UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO

IN RE: DAVOL INC./C. R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION	**Case No. 2:18-md-2846** **CHIEF JUDGE EDMUND A. SARGUS, JR.** **Magistrate Judge Kimberly A. Jolson**
This document relates to: **ALL CASES**	

DEFENDANTS C. R. BARD, INC. AND DAVOL INC.'S OBJECTION TO *STINSON* AS THE THIRD BELLWETHER TRIAL FOR LACK OF REPRESENTATIVENESS

Defendants C. R. Bard, Inc. and Davol Inc. (collectively "Bard") hereby file their Objection to the selection of *Stinson v. Davol Inc., et al.*, Case No. Case No. 2:18-cv-01022, as the third bellwether trial case in this MDL.

INTRODUCTION

On January 24, 2020, the Court issued its Case Management Order No. 25: Selection of Initial Bellwether Trial Cases [ECF 318] selecting four cases for bellwether trials. All parties and the Court agreed on the sequencing of the bellwether trials. The first and second trials involve abdominal hernia repair products—the Ventralight ST and the Ventralex. *See* Case Management Order No. 25 [ECF 318]. CMO 25 also determined that "the party whose pick is selected for the first trial . . . will pick the case to be tried as the fourth trial . . . ." *See id*. at 3. As the first trial, *Johns v. C. R. Bard, Inc. et al.*, Case No. 2:18-cv-01509, is a defendant-selected case, Bard is entitled to select the fourth trial case. *See id*. at 4. Bard requested *Miller v. Davol Inc. et al.*, Case No. 2:18-cv-

01443, be set as the fourth trial.[1] *See* Defendants C. R. Bard, Inc. and Davol Inc.'s Request to Schedule and Select the Fourth Bellwether Trial [ECF 343].

As part of CMO 25, *Stinson v. Davol Inc. et al.*, Case No. 2:18-cv-01022—involving the extra-large PerFix Plug device, used to repair inguinal hernias—was selected as Bellwether Trial Case No. 3. Since the entry of CMO 25, the parties have conducted further discovery, including their respective evaluations of the expert reports and expert depositions in the bellwether cases including *Stinson*. That effort has made clear that the claims and issues raised in *Stinson* are not representative of other cases in this MDL, a declared goal of the bellwether process. Thus, a trial in *Stinson* would not provide an informative verdict that can be applied to the broader range of cases. As a result, *Stinson* is not an appropriate bellwether trial case, and should not proceed as the third case to be tried by this Court.

First, the alleged complication in *Stinson*, purportedly rolled up mesh that required surgical removal, is not representative of the complications alleged in the broader range of inguinal hernia cases in this MDL. The injuries alleged in *Stinson*, including difficulty with urination, impaired sex life, weight gain, and nerve entrapment, are similarly not representative of the injuries alleged in the broader range of cases. *Second*, the PerFix Plug and Patch (the "PerFix Plug") is not the sole hernia mesh product that has been

[1] Based on arguments provided at the February 2, 2021, Case Management Conference (the "CMC"), Bard understands Plaintiffs intend to object to *Miller* as an appropriate bellwether case in this MDL. The parties previously addressed the selection of this case in simultaneous briefing submitted on February 12, 2020. *See* Defendants' C. R. Bard, Inc. and Davol Inc.'s Request to Schedule and Select the Fourth Bellwether Trial [ECF 343]; Plaintiffs' Steering Committee's Brief on the Selection of the Fourth Bellwether Trial Case [ECF 344]. The parties and Court have subsequently discussed the scheduling of *Miller* as a bellwether trial case multiple times over the course of the past year. Bard reserves the right to respond to any objection(s) levied by Plaintiffs regarding the selection of *Miller* as a bellwether trial in a response to be filed on March 9, 2021, pursuant to the briefing schedule set by the Court at the CMC.

implanted in the Plaintiff in *Stinson*. Thus, the *Stinson* trial will necessarily involve testimony and evidence relating to two Bard hernia repair products implanted during separate surgeries, whereas the vast majority of pending cases in this MDL concern one hernia mesh device per Plaintiff. As a result, any verdict rendered in *Stinson* would be less meaningful as applied to single product cases in the MDL relating to the PerFix Plug or other devices. This cuts against the essential purpose of the MDL approach to large-scale litigation and potential ultimate resolution.

Instead, Bard recommends selecting a third bellwether trial case that is more representative of the claims and purported injuries at issue in a broader range of cases in the MDL. Such a case would involve a single hernia mesh product and more commonly alleged complications and purported injuries, such as alleged chronic pain from either purported contracture[2] or adhesions. Additionally, a case involving less complicated post-implant medical treatment, involving either no explant surgery or a more limited explant surgery, will provide information meaningful to resolving common issues and inform any settlement for a larger number of cases. Bard therefore proposes that *Stinson* be removed as a bellwether trial case in this MDL and recommends proceeding with a more representative case for inguinal hernia related claims raised in the MDL inventory as the third bellwether trial.[3]

[2] Bard rejects Plaintiffs' contention that mesh contracts post-implantation. Tissue contracts as part of the natural healing process after surgery with or without mesh, but the mesh itself is inert and does not contract.

