SUPREME COURT - STATE OF NEW YORK

PRESENT: ***Honorable Anna R. Anzalone***
Justice of the Supreme Court

----------x

FRANCIS MCGOVERN,

Plaintiff,

- against -

DAVOL INC. and C.R. BARD, INC.,

Defendants.

----------x

TRIAL/IAS, PART 20
NASSAU COUNTY

Index No. 603965/14

Motion Seq. No.: 002

The following papers read on this motion:

Motion for Summary Judgment	1
Memo of Law in Support of Summary Judgment	2
Affirmation in Support of Summary Judgment	3
Affirmation in Opposition	4
Memo of Law in Further Support of Summary Judgment	5
Affirmation in Further Support of Summary Judgment	6

Motion by Defendants for an Order of this Court, pursuant to CPLR 3212, granting summary judgment dismissing Plaintiff's Complaint, is determined as hereinafter provided.

In this action, Plaintiff, FRANCIS MCGOVERN, seeks to recover for strict products liability and breach of implied warranty of fitness and/or merchantability from Defendants, DAVOL INC. (Davol) and C.R. BARD, INC. (Bard). Plaintiff has alleged that the Defendants negligently designed, manufactured, tested, and marketed their product, Marlex mesh, as a medical device safe for permanent implantation into the human body. Marlex mesh was implanted in Plaintiff in 1995 as part of a hernia repair surgery, and was ultimately removed in a 2012 surgery.

Specifically, Plaintiff alleges that the Defendants introduced Marlex mesh to the medical community and the public at large, unaccompanied by any, or improper, warnings regarding the known risks of polypropylene, the material used to make Marlex mesh, the design of Marlex mesh's pore size, and the medical risks of permanent implantation in the human body. Plaintiff further alleges that it was known to Defendants at the time of her 1995 surgery that Marlex mesh should not be used for permanent implantation, and that Defendants improperly shielded this information.

Plaintiff testified in her Examination Before Trial (EBT) that on July 11, 1995, Dr. Lawrence A. Gordon performed surgery to repair an umbilical incisional

hernia (see Defendants' Exhibit 10). She adds that she had previously been hospitalized for abdominal issues in November of 1994, at which time a colostomy was performed (*Id.* at p. 47). A reversal of the colostomy was performed in January of 1995 (*Id.* at p. 48). Plaintiff testified that, following the July 11, 1995 hernia repair surgery, she felt okay (*Id.* at pp. 49-50). Plaintiff did not recall having any problems relating to her 1995 surgery prior to September of 2011 (*Id.* at p. 80).

In September of 2011, Plaintiff started experiencing symptoms associated with a recurrent hernia (*Id.* at p. 81). On March 12, 2012, Dr. Tereza Sardinha performed a surgical procedure to repair the hernia (*Id.* at p. 84). Plaintiff testified that, after the surgery, Dr. Sardinha told her that the Marlex mesh from her 1995 surgery was what had caused the problem (*Id.* at p. 92). Plaintiff's understanding, from speaking with Dr. Sardinha, was that the mesh had wrapped around and attached to certain body tissue, and the time needed to remove the mesh caused the surgery to take much longer than anticipated (*Id.* at p. 93).

Soon after the March 12, 2012 surgery, Plaintiff began experiencing complications which required an additional surgery, blood transfusions, and placement of multiple drains to remove fluid from Plaintiff's abdominal cavity (*Id.*

at pp. 94-7). After returning to work and feeling okay, Plaintiff again began to feel discomfort, though she does not recollect when this began (*Id.* at pp. 98-100). Plaintiff testified that her doctor, Dr. Smolow, told her that a new hernia had formed as a result of her 2012 surgery, which Plaintiff believes is attributable to the Marlex mesh (*Id.* at pp. 14-17).

Stephen Eldridge is an employee of Davol, which is a subsidiary of Bard. He testified in his Examination Before Trial that he has been employed as Senior Research and Development Manager since 2004, and that prior to 2004 he had worked for various divisions of Bard dating back to the 1980s (see Plaintiff's exhibit F). His responsibilities include evaluating new technology, analyzing designs of products, and ensuring compliance with U.S. Food and Drug Administration (FDA) regulations (*Id.* at pp. 12-13).

