CLOSED

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ROBERT JONES and KRISTA JONES, Plaintiffs, v. SYNTHES USA SALES, LLC, SYNTHES USA PRODUCTS, LLC, JOHN DOES 1-5, and ABC CORP. 1-5, Defendants.	Civil Action No. 08-2060 (JAP) **OPINION**

PISANO, District Judge.

Plaintiffs Robert and Krista Jones have brought this product liability action against Defendants Synthes USA Sales, LLC and Synthes USA Products, LLC ("Synthes") for physical injuries stemming from Defendants' allegedly defective surgical screws. Plaintiffs allege claims of negligence, product liability, breach of warranty and consumer fraud. This Court has original jurisdiction to hear this dispute pursuant to 28 U.S.C. § 1332 because this case is a civil action between citizens of different states and the amount in controversy exceeds $75,000.

Presently before the Court is Defendants' summary judgment motion and motion to preclude the testimony of Plaintiffs' expert. The Court heard oral arguments on May 24, 2010. For the reasons set forth herein, the Court grants Defendants' summary judgment motion.

I. Background[1]

Defendants Synthes manufactures the Anterior Tension Band ("ATB") which is a prescription medical device consisting of a metallic plate and four cancellous bone screws. ATB is used for spinal fusion surgery for the treatment of lumbar and lumbosacral spine instability. Spinal fusion surgery involves an attempt to fuse two vertebrae together whereby the ATB provides fixation during the expected bony fusion process. Each ATB package comes with an insert that reads "FOR THE PERSONAL ATTENTION OF THE OPERATING SURGEON" and communicates the following warnings:

- [T]hese implants are intended only to assist healing and not intended to replace normal body structures.
- If there is delayed union or nonunion of bone in the presence of weight bearing or load bearing, the implant could eventually break due to metal fatigue.
- Factors such as the patient's weight, activity level, and adherence to weight-bearing or load bearing instructions have an effect on the stresses to which the implant is subject, and therefore on the life of the implant. It is important to note that these implants may break at any time if they are subjected to sufficient stress.
- These devices can break when subjected to the increased loading associated with delayed union or non union.
- If healing is delayed or does not occur, the implant could eventually break due to metal fatigue.
- Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture has healed, particularly in young active patients.

Plaintiff Robert Jones is a forty-six year old corrections officer with a history of lower back pain with radiation stemming from injuries he sustained during his employment. After

[1] The background is drawn from the undisputed facts set forth in Defendants' Rule 56.1 Statement of Material Facts, Plaintiffs' Response to Defendants' Undisputed Facts Pursuant to Rule 56.1, Plaintiffs' Supplemental Statement of Material Facts, Defendants' Response to Plaintiffs' Supplemental Facts and attached exhibits.

increasing back pain, in March of 2004, Plaintiff began treatment with Dr. Marc Levine of the Trenton Orthopaedic Group and was diagnosed with degenerative disc disease. After Dr. Levine determined the extent of Plaintiff's pain levels, he recommended anterior lumbar interbody fusion to reduce the pain. On July 22, 2005, Dr. Levine performed the fusion surgery on Plaintiff using Defendants' ATB. From August 2005 through May 2006, Plaintiff had multiple check-up appointments with Dr. Levine who noted that Jones was "doing quite well overall." On September 8, 2005 and October 24, 2005, x-rays showed that the instrumentation was in place and Plaintiff reported that his pain had "dramatically improved." Additionally, despite the onset of back pain with numbness and tingling, an x-ray showed on April 18, 2006 that the instrumentation was still in place.

In late April or early May, while bending over a drawer, Plaintiff felt something pop in his back, heard an audible snap, and felt sensations of extreme pain. On May 11, 2006, an x-ray showed a failure of the left S1 screws of the ATB system with breakage within the bone. Dr. Levine believed that the lack of complete bony fusion post-surgery had allowed ongoing micromotion which fatigued the hardware causing the screws to fail. On August 4, 2006, Dr. Levine performed a posterior spinal surgery on Plaintiff. After the second surgery, Plaintiff continued to complain of lower back pain and pain going down both legs.

