UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No.: 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
Johns v. CR Bard Inc., et al.,
Case No.: 2:18-cv-01509

CASE MANAGEMENT ORDER NO. 23-G

The Court held the final pretrial conferences in this case on July 19, 2021, at 10:00 a.m. and July 21, 2021, at 9:00 a.m., pursuant to Fed. R. Civ. P. 16.

I. APPEARANCES

For Plaintiff:

Tim O'Brien, Co-Lead Counsel
Kelsey Stokes, Co-Lead Counsel
David Butler, Liaison Counsel
Jeff Grand
Shannon Pennock
Alex Alvarez
Robert Price
Jonathan Olivito

For Defendants:

Michael K. Brown, Co-Lead Counsel
Eric L. Alexander, Co-Lead Counsel
Marilyn A. Moberg
William D. Kloss, Jr. Liaison Counsel
Matthew Jacobson
Jesse Ash

II. NATURE OF ACTION

A. This is a personal injury action.

B. The jurisdiction of the Court is invoked under Title 28, United States Code, Section 1332(a), in that complete diversity of citizenship between Plaintiff and Defendants exists in this action, and the amount in controversy exceeds $75,000, and Section 1441(b). In addition, venue is proper in this pursuant to Title 28, United States Code, Section 1391(a).

C. The jurisdiction of the Court is not disputed.

III. TRIAL LENGTH

The estimated length of trial is approximately five weeks and two days. (*see* ECF No. 484).

IV. AGREED STATEMENTS AND LISTS

A. General Nature of the Claims of the Parties

1.) **Plaintiff's Claims**

Plaintiff alleges that he suffered injuries from Defendants' medical device used for hernia repair, the Ventralight ST mesh. Plaintiff's position is that the device was defective and unreasonably dangerous in that it did not perform as reasonably expected given its intended use, and that there were safer alternative designs which were economically and technologically feasible at the time the device left Defendants' control. Plaintiff further alleges that Defendants failed to provide adequate warnings about the risks (including complications, frequency, severity, and duration), the inadequate research and testing prior to distribution, and the proper way to use the Ventralight ST mesh.

Mr. Johns has asserted the following claims against Defendants:

(1) Negligence – Design Defect;

(2) Negligence – Failure to Warn;

(3) Strict Products Liability – Design Defect;

(4) Strict Products Liability – Failure to Warn;

(5) Breach of Express Warranty;

(6) Breach of Implied Warranty of Merchantability;

(7) Breach of Implied Warranty for a Particular Purpose;

(8) Fraud;

(9) Negligent Misrepresentation; and

(10) "Intentionally fraudulent conduct" and/or "knowing and reckless indifference" related to the claim for Punitive Damages.

2) **Defendants' Claims**:

Defendants assert that Plaintiff's negligence and strict product liability claims for design defect and failure to warn, and his claims for breach of implied warranty fail for lack of evidence of any design defect, failure to warn, negligence, and causation. Defendants also contend that Plaintiff's negligent misrepresentation, and breach of express warranty claims fail because there is no evidence of misrepresentations or warranties made, and there is no evidence that either Plaintiff or his treating physician relied on any representations or warranties by Defendants. Defendants further assert that they did not act with malice towards Plaintiff such that punitive damages would be proper. Defendants do not believe there is a pending fraud claim and instead the only pending claims in negligent misrepresentation. *See* ECF No. 309 at p. 43. Finally, Defendants claim that Plaintiff's diastasis recti recurred and not his hernia.

B. Uncontroverted Facts:

1. The Ventralight ST is a prescription medical device used for hernia repair. The FDA first cleared it for use through its Special 510(k) process, July 15, 2010, and later first cleared for use with the Echo Positioning System on April 1, 2011.

2. The Ventralight ST is a multicomponent device. It is co-knitted using polypropylene monofilament and polyglycolic acid ("PGA") fibers and contains an absorbable hydrogel barrier based on Sepra Technology ("ST") on the posterior side.

3. On July 29, 2015, Dr. Joseph Jensen diagnosed Plaintiff with a ventral hernia within a diastasis recti.

4. On August 7, 2015, Dr. Jensen selected and utilized a Ventralight ST with Echo Positioning System to repair Plaintiff's hernia.

5. On October 4, 2016, Dr. Jensen performed another surgery on Plaintiff.. During the procedure, Dr. Jensen removed Plaintiff's Ventralight ST. Dr. Jensen noted there were adhesions attached to the Ventralight ST and took down the adhesions. Dr. Jensen replaced the Ventralight ST he removed with another Ventralight ST that was the same size as the previous one implanted.