[3] In arguing that *Stinson* should be replaced by another case in this MDL, Bard continues to maintain that it chooses Bellwether Trial Case No. 4 pursuant to CMO 25.

ARGUMENT

Bellwether trials are intended to provide "[r]epresentative verdicts and settlements to enable the parties and the court to determine the nature and strength of the claims ... and what range of values the cases may have." *In re E. I. Du Pont De Nemours & Co. C-8 Personal Injury Litig.*, 204 F. Supp. 3d 962, 968 (S.D. Ohio 2016) (quoting The Manual for Complex Litigation, § 22.315 (2004)). Bellwether trials are commonly used to "facilitate settlement in similar cases by demonstrating the likely value of a claim or by aiding in predicting the outcome of tricky questions of causation or liability." *Id*. at 968. While courts have great latitude in selecting bellwether trial cases, the ideal bellwether case is one which presents claims and issues representative of those commonly asserted in the broader range of cases in the MDL. *See id*. This Court's Orders establishing the bellwether process emphasized the need to have trial cases that were "[r]epresentative Plaintiff candidates . . . that [] represent a sample of the cases currently pending in the MDL and consistent with the guidelines set by the Court." CMO No. 10-A [ECF No. 207] at 2; CMO No. 10-B [ECF No. 217] at 2.

1. The Injuries Alleged in *Stinson* are Not Representative of the Injuries Alleged in the MDL

In August 2015, an extra-large PerFix Plug was implanted to repair Mr. Stinson's right direct inguinal hernia. He allegedly developed significant post-operative pain. Though Mr. Stinson was treated with steroid injections and nerve blocks in 2016, his pain continued. In June 2017, he underwent a subsequent operation, which included the removal of the PerFix Plug device. In the course of that explant procedure, his physician found what he described as "a large ball approximately 2.5 cm in diameter of rolled up mesh next to the pubic tubercle." After the PerFix Plug was removed, Mr. Stinson's

recurrent hernia was repaired in the course of that surgery with a different product, a flat sheet of 3x6 inch Bard Marlex Mesh, which currently remains in place in Mr. Stinson.

While pain is a widespread alleged injury in inguinal cases in the total MDL inventory, the complication of alleged rolled up mesh is very rare and is not representative across cases in this MDL. Fewer than 1% of PerFix Plug cases involve claims relating to rolled or balled up mesh, as is alleged in *Stinson*. Likewise, *Stinson* involves less commonly alleged complaints resulting from hernia repair surgery, including difficulty with urination, impaired sex life, and nerve entrapment. For example, urinary complaints and impaired sex life or sexual dysfunction are alleged in fewer than 1% of cases in the MDL. Similarly, entrapped nerves are alleged in fewer than 1% of PerFix Plug cases.

Further, the Plaintiff in *Stinson* has a complex surgical history pre-dating implant of the PerFix Plug, including multiple years of complaints of chronic pain, physical trauma, and multiple surgeries, which weighs against representativeness. Prior to implant of the PerFix Plug, the Plaintiff in *Stinson* suffered traumatic injuries due to a motor vehicle accident, including fractured cheekbone, jaw and ribs, and left leg foot injury requiring a skin graft. Prior to implant, Mr. Stinson also suffered from renal complaints, disc herniation and bulging discs, and morbid obesity. Following implant, the Plaintiff in *Stinson* also underwent complicated medical treatment including repeated nerve block injections to address his purported pain, was diagnosed with osteoarthritis and degenerative disc disease, and, ultimately, underwent exploratory surgery that resulted in removal of one device and implant of another. As a result, *Stinson* involves consideration of a preexisting elevated pain response from multiple years of trauma, pain complaints, and surgeries. Any verdict would necessarily consider Mr. Stinson's specific elevated

pain response and would, as a result, be less meaningful or helpful for evaluating the broader range of cases not involving such a preexisting elevated pain response. It is precisely these two aspects of *Stinson* that make this case non-representative.

First, there is the complicated medical history that any jury would have to contend with and understand in evaluating both liability and damages and defenses presented as to both. Further, there is the nature of the far more serious alleged injuries being asserted, including things like urinary, sexual, and intimacy issues to name a few, on top of the pain-related issues.[4] Both of those components make the damages alleged in Stinson more complex (and certainly much higher) than the typical inguinal repair case in the MDL.

Because *Stinson* involves more unusual alleged injuries and a complicated post-implant medical history, a trial verdict in *Stinson* would be less instructive to this MDL than a verdict rendered in a more representative case.

2. A Case Involving Testimony and Evidence of Two Mesh Products is Not Representative of the Broader Range of Cases in the MDL

Moreover, *Stinson* is not representative because trial in *Stinson* would involve evidence and testimony relating to a second product, the Bard Mesh, in addition to the extra-large PerFix Plug at issue. Mr. Stinson's PerFix Plug (and Patch) was completely explanted in 2017 and replaced with Bard Mesh.[5] The vast majority of cases in this MDL involve only one hernia mesh product, and it was always envisioned by this Court that

[4] Plaintiffs have previously cited Mr. Stinson's post-implant medical treatment, including his 18 months of unsuccessful nerve block injections to treat pain, to contend that his injuries are purportedly more serious. *See* Plaintiffs' Steering Committee's Reply Brief on the Selection of the Initial Bellwether Trial Cases, at 4 [ECF 308].