On March 12, 2008, Plaintiffs filed their complaint in the Superior Court of New Jersey, Law Division, Mercer County. On April 28, 2008, the case was removed to the United States District Court pursuant to 28 U.S.C. §1441(a).

II. Discussion

A. Summary Judgment Standard

To prevail on a motion for summary judgment, the moving party must establish "that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The district court must determine whether disputed issues of material fact exist, but the court cannot resolve factual disputes in a motion for summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249-50 (1986).

In determining whether a genuine issue of material fact exists, the court must view the facts in the light most favorable to the non-moving party and extend all reasonable inferences to that party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986); *Stephens v. Kerrigan*, 122 F.3d 171, 176-77 (3d Cir. 1997). The moving party always bears the initial burden of demonstrating the absence of a genuine issue of material fact, regardless of which party ultimately would have the burden of persuasion at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Once the moving party has met its opening burden, the non-moving party must identify, by affidavits or otherwise, specific facts showing that there is a genuine issue for trial. *Id*. at 324. Thus, the non-moving party may not rest upon the mere allegations or denials of its pleadings. *Id*. "[T]he plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Id*. at 322.

Once the moving-party has demonstrated to the court the absence of a material fact at issue, the Supreme Court has stated that the non-moving party "must do more than simply show that there is some metaphysical doubt as to the material facts . . . ." *Matsushita*, 475 U.S. at 586-

87 (citations omitted). In other words, "[i]f the evidence [submitted by the non-moving party] is merely colorable . . . or is not significantly probative . . . summary judgment may be granted." *Anderson*, 477 U.S. at 249-50 (citations omitted).

The Supreme Court has specifically recognized that "[o]ne of the principal purposes of the summary judgment rule is to isolate and dispose of factually unsupportable claims or defenses, and [] that [the rule] should be interpreted in a way that allows it to accomplish this purpose." *Celotex*, 477 U.S. at 323-24. Thus, "[w]hen the record is such that it would not support a rational finding that an essential element of the non-moving party's claim or defense exists, summary judgment must be entered for the moving party." *Turner v. Schering-Plough Corp.*, 901 F.2d 335, 341 (3d Cir. 1990).

B. Legal Analysis

In New Jersey, product liability actions are governed by the New Jersey Products Liability Act ("NJPLA"). N.J. Stat. Ann. § 2A:58C-1, et seq. The NJPLA encompasses "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory of the underlying claim, except actions for harm caused by breach of an express warranty."[2] *Id.* § 2A:58C-1(b)(3). NJPLA provides that

> [a] manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from design specification, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.

Id. § 2A:58C-2. In a defective design case, a plaintiff must show the existence of a reasonable alternative design whereby the foreseeable risks of harm posed by the product could have been

[2] Plaintiffs allege claims in negligence, breach of warranty, strict product liability and consumer fraud. Since there are no allegations by Plaintiffs for an express breach of warranty, all claims are governed by NJPLA.

reduced or avoided by the adoption of such a design. *Cavanaugh v. Skill Corp.*, 164 N.J. 1, 6-7 (2000). To succeed on this claim, a plaintiff is required to prove that the alternative design that would have reduced or prevented the harm is both practical and feasible. *Lewis v. Am. Cyanamid Co.*, 155 N.J. 544, 559 (1998). For product liability claims, "expert testimony is only required to support a claim when the subject matter is so esoteric that jurors of common judgment and experience are unable to make a determination without the benefit of the information and opinions possessed by a person with specialized knowledge." *Macri v. Ames McDounough Co.*, 211 N.J. Super. 636, 642 (App. Div. 1986).