6. Plaintiff's October 2016 Ventralight ST remains implanted in him.

7. For purposes of trial, C.R. Bard, Inc. and Davol, Inc. shall be used interchangeably and will sometimes collectively be referred to as "Defendants".

C. Contested Issues of Fact and Law

Contested Issues of Fact

Plaintiff contends that the contested issues of fact remaining for decision are:

Negligence—Design Defect

- Whether:
  - There was a design defect in the Ventralight ST hernia mesh patch;
  - The design defect made the Ventralight ST hernia mesh patch unreasonably; dangerous;
  - The Ventralight ST hernia mesh patch's defect was the result of Defendants' failure to use reasonable care;
  - The defect was a cause of Mr. Johns's injuries.

Negligence—Failure to Warn

- Whether:
  - Defendants were required to provide a warning;
  - Defendants failed to exercise reasonable care because they did not provide an adequate warning;

- The lack of an adequate warning made the Ventralight ST mesh defective and unreasonably dangerous;
- The lack of an adequate warning was a cause of Mr. Johns's injuries.

Strict Products Liability – Design Defect

- Whether:
  - There was a design defect in the Ventralight ST mesh;
  - The design defect made the Ventralight ST mesh unreasonably dangerous;
  - The design defect was present at the time Defendants manufactured, distributed, or sold the Ventralight ST mesh;
  - The design defect was a cause of Mr. Johns's injuries.

Strict Products Liability – Failure to Warn

- Whether:
  - Defendants were required to provide a warning;
  - Defendants failed to provide an adequate warning at the time the Ventralight ST mesh was manufactured, distributed, or sold;
  - The lack of an adequate warning made the Ventralight ST mesh defective and unreasonably dangerous;
  - The lack of an adequate warning was a cause of Mr. Johns's injuries.

Breach of Express Warranty

- Whether:
  - Defendants made an express warranty about the Ventralight ST mesh;
  - Mr. Johns or his physicians or healthcare providers relied upon this warranty;
  - The Ventralight ST mesh did not conform to this warranty, resulting in a defective and unreasonably dangerous condition;
  - Mr. Johns was harmed;
  - The defective condition and failure of the Ventralight ST mesh to conform to the warranty was a cause of Mr. Johns's harm;
  - Mr. Johns could have reasonably been expected to use or be affected by the Ventralight ST mesh.

Breach of Implied Warranty of Merchantability

- Whether:
  - Defendants sold the Ventralight ST mesh;
  - At the time of sale, the Ventralight ST mesh
    - Was not reasonably fit for the ordinary purposes for which such mesh are used, OR
    - Was not of the same kind and quality as other mesh with which it was sold, OR
    - Would not pass without objection in the industry;
  - This condition rendered the Ventralight ST mesh defective and unreasonably dangerous;
  - Mr. Johns was harmed;

- The defective condition of the Ventralight ST mesh was a cause of Mr. Johns's harm.

Breach of Implied Warranty for a Particular Purpose

- Whether:
  - Defendants knew or had reason to know that Mr. Johns or his physicians or healthcare providers were buying the Ventralight ST mesh for a particular purpose;
  - Defendants knew or had reason to know that Mr. Johns or his physicians or healthcare providers were relying on Defendants' skill or judgment to select or furnish a suitable product;
  - The Ventralight ST mesh was defective, unreasonably dangerous, and unfit for the particular purpose Mr. Johns or his physicians or healthcare providers bought it for;
  - Mr. Johns was harmed;
  - The defective condition was a cause of Mr. Johns's harm.

Fraud

- Whether:
  - Defendants made a false statement about an important fact;
  - Either:
    - Defendants made the statement knowing it was false, OR
    - Defendants made the statement recklessly and without regard for its truth;
  - Defendants intended that Mr. Johns (or his physicians or healthcare providers) would rely on the statement;
  - Mr. Johns (or his physicians or healthcare providers) reasonably relied on the statement;
  - Mr. Johns suffered damages as a result of relying on the statement.

Negligent Misrepresentation

- Whether:
  - Defendants represented to Mr. Johns that an important fact was true;
  - Defendants' representation of fact was not true;
  - Defendants failed to use reasonable care to determine whether the representation was true;
  - Defendants were in a better position than Mr. Johns to know the true facts;
  - Defendants had a financial interest in the transaction;
  - Mr. Johns relied on the representation, and it was reasonable for him to do so;
  - Mr. Johns suffered damage as a result of relying on the representation.

