insert with labels like "contraindications," "warnings," or "precautions." (Bal Rep. at 13.) Dr. Bal believes that Defendant failed to provide an adequate warning by neglecting to include any information about risks for obese patients in those sections. Defendant responds that the warnings it did provide are accurate and complete. Rather than engaging in "linguistic nitpicking," Defendant urges, the court should read the warning "as a whole, [to see that] the warning conveys a meaning as to the consequences that is unmistakable." *DiBartolo v. Abbott Labs.*, 914 F. Supp. 2d 601, 612 (S.D.N.Y. 2012) (applying New York law).

But a contextual, holistic reading of Defendant's labeling actually puts Plaintiff's argument in its best light. As the court discussed above, the package insert provides the same

warning about "heavy" patients and "physically active" patients, which could theoretically apply to the vast majority of patients (especially given Plaintiff's evidence that Defendant knew that roughly 85% of female patients *were* obese), thus undermining the strength of the warning.[9] In addition, if the jury were to credit Dr. Bal's testimony about the portions of a warning label that physicians usually consult, then the fact that the "contraindications," "warnings," and "precautions" sections lack any mention of obesity may serve to "dilute[] the intensity of [the] caveat made in" the "patient counseling information" and "patient selection" sections. *Martin*, 83 N.Y.2d at 11, 628 N.E.2d at 1313. Whether Defendant's warnings are adequate may be a close question, and failure to use the proper heading in a warning label is arguably not the strongest foundation upon which to build a products liability claim. But "[g]enerally, whether a warning is adequate is an issue of fact to be determined at trial." *Figueroa*, 254 F. Supp. 2d at 370. And "the location and conspicuousness of the warning and the method in which the warning is communicated" are relevant factors for the jury to consider. *Id.*

Defendant also faults Dr. Bal and Plaintiff for failing to specify what an adequate warning from Defendant would have said. But Dr. Bal did opine about what Defendant's warning should have said: he testified that (a) Zimmer should have warned that it had not yet tested the device's performance when implanted in obese and morbidly obese patients or (b) if Defendant did test the device in those patient populations, it should have informed physicians about the increased rate of implant failure for patients with higher BMIs. (Bal Dep. 64:2–9.) During his deposition, Dr. Bal did not specify which of those two possible warnings Defendant should have provided, deferring to "the engineering experts" to answer that question, because Dr. Bal lacked information at the time about Defendant's internal data concerning implant performance in obese patients. (*Id.* 65:3–6.) As Defendant notes, no other engineering experts will be

[9] That is not to mention the fact that the word "heavy" refers only to weight, and not to body mass index, such that the warning might be read to apply to tall and fit (but still technically "heavy") patients, further expanding the reach of the alleged warning and thus diluting its impact.

testifying for Plaintiff in this case, but Plaintiff will be free to argue that Defendant's warning was inadequate because it failed to provide either of the two warnings in its product labeling.

B. Causation

Defendant argues that even if it failed to provide an adequate warning, Plaintiff cannot prove that the failure to warn caused her injury. According to Defendant, Plaintiff's claim suffers from three causation problems: (1) Dr. Windsor already knew of the increased risk of implant failure in obese patients, (2) Dr. Windsor did not, and does not, rely upon materials from the manufacturer to select the implant he uses during surgery, and (3) Plaintiff did not have a choice about whether to have surgery and thus would have had the device implanted even if a different warning had been provided. The court concludes these concerns also do not defeat Plaintiff's case as a matter of law.

Under New York law, where a physician is already aware of a medical device's potential adverse side effects, "such knowledge constitutes an intervening event relieving the manufacturer of any liability to a patient under the failure to warn theory." *Banker v. Hoehn*, 278 A.D.2d 720, 722, 718 N.Y.S.2d 438 (3rd Dep't. 2000). Defendant contends that because Dr. Windsor—and indeed, most orthopedic surgeons—knew, at the time of Plaintiff's surgery, that heavy and obese patients were at increased risk for implant failure, Defendant cannot be liable for failing to warn about that risk. But, as the court has discussed, Dr. Windsor appears to concede that he did not fully appreciate the risks of implant failure in morbidly obese individuals at that time. Because Plaintiff faults Defendant for failing to warn, in particular, about the increased risk of implant failure in *morbidly* obese individuals like herself, Dr. Windsor's general understanding of the knowledge of an increased risk of implant failure in all obese individuals does not defeat Plaintiff's theory. Defendant points out that Plaintiff claims that Dr. Windsor did not discuss any risks of surgery with her and thus has no reason to argue that Dr. Windsor would have warned her of any risks had Defendant provided a different warning. But Dr. Windsor testified that he does now tell morbidly obese patients that they are at a particularly

increased risk for mechanical loosening of their implants. (Pl.'s Stmt. Add'l Facts ¶ 13.) From these facts, a jury could infer that a different warning about the risk of implant failure in morbidly obese patients would have led Dr. Windsor to provide different counseling to morbidly obese patients at the time of Plaintiff's surgery.