Mr. Eldridge testified that Marlex mesh was developed in the late 1950's, and that there have been no design changes since the underlying material was changed to polypropylene in the early 1960's (*Id.* at pp. 19-20). A third-party company named Shakespeare acquires polypropylene from another third-party company named Chevron Phillips, and Shakespeare will then extrude the

polypropylene into a monofilament, which would then be purchased by the Defendants (*Id.* at pp. 50-1).

Mr. Eldridge further testified that, whenever a new product was developed, a biocompatibility evaluation, involving eight to ten standardized tests relied upon by the FDA, would be performed (*Id.* at p. 57). He adds that medical device companies test their products to prove that materials are safe for implantation, and that any recommendations from manufacturers would not be related to use in medical implantation (*Id.* at pp. 67-9). For example, if an issue existed with the heating process used to manufacture Marlex mesh, the biocompatibility testing would detect it (*Id.* at pp. 84-5). Mr. Eldridge notes that Marlex mesh is a "pre-amendment device," since it was on the market before FDA regulations came into effect (*Id.* at p. 95). However, a product called "Marlex dart," which is a specific configuration made from Marlex mesh, underwent a design change to better suit a certain type of surgical procedure and was therefore subjected to the FDA's premarket notification process in 1992 (*Id.* at pp. 113-5).

A party moving for summary judgment must make a *prima facie* showing of entitlement to judgment as a matter of law, offering sufficient evidence to demonstrate the absence of any material issues of fact (*see Winegrad v. New*

York Univ. Med. Ctr., 64 N.Y.2d 851 [1985]; *see also Zuckerman v. City of New York*, 49 N.Y.2d 557 [1980]). Once such a *prima facie* showing has been made, the burden shifts to the party opposing the motion for summary judgment to produce evidentiary proof in admissible form sufficient to raise material issues of fact which require a trial of the action (*see Alvarez v. Prospect Hosp.*, 68 N.Y.2d 320 [1986], *see also Zuckerman v. City of New York, supra*). However, bald, conclusory assertions or speculation and "[a] shadowy semblance of an issue" are insufficient to defeat summary judgment (*Stonehill Capital Mgt. LLC v. Bank of the W.*, 28 N.Y.3d 439 [2016]).

In order to establish a strict products liability claim or a claim based upon a breach of warranty theory, the Plaintiff has the burden of establishing that a defect in the product was a substantial factor in causing the injury and that the defect existed at the time the product left the manufacturer or other entity in the chain of distribution being sued (*see Speller v. Sears, Roebuck & Co.*, 100 N.Y.2d 38 [2003]; *Simon v. Nortrax N.E., LLC*, 94 A.D.3d 861 [2d Dept. 2012]; *Beckford v. Pantresse, Inc.*, 51 A.D.3d 958 [2d Dept. 2008]).

"A product may be defective when it contains a manufacturing flaw, is defectively designed or is not accompanied by adequate warnings for its use"

(*Guzzi v. City of New York*, 84 A.D.3d 871 [2d Dept. 2011]; *see also Liriano v. Hobart Corp.*, 92 N.Y.2d 232 [1998]; *Gebo v. Black Clawson Co.*, 92 N.Y.2d 387 [1998]).

"In a products liability case, 'if a defendant comes forward with any evidence that the accident was not necessarily attributable to a defect, the plaintiff must then produce evidence of a defect' in order to defeat the motion" (*Guzzi v. City of New York, supra quoting Schneidman v. Whitaker Co.*, 304 A.D.2d 642 [2d Dept. 2003]).

"'[A] defectively designed product is one which, at the time it leaves the sellers hands, is in a condition not reasonably contemplated by the ultimate consumer and is unreasonably dangerous for its intended use' and 'whose utility does not outweigh the danger inherent in its introduction into the stream of commerce'" (*Hoover v. New Holland N. Am., Inc.*, 23 N.Y.3d 41 [2014] *quoting Voss v. Black & Decker Mfg. Co.*, 59 N.Y.2d 102 [1983]; *Robinson v. Reed-Prentice Div. of Machine Co.*, 49 N.Y.2d 471 [1980]). "To establish a *prima facie* case for design defect, the plaintiff must show that the defendant 'breached its duty to market safe products when it marketed a product designed so that it was not reasonably safe and that the defective design was a substantial factor in

causing plaintiff's injury'" (*Hoover v. New Holland N. Am. Inc., supra quoting Voss v. Black & Decker Mfg. Co., supra* at p. 107).