Defendants contend that the contested issues of fact remaining for decision are:

- Whether Plaintiff's alleged injuries, omental adhesions, were specifically and proximately caused by a defect in the Ventralight ST, and would not have occurred but for the implantation of that device.
- Whether Plaintiff, as a direct and proximate cause of Defendants' conduct, suffered any compensable damages related to the omental adhesions discovered during his 2016 surgery, and if so, how much.

- Whether Plaintiff's omental adhesions were the result of Defendants acting with actual malice towards him.
- Whether there was a feasible alternative design available to Dr. Jensen at the time of Mr. Johns's implant.

Contested Issues of Law

Plaintiff contends there are no special issues of law reserved other than those implicit in the foregoing issues of fact other than those that have been addressed through motion practice.

Defendants contend that the contested issues of law, in addition to those implicit in the foregoing issues of fact, are:

- Whether Plaintiff has a pending standalone fraud claim that is not encompassed as part of the negligent misrepresentation claim.
- Whether Defendants were negligent in the design or warnings of the Ventralight ST implanted in Plaintiff.
- Whether the Ventralight ST is defective in its design.
- Whether an alleged design defect in the Ventralight ST proximately caused Plaintiff's omental adhesions.
- Whether Defendants adequately warned of the risk of adhesions.
- Whether an alleged deficiency in Defendants' warnings proximately caused Plaintiff's omental adhesions.
- Whether Defendants breached any implied warranties.
- Whether Defendants made an express warranty and whether Dr. Jensen relied on the warranty.
- Whether Defendants' alleged breach of an express warranty proximately caused Plaintiff's omental adhesions.
- Whether Defendants made a misrepresentation to Dr. Jensen and whether Dr. Jensen relied on that misrepresentation.
- Whether Defendants' alleged misrepresentation proximately caused Plaintiff's omental adhesions.
- Whether Defendants misrepresented or concealed information regarding the Ventralight ST that proximately caused Plaintiff's omental adhesions.
- Other legal issues raised in the extensive prior motion practice in this case.

D. Witnesses

In the absence of reasonable notice to opposing counsel to the contrary, Plaintiff will call, or will have available at trial:

1) Plaintiff Steven Johns

2) Amit Badhwar, Ph.D., M.Sc.

3) Joseph Weldon Jensen, D.O. (treating physician)

Plaintiff may call:

1) Mrs. Valeria Johns

2) Steven Eldridge (videotape deposition)

3) Dan LaFever (videotape deposition)

4) Roger Darois (videotape deposition)

5) Geoff Brown (videotape deposition)

6) David Calabrese (videotape deposition)

7) Albert Marchal (videotape deposition)

8) Craig Wisman (videotape deposition)

9) Christopher Paolo (videotape deposition)

10) Thomas Hutchinson (videotape deposition)

In the absence of reasonable notice to opposing counsel to the contrary, Defendants will call, or will have available at the trial:

1) Roger E. Darois – Defendants intend to call Mr. Darois live. He is primarily expected to testify regarding his work for Defendants, including their acquisition of the Sepramesh IP device, development of the Ventralight ST, its predicate devices, and other hernia repair devices that contain Sepra Technology.

2) Stephanie Baker – Defendants intend to call Ms. Baker live. She is primarily expected to testify regarding her work for Defendants, including their compliance with FDA regulations.

3) John DeFord, Ph.D., M.S. – Defendants intend to call Dr. DeFord live. He is primarily expected to testify regarding his work for Defendants, including research and development of the Ventralight ST, its predicate devices, and other hernia repair devices that contain Sepra Technology.

4) Amit Badhwar, Ph.D., M.Sc. – Plaintiff intends to call Mr. Badhwar in his case; Defendants also intend to call Mr. Badhwar live if Plaintiff does not. He is primarily

expected to testify regarding his work for Defendants, including preclinical studies and development of the Ventralight ST, its predicate devices, and other hernia repair devices that contain Sepra Technology.

5) Jim Keegan – Defendants intend to call Mr. Keegan by videotaped deposition. He is primarily expected to testify regarding his work for Defendants, including their marketing efforts of the Ventralight ST, its predicate devices, and other hernia repair devices that contain Sepra Technology.

6) Jeremy Jeppesen – Defendants intend to call Mr. Jeppesen by videotaped deposition. He is primarily expected to testify regarding his work for Defendants, including knowledge about the Ventralight ST, its predicate devices, and other hernia repair devices that contain Sepra Technology.

7) Casey Stelter, M.D. – Defendants intend to call Dr. Stelter by videotaped deposition. Dr. Stelter is primarily expected to testify about his treatment of Plaintiff and Plaintiff's medical condition.