Defendant also points to the fact that Dr. Windsor selects the implants to use in TKR surgery based on his surgical experience and his experience with the products at issue, and not base on any of Defendant's warning or marketing materials. Thus, they argue, Dr. Windsor would have selected the same implant for Plaintiff regardless of any additional warning Defendant provided. This argument is strengthened by Dr. Windsor's testimony that, even having reviewed the materials in this litigation and even with his current knowledge of the risks for morbidly obese patients, Dr. Windsor still believes that the implant Plaintiff received was not defective and did not put her at greater risk for implant failure than would any other device. (Windsor Dep. 152:17–24, 217:20–218:10.) There is therefore little basis for believing that a different warning would have led Dr. Windsor to choose a different implant for Plaintiff. Plaintiff herself played no role in choosing her implant, and there is little reason to think that a different warning from Zimmer would have involved her more directly in that decision. Nor has Plaintiff so much as argued, let alone provided evidence, that another device available to Dr. Windsor would have fared better than the NexGen Flex. Even absent a basis for finding that Plaintiff might have requested a different implant, however, a jury could find that had Dr. Windsor supplied her with different counseling in response to a stronger warning from Defendant—a plausible inference given that Dr. Windsor updated his counseling after reading updated literature about implant failure in morbidly obese patients—Plaintiff would have chosen to forego surgery altogether, or at least to postpone surgery until she lost additional weight.

Defendant denies that Plaintiff had any choice about whether or not to have TKR surgery because, by the time of her surgery, she had exhausted all non-surgical options and was suffering from severe pain. As Plaintiff contends, however, she "always had the option simply to

endure the pain rather than go through surgery and risk even greater pain and further surgeries." (Pl.'s Summ. J. Resp. at 33.) And indeed, Plaintiff testified during her deposition that she does not believe she exhausted her treatment options before choosing to undergo surgery, saying that she was "not given the information," and that with better information, she might have opted for "not a knee replacement at all." (Pl.'s Resp. to Def.'s Stmt. ¶ 9.) A jury might not find this plausible; but there is evidence from which the jury might also find that with more specific counseling from Dr. Windsor, resulting from a strengthened warning from Defendant, Plaintiff would have decided that it would be better to live with pain than to take the risk of undergoing TKR surgery at her weight.[10] Defendant has not established that there are no disputes of fact on this claim.

C. Punitive Damages

Under New York law, an award of punitive damages is justified where the defendant engages in conduct that has a "high degree of moral culpability, which manifests a conscious disregard of the rights of others or conduct so reckless as to amount to such disregard." *Home Ins. Co. v. Am. Home Prod. Corp.*, 75 N.Y.2d 196, 203, 550 N.E.2d 930 (1990) (internal citations and quotation marks omitted). Plaintiff contends that there is evidence that Defendant engaged in such conduct in this case. In particular, she argues that Defendant acted with wanton and reckless disregard for the rights of obese and morbidly obese individuals. According to Plaintiff, Defendant knew that many of the patients using its implants had high BMI scores and that those individuals were at greater risk for implant failure, but Defendant failed to warn of that risk and failed to conduct studies to determine the increased risk for obese individuals using high-flex implants. Plaintiff also notes evidence that some of Defendant's employees mocked obese individuals, referring to them as "fat asses" with a "huge hunk of lard in the back of their knees."

[10] The court recognizes that success on this theory at trial might not support a significant award for pain and suffering, in light of the fact that Plaintiff presumably would be experiencing considerable pain had she opted against surgery.

(Pl.'s Stmt. Add'l Facts ¶ 19.)

Although some of this alleged conduct may be reproachable, the court is skeptical that the conduct giving rise to Plaintiff's substantive claim—the alleged failure to warn of the risks to obese patients—manifests a conscious disregard of anyone's rights. After all, Defendant's labels and instructions do contain references to the possibility that obese patients might experience worse outcomes; the question is whether the language in those labels and instructions was sufficient. Ultimately, however, whether Defendant's conduct "constituted reckless disregard of the public's safety is essentially a jury question which can only be answered after the issue of the adequacy of the warning." *Bikowicz v. Nedco Pharmacy, Inc.*, 130 A.D.2d 89, 94, 517 N.Y.S.2d 829, 833 (3rd Dep't. 1987). At the close of evidence, it may become clear that Plaintiff failed to show that Defendant engaged in willful and wanton conduct. In that case, the court will have the opportunity to determine whether the issue of punitive damages should be submitted to the jury. The court declines to grant summary judgment on this claim.

CONCLUSION

For the reasons stated above, Defendant's motions [43], [53] are granted in part and denied in part.

ENTER:

Date: January 3, 2017

REBECCA R. PALLMEYER
United States District Judge