Plaintiffs argue that the "defective condition" of Defendants' screws rendered them "unreasonably dangerous" because the product was both designed in a defective manner and did not contain adequate warnings. *See* Amended Complaint, ¶ 32. Specifically, Plaintiffs' theory of liability is premised on the fact that "a more robust screw design would have provided a more resilient, stronger screw that would have lasted long enough for a fusion to take hold." Pls. Opp. Br., at 3. In other words, Synthes' screws were defective in that they were not strong enough to withstand the necessary time period for bone fusion to occur. Further, Plaintiffs also argue that Defendants failed to provide adequate warnings by not suggesting a "timeline or possible lifespan for the devices . . . [or providing] an estimated timespan for a spinal fusion to take hold." *Id*. at 8. Although Defendants warned that breakage could occur at "any time" with "delayed union or nonunion," Plaintiffs contend that fusion had not been delayed, but rather that the "fusion was not afforded the opportunity to grow properly due to the failure of the stabilization of the hardware." *Id*. at 3. Based on this theory, Plaintiffs maintain that the package insert did not provide warnings for failure of the hardware which caused the lack of bony fusion.

In this motion, Defendants argue that Plaintiffs' expert does not meet the standards established in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and as such Plaintiffs cannot establish their alternative design theory nor can they challenge the adequacy of Defendants' warnings. The parties approach the problem from opposite sides: Defendants' product secures the bony structures while fusion occurs. According to Plaintiffs, any device which fails before fusion would be defective. Defendants, on the other hand, argue that bone fusion depends upon many factors, and the product's warnings alert the physician that the device is not designed, or intended, to substitute for fusion.

However one structures the issue, it is clear that Plaintiffs must rely upon expert testimony to establish liability under either an alternative design or inadequate warning theory.[3]

i. Alternative Design

Federal Rule of Evidence 702 governs the admissibility of expert testimony and states:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon

[3] Defendants' motion papers include an argument that, under the "learned intermediary doctrine," the product warning must be found adequate as a matter of law. According to the doctrine, "an adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product . . . in the case of prescription drugs, taking into account the characteristics of, and ordinary knowledge common to, the prescribing physician." N.J. Stat. Ann. § 2A:58C-4. The NJPLA applies the doctrine to pharmaceutical products, but no New Jersey case has expanded the doctrine to cases involving medical devices.

The doctrine is explained in *Perez v. Wyeth Laboratories*, 161 N.J. 1 (1999), as having a rationale which (1) prevents the court from intruding upon the doctor-patient relationship, (2) recognizes that physicians are in a superior position to convey information for patient's informed consent, (3) acknowledges that manufacturers lack the ability to communicate directly with the patients, and (4) appreciates that the complexity of the subject matter makes lay instructions and warning comprehension problematic.

Other courts have applied the doctrine to medical devices, *see, e.g., Spychala v. G.D. Searle & Co.*, 705 F. Supp 1024 (1988) (applied the learned intermediary doctrine to a product liability action for an intrauterine contraceptive medical device); *see also Ellis v. C.R. Bard*, 311 F.3d 1272 (11th Cir. 2002); *Willett v. Baxter Int'l, Inc.*, 929 F.2d 1094 (5th Cir. 1991); *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142 (D. Or. 1989); *McKee v. Moore*, 1983 OK 71 (1982); *Terhune v. A.H. Robins Co.*, 90 Wn.2d 9 (Wash. 1978), and this Court finds the logic of the discussions in these cases to be persuasive.

However, since the Court decides this motion on other grounds, it is unnecessary in this opinion to predict whether the New Jersey Supreme Court would also expand the doctrine to cases involving medical devices.

> sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Two particular requirements apply to the admissibility of expert testimony: (1) the testimony must have sufficient grounds in scientific knowledge, such that the "reasoning or methodology underlying the testimony is scientifically valid," and (2) the opinion must be helpful to the fact finder. *Daubert*, 509 U.S. at 592-93.

Such requirements are met if the proffering party sustains a three-pronged inquiry: (1) the witness is qualified as an expert in a particular field; (2) the methodology applied by the witness is sufficiently reliable; and (3) the witness's testimony "fits" the facts of the case in dispute—that is, the proffered testimony would assist the trier of fact. *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (2008) (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741-42 (3d Cir. 1994)). Essentially, "an expert must have the requisite 'qualifications, reliability, and fit.'" *Jaasma v. Shell Oil Co.*, 412 F.3d 501, 513 (3d Cir. 2005) (quoting *In re Unisys Sav. Plan Litig.*, 173 F.3d 145, 156 (3d Cir. 1999)). The burden of meeting these elements, and of showing that "good grounds" exist for the expert's opinion, lies with the proponent. *U.S. v. Mitchell*, 365 F.3d 215, 244 (3d Cir. 2004). The proponent must establish that "his expert is qualified and his testimony is admissible by a preponderance of the evidence." *Poust v. Huntleigh Healthcare*, 998 F. Supp. 478, 490 (D.N.J. 1998) (citing *Daubert*, 509 U.S. at 593 n.10).

