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 BRIEF REGARDING BELLWETHER TRIAL CASE SELECTION

Defendants C. R. Bard, Inc. and Davol Inc. (collectively "Bard"), pursuant to Case Management Order No. 20A (ECF No. 274), hereby identify the cases Bard proposes for the trials scheduled for May 11, 2020, July 13, 2020, and September 14, 2020. The bases for Bard's proposal are explained more fully below.

INTRODUCTION

The parties selected the original twelve cases for the Bellwether Discovery Pool with the intention that they would be representative of the cases in this MDL. The same intention guided the parties' decisions when they selected six of the twelve cases for the Bellwether Trial Pool ("Pool"). It is no accident that the six remaining cases involve the four devices that are most prevalent among the plaintiffs in this MDL.

It also is not surprising that the parties each picked case involving the same device. Both Plaintiffs and Bard selected a case involving a Ventralight ST device (Johns, McCourt), and both Plaintiffs and Bard selected a case involving a Ventralex device (Campos, Milanesi). Although the two remaining cases (Miller and Stinson) do not involve the same device, the devices they do involve, a 3DMax and a PerFix Plug, are both used to treat inguinal (groin) hernias. (The

Ventralight ST and Ventralex devices, in contrast, are used to treat abdominal hernias.) The devices at issue in the parties' respective selections, in combination with the Court's decision to alternate between plaintiff and defense picks, provides an efficient and effective framework for determining the order of the first three trials.

As demonstrated by the selections below, Bard prioritized the cases in which the device at issue represents a significant part of the MDL inventory as a whole (particularly if one included similar devices with the same technology) over the cases in which the device at issue was previously (or will be) the subject of a trial elsewhere by the time the first trial in this MDL begins. This approach to the order of trials seeks to maximize the opportunity to use this process to determine the value, if any, of the cases in this MDL.

In accordance with the above-explained methodology, Bard proposes that the first three trials proceed as follows:

1. **May 11, 2020 Trial Setting – Ventralight ST**

Plaintiff's Name (Last, First)	Johns, Steven
Case No.	2:18-cv-01509-EAS-KAJ
Plaintiff's Counsel	McDonald Worley, P.C. Krause & Kinsman LLC
Allegations	Plaintiff alleges he had a recurrence and additional surgery.

OR

Plaintiff's Name (Last, First)	McCourt, Thomas
Case No.	2:19-cv-01011-EAS-KAJ
Plaintiff's Counsel	Fleming, Nolen & Jez, L.L.P Hollis Law Firm

Allegations	Plaintiff alleges he had a small bowel obstruction and bowel resection.

2. July 13 Trial Setting – Ventralex

Plaintiff's Name (Last, First)	Campos, Jesus
Case No.	2:18-cv-00915-EAS-KAJ
Plaintiff's Counsel	Robert J. DeBry & Associate
Allegations	Plaintiff alleges infection.

OR

Plaintiff's Name (Last, First)	Milanesi, Antonio
Case No.	2:18-cv-01320-EAS-KAJ
Plaintiff's Counsel	Levin, Papatonio, Thomas, Mitchell, Rafferty & Proctor, P.A.
Allegations	Plaintiff alleges he had bowel erosion and bowel resection.

3. September 14 Trial Setting – Inguinal Hernia (3DMax v. PerFix Plug)

Plaintiff's Name (Last, First)	Miller, Gregory
Case No.	2:18-cv-01443-EAS-KAJ
Plaintiff's Counsel	Douglas & London, P.C.
Allegations	Plaintiff alleges nerve irritation and pain.

OR

Plaintiff's Name (Last, First)	Stinson, Aaron
Case No.	2:18-cv-01022-EAS-KAJ
Plaintiff's Counsel	Fleming, Nolen & Jez, L.L.P.
Allegations	Plaintiff alleges pain.

Consistent with the Court's language in CMO 20A that "the presumptive sequence of trials shall be alternating picks, such that no one side has two selections tried, consecutively," we believe if a defense pick is the first trial, the second trial (presumably involving the Ventralex device) will be a plaintiff pick. Similarly, if a plaintiff pick is the first trial, a defense pick will be the second trial. For the reasons set out below, Defendants believe that *Johns*, the Ventralight ST case selected by Defendants, should be the first trial.

ARGUMENT

I. VENTRALIGHT ST IS THE MOST REPRESENTATIVE DEVICE, FOLLOWED BY VENTRALEX

Bard's case selections involve Ventralight ST, Ventralex, and 3DMax. Of the devices that have been agreed upon for consideration, Ventralight ST and Ventralex have the largest inventory in the MDL, making up approximately 12% and 13.5%, respectively.

