

**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:
AARON STINSON**

Case No.: 2:18-cv-01022

CASE MANAGEMENT ORDER NO. 37-E

The Court held the final pretrial conferences in this case on October 10, 2023, at 9:00 a.m. and October 11, 2023, 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
Jeff Grand
David Butler, Liaison Counsel
Andrea Giovannone
Brett Vaughn

For Defendants:

Michael K. Brown, Co-Lead Counsel
Eric L. Alexander, Co-Lead Counsel
Marilyn A. Moberg
Matthew Jacobson
Henrique Geigel

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 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 four weeks. The Court has directed that each side is limited to 33.5 hours.¹ This time limit does not include voir dire, opening statement, closing argument, or time spent on objections.

IV. AGREED STATEMENTS AND LISTS

A. General Nature of the Claims of the Parties

1. Plaintiff's Claims

Plaintiff alleges that Mr. Stinson suffered injuries from Defendants' medical device used for hernia repair, the PerFix Plug, size extra-large. Plaintiff's position is that the device is defective and the risk of danger in the PerFix Plug outweighs the benefits of the device; and that it fails to perform as safely as an ordinary surgeon would expect. 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 PerFix Plug.

Mr. Stinson has 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 Plaintiff is not pursuing the following claims: Express Warranty, Implied Warranty, Intentional Infliction of Emotional Distress, Negligent Infliction of Emotional Distress, and Manufacturing Defect. The Court dismissed via summary judgment Plaintiff's claims for Gross Negligence, Fraud, Fraudulent Misrepresentation, Fraudulent Concealment, and Negligent Misrepresentation, and denied as moot his claim for Negligence Per Se.

- (1) Negligence;
- (2) Strict Products Liability – Failure to Warn; and
- (3) Strict Products Liability – Design Defect.

2. Defendants’ Contentions

Defendants assert that Plaintiff’s negligence, warnings, and design defect claims fail for lack of evidence of any design defect, failure to warn, negligence, and causation. Defendants further assert that they did not breach any warranty owed to Plaintiff and did not act with malice towards Plaintiff such that punitive damages would be proper.

B. Uncontroverted Facts

1. The PerFix Plug is a prescription medical device used for hernia repair. It was originally available in three sizes: small, medium, and large, with an accompanying onlay patch. In 1996, Bard introduced the extra large PerFix Plug using a no-510(k) rationale.

2. The XL PerFix Plug plug consists of three preformed medium shells held in place, side by side, inside a preformed large shell by a single polypropylene monofilament thread that is 6mil in diameter. The base is approx 2" in width. The XL plug is packaged with an unattached onlay patch (base) which provides the user with the option of its use. The XL plug is intended to be used for the repair of groin hernia defects.

3. On August 5, 2015, Dr. Amy Tan selected and utilized an extra-large PerFix Plug to repair Mr. Stinson’s right inguinal hernia.

4. On June 20, 2017, performed an exploratory surgery on Mr. Stinson. Dr. Radke found that the tissue around the area of mesh “was very significantly scarred.” Dr. Radke explanted the PerFix Plug and implanted another polypropylene hernia mesh device.

5. On May 10, 2023, Dr. Dylan Jacobus explanted the other polypropylene mesh device and removed Mr. Stinson's testicle.

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

1. Contested Issues of Fact

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

Negligence

Whether Defendants were negligent and whether the Defendants were a cause of Mr. Stinson's injury and consequent damages.

Strict Product Liability – Failure to Warn

Whether, the Defendants had a duty to warn the user of the product hazard;

Whether the defective warning existed at the time the defendant sold the product;

Whether the product reached the user without significant change in the warning in place when it was sold;

Whether any actual warning on the product was inadequate; and

Whether the defective warning caused Mr. Stinson's injury.

Strict Products Liability – Design Defect

Whether the PerFix was defective and defectively designed thereby exposing Mr. Stinson to an unreasonable risk of harm. Whether the PerFix is unreasonably dangerous because of its design.

Whether the defect existed at the time the Defendants sold the product;

Whether the PerFix reached the user without significant change in the condition in which it was sold;

Whether the defect was a cause of the Mr. Stinson's injuries; and

Whether, the PerFix was being used in a manner reasonably foreseeable by the Defendants.

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

- Whether the PerFix Plug was defectively designed.
- Whether there was a feasible alternative design available to Dr. Tan at the time of Mr. Stinson's implant.
- Whether the PerFix Plug was state of the art as of August 5, 2015.
- Whether the PerFix Plug was legally adequate.
- Whether Plaintiff's alleged injuries were proximately caused by a defect in design of the PerFix Plug, and would not have occurred but for the implantation of that device.
- Whether Plaintiff's alleged injuries were proximately caused by inadequate warnings for the PerFix Plug, and would not have occurred but for the implantation of that device.
- Whether Plaintiff, as a proximate cause of Defendants' conduct, suffered any compensable damages, and if so, how much.
- Whether Plaintiff's injuries were the result of Defendants acting with actual malice towards him.
- Whether Dr. Tan had independent knowledge of the risk of the complications that Plaintiff claims.
- Whether the complications that Plaintiff claims were generally known in the medical community.

2. Contested Issues of Law

Plaintiff contends 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 Defendants were negligent in the design or warnings of the PerFix Plug implanted in Mr. Stinson.
- Whether the PerFix Plug is defective in its design.

- Whether an alleged design defect in the PerFix Plug proximately caused Plaintiff's injuries.
- Whether Defendants adequately warned Dr. Tan of the risk of injuries.
- Whether an alleged deficiency in Defendants' warnings proximately caused Mr. Stinson's injuries in that Dr. Tan would not have implanted the PerFix Plug if said deficiency did not exist.
- Whether Defendants breached any warranty owed to Mr. Stinson.
- Other legal issues raised in the extensive prior motion practice in this case.

