UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

BEVERLY R. MAXWELL,

Plaintiff,

v.

5:07-CV-1062
(GTS/DEP)

HOWMEDICA OSTEONICS CORP.,

Defendant.

APPEARANCES:

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HON GLENN T. SUDDABY, United States District Judge

DECISION and ORDER

Currently before the Court in this products liability action, filed by Beverly Maxwell ("Plaintiff") against Howmedica Osteonics Corp. ("Defendant"), is Defendant's motion for summary judgment. (Dkt. No. 28.) For the reasons set forth below, Defendant's motion is granted in its entirety, and Plaintiff's Complaint is dismissed.

I. RELEVANT BACKGROUND

A. Plaintiff's Complaint

On March 27, 2008, Plaintiff filed her Complaint in this action. (Dkt. No. 7.) Liberally construed, Plaintiff's Complaint, brought under theories of negligence and strict products liability, asserts against Defendant claims of design defect and failure to warn, arising from the injuries she sustained during a total knee replacement surgery on June 15, 2004. (Dkt. No. 2.) More specifically, Plaintiff alleges that she sustained personal injuries as a result of (1) Defendant's defective design of a total knee-replacement system known as the Duracon Total Knee System ("Duracon System"), which it manufactured, and (2) Defendant's failure to provide adequate warning labels regarding the Duracon System's metallic components in its prosthetic knee, in particular, the prosthetic knee's "high percentage of nickel," which created a foreseeable danger, and caused her to suffer an allergic reaction. (*Id.*) Familiarity with the remaining factual allegations supporting Plaintiff's claims in her Complaint is assumed in this Decision and Order, which is intended primarily for review by the parties.

B. Deadline for Service of Expert Disclosures

On April 18, 2008, United States Magistrate Judge David E. Peebles issued a Uniform Pretrial Scheduling Order in this action. (Dkt. No. 14.) That Order required, among other things, Plaintiff to serve expert disclosures by June 1, 2009. (*Id*. at 2.) On May 28, 2009, upon the request of the parties, Magistrate Judge Peebles reluctantly issued an Amended Scheduling Order, noting that there would be "NO FURTHER EXTENSIONS OF THE DEADLINES UNDER ANY CIRCUMSTANCES." (Text Amended Scheduling Order filed May 28, 2009.) That Amended Order required, among other things, Plaintiff's expert disclosures to be served by

July 15, 2009, and Defendant's expert disclosures to be served by September 14, 2009. (*Id.*)[1]

C. Undisputed Material Facts

The following material facts are asserted and established (through the citation to admissible record evidence) by Defendant in its Local Rule 7.1 Statement, and either expressly admitted by Plaintiff or unsuccessfully controverted by her in her Local Rule 7.1 Response. (*Compare* Dkt. No. 28, Attach. 3 [Def.'s Rule 7.1 Statement] *with* Dkt. No. 33 [Plf.'s Rule 7.1 Response].)[2]

On June 15, 2004, Plaintiff underwent a total knee replacement procedure at Oswego Hospital in Oswego, New York. The procedure was performed by Dr. William Mahon, an orthopedic surgeon. The product implanted into Plaintiff was the Duracon System manufactured by Defendant. The product labels reveal that the following metal components were implanted into Plaintiff: (1) Howmedica Cemented Stem Extender (Cat# 6476-8-250; Lot# LCM123); (2) Duracon Non-Beaded Femoral Component (Cat# 6630-0-515; Lot# LTTLK); and (3) Howmedica Universal Tibial Baseplate (Cat# 6632-3-620; Lot# NOKF).

The Duracon System is an FDA-regulated medical device that can only be sold to licensed health care providers and must be prescribed for use by a licensed surgeon based upon

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[1] Although Plaintiff timely disclosed one expert, Dr. Michael Clarke (an orthopedic surgeon who performed Plaintiff's "revision" surgery on August 8, 2005), Plaintiff failed to disclose any experts on the issues of the design, manufacture or metallic composition of the subject medical device, or on the adequacy of the product warnings.

[2] Plaintiff's 7.1 Statement is identical to Defendant's 7.1 Statement, except for Defendant's assertion of fact number "8", which lists the specific warnings contained in the package inserts accompanying the Duracon System, and Defendant's assertion of fact number "9", which states that Plaintiff has not disclosed any experts on the issues of design, manufacture, or the adequacy of the product warnings. Plaintiff neither admits nor denies either of these factual assertions. Upon review of the record, the Court has verified the accuracy of these assertions.

his or her education, training and experience, and based upon his or her own medical judgment and assessment of the patient's specific needs. All potential risks associated with use of the Duracon System were provided by Defendant to Dr. Mahon as the learned intermediary. The package inserts for the Duracon System components distributed with the components themselves contained specific information regarding the metallic composition of the components. The package inserts for the Duracon System warned specifically of the potential for material sensitivity and reactions to the metallic components.