"While the manufacturer is under a nondelegable duty to design and produce a product that is not defective, that responsibility is gauged as of the time the product leaves the manufacturer's hands" (*Robinson v. Reed-Prentice Div. of Machine Co., supra*). Further, "[a] manufacturer need not incorporate safety features into its product so as to guarantee that no harm will come to every user no matter how careless or reckless... The duty of a manufacturer, therefore, is not an open-ended one. It extends to the design and manufacture of a finished product which is safe at the time of sale" (*Robinson v. Reed-Prentice Div. of Machine Co., supra*; *Hoover v. New Holland N. Am., Inc., supra*).

In 1976, Congress enacted the Medical Device Amendments to, in the words of the statute's preamble, "provide for the safety and effectiveness of medical devices intended for human use" (Pub L 94-295, 90 US Stat 539 [MDA]). Devices already on the market as of 1976 were "grandfathered" in without FDA approval (*see* 21 USC § 360c [f] [1] [A] [i] [I]).

In support of their motion, Defendants submit, *inter alia*, the affidavit of Peter L. Geller, M.D., FACS, the affidavit of Dr. Maureen Reitman, the affidavit

of Karen Becker, Ph.D., and the Examination Before Trial transcripts of Dr. Gordon and Dr. Sardinha.

Dr. Reitman is employed as Principal Engineer, Corporate Vice President and Director of Polymer Science & Materials Chemistry at Exponent, an engineering firm dedicated to engineering and scientific analysis (see Defendants' exhibit 12). Dr. Reitman describes that polypropylene was introduced in the 1960's, is the most commonly used material for use in repairing certain types of hernias, and is associated with a decrease in recurrence rate of hernias (*Id.* at p. 2). Dr. Reitman states that "Marlex mesh is recognized as a biocompatible material with decades-long history of successful clinical use" (*Id.* at p. 3). Having reviewed the manufacturing records for the lot related to Plaintiff's mesh, she found no indication of a manufacturing defect (*Id*). Further, Dr. Reitman's firm conducted independent testing and found that the material remains stable in the body and is not subject to oxidative degradation (*Id*). Dr. Reitman opines that the design and development of Marlex mesh was performed in accordance with accepted engineering and scientific practices (*Id.* at p. 4).

Dr. Becker is employed as Managing Director for Translational and Regulatory Sciences at Precision for Medicine, Inc., which provides scientific and

regulatory solutions in support of research, development, marketing authorization and regulatory compliance for healthcare products regulated by the FDA (*see* Defendants' exhibit 13). Dr. Becker describes the FDA's regulation of medical devices under the Medical Device Amendment of 1976, as well as the Premarket Notification process, commonly referred to as a "510(k) submission" (*Id.* at p. 3). Exceptions exist to the 510(k) submission requirements, including for "pre-amendment devices" like Marlex mesh, and as such, Marlex mesh was properly introduced into interstate commerce without the need for a 510(k) submission (*Id*). Device manufacturers are further obligated to establish and follow quality systems to ensure compliance with FDA regulations as well as their own specifications (*Id*). Having reviewed the manufacturing documents for the specific Marlex mesh implanted in Plaintiff, Dr. Becker observed no evidence that the Defendants deviated from specifications in the manufacture of Marlex mesh (*Id.* at pp. 3-4). Dr. Becker additionally reviewed the Instructions For Use (IFU) that may have accompanied Marlex mesh around the time of Plaintiff's 1995 surgery, and opines that the IFU adequately informs physicians of the known risks associated with Marlex mesh, and reasonably addresses potential risks and complications (*Id.* at p. 4).