D. Fact Witnesses

Plaintiff will call, or will have available at trial, the following fact witnesses:

- 1) Plaintiff Aaron Stinson (live)
- 2) Gail Stinson (live)
- 3) Abigail Stinson (live)
- 4) Amit Badhwar, Ph.D. (videotape deposition)
- 5) David Calabrese (videotape deposition)
- 6) John Califano, M.D. (videotape deposition)
- 7) Derek Chaves (videotape deposition)
- 8) David Ciavarella, M.D. (videotape deposition)
- 9) Roger Darois (live)
- 10) Stephen Eldridge (videotape deposition)
- 11) Daniel LaFever (videotape deposition)
- 12) Frederick Littlejohn, M.D. (videotape deposition)
- 13) Amy Tan, M.D. (videotape deposition)

Plaintiff may call:

- 1) Bruce Hamilton-Dick, M.D. (videotape deposition)
- 2) Dylan Jacobus, M.D. (videotape deposition)

- 3) Frederick Radke, M.D. (videotape deposition)
- 4) Thomas Hutchinson (videotape deposition)
- 5) Craig Wisman, M.D. (videotape deposition)
- 6) 30(b)(6) witnesses discussed with the Court at the October 4, 2023, Case Management Conference
- 7) Any witness required to lay foundation for exhibits
- 8) Defendants' Custodian of Records
- 9) Defendants' Corporate Representative at Trial
- 10) All witnesses identified by Defendants
- 11) Any witness whose deposition has not been taken at the time of this submission

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 if Plaintiff does not call him. He is primarily expected to testify regarding his work for Defendants, including development of the PerFix Plug.
- 2) Lori Whitehead – Defendants intend to call Ms. Whitehead live. She is primarily expected to testify regarding her work for Defendants, including development of the PerFix Plug.
- 3) Bruce Hamilton-Dick, M.D. – Defendants intend to call Dr. Hamilton-Dick by videotaped deposition if Plaintiff does not call him. He is primarily expected to testify regarding his treatment of Mr. Stinson.
- 4) Dylan Jacobus, M.D. – Defendants intend to call Dr. Jacobus by videotaped deposition if Plaintiff does not call him. He is primarily expected to testify regarding his treatment of Mr. Stinson.
- 5) Frederick Radke, M.D. – Defendants intend to call Dr. Radke by videotaped deposition if Plaintiff does not call him. He is primarily expected to testify regarding his treatment of Mr. Stinson.
- 6) Amy Tan, M.D. – Defendants intend to call Dr. Tan by videotaped deposition if Plaintiff does not call her. She is primarily expected to testify regarding her treatment of Mr. Stinson.

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

- 1) Stephen Eldridge – Defendants may call Mr. Eldridge by videotaped deposition. He is primarily expected to testify regarding his work for Defendants, including research and development of the PerFix Plug.
- 2) Alyssa Watson – Defendants may call Ms. Watson by videotaped deposition. She is primarily expected to testify regarding the development of the PerFix Plug.
- 3) Derek Chaves – Defendants may call Mr. Chaves by videotaped deposition if there is a punitive damages phase of trial. Mr. Chaves is primarily expected to testify regarding Defendants’ financial condition.
- 4) John Califano, M.D. – Defendants may call Dr. Califano by videotaped deposition. He is primarily expected to testify regarding his treatment of Mr. Stinson.
- 5) Larry Fraley, M.D. – Defendants may call Dr. Fraley by videotaped deposition. He is primarily expected to testify regarding his treatment of Mr. Stinson.
- 6) Anthony Fusco, D.O. – Defendants may call Dr. Fusco by videotaped deposition. He is primarily expected to testify regarding his treatment of Mr. Stinson.
- 7) Frederick Littlejohn, M.D. – Defendants may call Dr. Littlejohn by videotaped deposition. He is primarily expected to testify regarding his treatment of Mr. Stinson.
- 8) Brittany Misercola, M.D. – Defendants may call Dr. Misercola by videotaped deposition. She is primarily expected to testify regarding her treatment of Mr. Stinson.
- 9) Any witnesses needed for impeachment or rebuttal.
- 10) 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 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 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. Ahmed El-Ghannam
- b. David Grischkan, M.D.
- c. Robert W. Johnson
- d. David A. Kessler, M.D.
- e. Jimmy Mays, Ph.D.
- f. Dipak Panigrahy, M.D. (subject to motion)

2. Defendants

- a. Stephen F. Badylak, D.V.M., Ph.D., M.D. (Attached to Appendix A as Exhibit 1)
- b. B.J. Pomerants, M.D., F.A.C.S. (Attached to Appendix A as Exhibit 2)

- c. Maureen T.F. Reitman, Sc.D., F.S.P.E., P.E. (Attached to Appendix A as Exhibit 3)
- d. Donna-Bea Tillman, Ph.D., MPA, FRAPS (ECF No. 98-1)
- e. Robert D. Tucker, M.D., Ph.D. (ECF No. 102-1)

F. Depositions

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

G. Exhibits

Appendix A Certain of Defendants' Experts' Curriculum Vitae.

Appendix B Joint Exhibits—None.

Appendix C Plaintiff's Exhibits—see attached.

Appendix D Defendants' Exhibits—see attached.

Appendix E 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 trial record of videos played in trial.

No other stipulations have been made between the parties as of this time.

I. Completion of Discovery

Plaintiff's 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 State of the Art.
- Remaining deposition objections and designations.
- Remaining rulings on outstanding motions.

10/13/2023
DATE

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

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