In accordance with expert disclosure deadlines, Plaintiff disclosed one expert, Dr. Michael Clarke, an orthopedic surgeon who performed Plaintiff's "revision" surgery on August 8, 2005. Dr. Clarke opines that "Plaintiff suffered from an exacerbation of a probable true nickel allergy arising out of insertion of the [Duracon System] . . ." and that, during the revision surgery, the Duracon System had to be removed and replaced with a Smith & Nephew Genesis II Oxinium femur ("the Genesis II") which "is almost nickel free." (Dkt No. 32, Attach. 1 [Affid. of Dr. Clarke].)

Familiarity with the remaining undisputed material facts of this action, as set forth in the parties' Local Rule 7.1 Statement and Local Rule 7.1 Response, is assumed in this Decision and Order, which is intended primarily for review by the parties. (*Id.*)

D. Defendant's Motion for Summary Judgment

On August 6, 2009, Defendant filed a motion for summary judgment in this action. (Dkt. No. 28.) Generally, in support of its motion, Defendant asserts the following two arguments: (1) Plaintiff's entire Complaint should be dismissed because she has failed to introduce expert witness testimony demonstrating either a design defect or the existence of inadequate warnings,

and such testimony is required to establish such claims; and (2) Plaintiff's failure-to-warn claim should be dismissed because Defendant warned physicians and the medical community of the specific risk at issue in this action. (Dkt. No. 28, Attach. 1, at 5-11 [Def.'s Mem. of Law].)

On September 11, 2009, after receiving an extension by the Court, Plaintiff filed an opposition to Defendant's motion. (*See* Text Order filed 9/2/09; Dkt. No. 32.) In her opposition, Plaintiff addresses only Defendant's first argument (i.e., its argument regarding Plaintiff's failure to adduce expert testimony), neglecting to address Defendant's second argument (i.e., its argument regarding its having provided warnings to physicians and the medical community). (*Id*. at 6-7.) More specifically, Plaintiff argues that expert testimony is not necessary under the circumstances for three reasons: (1) "[n]ickel is widely known and accepted in the medical profession as highly toxic," a fact of which the Court can, and should, take judicial notice; (2) the medical records in the action establish that Plaintiff's body was harmed by the implantation of the Duracon System; and (3) Plaintiff has adduced an affidavit establishing the existence of a feasible alternative to the Duracon System (i.e., a device manufactured by Smith & Nephew, which contains a negligible amount of nickel). (*Id*.)

On September 18, 2009, Defendant filed a reply in further support of its motion for summary judgment. (Dkt. No. 36.) Generally, in its reply, Defendant (1) rejects Plaintiff's three arguments regarding her failure to adduce expert testimony, and (2) argues that Plaintiff has failed to address Defendant's argument regarding its having provided warnings to physicians and the medical community. (*Id*. at 2-7.)

II. LEGAL STANDARD GOVERNING MOTIONS FOR SUMMARY JUDGMENT

In their motion papers, the parties demonstrated an accurate understanding of the general standard governing motions for summary judgment. As a result, and for the sake of brevity, the Court will not recite the well-known general legal standard governing motions for summary judgment in this Decision and Order, but will direct the reader to the Court's decision in *Pitts v. Onondaga County Sheriff's Dep't*, 04-CV-0828, 2009 WL 3165551, at *2-3 (N.D.N.Y. Sept. 29, 2009) (Suddaby, J.), which accurately recites that general legal standard.

The Court will add only one point. Implied in the burden-shifting legal standard described in *Pitts v. Onondaga County Sheriff's Dep't* is the fact that, where a nonmoving party willfully fails to adequately respond to a properly filed motion for summary judgment, a district court has no duty to perform an independent review of the record to find proof of a factual dispute.[3]