Dr. Geller was the Director of Columbia University Hernia Center and Professor of Surgery at Columbia University Medical Center until his recent retirement (*see* Defendants' exhibit 11). Dr. Geller has performed thousands of hernia repair surgeries, the vast majority of which have included some type of mesh because of the high likelihood of recurrence if mesh is not used (*Id.* at p. 1). Dr. Geller describes how hernias can form and recur, as well as the purpose of hernia repair surgery, which is to relieve pain and to reduce the risk of complications (*Id.* at p. 2). He notes that all surgeons who repair ventral hernias are aware of the risks, which include infection, bleeding resulting in hematoma, hernia recurrence, adhesion formation and chronic pain (*Id.* at p. 3). He further explains that, while these complications can occur regardless of whether mesh is used, the vast majority of surgeons choose to use mesh because of the lower recurrence rate and because it is well established to be safe and effective (*Id*). Dr. Geller further opines that the IFU that may have accompanied Marlex mesh at the time it was implanted in Plaintiff provided adequate warnings and reasonably addressed risks and complications (*Id.* at p. 6). As such, Dr. Geller opines that Plaintiff's treating surgeons were appropriately informed of risks associated with Marlex mesh (*Id*).

Dr. Geller additionally describes Plaintiff's condition at the time of her 2012 surgery, including the initial diagnosis of incisional hernia and a small bowel obstruction with pelvic adhesions, as well as Dr. Sardinha's discovery of multiple ventral hernias including a large right ilium hernia containing unobstructed loops of colon and distal small bowel (*Id.* at p. 4). Dr. Sardinha performed an exploratory laparotomy, which included extensive lysis of adhesions, left ovarian cystectomy, hernia repair and abdominal wall reconstruction with Strattuce mesh (*Id*). Dr. Geller notes that, within a year of this surgery, following an office visit in which Dr. Sardinha deemed Plaintiff fully recovered, Plaintiff's abdominal pain returned and she was diagnosed with a new hernia, for which she has not sought treatment to date (*Id*).

Dr. Geller opines that Plaintiff's abdominal pain and the adhesions found in her 2012 surgery were not caused by any failure of the Marlex mesh, noting that Dr. Sardinha did not find any tear or defect in the mesh (*Id.* at p. 5). Rather, Dr. Geller opines, Plaintiff's history of sporadic abdominal pain is consistent with her development of new hernias (*Id*). Dr. Geller notes that Dr. Sardinha had offered multiple possible causes why the Marlex mesh may have adjusted, including the sutures used by Dr. Gordon and the Plaintiff's body habitus, which could have

created tension on her abdominal wall which led to the new hernia (*Id.* at p. 5). Dr. Geller concludes that Plaintiff's symptoms are inconsistent with any injury caused by Marlex mesh (*Id.* at p. 7).

In his EBT, Dr. Gordon testified that in his career, he performed hundreds or possibly thousands of hernia repair surgeries using mesh (see Defendants' exhibit 5). He added he understood Marlex mesh to be intended for permanent use (*Id.* at p. 20). It was Dr. Gordon's custom and practice to warn his patients about possible issues that might arise prior to surgery (*Id.* at p. 19). Dr. Gordon has never had to remove a mesh, and would not typically include a discussion with patients about what might be entailed if a mesh would have to be removed, since the mesh was intended to be permanent (*Id.* at p. 27). Dr. Gordon further testified that Marlex mesh was the standard mesh at the time of Plaintiff's surgery, and that addressing incisional hernias without the use of mesh would have caused the recurrence rate to be unacceptably high (*Id.* at p. 22). Dr. Gordon did not recall any other types of materials that were used in meshes in 1995 (*Id*).

Dr. Gordon explained that the use of mesh does not cause recurrent hernias, nor does it eliminate the possibility of recurrence, rather it cuts down on the recurrence rate (*Id.* at p. 23). Throughout his career, Dr. Gordon would learn

about issues or complications with medical devices such as mesh through a variety of means, including reading medical journals and attending conferences and meetings, as well as possibly through information disseminated by manufacturers (*Id.* at p. 15).