1. Plaintiffs' Expert Witness: Mr. Liebermann

In order to show a feasible alternative design to Synthes's screws, Plaintiffs rely on the expert testimony of Mr. Warren Lieberman. Lieberman has a Bachelor of Science degree in Metallurgical Engineering and a Master of Science degree in Engineering Science. Synthes Exhibit E. Prior to joining the firm Consulting Engineers & Scientists, Inc., Lieberman spent

thirty-four years as a metallurgical engineer for Boeing Company responsible for aircraft design, failure analysis and accident investigation. *Id*. Admittedly, Lieberman has never studied biomechanics in terms of implantable surgical devices, has never pursued a medical degree, has never been a licensed engineer, has no experience with respect to the manufacturing of any medical devices and has never conducted research or published papers with respect to medical devices. Lieberman Dep., 9, 11, 12, 36, Synthes Ex. S.

In his June 2009 report, Lieberman attributed Plaintiff's injuries to the failure of the cancellous screw implanted with the ATB system into Plaintiff's body. Such a failure, Lieberman postulated, was a "result of the manufacturing error or the failure on the part of Synthes to properly test and understand all the normal variables that affect the fatigue strength of the ATB system . . . ." 2009 Lieberman Rpt., 3, Synthes Ex. F. In this initial examination, Lieberman opined that Defendants' screws were not strong enough and a more robust design could have created more resilient and stronger screws. *Id*. Lieberman formulated this opinion based on the fact that the screw broke before the two year period of time when spinal fusion should have taken place. Lieberman Dep., 73, Synthes Ex. S. In drawing these conclusions, Lieberman did not review any medical textbooks or medical journals dealing with the spine, spinal fusion, medical devices or biomechanics, but "did look up on the Internet to understand the structure of the spine." *Id*. at 38. Additionally, Lieberman did not base his opinion on any discussions with spine surgeons or experts on medicine or biomechanics. *Id*. at 41. Further, Lieberman drew his conclusions without ever physically examining or ever viewing the ATB system, cancellous screws or any implantable surgical devices. *Id*. at 30, 201.

In a supplemental report dated September 24, 2009, Lieberman proposed three alternative designs methods[4] which in his opinion would have improved the screw's fatigue life: shot peening, gray anodization and dye penetrant testing. Sept. 24, 2009 Supp. Lieberman Rpt., Synthes Ex. G. Shot peening is a process whereby the surface of a component is bombarded with small spherical particles of metal, glass and ceramic in order to create uniform compression stress. Lieberman Dep., 87, Synthes Ex. S. While Lieberman believed shot peening would improve the fatigue life of the screw, he noted that a "specific improvement on the fatigue life" could not be determined without testing. Sept. 24, 2009 Supp. Lieberman Rpt., Synthes Ex. G. Additionally, Lieberman conceded that he was unaware of any study that showed with statistical significance that shot-peened screws improved the fusion rate for spinal surgery. Lieberman Dep., 98, Synthes Ex. S. Admittedly, Lieberman had never documented[5] his alternative design of shot peening cancellous screws and as such his design had never been peer reviewed. *Id*. at 77, 81, 83. Furthermore, Lieberman has not performed any testing on his alternative design and has not determined, for instance, if increasing the strength of the screw would actually impede bone growth and fusion or whether shot peening would damage the specially-designed threads of cancellous screws. *Id*. at 182, 221-222, 246. Lieberman also was unable to identify any company manufacturing spinal screws at the point in time when the screw in question was made who utilized the shot peening technique. *Id*. at 215-217.