8) Karen West, Representative of Secant Medical, Inc. – Defendants intend to call this witness by videotaped deposition. If called, said representative is primarily expected to testify regarding communications with Defendants concerning polypropylene and certain statements in Material Safety Data Sheets on polypropylene resin and monofilament.

9) Michael Barnette, Representative of Red Oak Sales Company. – Defendants intend to call this witness by videotaped deposition. If called, said representative is primarily expected to testify regarding communications with Defendants concerning polypropylene and certain statements in Material Safety Data Sheets on polypropylene resin and monofilament.

Defendants currently expect that they may call the following fact witnesses at trial:

1) Donald Coelho, Jr. – Defendants may call Mr. Coelho live or by videotape deposition. He is primarily expected to testify regarding his work for Defendants, including surgical education about the Ventralight ST, its predicate devices, and other hernia repair devices that contain Sepra Technology.

2) Andrew Topoulos – Defendants may call Mr. Topoulos live or by videotape deposition. He is primarily expected to testify regarding his work for Defendants, including field assurance and complaint handling for the hernia devices, specifically the Ventralight ST, its predicate devices, and other hernia repair devices that contain Sepra Technology.

3) Any witnesses needed for impeachment or rebuttal.

4) Any other witness who might become necessary based on the testimony and evidence presented at trial.

Defendants reserve the right to call, or not call, any or all of the witnesses identified above, and also reserves the right to limit the direct examination on any of the witnesses listed. Defendants also reserve the right to call one or more of the witnesses (fact or expert) who Plaintiff calls at trial, or has identified on his witness list.

In the event other witnesses are to be called at the trial, a statement of their names and addresses and the general subject matter of their testimony will be served upon opposing counsel and filed with the Court at least five (5) days prior to trial.

There is reserved to each of the parties the right to call such rebuttal witnesses as may be necessary, without prior notice to the other party. Questions frequently arise as to whether a witness will offer rebuttal testimony or is more appropriately designated as part of the case-in-chief. If questions arise as to the nature of a witness' testimony, the Court will err on the side of required disclosure five (5) days prior to trial of rebuttal witnesses. If no disclosure is made, the Court shall not permit such witness to testify.

Note: *Only witnesses listed in the Final Pretrial Order will be permitted to testify at the trial, except witnesses called solely for the purpose of impeachment or for good cause shown.*

E. Expert Witnesses

The parties are limited to the following number of expert witnesses, including treating physicians, whose names have been disclosed to the other side.

1. Plaintiff:

    a. Jimmy Mays, Ph.D. (see *curriculum vitae* at ECF No. 68-1, PageID #3554)

    a. David Grischkan, M.D. (see *curriculum vitae* at ECF No. 31-1, PageID #992)

b. Ahmed El-Ghannam, Ph.D. (see *curriculum vitae* at ECF No. 33-1, PageID #1508)

c. Julia Babensee, Ph.D. (see *curriculum vitae* at ECF No. 112-4, PageID #7632)

d. Michael Beatrice, Ph.D. (see *curriculum vitae* at ECF No. 467-1, PageID #24011)

e. Robert W. Johnson (pending Bard's production of financial discovery and supplemental report) (see *curriculum vitae* at ECF No. 91-1, PageID #6197)[1]

f. Tamas Nagy, D.V.M, Ph.D., DACVP (rebuttal) (see *curriculum vitae* at ECF No. 26-1, PageID #197)

2. Defendants:

a. David Renton, M.D. (curriculum vitae attached as Appendix E)

b. Yuri Novitsky, M.D. (ECF No. 70-1)

c. Donna-Bea Tillman, Ph.D., MPA, FRAPS (ECF No. 113-1)

d. Maureen T.F. Reitman, Sc.D., F.S.P.E., P.E. (curriculum vitae attached as Appendix E)

e. Stephen F. Badylak, D.V.M., Ph.D., M.D. (curriculum vitae attached as Appendix E)

f. Kimberly A. Trautman, M.S. (curriculum vitae attached as Appendix E)

g. James M. Anderson, M.D., Ph.D. (ECF No. 409-1)

F. Depositions

Plaintiff may present the testimony of the following witnesses by deposition/videotape:

1) Steven Eldridge (videotape)
2) Dan LaFever (videotape)
3) Roger Darois (videotape)

[1] Defendants disagree that Mr. Johnson is an expert witness in this case because the Court has excluded him. ECF No. 531.

