IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION

MARTHA CARLSON,

Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION,

Defendant.

LEAD CASE NO. 5:15-CV-57

Individual Case No. 3:15-CV-211

PLAINTIFF'S TRIAL BRIEF

This is a personal injury product liability action arising from severe and permanent injuries sustained by Martha Carlson as a result of being surgically implanted with a defective and dangerous Uphold synthetic vaginal mesh device manufactured by Boston Scientific Corporation. The live causes of action allege: negligent design defect, breach of implied warranty of merchantability, and punitive damages. Plaintiff is also awaiting the Court's Order on her Motion for Reconsideration on the issue of negligent failure to warn, which she believes was improperly dismissed. The defects Martha Carlson will prove in this trial include:

(1) The Uphold mesh—marketed and sold as "permanent" and "flexible" for implantation in the human body—is, in fact, made of impure, non-medical-grade polypropylene, and shrinks, hardens, bunches, and degrades;

(2) The weave of the mesh produces very small interstices which allow bacteria to enter and to hide from the host defenses designed to eliminate them; this same weave entraps nerves, causing permanent pelvic pain;

(3) Removing all the mesh is extremely difficult, if not impossible, because the tensile strength of the polypropylene in its process of degradation is lower than the strength of the cells attaching it to the body, so when surgeons try to uproot the mesh it breaks into smaller pieces that remain in the body.

LIABILITY

Boston Scientific Made Its Uphold Vaginal Mesh Implant From Non-Medical-Grade Polypropylene That Shrinks, Hardens, Twists and Degrades in the Human Body After Implant

The raw material that Boston Scientific used to make the Uphold mesh that was implanted in Martha Carlson was a non-medical-grade, petroleum-based product manufactured by Chevron Phillips (later Phillips Sumika) and marketed under the trade name Marlex. The Manufacturers Safety Data Sheet for Marlex at the time Boston Scientific obtained the Marlex included the following warning:

> "**MEDICAL APPLICATION CAUTION: DO NOT USE THIS CHEVRON PHILLIPS CHEMICAL MATERIAL IN MEDICAL APPLICATIONS INVOLVING PERMANENT CONTACT WITH INTERNAL BODILY FLUIDS OR TISSUES**."

Polypropylene, when implanted in the human body, is known to induce an acute inflammatory response, chronic inflammatory reaction, and a well-documented foreign-body response. Polypropylene mesh implanted in the vagina degrades, shrinks, twists, bunches and becomes stiff, which leads to many adverse consequences. The fact that polypropylene degrades after implant has been known within the industry since at least 1984. Studies of explanted mesh have revealed degradation and mesh surface changes, including cracks, surface roughness and peeling. This degradation elicits a continued foreign-body response, which in turn results in increasing levels of long-term, chronic pain.

Boston Scientific Has a History of Putting Dangerous Pelvic Health Products on the Market Without Proper Clinical Testing

In the 1990s, Boston Scientific introduced a collagen synthetic vaginal sling on the market with disastrous results. This sling—marketed and sold as Protogen—was ultimately recalled after large numbers of women experienced serious, life-altering complications,

including high rates of erosion and infections. The evidence will show that Boston Scientific performed no clinical trials of the Uphold device before it sold the product for human implantation.

DAMAGES

On July 16, 2010, then-65-year-old Martha Carlson was implanted with Boston Scientific's Uphold system by Michael Kennelly, MD at Carolinas Medical Center in Charlotte North Carolina. Her operative report does not indicate any improper technique in the placement of the Uphold.

Ms. Carlson had a relatively uncomplicated post-operative course, except for approximately three months of vulvar pain that completely resolved in a relatively short period of time.

Ms. Carlson suffers chronic and debilitating vaginal pain, incontinence, and sexual discomfort caused by a shrunken, hardened, twisting and degrading vaginal implant device that cannot be safely removed. She seeks damages for permanent and partial disability; chronic physical and mental pain and suffering (past and future); deprivation of enjoyment of life; nonmedical expenses; reasonable attorney fees; punitive damages; interest and costs as provided by law; and all other relief to which she is entitled.

ISSUES OF LAW

Plaintiff's Claim for Negligent Design

Plaintiff will prove the Uphold device was negligently designed. Following her implantation with the Uphold device, Ms. Carlson suffered from severe and persistent vaginal pain, pelvic pain, groin pain, abdominal pain, and bowel and urinary complications. Plaintiff will

provide expert testimony opining that the Uphold is capable of causing chronic and persistent pelvic pain, vaginal pain, groin and leg pain, and bowel and urinary complications. Plaintiff will also present evidence that her pelvic and vaginal pain, persistent pain in other areas, and her bowel and urinary problems have been caused by the Uphold device. Ms. Carlson will testify that she would have sought other options had she been informed of the risks associated with the Uphold device.