In his report, Lieberman, however, relied on a periodical publication which expressed the viewpoint that shot peening allows for the manufacturing of implants that are smaller, stronger and lighter. Sept. 24, 2009 Supp. Lieberman Rpt., Synthes Ex. G. The periodical relied upon

[4] Lieberman does not purport to suggest that Synthes could have redesigned the screw in terms of dimensions. Lieberman limits his alternative design opinions to what Synthes could have done to make the screw stronger. Lieberman Dep., 76, Synthes Ex. S.

[5] Lieberman admitted that his design plan of shot peening only exists in his mind and that he does have a plan but does not have "specific details." Lieberman Dep., 77-78, Synthes Ex. S.

was a Spring 2008 article in the magazine "The Shot Peener" called *Validating the Shot Peening Process*. Lieberman found this article on the internet and the article had no specific author and did not appear to be peer-reviewed. Lieberman Dep., 203-206, Synthes Ex. S. Lieberman testified that while the subject matter of the article refers to surgical crews, cancellous screws with their specific thread configuration were not addressed in the article. *Id*. at 209, 244.

Additionally, Lieberman also proposed that Synthes should have investigated gray anodization[6] as a mean to improve the fatigue strength of the cancellous screws. *Id*. at 257. Lieberman postulated that gray anodization would have improved the fatigue curve ten to twenty percent. *Id*. at 258. Lieberman supported his opinion on gray anodization with an article entitled *Surface Treatments of Titanium Implants*. Lieberman explained that he found this article on the internet, does not know the academic or professional background of the author, and doesn't know if the article was peer reviewed. *Id*. at 255-56.

Finally, Lieberman opined that Synthes could have used dye penetrant testing to identify potential surface flaws in the materials used to manufacture the screws. *Id*. at 190. Dye penetrant testing involves spraying a low viscosity dye on the surface of a material which is subsequently removed leaving dye embedded in any flaws or cracks. *Id*. Lieberman asserted this alternative design theory based on an unauthored article from the internet site Wikipedia.[7] *Id*. at 223. Lieberman noted that the article did not discuss the use of dye penetrant inspection on surgical screws meant for spinal fusion surgery nor was he aware of any company that used such a procedure to inspect screws meant for spinal fusion surgery. *Id*. Further, Lieberman could not identify a kit for dye penetrant testing that has been approved for use on a screw meant for

[6] In his reports and deposition, Lieberman never defined gray anodization or explained the process. Dr. Zardiackas explained that gray anodization is a process which "imparts a gray color to the surface, imparts increased lubricity and increases the fatigue strength of titanium." Zardiackas Aff., ¶ 17, Synthes Ex. I.

[7] Wikipedia is a free web-based encyclopedia written by individuals from all around the world. According to the website, almost all of its articles can be edited by anyone accessing the site which places its reliability and accuracy in question. *See* http://en.wikipedia.org/wiki/Wikipedia.

implantation into the body.[8] *Id*. at 231. Lieberman also did not perform any testing to determine whether chemical residue from dye penetrant testing could be completely removed prior to implantation. *Id*. at 268.

2. *Daubert* Expert Witness Analysis

a. *Expert's Qualifications*

The first step in determining the admissibility of an expert witness's testimony is for the court to determine if the witness is qualified. An expert is qualified where the witness possesses the requisite "knowledge, skill expertise, training or education." Fed. R. Evid. 702. This "qualification requirement of Rule 702 has been interpreted liberally" and the Court may accept a "broad range of knowledge, skills and training [to] qualify an expert." *In re Paoli*, 35 F.3d at 741. However, the Court must also set a floor with respect to expert witness's qualifications in so much as an expert must have "minimal qualifications, either through experience or education, in a field that is relevant to a subject which will assist the trier of fact." *Poust*, 998 F. Supp. at 491.