[5] *Stinson* does not allege any claims arising out of the Bard Mesh.

the initial bellwether trials in this MDL concern only one product per case. Further, only a handful of cases in this MDL involve both the PerFix Plug and the Bard Mesh devices, as *Stinson* does.

The design of the PerFix Plug and the Bard Mesh differ, presenting different issues and information for a jury to understand at trial. For example, the Bard Mesh implanted during Mr. Stinson's second surgery is a 3x6 inch flat piece of mesh that can be trimmed to a surgeon's need. In contrast, the Plug portion of the PerFix contains pleated edges and inner petals that can be removed or trimmed. The most common sizes of the PerFix Plug at issue in the MDL are small, medium, and large. However, Mr. Stinson's surgery involved an extra-large PerFix Plug. The extra-large size of the PerFix Plug is different because it consists of three pre-formed cones of mesh contained within a larger cone (as opposed to pleated edges and inner petals). Indeed, the extra-large size is the least common size represented in the MDL inventory, which further reduces the representativeness of the case.

In addition, Mr. Stinson does not assert any allegations of defect or any criticisms of the Bard Mesh. Mr. Stinson does not allege any purported injuries (whether now or in the future) arising out of the implantation of Bard Mesh product during his second surgery. Put differently, his specific causation allegations are limited to the PerFix Plug implant and first hernia repair surgery. He does not claim any injuries at all from the second surgery or the Bard Mesh. Indeed, Mr. Stinson's one case-specific expert, Dr. David Grischkan, has confirmed that his specific causation opinions and criticisms relate solely to the PerFix Plug implant in 2015 and he is not offering any opinions or criticisms specific to the Bard Mesh device that was later implanted in 2017. Nonetheless, a trial

in *Stinson* would necessarily involve evidence and testimony as to both the PerFix Plug and Bard Mesh devices, with the jury potentially needing to keep separate the unique issues as to product design, use, and potential role of the Bard Mesh as it remains in Mr. Stinson. Discussion of two different products would consume more trial time and potentially lead to jury confusion as to which attributes and characteristics relate to the PerFix Plug. Moreover, cases involving two different products are not representative or meaningful for bellwether purposes, as verdicts from such cases do not provide as meaningful information to the parties as single product cases. The mere fact that *Stinson* involves two products, rather than one, makes it less representative. In contrast to *Stinson*, a case that does not involve evidence or testimony relating to a second device (let alone any other hernia mesh product) would be more representative of the broader range of cases in the MDL.

3. A More Representative Case Involving a Single Product and Straight-Forward Medical History Would Provide More Guidance for the Parties

Bard recommends substituting *Stinson* with a more representative case for this MDL. A more representative inguinal hernia case would involve a single product, more commonly alleged injuries, more representative damages claims, and a more common alleged complication. For example, allegations of "contracture" or adhesions are more commonly asserted complications than rolled up mesh. Accordingly, a more representative case could be one involving allegations of purported "contracture" or adhesions.[6] Similarly, a more representative case would reflect allegations focused more

[6] Plaintiffs have already conceded that a case involving purported adhesions could be representative. PSC Proposal for the Selection of Initial Bellwether Cases [ECF 298] at 3 n.2 (noting that adhesion allegations comprise 64% of the data collected for the overall MDL inventory).

specifically on chronic pain and/or on largely pain-related alleged injuries as those are the more commonly asserted and therefore far more representative injuries in the broader range of cases in the MDL. Additionally, a case involving a less complicated post-implant medical history, with either no revision/removal hernia repair surgery or a less complex revision procedure, would provide more meaningful information to the parties to inform settlement.

For the reasons stated above, the injury, claims, and medical issues presented in *Stinson* are less representative of the claims in the broader range of cases in this MDL. Therefore, a verdict rendered in a more straightforward and representative case, fitting the parameters outlined above, would provide more meaningful information and experience for the parties.

CONCLUSION

The unique facts and issues raised in *Stinson* are not representative of the issues raised in the broader MDL inventory, and a trial verdict in *Stinson* would not provide the parties with meaningful information for resolving issues or informing settlement. Accordingly, *Stinson* should be removed as a bellwether trial case and a more representative case, raising more commonly alleged injuries and complications, would produce a more representative verdict than one rendered in *Stinson*. Proceeding with a more representative case as the first inguinal hernia cases in the MDL inventory would provide more meaningful information to the parties to provide a basis for resolving common issues or claims, and ultimately for enhancing prospects of settlement.

As always, Bard is available to discuss its selections with the Court at a time that is mutually convenient for the Court and the parties.

DATED: February 23, 2021

/s/ *Lori G. Cohen*

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CERTIFICATE OF SERVICE

I hereby certify that on February 23, 2021, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of this electronic filing to all counsel of record.

/s/ *Lori G. Cohen*