Dr. Sardinha testified in her EBT that she removed the Marlex mesh that was implanted by Dr. Gordon in a March 12, 2012 surgery (*see* Defendants' exhibit 8). The surgery began with an exploratory laparotomy, revealing Plaintiff's history of bowel obstructions as well as adhesions due to multiple previous surgeries, which occur regardless of whether mesh was used (*Id.* at pp. 33-4). To perform the surgery, Dr. Sardinha had to completely remove the mesh from Plaintiff's abdominal wall (*Id.* at p. 35). Dr. Sardinha addressed two hernias which she found around the Marlex mesh (*Id.* at p. 36). Dr. Sardinha did not identify a defect in the Marlex mesh, but found it was retracted to the side (*Id.* at pp. 37-8). She stated that there was nothing unusual about the appearance of the Marlex mesh after it was removed (*Id.* at p. 50). Dr. Sardinha noted that there were no complications during the operation (*Id.* at pp. 46-7).

In sum, Defendants argue that there is no evidence of a defect or failure with regard to the Marlex mesh used on Plaintiff. Defendants point to Plaintiff's

extensive medical history, including multiple surgeries, recurrent hernias, diverticulitis, and obesity, as some of the many factors responsible for Plaintiff's injuries. Defendants further argue that Plaintiff is contributing to her own issues as she continues to refuse surgery on her latest hernia. Dr. Reitman concluded that the design and development of Marlex mesh was performed in accordance with accepted practices, Dr. Becker concluded that the Defendants are in compliance with FDA regulations and standards, and Dr. Geller found that Plaintiff's abdominal pain, hernias and adhesions were not due to any defect or failure of the Marlex mesh. In addition, Dr. Gordon stated that Marlex mesh was the standard of care at the time of Plaintiff's surgery and that he had not experienced any issues with Marlex mesh. Further, following Plaintiff's 2012 surgery, Dr. Sardinha found no complications to Plaintiff, nor defects or abnormalities to the Marlex mesh. In all, Defendants offer the opinion of three doctors, Dr. Gordon, Dr. Sardinha, and Dr. Geller, who each understood Marlex mesh to be safe for permanent implantation and to decrease the rate of hernia recurrence. As such, there is no indication that any design or manufacturing defect existed with regard to Marlex mesh, or that any alternate warning the Defendants could have possibly provided would have changed Dr. Gordon's decision to use Marlex mesh in Plaintiff's 1995 surgery.

The above evidence sufficiently establishes the Defendants' *prima facie* entitlement to judgment as a matter of law. Accordingly, the burden shifts to the Plaintiff to come forward with evidence to overcome the Defendants' submissions by demonstrating a triable issue of fact.

In opposition, the Plaintiff provides the affidavit of James Pugh, Ph.D. Dr. Pugh is the President and Director, as well as Director of Biomedical Engineering/Materials Science & Engineering of the Inter-City Testing & Consulting Corporation (*see* Plaintiff's exhibit A).

Dr. Pugh opines that the Defendants defectively designed Marlex mesh by using an unnecessarily small pore size, which in turn requires use of more polypropylene material than needed, resulting in a heavier mesh (*Id.* at p. 21). Dr. Pugh opines that the pore size of Marlex mesh creates unnecessary issues including inflammation, adhesions, and damage to the body that could be avoided by using mesh with larger pore size (*Id*). Dr. Pugh cites a 1985 study, which states that a pore size greater than 100 microns is needed for rapid ingrowth of vascularized connective tissue, and Dr. Pugh claims that the pore size of Marlex mesh ranges from 23 to 68 microns in length (*Id.* at p. 15). Dr. Pugh adds that Marlex mesh, as designed with small pores, causes more erosion of intra-

abdominal viscera, excessive scarring and adhesions, greater inflammatory responses, and loss of abdominal wall compliance, as well as increases in pain, discomfort, and other adverse effects (*Id.* at p. 22).

