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:
***Milanesi, et al. v. CR Bard et al.*,**
Case No. 2:18-cv-1320

CASE MANAGEMENT ORDER NO. 29-D

The Court held the final pretrial conferences in this case on December 14, 2021, at 9:00 a.m. and December 15, 2021, at 9:00 a.m., pursuant to Fed. R. Civ. P. 16.

I. APPEARANCES

For Plaintiffs:

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

For Defendants:

Michael K. Brown, Co-Lead Counsel
Eric L. Alexander, Co-Lead Counsel
William D. Kloss, Jr. Liaison Counsel
Matthew Jacobson

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 Plaintiffs 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 15 court days. (*See* ECF No. 559).[1] The Court previously has directed that each side is limited to 37.5 hours for their respective direct-examination and cross-examination time.

IV. AGREED STATEMENTS AND LISTS

A. General Nature of the Claims of the Parties

1.) **Plaintiff's Claims**

Plaintiffs allege that Mr. Milanesi suffered injuries from Defendants' medical device used for hernia repair, the Ventralex Hernia Patch size large ("Ventralex"). Plaintiffs' position is that the device is defective and the risk of danger in the Ventralex outweighs the benefits of the device; and that it fails to perform as safely as an ordinary surgeon would expect. Plaintiffs further allege 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 Ventralex Hernia Patch.

Plaintiffs have asserted the following claims against Defendants:[2]

[1] This does not include jury deliberations and any Phase 2/Punitive Damages phase of the trial.
[2] Plaintiffs are not pursuing the following claims: Strict Liability-Failure to Warn; Express

(1) Negligence;

(2) Negligent Failure to Warn;

(3) Strict Products Liability – Design Defect;

(4) Gross Negligence;

(5) Negligent Misrepresentation;

(6) Fraudulent Misrepresentation;

(7) Fraudulent Concealment; and

(8) Loss of Consortium.

2) **Defendants' Contentions**:

Defendants assert that Plaintiffs' negligence and strict product liability claims fail for lack of evidence of any design defect, failure to warn, negligence, and causation. Defendants also contend that Plaintiffs' fraud and misrepresentation claims fail because there is no evidence of misrepresentations made or fraudulent concealments, and there is no evidence that Dr. Gill relied on any representations by Defendants. Defendants further assert that they were not grossly negligent in any regard and did not act with malice towards Plaintiffs such that punitive damages would be proper.

B. Uncontroverted Facts:

1. The Ventralex Hernia Patch is a prescription medical device used for hernia repair. The Ventralex Hernia Patch was legally on the market in the United States in July 2007.

Warranty; Implied Warranty of Merchantability; and Implied Warranty of Fitness for Particular Purpose. The Court previously granted summary judgment on Plaintiffs' manufacturing defect claims.

2. The Ventralex Hernia Patch is a multicomponent device. It is made of three layers—two of polypropylene mesh on one side and one of a permanent expanded polytetrafluoroethylene ("ePTFE") film on the other side. The device contains a non-absorbable ring made of PET polymer.

3. On July 11, 2007, Dr. Gill selected and utilized a size large Ventralex Hernia Patch to repair Mr. Milanesi's umbilical hernia.

4. On May 25, 2017, Dr. Michael Caluda recommended immediate surgery to address the unreducible mass above Mr. Milanesi's umbilicus. The surgery was performed on May 26, 2017. During the May 26, 2017, surgery, Dr. Caluda observed that a loop of small bowel was densely adherent to the overlying mesh and an erosion of the bowel was evident into an abscess cavity involving a portion of the mesh, which had turned to expose the polypropylene to the bowel at some point, causing an area of adherence. On May 26, 2017, Dr. Caluda explanted the infected Ventralex Hernia Patch from Mr. Milanesi and surgically repaired the fistula that had developed between the bowel and the Patch, leading to the infection of the Patch. Dr. Caluda also resected the segment of small intestine that had eroded into the mesh. Dr. Caluda performed a side-to-side stapled anastomosis.

5. On June 1, 2017, Mr. Milanesi underwent another surgery due to a high grade post-operative bowel obstruction.

6. 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

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

Negligence

Whether Bard and Davol failed to use reasonable care in the design, testing, or research of the Ventralex, and, if so, whether that was a legal cause of the injury to Mr. Milanesi.