The admissibility of Mr. Lieberman's expert testimony hinges on whether Lieberman has the requisite qualification to offer testimony regarding how to make biomaterials and surgical devices meant for bodily implantation suitable for spinal fusion surgery. Lieberman is a metallurgical engineer with a long career at Boeing Company performing aircraft development. Synthes Exhibit E. Lieberman admittedly has no education, training or experience in medicine, fusion surgery, or internal fixation devices. Lieberman Dep., 8-9, 11-12, 35, Synthes Ex. S. Lieberman has never been employed by or consulted for a company that designs, manufacturers

[8] At his deposition, Lieberman testified that he did not believe there would be any difference between dye penetrant materials used on a screw for human implantation compared to those for use in a mechanical application. Lieberman Dep., 233, Synthes Ex. S. Subsequently, however, Lieberman conceded that he has never studied biocompatibility and does not know if the body would have an immune or autoimmune response to such materials. *Id*. at 236-37, 271.

or tests medical devices. *Id*. at 35. Lieberman has never designed a medical device or conducted clinical trials of a medical device. *Id*. 35-37. Lieberman does not consider himself an expert with respect to spinal fusion and admitted that he has no formal training in orthopedics and has never observed a surgical procedure. *Id*. at 20, 43. Additionally, Lieberman has never published any scientific papers with respect to medical devices. *Id*. at 36. Lieberman has never taught, given lectures or written any peer-reviewed articles on spinal surgery, orthopedic surgery, medical devices, biomechanics or the effect of blood, body tissue and bone on implantable surgical devices. *Id*. at 22-23.

This lack of specific expertise on the subject matter of the case was shown numerous times throughout Lieberman's deposition. For instance, Lieberman admitted that he had to "look up on the internet to understand the structure of the spine, just to get a feel for where was this implant done." *Id*. at 38. He conceded that he has no expertise with respect to how spinal surgery is supposed to reduce a patient's pain or the steps a surgeon takes to implant a spinal fusion device. *Id*. at 39, 53-54. Additionally, Lieberman admitted that had never heard of some the basic tenets of fusion surgery and fixation devices such as the "race to fusion" and the term stress shielding. *Id*. at 59-62, 64.

While the standard to deem an expert "qualified" is liberally applied, in this case, the Court finds that Lieberman does not have even the minimal qualifications, experience or education, in a field that is relevant to a subject which will assist the trier of fact. Lieberman clearly is qualified to attest to the properties of metal generally; however, to assist a trier of fact in determining whether Synthes could have produced a stronger screw for implantation, such general knowledge on metal does not suffice. Given Lieberman's lack of education, training and

experience in the fields of internal fixation devices, biomaterials, orthopedics and fusion surgery, his testimony is not relevant to the subject matter of this case.

b. *Reliable Methodology*

The second requirement under Rule 702 is that an expert must testify to "scientific, technical or other specialized knowledge . . . ." Fed. R. Evid. 702. The Court in *Daubert* explained that an expert's testimony must be grounded in the methods and procedures of science, provide more than a subjective belief or unsupported speculation, and be not only relevant, but reliable. *Daubert*, 509 U.S. at 589-90. "Proposed testimony must be supported by appropriate validation – i.e., 'good grounds,' based on what is known." *Id*. *Daubert* suggests several factors the court should consider when determining whether an opinion is reliable: (1) "whether a theory or technique can be (and has been) tested," (2) "whether the theory or technique has been subject to peer review and publication," (3) the frequency by which the methodology leads to erroneous results, (4) "the existence and maintenance of standards controlling the technique's operation," and (5) whether the methodology has been generally accepted in the scientific community. *Id*. at 593-94.

Here, Lieberman opined that Synthes should have utilized the alternative manufacturing methods of shot peening and gray anodization to improve the ATB screw's fatigue strength. Additionally, Lieberman suggests that Synthes should have used dye penetrant inspection to reveal surface flaws present in the screws. In analyzing the *Daubert* factors in light of Lieberman's recommendation of shot peening, none of the factors indicate a sound and reliable methodology. As an initial point, Lieberman has not written or documented a design plan for shot peening, the plan is only formulated in his mind and lacks specific details. Lieberman Dep., 77, Synthes Ex. S. Lieberman also has not performed any testing on shot peening cancellous