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[3] *See In re Agent Orange Prod. Liab. Litig.*, 517 F.3d 76, 92 n.4 (2d Cir. 2008) ("Fed. R. Civ. P. 56 does not impose an obligation on the court considering a motion for summary judgment to perform an independent review of the record to find proof of a factual dispute.") [citation omitted]; *N.Y. State Teamsters Confer. Pension and Ret. Fund v. Express Servs., Inc.*, 426 F.3d 640, 647 (2d Cir. 2005) ("We have previously recognized that district courts have the authority to institute local rules governing summary judgment submissions, and have affirmed summary judgment rulings that enforce such rules. Rules governing summary judgment practice are essential tools for district courts, permitting them to efficiently decide summary judgment motions by relieving them of the onerous task of 'hunt[ing] through voluminous records without guidance from the parties.'"); *Amnesty Am. v. Town of W. Hartford*, 288 F.3d 467, 470-71 (2d Cir. 2002) ("We agree with those circuits that have held that Fed. R. Civ. P. 56 does not impose an obligation on a district court to perform an independent review of the record to find proof of a factual dispute. . . . Furthermore, because nothing in the federal rules mandates that district courts conduct an exhaustive search of the entire record before ruling on a motion for summary judgment, district courts are entitled to order litigants to provide specific record citations."); *accord*, *Lee v. Alfonso*, No. 04-1921, 2004 U.S. App. LEXIS 21432 (2d Cir. Oct. 14, 2004), *aff'g*, 97-CV-1741, 2004 U.S. Dist. LEXIS 20746, at *12-13 (N.D.N.Y. Feb. 10, 2004) (Scullin, J.) (granting motion for summary judgment); *Fox v. Amtrak*, 04-CV-1144, 2006 U.S. Dist. LEXIS 9147, at *1-4 (N.D.N.Y. Feb. 16, 2006) (McAvoy, J.) (granting motion for summary judgment); *Govan v. Campbell*, 289 F. Supp.2d 289, 295 (N.D.N.Y. Oct.

For this reason, this Court has often enforced Local Rule 7.1(a)(3) by deeming facts set forth in a moving party's Rule 7.1 Statement to have been admitted where (1) those facts were supported by accurate record citations, and (2) the nonmoving party has willfully failed to properly respond to those facts in its Rule 7.1 Response.[4] Similarly, where a non-movant has willfully failed to respond to a movant's properly filed and facially meritorious memorandum of law (submitted in support of its motion for summary judgment), the non-movant is deemed to have "consented" to the legal arguments contained in that memorandum of law under Local Rule 7.1(b)(3).[5] Stated another way, where a movant has properly filed a memorandum of law (in

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29, 2003) (Sharpe, M.J.) (granting motion for summary judgment); *Prestopnik v. Whelan*, 253 F. Supp.2d 369, 371-372 (N.D.N.Y. 2003) (Hurd, J.).

[4] *See, e.g., Murray v. Weissman*, 05-CV-1186, 2009 WL 3815708, at *2, n.9 (N.D.N.Y. Nov. 12, 2009) (Suddaby, J.) (collecting cases); *see also Vermont Teddy Bear Co., Inc. v. 1-800 Beargram Co.*, 373 F.3d 241, 243 (2d Cir. 2004) (permitting practice); *Champion v. Artuz*, 76 F.3d 483, 486 (2d Cir. 1996) (permitting practice); N.D.N.Y. L.R. 56.2; Fed. R. Civ. P. 83(b) (allowing district court to regulate motion practice in any manner consistent with federal law and the federal rules); Fed. R. Civ. P. 83, Advisory Committee Notes: 1995 Amendments ("The proscription of [not enforcing a local rule in a way that causes a party to lose any right because of a nonwillful failure to comply] is narrowly drawn . . . [and does not] affect the court's power to enforce local rules that involve more than mere matters of form–for example, a local rule requiring parties to identify evidentiary matters relied upon to support or oppose motions for summary judgment."). Among other things, Local Rule 7.1(a)(3) requires that the nonmoving party file a response to the moving party's Statement of Material Facts, which admits or denies each of the moving party's factual assertions in matching numbered paragraphs, and supports any denials with a specific citation to the record where the factual issue arises. N.D.N.Y. L. R. 7.1(a)(3).

[5] *See*, *e.g.*, *Beers v. GMC*, 97-CV-0482, 1999 U.S. Dist. LEXIS 12285, at *27-31 (N.D.N.Y. March 17, 1999) (McCurn, J.) (deeming plaintiff's failure, in his opposition papers, to oppose several arguments by defendants in their motion for summary judgment as consent by plaintiff to the granting of summary judgment for defendants with regard to the claims that the arguments regarded, under Local Rule 7.1[b][3]; *Devito v. Smithkline Beecham Corp.*, 02-CV-0745, 2004 WL 3691343, at *3 (N.D.N.Y. Nov. 29, 2004) (McCurn, J.) (deeming plaintiff's failure to respond to "aspect" of defendant's motion to exclude expert testimony as "a concession by plaintiff that the court should exclude [the expert's] testimony" on that ground).

support of a properly filed motion for summary judgment), and the non-movant has failed to respond to that memorandum of law, the only remaining issue is whether the legal arguments advanced in the movant's memorandum of law are *facially meritorious*.[6] A movant's burden in making legal arguments that are facially meritorious has appropriately been characterized as "modest."[7]

III. ANALYSIS

A. Defendant's Duty to Plaintiff

As a threshold matter, a manufacturer must owe a duty to an individual injured by the