Negligent Failure to Warn

Whether Bard and Davol negligently failed to warn about particular risks involved in the use of the Ventralex, and, if so, whether that failure to warn was a legal cause of the injury to Mr. Milanesi.

Strict Products Liability – Design Defect

Whether the Ventralex (1) either (a) failed to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable by the manufacturer or (b) the risk of danger in the design of the Ventralex outweighs the benefits of the Ventralex and (2) the Ventralex reached Mr. Milanesi without substantial change affecting the condition and, if so, (3) whether that failure was a legal cause of the injury to Mr. Milanesi.

Gross Negligence (Design Defect)

Whether Bard and Davol were grossly negligent in designing the Ventralex, and, if so, whether that was a legal cause of the injury to Mr. Milanesi.

Gross Negligence (Failure to Warn)

Whether Bard and Davol were grossly negligent in failing to warn about particular risks involved in the use of the Ventralex, and, if so, whether that failure to warn was a legal cause of the injury to Mr. Milanesi.

Negligent Misrepresentation

Whether:

(1) Bard and Davol made a statement concerning a material fact that they believed to be true but which was in fact false;

(2) Bard and Davol were negligent in making the statement because they should have

known the statement was false;

(3) in making the statement, Bard and Davol intended or expected that another would rely on the statement;

(4) Mr. Milanesi or his surgeon justifiably relied on the false statement; and

(5) the false statement was a legal cause of the injury to Mr. Milanesi.

Fraudulent Misrepresentation

Whether:

(1) Bard and Davol intentionally made a false statement concerning a material fact;

(2) Bard and Davol knew the statement was false when they made it or made the statement knowing they did not know whether it was true or false;

(3) Bard and Davol intended that another would rely on the false statement;

(4) Mr. Milanesi or his surgeon relied on the false statement; and

(4) the false statement was a legal cause of injury to Mr. Milanesi.

Fraudulent Concealment

Whether:

(1) Bard and Davol concealed or failed to disclose a material fact;

(2) Bard and Davol knew or should have known the material fact should be disclosed;

(3) Bard and Davol intended that another would rely on their concealment of or failure to disclose the material fact;

(4) Mr. Milanesi or his surgeon relied on the concealment or failure to disclose; and

(5) the concealment or failure to disclose was a legal cause of injury to Mr. Milanesi.

Loss of Consortium

Whether Mrs. Milanesi has lost affection, solace, comfort, companionship, conjugal life, fellowship, society, company, cooperation, assistance, or aid from Mr. Milanesi because of Bard and Davol's conduct.

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

- Whether Plaintiffs' alleged injuries were proximately caused by a defect in the Ventralex, and would not have occurred but for the implantation of that device.
- Whether Plaintiffs, as a proximate cause of Defendants' conduct, suffered any compensable damages, and if so, how much.
- Whether Plaintiffs' injuries were the result of Defendants acting with actual malice[3] towards them.
- Whether there was a feasible alternative design available to Dr. Gill at the time of Mr. Milanesi's implant.[4]
- Whether Dr. Gill had independent knowledge of the risk of the complications that Plaintiffs claim.
- Whether the complications that Plaintiffs claim were generally known in the medical community.

Contested Issues of Law

Plaintiffs contend there are no special issues of law reserved other than those implicit in the foregoing issues of fact and 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 Plaintiffs have any active and/or actionable negligence theories, besides negligent design and negligent failure to warn, in light of the fact that Defendants moved for summary judgment against any negligence theories that were not contained within the traditional products liability theories and the Court ruled that Plaintiffs' negligence theories *were* confined to those traditional theories (except for manufacturing defect, which is not at issue in this case). *See* Dispositive Motions Order No. 3, ECF No. 167, at 26 ("Next, Defendants argue that summary judgment is appropriate on Plaintiffs' other negligence claims to the extent that they raise negligence claims distinct from their design defect, manufacturing defect, and failure to warn claims, and on Plaintiff's negligence per se claim. . . . Plaintiffs do not appear to raise negligence claims apart from their product liability claims, though Plaintiffs fail to make an adequate showing as to their negligence per se claim."); *see also* Plaintiffs' Proposed Jury Instructions, at 38 (describing Plaintiffs' negligence claim as falling under either "design defect" or "failure to warn").
- Whether Defendants were negligent in the design or warnings of the Ventralex implanted in Mr. Milanesi.
- Whether the Ventralex is defective in its design.