screws and was unaware of any manufacturers using shot peening for cancellous screws so as to indicate such a methodology would be generally accepted in the biomaterials community. *Id*. at 182, 215-17. Further, since his design exists only in his mind, Lieberman's opinion of shot peening cancellous screws has not been subject to peer-review or publication. *Id*. at 81, 83. Additionally, because this technique has not been tested, the frequency by which the methodology leads to erroneous results and the existence and maintenance of standards controlling the technique's operation would be purely speculative. While Lieberman indicated that he believed shot peening would improve the fatigue life of the screw, such an opinion has no grounding as he conceded that a "specific improvement on the fatigue life" could not be determined without testing and was unaware of any study that showed with statistical significance that shot-peened screws improved the fusion rate for spinal surgery. *Id*. at 98.

Additionally, Lieberman drew conclusions regarding the technique of shot peening and its ultimate feasibility simply based on the review of an article that was found on the internet, which had no specific author, did not appear to be subject to peer review and, most importantly, did not concern the same materials of the cancellous screws in question. *Id*. at 89, 209, 244. Repeatedly, Lieberman made assertions without the appropriate validation and which he did not substantiate. For instance, Lieberman opined without citation, testing or a medical background that there would be no negative impact on fusion if the medical device permanently took the entire load and no load was transferred to the bones. *Id*. at 121. Additionally, Lieberman promoted shot peening as an alternative design theory without showing any substantiated evidence that increasing the strength of the screw would not actually impede bone growth and fusion or whether shot peening would damage the specially-designed threads of cancellous screws. *Id*. at 182, 221-222, 246. Therefore, appearing to be based solely on Lieberman's

subjective belief and unsupported speculation, the Court finds that Mr. Lieberman's opinion advancing shot peening as an alternative design is not based on a reliable methodology according to the *Daubert* factors.

Similarly, Lieberman's suggestion that Synthes should have investigated[9] gray anodization to increase fatigue strength lacks a reliable basis. Lieberman has never performed testing of gray anodization to determine whether the technique is feasible, safe or would improve the life of cancellous screws. *Id*. at 274, 284. Additionally, Lieberman has not reviewed any tests by third parties that demonstrate that gray anodization improves fatigue strength for screws implanted in the human spine. *Id*. at 274. Further, Lieberman based his opinion solely on an article he found on the internet. *Id*. at 255. In regards to the article, Lieberman did not know anything about the professional or academic backgrounds of the authors and was not able to assess whether the article had been peer reviewed. *Id*. at 255-56. Moreover, the article's postulation regarding how gray anodization strengthens screws was not based on screws meant for implantation into the body. *Id*. at 259. Because Lieberman's recommendation of gray anodization appears to be highly speculative and has not satisfied the *Daubert* factors to qualify as being grounded in the methods and procedures of science, the Court finds that Lieberman's testimony regarding gray anodization is not reliable.

Finally, Lieberman testified that as an alternative manufacturing method Synthes should have used dye penetrant testing to reveal any surface flaws in their ATB screws. In support of this recommendation, Lieberman relied on an article found on Wikipedia. *Id*. at 223. Since Wikipedia is an on-line encyclopedia which could be written and edited by any internet user,

[9] Lieberman clarified in his deposition that he was not suggesting that Synthes should have utilized gray anodization, but only that they should have investigated the use of gray anodization. Lieberman Dep., 257, Synthes Ex. S. Such a statement seems to suggest that Lieberman does not have the "good grounds" to provide a trier of fact with an opinion that gray anodization is a feasible alternative design theory.

such an article is not grounded in any legitimacy or reliability with regards to scientific authority. Notwithstanding the fact that the article had no author and has not been peer reviewed, the subject matter also does not address dye penetrant inspection in relation to surgical screws meant for spinal fusion surgery. *Id*. Furthermore, Lieberman was not aware whether dye penetrant had ever been used on surgical screws and could not identify a company that used such a procedure to inspect screws meant for spinal fusion surgery. *Id*. Lieberman also did not perform any testing to determine whether chemical residue from dye penetrant testing could be completely removed prior to implantation or whether the solvents were biocompatible with humans. *Id*. at 268, 271-72. As part of his recommendation, Lieberman also failed to provide an analysis as to whether it would be feasible from a manufacturing and cost perspective to dye penetrant test surgical screws. *Id*. at 238. Therefore, the Court finds that Lieberman's opinion on dye penetrant testing lacks reliable scientific grounds.