Plaintiff will put forth significant evidence, including expert testimony, that Boston Scientific acted unreasonably in the design of the Uphold device; that safer, practical, feasible, and otherwise reasonable alternative designs make the risks associated with the Uphold unreasonable and its utility questionable at best; that the Uphold device proximately caused Ms. Carlson's injuries, and that Boston Scientific failed to adopt a safer, practical, feasible, and otherwise reasonable alternative design that was available to it at the time Ms. Carlson was implanted with the Uphold device.

Plaintiff's Claim of Implied Warranty of Merchantability

To establish a breach of implied warranty of merchantability, a plaintiff must prove the following elements: (1) "that the goods bought and sold were subject to an implied warranty of merchantability"; (2) "that the goods did not comply with the warranty in that the goods were defective at the time of sale"; (3) "that [her] injury was due to the defective nature of the goods"; and (4) "that damages were suffered as a result." *Morrison v. Sears, Roebuck & Co.*, 319 N.C. at 301, 354 S.E.2d at 497 (quoting *Cockerham v. Ward*, 44 N.C. App. 615, 624-25, 262 S.E.2d 651, 658 (1980)).

North Carolina law further provides that if a consumer has relied on warnings, directions and implied warranties attached to a product and is injured by the product and the consumer's use conformed to those directions, the correct inquiry is "whether, in view of the consumer's reliance upon the warnings, directions and implied warranties, any inadequacy of the warnings was the proximate cause of the consumer's injuries." N.C.G.S. § 25-2-314; *see also Reid v. Eckerds Drugs, Inc.*, 253 S.E.2d 344, 349 (1979). In addition, North Carolina law clearly provides that the sufficiency and adequacy of warnings is a question of fact for the jury to decide. *Reid*, 253 S.E.2d at 349.

Plaintiff will present evidence that neither she nor her doctor was warned about the complications and risks associated with the Uphold device, or about the extent of the serious complications now suffered by Ms. Carlson. Plaintiff will further present evidence that if her doctor had been properly informed of all the complications and risks associated with the Uphold, he would have provided this information to Plaintiff.

Prima Facie Evidence Supports Reinstating Plaintiff's Failure To Warn Claim

On April 29, 2015, the MDL Court granted summary judgment in favor of Boston Scientific on, *inter alia*, Plaintiff's claim for negligent failure to warn. In its Memorandum and Order (hereinafter, "Order"), the MDL Court ruled on the mistaken belief that "the record is void of any evidence that would permit a reasonable juror to infer that Dr. Kennelly read or relied on the Uphold DFU in prescribing the device to Ms. Carlson." Order at 7.

However, Dr. Kennelly testified on multiple occasions that he did, in fact, read and rely on the Uphold DFU in prescribing it to Plaintiff. Dr. Kennelly clearly testified that he reviewed the Uphold DFU prior to Plaintiff's surgery and was familiar with its contents. Kennelly Dep.

58:21-24; 67:13-16, July 2, 2014. He also testified that product DFUs are among the sources of information upon which he relies in the treatment of his patients, and that he reasonably relied on BSC to disclose information about all risks associated with their products as well as the severity of those risks. *Id.* at 147:20-148:1; 175:24-176:7. Dr. Kennelly specifically testified that he relied on the Uphold DFU, among other sources, in his risk-benefit analysis when deciding to prescribe the Uphold device to Plaintiff. *Id.* at 83:13-17.

Dr. Kennelly testified that, if he had had additional information about the risks associated with the Uphold product, such as occurrence rates for the risks listed in the DFU, he would have taken this information into consideration when deciding whether or not to recommend the Uphold product to Plaintiff. *Id.* at 176:24-177:1, 3-9, 17-19. He also testified that, if he had had additional information about the risks associated with the Uphold product, he would have communicated that information to Plaintiff. *Id.* at 190:16-22; 190:25-191:7.

CONCLUSION

Boston Scientific knew the Uphold would shrink and degrade, but told doctors and patients that it was appropriate for use as a permanent implant.

Boston Scientific knew that when the Uphold shrank and degraded it would cause pain, and knew that the only way to effect even a partial cure was removal, but never told doctors or patients that removal would be nearly impossible.

Boston Scientific acted unreasonably in manufacturing a product that no person (man or woman) would allow to be permanently implanted inside their body if they knew the true facts about the shortcomings in its design and manufacture.

A jury in this case will determine that Boston Scientific negligently designed this product and breached its duty to Ms. Carlson, leaving her with life-altering, inoperable complications.

Dated: September 21, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 21, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this matter.

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