The Ventralight ST is a dual sided hernia mesh, with an uncoated medium weight monofilament polypropylene mesh on the anterior side (the side that will be placed facing the abdominal wall) with an absorbable hydrogel barrier based on Sepra Technology ("ST"). The Ventralight ST also has absorbable PGA fibers on the posterior side (the side that will be placed facing the intestines). The polypropylene side is intended to incorporate in the patient's tissue to promote a strong hernia repair. The absorbable barrier is intended to last until the peritoneum (membrane that coves most of the intra-abdominal organs) covers over that side of the mesh so that it minimizes the chances of the intestines adhering to the mesh. Once the peritoneum, which is cut open by the physician to perform the hernia repair, fully heals, it will act as the barrier to help minimize the mesh from adhering to the intestines.

The Ventralex also is a dual-sided hernia mesh with two layers: an uncoated traditional weight monofilament polypropylene mesh on the anterior side, with a permanent barrier composed of ePTFE on the posterior side. The Ventralex also contains a memory recoil ring, which depending on the year of manufacture is either made of a permanent material, PET, or an absorbable material, PDO, and a pocket and removable strap on the anterior side, all of which help facilitate placement, positioning and fixation.

One of the main differences between Ventralight ST and Ventralex is that Ventralight ST has an absorbable barrier that is intended to minimize tissue attachment from the visceral (organ) side, whereas the Ventralex has a permanent barrier intended for the same purpose. Each of the plaintiffs in the four Pool cases that involve these devices (Johns, McCourt, Campos, Milanesi) claims, in part, that the barrier did not prevent the intestines from adhering to the device and requiring a reoperation.

The majority of the abdominal hernia devices in this MDL contain a barrier to minimize tissue attachment. Of the total cases in this MDL, 32.5% contain an ePTFE barrier like the Ventralex and 31% contain the ST absorbable barrier like Ventralight ST. Together, these cases account for close to two-thirds of the total cases in the MDL.

Although there is no meaningful difference between the percentages of Ventralight ST cases and Ventralex cases in the MDL inventory as a whole, and although the same is true for cases involving absorbable barriers vs. permanent barrier cases, Bard proposes a Ventralight ST case for the first trial because there has never been a trial involving the Ventralight ST device. The same cannot be said for the Ventralex, because two cases involving that device are set for trial in the upcoming months in the Rhode Island state court litigation. The results from these trials will

be representative of the litigation as a whole, and will aid the parties' understanding of the strengths and weaknesses of cases involving this device.

Thus, the Ventralight ST device highlights the materials, claims, and issues that are most representative of the claims in this MDL and do not have a previous history of being tried. Because the Ventralex is also representative of the majority of the cases in this MDL, it makes sense for it to have the second trial setting.

Bard proposes an inguinal case for the third setting because inguinal cases make up so much less of the total inventory. Inguinal cases constitute approximately one third of the total inventory; Perfix Plug at 15.75% and 3DMax at 6.18% of the total cases. For the reasons explained more fully below, of the two inguinal cases in the Pool, the 3DMax case is more representative of the injuries alleged in inguinal cases than the PerFix Plug case, thus rendering it a better selection for the third bellwether trial.

Bard believes the cases and order it proposes will be most representative of all of the cases currently filed in the MDL. For that reason, a trial on these cases in this order should inform the parties in their evaluation of the entire inventory.

II. OF THE TWO VENTRALIGHT CASES, *JOHNS* IS MORE REPRESENTATIVE THAN *MCCOURT*.

Both Johns, a defense pick, and McCourt, plaintiff pick, involve the Ventralight ST. Between the two, Johns is more representative of the cases in the MDL.

When Mr. Johns presented to his physician in July 2015, he had been experiencing an abdominal hernia for approximately one year, and it was getting larger and more uncomfortable. He had both a hernia and a diastasis (a stretching of the fibrous sheath between the two rectus muscles (the "6-pack muscles") in the midline). His surgeon repaired his diastasis by restoring his normal abdominal wall and repaired the hernia using a Ventralight ST. Over a year later, Mr.

Johns' hernia recurred, and he underwent a second surgery. The operative report for the second surgery states that the tissue "slid" underneath the mesh, and that only the diastasis had returned. During this surgery the Ventralight ST that was implanted in 2015 was explanted and another Ventralight ST was implanted. Mr. Johns underwent a third surgery where his diastasis and hernia were repaired again and another hernia mesh not manufactured by Bard was implanted in the rectus abdominal muscle.