c. *Opinion Fits the Facts of the Case*

The final requirement in determining the admissibility of an expert's testimony is that such testimony must assist the trier of fact. For an expert's testimony to "fit' the facts of the case, the testimony proffered must be "sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." *Daubert*, 509 U.S at 591 (quoting *United States v. Downing*, 753 F.2d 1224, 1242 (3d Cir. 1985)). "Expert testimony which does not relate to any issue in the case is not relevant and ergo, non-helpful." *Id*. (quoting 3 Weinstein & Berger 702-18). *Daubert* explains that "fit" is "not always obvious and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes." *Id*. A court need not admit evidence "which is connected to existing data only by the *ipse dixit* of the expert . . . [where]

there is simply too great an analytical gap between the data and the opinion proffered." *GE v. Joiner*, 522 U.S. 136, 146 (1997).

Here, the Court finds that Lieberman's purported testimony would not assist the trier of fact because his opinion does not "fit" the facts of the case. Notwithstanding the fact that Lieberman is not qualified as an expert or that the basis for his opinions are not reliable, Lieberman's testimony is limited to basic techniques on how to strengthen metal screws. There is no apparent connection to his theories that will strengthen screws generally and legitimate alternative design theories for medical screws for implantation in the human body. The issue at hand cannot be resolved without some discussion of biomechanics, which Lieberman is not qualified to provide. Beyond Lieberman's unqualified opinion that basic metal strengthening techniques are applicable to devices placed in the body, the opinion proffered provides no substantiation to Plaintiffs' "more robust screw" design. As such, Lieberman fails to provide testimony of an alternative design method for cancellous screws and, therefore, his opinion does not fit the facts of this case.

According to the requirements of *Daubert* and Fed. R. Evid. 702, Lieberman's testimony fails to provide reliable scientific, technical or other specialized knowledge which will assist the fact finder. Hence, the Court finds that Lieberman is precluded from testifying. Without Mr. Lieberman's testimony, Plaintiffs have failed to present any feasible or practical alternative design theories to support their defect-design product liability action. Plaintiffs cannot establish without expert testimony a factual basis for their theory that "a more robust screw design would have provided a more resilient, stronger screw that would have lasted long enough for fusion to take hold." Therefore, the Court grants Defendants' motion for summary judgment as to their alternative design claim.

ii. *Adequacy of Warnings*

Similar to their alternative design claim, Plaintiffs' theories for a claim of inadequate warnings under NJPLA are unsupported by expert testimony. Plaintiffs have based their argument on the premise that the warnings were inadequate because Synthes' package insert did "not warn that the implant could fail within the normal time period for fusion to take place." Plaintiffs, however, have failed to provide expert medical testimony refuting Defendants' "race to fusion theory" and supporting their own theory that the hardware's failure caused the lack of fusion. As this is crucial to their inadequate warning claim, their claims must ultimately fail. Further, Plaintiffs have not offered testimony of any expert to support their criticisms of Synthes' warnings. Without a qualified expert's opinion, Plaintiffs have not refuted Defendant's expert Dr. Joel Spielman's testimony that the package insert contains appropriate information as to the risks and benefits of the ATB system. *See* Levine Dep., 21-22, Synthes Ex. R; Spielman Rpt., 7, Synthes Ex. H. Additionally, the only expert offered by Plaintiffs, Lieberman, testified that he had no criticisms of the package insert and did not find anything contrary in the warning to his own conclusions. Lieberman Dep., 108-109, Synthes Ex. S. Hence, because Plaintiffs have not met their burden of providing any evidence to support their claims for inadequate warnings, the Court grants Defendants' motion for summary judgment as to such claims.

III. Conclusion

For the reasons set forth above, the Defendants' motion for summary judgment is granted and this case is closed. An appropriate Order accompanies this Opinion.

/s/ JOEL A. PISANO
United States District Judge

Date: August 19, 2010