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:
***Stinson v. Davol, Inc., et al.*,**
Case No. 2:18-cv-01022

MOTIONS IN LIMINE OPINION & ORDER NO. 59

Plaintiff's Memorandum in Support of Summary Exhibit Pursuant to Federal Rule of Evidence 1006

Before the Court is Plaintiff Aaron Stinson's Memorandum in Support of Summary Exhibit Pursuant to Federal Rule of Evidence 1006. (Memo., ECF No. 329.) Plaintiff seeks to introduce a summary exhibit at trial in response to evidence and argument he anticipates will be offered by Defendants C.R. Bard, Inc. and Davol, Inc. (*Id.*) Defendants oppose admission of the summary exhibit. (Opp., ECF No. 343.) For the reasons stated below, Plaintiff's request is **DENIED**.

I. Background[1]

Plaintiff's case is being tried as the third bellwether selected from thousands of cases in this multidistrict litigation ("MDL") titled *In Re: Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Products Liability Litigation*, 2:18-md-2846. The Judicial Panel on Multidistrict Litigation described the cases in this MDL as "shar[ing] common factual questions arising out of

[1] For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order in this case. (Dispositive Motions Order ("DMO") No. 7, ECF No. 225.) All docket citations are to the *Stinson* case, 2:18-cv-1022, unless otherwise noted.

allegations that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections." (Case No. 2:18-md-02846, ECF No. 1 at PageID 1–2.)

Plaintiff brings this action to recover for injuries sustained as a result of the implantation of an Extra-Large PerFix Plug hernia mesh device, alleging that Defendants knew of the risks presented by the device but marketed and sold it despite these risks and without appropriate warnings. The following claims remain for trial: design defect, failure to warn, and negligence.

The relevant facts here are that in 2015 Plaintiff underwent a right inguinal hernia repair with an Extra-Large PerFix Plug mesh, a product manufactured by Defendants. In 2017, Plaintiff underwent exploratory surgery to determine if he had a recurrent hernia or nerve entrapment because of chronic pain in his right groin area. The explanting surgeon, Dr. Radke, noted extensive scarring and found "a large ball approximately 2.5 cm in diameter of rolled up mesh next to the pubic tubercle." (ECF No. 89-22 at PageID 1134.) Dr. Radke removed the mesh, which he described as "slow going and extremely difficult" because of the significant scarring. (*Id.*) Dr. Radke then repaired the hernia with another of Defendants' products, Bard Marlex Mesh. (*Id.*) Even after the explant surgery, Plaintiff claims to have continuing chronic pain and other complications.

II. Standards

"Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize a court to rule on an evidentiary motion *in limine*." *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 348 F. Supp. 3d 698, 721 (S.D. Ohio 2016). The practice of ruling on such motions "has developed pursuant to the district court's inherent authority to manage the course of

trials." *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). "The purpose of a motion *in limine* is to allow a court to rule on issues pertaining to evidence prior to trial to avoid delay and ensure an evenhanded and expedient trial." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (citing *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004)). However, courts are generally reluctant to grant broad exclusions of evidence before trial because "a court is almost always better situated during the actual trial to assess the value and utility of evidence." *Koch v. Koch Indus., Inc.*, 2 F. Supp. 2d 1385, 1388 (D. Kan. 1998); *accord Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975). Unless a party proves that the evidence is clearly inadmissible on all potential grounds—a demanding requirement—"evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context." *Ind. Ins. Co.*, 326 F. Supp. 2d at 846; *see also Koch*, 2 F. Supp. 2d at 1388 ("[A] court is almost always better situated during the actual trial to assess the value and utility of evidence."). The denial, in whole or in part, of a motion *in limine* does not give a party license to admit all evidence contemplated by the motion; it simply means that the Court cannot adjudicate the motion outside of the trial context. *Ind. Ins. Co.*, 326 F. Supp. 2d at 846.

Relevant evidence is "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. "Irrelevant evidence is" inadmissible. Fed. R. Evid. 402. A court may exclude relevant evidence under Federal Rule of Evidence 403 "if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. Evidentiary rulings are made subject to the district court's sound discretion. *Frye v. CSX Trans., Inc.*, 933 F.3d 591, 598 (6th Cir. 2019); *see also Paschal v. Flagstar Bank*,

295 F.3d 565, 576 (6th Cir. 2002) ("In reviewing the trial court's decision for an abuse of discretion, the appellate court must view the evidence in the light most favorable to its proponent, giving the evidence its maximum reasonable probative force and its minimum reasonable prejudicial value.").