Dr. Pugh opines that Marlex mesh was unreasonably unsafe and defectively designed due to the use of polypropylene and/or using excessive, unnecessary amounts of polypropylene (*Id.* at p. 23). Dr. Pugh states that the Defendants knew or should have known that Marlex mesh is not fit for permanent implantation because the polypropylene used to make the mesh deteriorates inside the human body over time (*Id*). Dr. Pugh describes a thermal heating process that takes place when the polypropylene is manufactured, and opines that the Defendants knew or should have known that this process would cause degradation of the polypropylene materials (*Id.* at pp. 23-4). Dr. Pugh additionally opines that polypropylene is susceptible to oxidation, and that if oxidized, polypropylene could be expected to degrade or deteriorate inside the human body (*Id.* at pp. 24-6).

Dr. Pugh further opines that the Defendants failed to properly warn of the risks that Marlex mesh could be susceptible to degradation, shrinkage, or that subsequent infection could require removal of mesh (*Id.* at pp. 29-30).

On reply, Defendants note that Plaintiff improperly reports the pore size of Marlex mesh based on an error in the 1985 study cited by Dr. Pugh. Defendants provide an additional affidavit of Dr. Reitman, who states that she directly examined Marlex mesh and that the pore size ranges from 200 to 800 microns (*see* Defendants' Reply, exhibit B). Dr. Reitman notes that, contrary to Dr. Pugh's contentions, a contributor to the 1985 study cited by Dr. Pugh acknowledged in a subsequent 1989 study that the measurements regarding Marlex mesh's pore size were incorrectly reported in the 1985 study (*Id.* at p. 3). Dr. Reitman additionally provides a Scanning Electron Micrograph with a scale bar, depicting Marlex mesh's pore size as 476 microns (*Id.* at p. 4).

Dr. Reitman adds that Dr. Pugh's conclusions are based on studies of polypropylene products with conditions different to those of the Marlex mesh implanted in Plaintiff, such as unstabilized polypropylene and polypropylene from other manufacturers that differ in specific composition (*Id.* at p. 6). Dr. Reitman further notes that, throughout decades of use and many studies regarding Marlex mesh as a surgical material, she has never seen so much as a suggestion that medical mesh made from polypropylene could degrade *in vivo* (*Id.* at p. 8).

Defendants additionally provide a reply affidavit of Dr. Geller, who notes that Dr. Pugh is not a medical doctor and has no experience in hernia surgery, and as such, should not be relied upon for clinical opinions regarding Plaintiff's medical outcomes (*see* Defendants' Reply, exhibit A). Dr. Geller reiterates that there is no evidence that the Marlex mesh degraded or shrunk while implanted in the Plaintiff, and that there is no defect in the Marlex mesh used on Plaintiff (*Id.* at p. 4). Dr. Geller distinguishes between the degradation or shrinkage referred to by Dr. Pugh and the situation where mesh merely loses fixation and becomes "balled up" (*Id*).

Here, Plaintiff fails to raise an issue of fact. The litany of issues that Plaintiff claims stem from the defective design of Marlex mesh are based upon a small pore size and therefore a heavier mesh with more polypropylene than would be present if the pore size were larger. However, the pore size is actually larger than Plaintiff claims necessary. As such, Plaintiff's allegations regarding any defect or complications due to the pore size of Marlex mesh are meritless. Further, as noted by Mr. Eldridge, biocompatibility testing, including animal testing, was performed and would have revealed any issues or complications

created by any processes, including the thermal heating process, associated with the manufacture of Marlex mesh.

None of the Plaintiff's submissions support her contention that Marlex mesh was known in 1995 to be unsafe as a medical device for permanent implantation, or that any unreasonably dangerous condition existed that outweighed its utility (*see Hoover v. New Holland N. Am. Inc., supra*). Even if such a showing was made, Plaintiff fails to provide a medical expert who could opine that such a defect was a substantial factor in causing Plaintiff's injury (*see Speller v. Sears, Roebuck & Co., supra*).

Accordingly, it is hereby

ORDERED, that the Defendants, DAVOL INC. and C.R. BARD, INC's motion seeking summary judgment dismissing the Plaintiff's complaint is **GRANTED**.

This decision constitutes the decision and Order of the Court.

DATED: March 5, 2018

ENTER:

ENTERED
MAR 15 2018
NASSAU COUNTY
COUNTY CLERK'S OFFICE

Anna R. Anzalone

Hon. Anna R. Anzalone, JSC