[3] Plaintiffs object this is not the standard under Florida law.
[4] Plaintiffs object this is not the standard under Florida law.

- Whether an alleged design defect in the Ventralex proximately caused Plaintiffs' injuries.
- Whether Defendants adequately warned physicians of the risk of injuries.
- Whether an alleged deficiency in Defendants' warnings proximately caused Plaintiffs' injuries in that Dr. Gill would not have implanted the Ventralex if said deficiency did not exist.
- Whether Defendants made a misrepresentation to Dr. Gill, whether Dr. Gill relied on that misrepresentation, and whether Dr. Gill would not have implanted the Ventralex if the alleged misrepresentation did not occur.
- Whether Defendants' alleged misrepresentation proximately caused Plaintiffs' injuries.
- Whether Defendants misrepresented or concealed information regarding the Ventralex that proximately caused Plaintiffs' injuries in that Dr. Gill would not have implanted the Ventralex if said misrepresentation or concealment did not occur.
- Whether Plaintiffs have viable misrepresentation- or concealment-based claims based on alleged representations made to Mr. Milanesi, as opposed to Dr. Gill, given the learned intermediary doctrine and this Court's ruling on summary judgment that Plaintiffs have no such claim as a matter of law. *See* Dispositive Motions Order No. 3, ECF No. 167, at 24 ("Contrary to Defendants' contention, this line of cases does not stand for the proposition that all fraud-based claims are 'repackaged' failure-to-warn claims if they address the same conduct; ***the operative issue is whether Plaintiffs are attempting to do an end-run around the learned intermediary doctrine by focusing on Defendants' statements to Mr. Milanesi, not Dr. Gill. Plaintiffs point to only the representations Defendants made to Dr. Gill—not Mr. Milanesi—and they do not argue that the learned intermediary rule does not apply***. . . . Accordingly, there is no indication that the Court should treat Plaintiffs' fraud-based claims as part of their failure to warn claims.").
- Whether Plaintiffs' claim for "gross negligence" is a viable standalone claim under Florida law, as opposed to being an element of Plaintiffs' claim for punitive damage for which they carry the burden of proof by clear and convincing evidence. See *Smith v. Ethicon, Inc.*, Case No.:4:20cv394-MW/MAF, 2020 WL 9071685, at *3 (N.D. Fla. Dec. 28, 2020) ("[G]ross negligence is a heightened standard of proof to receive punitive damages under Florida law and not a stand-alone claim.").
- 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, Plaintiffs will call, or will have available at trial:

1) Plaintiff Antonio Milanesi

2) Plaintiff Alicia Milanesi

3) Roger E. Darois (adversely)

4) Karanbir Gill, M.D. (videotape deposition)

5) David Krpata, M.D.

Plaintiffs may call:

1) Steven Eldridge (videotape deposition)

2) Dan LaFever (videotape deposition)

3) David Ciavarella, M.D. (videotape deposition)

4) David Calabrese (videotape deposition)

5) Craig Wisman (videotape deposition)

6) Christopher Paolo (videotape deposition)[5]

7) Amit Badhwar, Ph.D. (videotape deposition)

8) Michael Caluda, M.D. (videotape deposition)

9) Kurt Stockamp, M.D. (videotape deposition)

10) Julia Babensee, Ph.D.

11) Michael Beatrice, Ph.D.

12) Ahmed El-Ghannam, Ph.D

13) Robert Johnson[6]

[5] Per the parties' agreement, if Defendants do not call Mr. Paolo live in their case-in-chief, Defendants have agree to give Plaintiffs adequate notice and Plaintiffs will make a determination at that time whether they will play the Paolo testimony by deposition. And, if the decision not to call Mr. Paolo live is made by Defendants after the close of Plaintiffs' case-in-chief, Defendants will not object to the reopening of Plaintiffs' case-in-chief solely for the purpose of playing both sides' designations from the deposition of this witness if so chosen by Plaintiffs.

[6] The Court has requested that Defendants file objections to the report and anticipated testimony

14) Jimmy Mays, Ph.D.

15) John L. Quick

16) Any witnesses needed for impeachment or rebuttal.