III. Analysis

Based on arguments Defendants made in the two prior bellwether trials, Plaintiff anticipates Defendants will introduce evidence and argument at this trial about a "lack of complaints" involving the PerFix Plug. (Memo. at PageID 12480.) Plaintiff contends that Defendants will suggest that if Plaintiff's allegations were an issue, the medical community would have been aware of the issue. (*Id.*) To rebut such evidence, Plaintiff asks the Court to admit the summary exhibit created by his litigation team, which tabulates patient complaints from Plaintiff Profile Forms ("PPF") by those who were implanted with PerFix Plugs. (*See* Summary Ex., ECF No. 329-1.) Plaintiff patients who completed the PPFs could indicate that they had, among other things, pain and suffering, nerve damages, mesh shrinkage, loss of a testicle(s), and adhesions.[2] (*Id.*)

Plaintiff urges that his summary exhibit is admissible under Federal Rule of Evidence 1006, and that Defendants are already in possession of the underlying documents and his calculations. (Memo. PageID 12480.) Plaintiff argues that "Defendants have used the Court's prohibition on evidence or argument of other lawsuits, as a shield, while they simultaneously argue that there is a 'lack of complaints' for their products." (*Id.* at PageID 12487.)

[2] The PPFs are for individuals who filed claims against Defendants in this MDL. (Certification of David Hobbs, ECF No. 329-2 at ¶ 2.) Claims that did not relate to the Perfix Plug were filtered out, resulting in 5,870 PPFs relied on to create the summary exhibit. (*Id.* ¶ 4.)

Federal Rule of Evidence 1006 provides that:

> The proponent may use a summary, chart, or calculation to prove the content of voluminous writings, recordings, or photographs that cannot be conveniently examined in court. The proponent must make the originals or duplicates available for examination or copying, or both, by other parties at a reasonable time and place. And the court may order the proponent to produce them in court.

The Sixth Circuit has interpreted Rule 1006 as imposing the following requirements for admission of an evidentiary summary:

> (1) the underlying documents must be so voluminous that they cannot be conveniently examined in court, (2) the proponent of the summary must have made the documents available for examination or copying at a reasonable time and place, (3) the underlying documents must be admissible in evidence, (4) the summary must be accurate and nonprejudicial, and (5) the summary must be properly introduced through the testimony of a witness who supervised its preparation.

United States v. Modena, 302 F.3d 626, 633 (6th Cir. 2002). Defendants contend that *Modena* requirements (2)–(5) are not met. (Opp. at PageID 12757–12761.) Because the Court finds Plaintiff has not met his burden of showing that the underlying documents are all admissible and that the summary exhibit is accurate and nonprejudicial, it need not address the other requirements.

A. The underlying PPFs are inadmissible.

Plaintiff generally argues that the summary exhibit is admissible but fails to address the admissibility of the underlying documents relied on to create the summary. (*See generally* Memo.) Defendants urge that the Court has already excluded evidence of the number of the lawsuits involving Bard (ECF No. 269, MIL Order No. 51 at PageID 9745), and so Plaintiff could not introduce the underlying PPFs into evidence because collectively they would reveal the number of cases against Defendants involving the PerFix Plug. (Opp. at PageID 12757–58.) Defendants also point out that this Court held individual complaints may be admitted only if they are "substantially similar" to Plaintiff's case (ECF No. 269, MIL Order No. 51 at PageID 9745), and Plaintiff cannot establish substantial similarity of the PPFs. (Opp. at PageID 12758.)

"[A]ll documents underlying a Rule 1006 summary must be admissible into evidence." *United States v. Jamieson*, 427 F.3d 394, 411 (6th Cir. 2005) (citing *Martin v. Funtime, Inc.,* 963 F.2d 110, 116 (6th Cir.1992)). The burden is on the proponent of the summary exhibit to establish that the underlying documents are admissible. *Martin,* 963 F.2d at 116. For example, if the underlying documents are inadmissible for any reason, "such as irrelevancy, unfair prejudice, or lack of authenticity," then this principle would "render inadmissible a summary based on [those] documents." *United States v. Bray*, 139 F.3d 1104, 1110 (6th Cir. 1998).