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[6] *Hernandez v. Nash*, 00-CV-1564, 2003 U.S. Dist. LEXIS 16258, at *7-8 (N.D.N.Y. Sept. 10, 2003) (Sharpe, M.J.) [citations omitted]; *accord*, *Topliff v. Wal-Mart Stores East LP*, 04-CV-0297, 2007 U.S. Dist. LEXIS 20533, at *28 & n.43 (N.D.N.Y. March 22, 2007) (Lowe, M.J.); *Sledge v. Kooi*, 04-CV-1311, 2007 U.S. Dist. LEXIS 26583, at *28-29 & n.40 (N.D.N.Y. Feb. 12, 2007), *adopted by* 2007 U.S. Dist. LEXIS 22458 (N.D.N.Y. March 28, 2007) (McAvoy, J.); *Kele v. Pelkey*, 03-CV-0170, 2006 U.S. Dist. LEXIS 95065, at *5 & n.2 (N.D.N.Y. Dec. 19, 2006), *adopted by* 2007 U.S. Dist. LEXIS 4336 (N.D.N.Y. Jan. 22, 2007) (Kahn, J.).

[7] *See* N.D.N.Y. L.R. 7.1(b)(3) ("Where a properly filed motion is unopposed and the Court determines that the moving party has met its burden to demonstrate entitlement to the relief requested therein, the non-moving party's failure to file or serve any papers as this Rule requires shall be deemed as consent to the granting or denial of the motion, as the case may be, unless good cause is shown."); *Rusyniak v. Gensini*, 07-CV-0279, 2009 WL 3672105, at *1 n.1 (N.D.N.Y. Oct. 30, 2009) (Suddaby, J.) (citing cases that stand for the proposition that, where plaintiffs do not respond to defendants' argument made in their summary judgment motion, plaintiffs are deemed to have consented to defendants' argument, and thus defendants must only satisfy their "modest threshold burden" of demonstrating entitlement to the relief requested in their motion for summary judgment); *accord, Cossey v. David,* 04-CV-1501, 2007 WL 3171819, at *4 & nn. 21, 22 (N.D.N.Y. Oct. 29, 2007) (Lowe, M.J. adopted by Scullin, J.) (collecting cases); *Niles v. Nelson*, 72 F. Supp.2d 13 (N.D.N.Y. 1999) (McAvoy, J.) (holding that, when a party does not respond to a portion of the opposing party's motion, they indicate that they consent to the granting of summary judgment with respect to that portion of the motion or have abandoned the claim); *cf. Di Giovanna v. Beth Isr. Med. Ctr*., 08-CV-2750, 2009 WL 2870880, at *10 n.108 (S.D.N.Y. Sept. 8, 2009) (citing cases for proposition that plaintiff's failure to respond to argument made in summary judgment motion as to why certain claim should be dismissed constitutes abandonment of claim).

manufacturer's product before the manufacturer can potentially incur liability for the injured party's injuries. *See McCarthy v. Olin Corp*., 119 F.3d 148, 170 (2d Cir. 1997) (Calabresi, J., dissenting) (noting that, for either a strict products liability or negligent products liability claim, "a duty is needed; . . . that duty must be breached by the defendant's manufacture or sale of a defective product; . . . the plaintiff must suffer an injury; and . . . the defect must be the cause of the plaintiff's injury. These are not the elements of a cause of action in strict products liability. Those elements are much more specific, and depend on the theory of liability being asserted.").

Manufacturers of a product have a duty to market safe products. *Dalton v. Stedman Machine Co.*, 05-CV-0452, 2008 WL 351676, at *4 (N.D.N.Y. Feb. 7, 2008) (McAvoy, J.). This duty is owed, at a minimum, to all foreseeable users of the product. *Liriano v. Hobart Corp*., 132 F.3d 124, 126 (2d Cir. 1998) ("It is well-settled under New York law that a manufacturer is under a duty to use reasonable care in designing its product so that it will be safe when used in the manner for which the product was intended, as well as unintended yet reasonably foreseeable use."). Here, the Court finds that Plaintiff was a foreseeable user of Defendant's knee replacement system. As a result, the Court finds that Defendant owed Plaintiff a duty to manufacture a safe knee replacement system.

B. Strict Products Liability Based Upon Design Defect[8]

A plaintiff seeking to impose liability for a design defect must demonstrate the following:

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[8] Plaintiff asserts his design defect claim under theories of strict liability and negligence. Essentially, Plaintiff must make out the same *prima facie* case under both theories. *See Galletta v. Valmet, Inc*., 04-CV-0313, 2007 WL 963288 at *4 (N.D.N.Y. Mar. 30, 2007) (Mordue, C.J.) (noting that "the question of whether these two causes of action are substantially similar remains unsettled . . . . Nonetheless, because Plaintiff must essentially make out the same *prima facie* case under both theories, the Court will analyze the claims together . . . .") (citations omitted). Therefore, the Court will analyze the theories together.