4) Geoff Brown (videotape)
5) David Calabrese (videotape)
6) Albert Marchal (videotape)
7) Craig Wisman (videotape)
8) Christopher Paolo (videotape)
9) Thomas Hutchinson (videotape)

In Section IV(D), Defendants identified the witnesses who might present testimony by videotaped deposition.

G. Exhibits

Appendix A Joint Exhibits—None.

Appendix B Plaintiff's Exhibits—see attached.

Appendix C Defendants' Exhibits—see attached.

Appendix D Third-Party Exhibits—None.

Appendix E Certain of Defendants' Experts' Curriculum Vitaes.

H. Stipulations

The parties have entered into the following stipulations:

- To notify each other of witnesses expected to be called at trial, and the order of the witnesses, no less than forty-eight hours in advance of the witness being called.
- Procedures for Sequestration of Witnesses.

No other stipulations have been made between the parties. A procedure for finalizing videos for witnesses whose testimony is to be introduced in that fashion is being finalized pursuant to an agreement in principle.

I. Completion of Discovery

Plaintiff's Position:

Plaintiff contends that further discovery in this action is limited to:

- Potential supplemental deposition of Red Oak Sales 30(b)(6) witness as discussed at the Court's July 12, 2021 Telephonic Hearing.
- Potential supplemental deposition of Albert Marchal.
- The production of Defendant C.R. Bard, Inc's Financials and supplemental expert report of Johnson and any related depositions.

Defendants' Position:

Defendants contend that case-specific discovery is completed. Defendants do not believe a supplemental report of Mr. Johnson is appropriate given he has been excluded by the Court. ECF No. 531. Defendants are currently negotiating with Plaintiff over Bard's financials to be provided to Plaintiff.

V. MODIFICATION

The Final Pretrial Order may be modified at or prior to the trial of this action to prevent manifest injustice. Such modification may be made by application of counsel or on motion of the Court.

VI. REMAINING ISSUES AND OTHER MATTERS

The following legal issues must be resolved before the beginning of trial:

- Plaintiff's Motion to Strike the Undisclosed Opinions of Defense Expert James Anderson [ECF No. 463]
- Defendants' Motion to Strike New Opinions Proffered By Plaintiff's Substitute Expert, Michael G Beatrice, Ph.D. [ECF No. 464]
- Defendants' Motion to Exclude the Opinions and Testimony of Plaintiff's Expert Michael Beatrice, Ph.D. [ECF No. 467]
- Plaintiff's Proffer Related to Trial Use of evidence of Composix Kugel Recall, FDA Inspections, and Audits [ECF No. 486]
- Defendants' Motion to Exclude the Opinions and Testimony of Plaintiff's Rebuttal Expert Tamas Nagy, DVM, Ph.D. [ECF No. 488]

- While jury instructions do not need to be decided prior to the beginning of trial, there are still outstanding proposed general instructions.

- Remaining deposition and exhibit objections. The parties are endeavoring to decrease the number of outstanding issues and intend on presenting the Court with a new system for dealing with the objections per the Court's Order (ECF No. 483).

Counsel bring the following additional matters to the Court's attention:

- Plaintiff's position is that the depositions of Third Party 30(b)(6) witnesses are objectionable in their entirety in that both witnesses lacked personal knowledge as to how or why the Marlex MSDS changed in 2004 to include a medical application caution.

  Defendants disagree with Plaintiff's position in that the witnesses possess the relevant personal knowledge to offer testimony on, but not limited to, the relevant MSDS, how MSDSs are used in their line of work, their relationship with Defendants and how polypropylene resin in manufactured. Consistent with the Court's orders on the admissibility of MSDS evidence, these witnesses testify to interaction with Defendants about certain language in MSDS prior to the development of the Ventralight ST and the implant at issue in this case. Defendants believe the best course of action with these witnesses is to handle as the rest of the witnesses appearing by deposition presenting unresolved objection to the Court by page and line.

- The issue of Defendants playing Roger Darois's direct exam on videotape in Plaintiff's case in chief if they intend on calling Mr. Darois live in Defendants' case in chief needs to be addressed.

Defendants' position is that the issue of cumulative testimony can be addressed at trial as Mr. Darois' testifies at trial either by videotape or live. Defendants offered to have Mr. Darois called in Plaintiff's case to avoid this issue, but Plaintiff declined. Defendants contend that they should be allowed to introduce their counters at the same time as Plaintiff introduces his designations. Defendants contend that if Mr. Darois is also called live in Defendants' case, then he, like any witness after the first one will be subject to potential objections that his evidence is cumulative of evidence already introduced.

7/29/2021
DATE

s/Edmund A. Sargus, Jr.
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UNITED STATES DISTRICT JUDGE

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