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

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

1) Roger E. Darois – Defendants intend to call Mr. Darois live. He is primarily expected to testify regarding his work for Defendants, including development of the Ventralex.

2) Christopher Paolo – Defendants intend to call Mr. Paolo by videotaped deposition. He is primarily expected to testify regarding his work for Defendants, including quality engineering of the Ventralex.

3) Kurt Stockamp, M.D. – Defendants intend to call Dr. Stockamp by videotaped deposition if Plaintiffs do not. He is primarily expected to testify regarding his treatment of Mr. Milanesi.

4) Miguel Gutierrez-Diaz, D.O. – Defendants intend to call Dr. Gutierrez-Diaz by videotaped deposition. He is primarily expected to testify regarding his treatment of Mr. Milanesi.

5) Michael Caluda, M.D. – Defendants intend to call Dr. Caluda by videotaped deposition if Plaintiffs do not. He is primarily expected to testify regarding his treatment of Mr. Milanesi.

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

1) John DeFord, Ph.D., M.S. – Defendants may call Dr. DeFord live. He is primarily expected to testify regarding his work for Defendants, including research and development of the Ventralex.

2) Jim Keegan – Defendants may call Mr. Keegan by videotaped deposition. He is primarily expected to testify regarding his work for Defendants, including their marketing efforts of the Ventralex.

3) Any witnesses needed for impeachment or rebuttal.

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of Mr. Johnson by March 16, 2022.

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 reserve 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 Plaintiffs call at trial, or has identified on their 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 and only for good cause shown.

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. David Krpata, M.D. (see *curriculum vitae* at ECF No. 63-1, PageID #1123)

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

c. Jimmy Mays, Ph.D. (see *curriculum vitae* at ECF No. 109-1, PageID#9880)

d. Julia Babensee, Ph.D. (see *curriculum vitae* at ECF No. 103-2, PageID #8836)

e. Michael Beatrice, Ph.D. (see *curriculum vitae* at ECF No. 322-2 , PageID #17628)

f. John L. Quick (see *curriculum vitae* at ECF No. 106-1, PageID # 9318)

g. Robert W. Johnson (see *curriculum vitae* at ECF No. 102-2 , PageID #8724)

2. Defendants:

a. Kevin Gillian, M.D. (ECF No. 77-5)

b. Donna-Bea Tillman, Ph.D., MPA, FRAPS (ECF No. 73-2)

c. Maureen T.F. Reitman, Sc.D., F.S.P.E., P.E. (ECF No. 84-1)

d. Stephen F. Badylak, D.V.M., Ph.D., M.D. (ECF No. 79-5)

e. Kimberly A. Trautman, M.S. (ECF No. 75-2)

f. James M. Anderson, M.D., Ph.D. (ECF No. 81-2)

F. Depositions

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

1) Steven Eldridge (videotape)

2) Dan LaFever (videotape)

3) David Calabrese (videotape)

4) Christopher Paolo (videotape)

5) David Ciavarella, M.D. (videotape)

6) Craig Wisman (videotape)

7) Amit Badhwar, Ph.D. (videotape)

8) Karanbir Gill, M.D. (videotape)

9) Michael Caluda, M.D. (videotape)

10) Kurt Stockamp, M.D. (videotape)

Defendants:

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

G. Exhibits

Appendix A Joint Exhibits—None.

Appendix B Plaintiffs' Exhibits—see attached.

Appendix C Defendants' Exhibits—see attached.

Appendix D Third-Party Exhibits—None.

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.
- Stipulation related to the authenticity of the financial documents produced by Defendants.
- Stipulation related to the Technique Guide used in discovery.
- Stipulation related to the trial record of videos played in trial.

No other stipulations have been made between the parties.

I. Completion of Discovery

Plaintiffs' Position:

Discovery has been completed.

Defendants' Position:

Discovery has been completed.

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:

- While jury instructions do not need to be decided prior to the beginning of trial, there are still outstanding proposed general instructions.
- The special instructions on FDA, MSDS, and the issue of post-sale duty to warn under Florida law are still outstanding.
- Remaining deposition objections and designations.

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

- Plaintiffs' Motion to Instruct the Jury Before Closing Arguments

3/17/2022
DATE

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

s/Kimberly A. Jolson
KIMBERLY A. JOLSON
UNITED STATES MAGISTRATE JUDGE

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