(1) the product, as designed, posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing plaintiff's injury. *Cuntan v. Hitachi Koki USA, Ltd.*, 06-CV-3898, 2009 WL 3334364 at *5 (E.D.N.Y. Oct. 15, 2009) (*citing Voss v. Black & Decker Mfg. Co.*, 59 N.Y.2d 102 [N.Y. 1983]) (citations omitted). Taken together, the first two prongs form a standard known as the "risk-utility test." *Id.* This standard is used to determine whether a product, as designed, is "unreasonably dangerous." *Id.* (citing *Sorto-Romero v. Delta Int'l Mach. Co.*, 05-CV-5172, 2007 WL 2816191 at *10 [E.D.N.Y. Sep. 24, 2007]) (citations omitted). "There must be something wrong with the product, and if nothing is wrong there will be no liability." *Galletta,* 2007 WL 963288 at * 4 (quoting *McCarthy*, 119 F.3d at 155).

It is not enough, however, to demonstrate that a product is dangerous. *Cuntan,* 2009 WL 3334364 at *5. A plaintiff must engage in

> 'an inquiry into such factors as [the following]: (1) the product's utility to the public as a whole; (2) its utility to the individual user; (3) the likelihood that the product will cause injury; (4) the availability of safer design; (5) the possibility of designing and manufacturing the product so that it is safer but remains functional and reasonably priced; (6) the degree of awareness of the product's potential danger that can reasonably be attributed to the injured user; and (7) the manufacturer's ability to spread the costs of any safety-related design changes.'

Id. (quoting *Clarke v. LR Sys.,* 219 F. Supp.2d 323, 330 [E.D.N.Y. 2002]). A careful consideration of these factors must establish that a different design would have (1) led to improved safety and (2) been "economically and technically feasible." *Id.* (citing *Ruthosky v. John Deere Co.*, 235 A.D.2d 620, 622 [NY App. Div., 3d Dept 1997]).

Finally, a plaintiff must show that the defective design was the proximate cause of her injury. *Galletta,* 2007 WL 963288 at * 4 (citations omitted). If there are multiple proximate causes, the test is whether defendant's defective or unreasonably dangerous design was a

"substantial cause" of the injury. *Id.* (citing *Bush v. Lamb-Grays Co.*, 246 A.D.2d 768, 771 [NY App. Div. 3d Dept 1998]).

1. Whether the Design Was Unreasonably Dangerous

a. Feasibility of Alternative Design

Generally, under New York law, a plaintiff seeking to establish a design defect is required to provide expert testimony as to the feasibility and efficacy of alternative designs. *Cuntan*, 2009 WL 3334364 at *6 (collecting cases).[9] In particular, unless a reasonable alternative design is both obvious to and understandable by a layperson, an expert is needed. *Guarascio v. Drake Assoc. Inc.*, 582 F. Supp.2d 459, 463 (S.D.N.Y. 2008). As a result, "New York courts uniformly rule that competent, non-conclusory expert testimony is needed in cases involving more complex design issues." *Guarascio,* 582 F. Supp.2d at 463 (collecting cases). Experts can prove the feasibility and efficacy of alternative designs either by (1) showing, "through testing and construction of a prototype, that such an alternative design is within the realm of practical engineering feasibility," or (2) identifying "makers of similar equipment who have already put into use the alternative design." *Rypkema*, 263 F. Supp.2d at 692.

Here, "after research and investigation," Dr. Clarke concluded that an alternative design has been put into use by makers of similar equipment. (Dkt. No. 32, Attach. 1.) Indeed, Dr.

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[9] *See also Rypkema v. Time Mfg. Co.*, 263 F. Supp.2d 687, 693 (S.D.N.Y. 2003) ("[A]n expert is required to ascertain feasability, to test alternative designs, and to address the engineering factors and tradeoffs that go into the design of a product for distribution in the marketplace."); *Tuosto v. Philip Morris USA Inc.*, 05-CV-9384, 2007 WL 2398507, at *12 (S.D.N.Y. Aug. 21, 2007) (dismissing design defect claim because plaintiff "[did] not introduce an expert to demonstrate that there actually was a feasible alternative to the cigarettes [he] smoked."); *Sita v. Danek Med., Inc.*, 43 F. Supp.2d 245, 257-58 (E.D.N.Y. 1999) (granting summary judgment against plaintiff on his design-defect claim due to his failure to adduce evidence that spinal system, of which screw was component, feasibly could have been designed more safely).