Plaintiff has not established that the underlying PPFs are all admissible as he must for his summary exhibit to also be admissible. Certain complaints underlying the PPFs are not substantially similar to Plaintiff's case. This Court found that for a complaint to be substantially similar to Plaintiff's case the patient must, among other things, have had the same injury as Plaintiff.[3] (MIL Order No. 51, ECF No. 269 at PageID 9745.) As Defendants note, in the "Outcome Attributed to Devices" section of the PPFs that Plaintiff uses for his calculation, the list of injuries refers only to "pain and suffering," not "chronic pain." (Opp. at PageID 12758.) "Pain and suffering" could include post-operative pain or emotional pain. Put differently, chronic pain is perhaps a subset of pain and suffering; pain and suffering is not necessarily a subset of chronic pain. They are not automatically the same injuries.

Equally problematic is that this Court has ruled "that neither party [can] introduce evidence of the number of cases pending in this MDL." (MIL Order No. 51, ECF No. 269 at PageID 9745;

[3] The Court's ruling, issued before discovery was completed on Plaintiff's new alleged injuries stemming from his May 2023 surgery, determined that substantial similarity here required: "(1) the patient had the same injury as Plaintiff, (2) the device at issue was a PerFix Plug or another polypropylene-only inguinal hernia device, (3) the repair was made to a hernia or other similar inguinal soft tissue injury, and (4) the device was placed preperitoneally." (MIL Order No. 51, ECF No. 269 at PageID 9745.)

see also Johns v. C.R. Bard et al., Case No. 18-cv-1509, MIL Order No. 3, ECF No. 332 at PageID 17888; *Johns*, Case No. 18-cv-1509, MIL Order No. 11, ECF No. 415 at PageID 22200–01; *Milanesi et al. v. C.R. Bard, Inc. et al.*, Case No. 18-cv-1320, MIL Order No. 37, ECF No. 313.) Introduction of all of the underlying PPFs into evidence would indicate the volume of cases in the MDL. Plaintiff's reasoning that he "does not intend to characterize the lawsuits as legal complaints but rather 'complaints received by Bard related to the PerFix Plug devices'" (Memo. at PageID 12481), does not convince the Court that prejudice will be averted.

Plaintiff has not shown the underlying PPFs are admissible.

B. The summary exhibit is inaccurate and therefore prejudicial.

Plaintiff concedes that a "summary or chart must be accurate, authentic, and properly introduced before it may be admitted in evidence," but does not expound upon why the summary exhibit is accurate. (Mot. at PageID 12485–86) (citing *United States v. Scales*, 594 F.2d 558, 563 (6th Cir. 1979).) Defendants point out flaws in the underlying PPF data. For example, they note that simply because a device has been identified in a PPF, does not mean that it is the device for which the plaintiff filling out the PPF is alleging injuries. (Opp. at PageID 12759.) Defendants explain that they sampled 500 PPFs in which the plaintiffs were implanted with a PerFix Plug and at least one other device and, of that sample, more that 20% of those plaintiffs were not making a claim for the PerFix Plug. (*Id.*) Thus, Plaintiff is overstating the number of complaints, Defendants explain. (*Id.*)

Defendants also note that if plaintiffs in the PPFs had multiple devices implanted, it "is impossible to ascertain from the data which injuries are being attributed to the other device(s)." (*Id.*) They highlight that certain plaintiffs allege complication of "ring break" in their PPFs, but do not indicate they were implanted with a device containing a ring. (*Id.* PageID 12760.) They also

note there are duplicative records. (*Id.*)

Defendants have pointed to some inaccuracies related to Plaintiff's use of the PPFs to create his summary exhibit, and the prejudice to Defendants that would result from the use of the exhibit. The Court agrees that the methodology used to create the summary exhibit lacks validity—the results do not represent what they are supposed to measure. Plaintiff has not met his burden of showing that the summary exhibit is accurate, and consequently, he has also not met his burden of demonstrating the summary exhibit is nonprejudicial.[4,5]

IV. Conclusion

Plaintiff's request is **DENIED**.

IT IS SO ORDERED.

10/24/2023
DATE

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

[4] This ruling does not prevent Plaintiff from introducing other evidence of individual complaints that are substantially similar to Plaintiff's case to rebut argument and evidence offered by Defendants that they were not on notice of the issues with the PerFix Plug. (*See Johns*, Case No. 18-cv-1509, MIL Order No. 7, ECF No. 375.)

[5] Plaintiff also "contends that [the] calculations are so straightforward, that if the Court deems the exhibit to be admissible, it may take judicial notice of the number of complaints." (Memo. at PageID 12481.) The Court did not deem the summary exhibit admissible, and it therefore does not need to address Plaintiff's judicial notice argument.