Clarke replaced the Duracon System with the Genesis II during Plaintiff's revision surgery, which occurred approximately fourteen months after the original surgery. Therefore, the Court will assume that an alternative design existed during the time in question, i.e., on June 15, 2004.[10]

However, it is not enough to demonstrate simply that an alternative design existed during the time in question. *See Cuntan,* 2009 WL 3334364 at *5. Rather, a plaintiff must demonstrate that the alternative design would have lead to overall improved safety (and that the defendant's design created a substantial likelihood of harm), which requires a risk-utility balancing. Here, Dr. Clarke does not address the utility of the Defendant's product or the replacement product, nor does he opine on the incidence of material sensitivity to nickel in the general population. *See Voss*, 59 N.Y.2d at 109.

b. Substantial Likelihood of Harm

Similarly, Plaintiff does not provide evidence that the product in question, as designed, was "unreasonably dangerous." *See Cuntan*, 2009 WL 3334364 at *5. Instead, Plaintiff argues that "the high level of nickel in [Defendant's] knee replacement device and generally accepted knowledge of nickel as highly toxic, would allow an ordinary juror to arrive at and reach a reasonable conclusion that the presence of nickel in the device is a product defect." (Dkt. No. 32, at 11 [Plf.'s Mem. of Law].)

By making this argument, Plaintiff implicitly concedes that Dr. Clarke is not being offered as an expert on the issue of whether there was anything "wrong" with Defendant's

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[10] The Court makes this assumption with some hesitation. Although this fact is not in the record (and is thus not considered by the Court in reaching its decision), the Court notes that the Genesis II, which is manufactured using Smith & Nephew's exclusive nickel-free Oxinium technology, did not enter the market until February of 2003, and was apparently not widely used in the industry in June of 2004, having been subjected to a recall in September 2003.

product. *See Galletta,* 2007 WL 963288 at *4. In other words, Plaintiff does not provide expert testimony for purposes of establishing a product defect; Plaintiff instead argues that this matter can be decided by a jury without the assistance of expert testimony.

This argument is without merit. Nickel's toxicity in knee replacement systems is not within the understanding of the ordinary juror, who is a layperson. *See Lusch v. Matrixx Initiatives, Inc.,* 05-CV-0292, 2007 WL 2816203, at *7 (D. Or. Sept. 25, 2007) (finding that, without admissible expert opinions or testimony linking plaintiff's use of homeopathic cold-remedy containing zinc with her loss of smell, plaintiff would be unable to show causation) (citation omitted).[11]

Apparently recognizing this point of law, Plaintiff asks the Court to take judicial notice of the fact that "nickel is highly toxic." However, Plaintiff fails to provide any reports or studies supporting the indisputability of this factual assertion, which is so vague in terms of quantity of nickel and level of toxicity as to render the "fact" asserted subjective in nature. For example, the fact asserted is as immune from reasonable dispute, and as capable of ready determination, as is the contrary statement "nickel is essential to good health" (since it appears that a small amount nickel is essential to good health in humans). Under the circumstances, the Court declines to take judicial notice of this broad factual assertion.[12]

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[11] *Cf. Guarascio,* 582 F. Supp.2d at 464 ("A lay person would neither readily understand nor necessarily find obvious the design and engineering of an air filtration manifold . . . . The design here at issue is certainly more complex than the design of a steak sauce bottle or ski binding, yet insufficiently probative expert testimony was fatal to design defect claims in cases involving those products.") (citations omitted.); *Gayle v. Nat'l R.R. Passenger Corp.*, 06-CV-6195, 2010 WL 430948 at *9 (S.D.N.Y. Feb. 8, 2010) ("The Court has no knowledge of the proper scope or manner of work expected of a crane inspector and there is no reason to believe that such knowledge is within the common knowledge and experience of ordinary jurors.").

[12] *See United Nat'l Ins. v. Motiva Enter., LLC,* 04-CV-2924, 2006 WL 83482, at *11, n.6 (S.D. Tex. Jan. 12, 2006) (denying motion to take judicial notice that hydrogen sulfide

Furthermore, even if the Court were to take judicial notice of the fact that, in certain quantities, nickel can be toxic to humans in general, the Court would be unable, under the circumstances, to take judicial notice of how little nickel can be toxic to humans (either to the average humans, or to humans with sensitivity to nickel). In reaching this conclusion, the Court relies on the case of *Patrick v. Sharon Steel Corp.*, in which the Northern District of West Virginia refused to take judicial notice of the "dangerous properties" of a list of twenty-one chemical compounds (including benzopyrene, antracene, sodium phenolate, or ammonium sulfate), because those chemical properties are "certainly not generally known within the territorial district of this, or any other[,] Court." *Patrick v. Sharon Steel Corp.*, 549 F. Supp. 1259, 1268-69 (D. W.Va. 1982). The Court notes that, in that case, Chief United States District Judge Charles H. Haden, had the following to say about nickel:

> The Court . . . notes that of the twenty-one compounds listed by Plaintiffs several are quite common and not generally considered to be dangerous. These include copper, lead, *nickel* and carbon dioxide. While the Court does not doubt that under certain conditions these compounds could be dangerous, it is incumbent upon the Plaintiffs to prove the existence of those 'certain conditions' or exposure levels. These matters should be decided by a jury after full development of the evidence at trial, not by a Court on a motion for judicial notice.

Patrick, 549 F. Supp. at 1269.

Here, Plaintiff has provided no evidence of the incidence and/or level of sensitivity to nickel in the general population. Similarly, Plaintiff has provided no evidence of the industry standard for acceptable levels of nickel in knee-replacement devices. Finally, Plaintiff has provided no evidence of the point at which the utility of using nickel in knee replacement

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and benzene are both irritants or contaminants); *cf. Sullivan v. Ford Motor Co.*, 2000 WL 343777 at *9, n.2 (S.D.N.Y. Mar. 30, 2000) ("[The] Defendants have requested that the Court take judicial notice of the 'laws of physics' . . . . [T]his request is overly broad [and] the Court declines to take judicial notice of the 'laws of physics.').

devices outweighs the risk.[13]

For all of these reasons, the Court concludes that Plaintiff has failed to introduce admissible record evidence from which a rational factfinder could conclude that the design of the Duracon System at the time of Plaintiff's surgery was defective.

2. Whether the Defective Design Proximately Caused Plaintiff's Injuries

Because the Court has concluded that, based on the record evidence, no rational factfinder could conclude that the Duracon System was defectively designed, the Court need not, and does not, decide the issue of proximate cause. The Court will only note that the bulk of Dr. Clarke's testimony pertained to this issue. (Dkt. No. 32, Attach. 1.)

C. Defendant's Duty to Warn[14]

As an initial matter, the Court notes that, as explained above in Part I.C. of this Decision and Order, Plaintiff failed to respond to Defendant's argument regarding Plaintiff's duty-to-warn claim, despite having been granted an extension of time in which to do so. As a result, Defendant's burden with regard to this portion of its motion is lightened such that, in order to

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[13] The Court notes that the fact that Dr. Clarke replaced Defendant's product with a product containing less nickel than was contained in the Duracon System does not establish that the replacement product's alternative design is a more reasonable alternative than is the Duracon System's design. *See Guarascio,* 582 F. Supp.2d, at 463 (citing *Voss,* 59 N.Y.2d 102 at 109) ("[E]vidence of the magnitude and probability of foreseeable harm may be offset by evidence that the proposed alternative design would reduce the efficiency and utility of the product."); *see also Sita*, 43 F. Supp.2d at 257 ("[Plaintiff's expert] does not . . . express the opinion that [Defendant's device is] unsafe as designed or state that reasonable persons would not conclude that the utility of using such systems outweighs the risks involved in their use."). For example, without an expert opinion, a jury would be unable to determine how the two products compare in terms of cost, durability, range of motion, and other adverse health effects.

[14] As with product defect claims (*see, supra,* Part III.B. of this Decision and Order), duty to warn claims for negligence and strict liability are one in the same. *Tompkins v. R.J. Reynolds Tobacco Co.*, 92 F. Supp.2d 70, 90 (N.D.N.Y. 2000) (Scullin, J.) ("New York courts consider a negligence claim for failure to warn to be equivalent.") (*citing Fane*, 927 F.2d at 130).

succeed on this portion, it need only show its entitlement to the relief requested in this portion, which has appropriately been characterized as a "modest" burden.[15] For the reasons stated by Defendant in its motion papers, the Court finds that Defendant has met this lightened burden. (*See generally* Dkt. No. 58.) In any event, the Court finds that Defendant's argument would survive even the heightened scrutiny appropriate on a contested motion.

The Duracon System is not available to the general public, but rather, is available only by prescription. (Dkt. No. 28, Attach 3.) Therefore, pursuant to 21 C.F.R. § 801.109, warning information was disseminated to Plaintiff's physician, rather than Plaintiff directly. 21 C.F.R. § 801.109. "Warnings are furnished to the medical community as the 'informed intermediary' between the manufacturer and the patient." *Fane*, 927 F.2d at 129 (citing *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87 [2d Cir. 1980] [citations omitted]). "[T]he physicians function is to evaluate a patient's needs, assess the risks and benefits of available [products] and then prescribe a [product], advising the patient of its risks and possible side effects." *Id.* (quoting *Wolfgruber v. Upjohn Co.*, 72 A.D.2d 59, 62 [NY App. Div., 4th Dept 1979]; *aff'd,* 52 N.Y.2d 768 [1980].)

The sufficiency of a manufacturer's warning for a prescription device is generally a question of fact for the jury. *Id.* (citing *Wolfgruber,* 72 A.D.2d at 61-62) (citations omitted). However, where a warning is provided by a manufacturer to a physician through package inserts which give specific detailed information on the risks of the product, the manufacturer is absolved from liability as a matter of law. *Id.* If the doctor is sufficiently warned, the product is not defective and summary judgment is appropriate. *Id.* (citing *Lindsay,* 637 F.2d at 91).

Here, the package inserts accompanying the Duracon System adequately warned Plaintiff's surgeon, Dr. Mahon, of the risks associated with the metallic components of the

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[15] *See*, *supra*, note 6 of this Decision and Order.

Duracon System. The package inserts for the Duracon System knee replacement provided, in pertinent part:

> **ATTENTION OPERATION SURGEON**
>
> In using total knee joint implants, the surgeon should be aware of the following: . . .
>
> **B. In selecting patients for total joint replacements, the following factors can be of extreme importance to the eventual success of the procedure:** . . .
>
> 4) **Foreign body sensitivity:** Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation. . . .
>
> **ADVERSE EFFECTS**
>
> . . .
> 2) Although rare, metal sensitivity reactions in patients following joint replacement have been reported. Implantation of foreign material in tissues can result in cellular reactions that may include lymphocytes, macrophages and fibroblasts. . . .
> 10) Allergic reactions to the materials utilized in the implant, although uncommon, can occur. . . .

(Dkt. No. 28, Attch. 10, at 7, 11-12, 19-20, 24, 31, 35-36.) Moreover, the package inserts distributed with the Duracon System contained specific information regarding the metallic composition of the components of the device:

> The metallic components (the femoral component, tibial and patellar baseplates, sintered beads, wedges and spacers) are manufactured from cast cobalt-chromium-molybdenum alloy (Vitallium Alloy) conforming to ASTM standard F75. The screws and stem extenders are manufactured from wrough cobalt-molybdenum alloy (Vitallium Alloy) conforming to ASTM standard F1537. The polyethylene components are manufactured from ultra-high-molecular weight polyethylene (UHMWPE) conforming to ASTM standard F648.

(*Id*. at 8, 20, 32.)

Indeed, Plaintiff acknowledges in her own Statement of Material Facts that "potential risks, warnings, indications and contraindications, and potential adverse events are provided to the physician as a learned intermediary [and] [t]hrough the learned intermediary the patient should be advised of the risks, benefits, indications, contraindications and potential adverse events in connection with the use of the device." (Dkt. No. 33 at 2.) More importantly, Plaintiff concedes that "[t]he package inserts for the [Duracon System] components distributed with the components themselves *contained specific information regarding the metallic composition of the components*." (*Id.* [emphasis added].) Therefore, Plaintiff's argument that Defendant did not make her aware of the risks and warnings regarding use of the device and its metallic components is unfounded as it contradicts her own Statement of Material Facts. (*Id.*)

In any event, it seems that Plaintiff has abandoned this claim. Indeed, Plaintiff does not even mention her failure to warn claim in the "Legal Argument" section of her opposition papers, but merely makes a conclusory statement in the "Relevant Factual Background" section that "[a]t no time did Defendant make Plaintiff aware of the risks and warnings regarding the use of the device." (Dkt. No. 32 at 4 [Plf.'s Mem. of Law].) This statement contradicts Plaintiff's own Rule 7.1 Statement, which expressly acknowledges that the package inserts contained such warnings. (Dkt. No. 33 at 2.)

Defendant provided an adequate warning to Dr. Mahon of the very risk which Plaintiff now complains of.[16] As the learned intermediary, it was Dr. Mahon who was required to communicate these warnings to Plaintiff. Therefore, Plaintiff has failed to demonstrate a *prima*

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[16] There is a dispute between the parties as to whether Plaintiff advised Dr. Mahon *prior* to surgery of her past reactions to "cheap jewelry." (Dkt. No. 32 at 6 n.2 [Def.'s Reply Mem. of Law].) This dispute is not material to Defendant's motion because it was Dr. Mahon's duty to inquire about such allergies once he was provided with a clear warning of the risks associated with the Duracon System.

facie claim of product defect based on a failure to warn. *See Fane*, 927 F.2d at 129 ("If the doctor is sufficiently warned, the product is not defective.").

ACCORDINGLY it is

ORDERED that Defendant's motion for summary judgment (Dkt. No. 28) is **GRANTED**; and it is further

ORDERED that all of Plaintiff's claims asserted in her Complaint (Dkt. No. 7), are **DISMISSED**.

Dated: May 10, 2010
Syracuse, New York

Hon. Glenn T. Suddaby
U.S. District Judge