Mr. McCourt had a hernia in 2003 that was incarcerated with small bowel and underwent an exploratory laparotomy where his surgeon repaired the hernia without mesh. This hernia recurred within a year. In 2005, Mr. McCourt underwent a liver transplant and was placed on lifelong immunosuppressants. In 2014, after living with the hernia for approximately 10 years, Mr. McCourt sought treatment. He underwent another hernia repair in September 2014, where his physician implanted a Ventralight ST. In July 2016, Mr. McCourt experienced abdominal pain that had worsened over a two week period and presented to the emergency room, where it was discovered that he had a small bowel obstruction. He underwent surgery and the physician noticed that a small portion of the polypropylene side of the Ventralight ST had adhered to the bowel causing the bowel obstruction. The Ventralight ST was explanted.

Both Johns and McCourt had subsequent operations and the Ventralight ST explanted. Regarding alleged injuries in both cases, recurrence as in Johns makes up approximately 13% of all cases in the MDL, and bowel obstruction as in McCourt makes up the 5% of all filed cases. Thus, because the alleged injury in Johns and the facts in that case are more representative of the inventory as a whole, Bard suggests that Johns would be a better case for the first bellwether trial. Moreover, the facts of McCourt, with a prior hernia repair without mesh and liver transplant and on the history immunosuppressants that impact tissue ingrowth, are less representative of the cases

as a whole, even though Mr. McCourt's medical history place him a high risk for recurrence and bowel obstruction with any kind of hernia repair technique or device.

Johns is the most representative of the six cases in the pool, based on device and alleged injuries.

III. OF THE TWO VENTRALEX CASES, CAMPOS IS MORE REPRESENTATIVE THAN MILANESI.

Campos and Milanesi both involve the Ventralex. Of the two, Campos is more representative of the MDL inventory.

Mr. Campos was implanted with a Ventralex in September 2015, for repair of an umbilical hernia. Shortly after surgery, he developed an infection of the tissue over the patch, which migrated down to the patch, and the Ventralex was explanted four months later on January 26, 2016. The explant report notes that Mr. Campos was on chronic high-dose steroids and unable to be taken off: "the mesh did not appear to be incorporated . . . likely from his high-dose steroid use."

Mr. Milanesi had a chronic umbilical hernia that he had for about two years before his surgeon repaired it using a Ventralex in July 2007. Approximately ten years later, in May 2017, he experienced some discomfort at the site of his umbilical hernia repair. His examination suggested a recurrent incisional hernia with entrapped intra-abdominal fat (omentum). He underwent surgery and his physician noted that a loop of intestine was adhered to the polypropylene side of the mesh. A portion of his bowel and the Ventralex were removed. After being discharged from the hospital, he developed a small bowel obstruction several days later which was corrected through another surgery.

Bowel erosion like the injury alleged in Milanesi, makes up approximately 3% of the total inventory. Infection, as alleged in Campos, makes up 7% of the alleged injuries for cases in the

MDL. Campos thus is more representative than Milanesi. In addition, Milanesi's two post-implant surgeries and his amount of time in hospital is less common than the single surgery that Campos had and less representative overall. Bard recommends Campos as the second bellwether trial because (i) the Ventralex is representative of one-third of the cases in the MDL, and (ii) the alleged injuries are more representative in Campos than in Milanesi compared to the total cases in the MDL.

IV. OF THE TWO INGUINAL HERNIA CASES, MILLER IS MORE REPRESENTATIVE THAN STINSON.

Both Miller and Stinson involve inguinal hernia repairs. Miller involves a 3DMax and is more representative than Stinson, which involves a PerFix Plug.

Mr. Miller was implanted with a 3DMax for laparoscopic repair of a right inguinal hernia in May 2013. In 2016, Mr. Miller underwent a diagnostic laparoscopy for complaints of chronic right groin pain. Per the 2016 operative note, the physician discovered Mr. Miller's appendix to be adherent to the 3DMax and elected to remove his appendix. The physician also found "numerous staples over the anterior surface of the mesh" and that "it appeared that the mesh had contracted somewhat and there were 6 to 7 staples in very close proximity to one another." He further noted that "this raised suspicion that this may have been the point of the presumed nerve irritation." Mr. Miller's physician elected to remove the staples and leave the 3DMax in place. He found no evidence of recurrent hernia.

Mr. Stinson was implanted with a PerFix Plug to repair a right direct inguinal hernia in August 2015. He developed significant post-operative pain following surgery which was treated with steroid injections and nerve blocks in 2016, without permanent relief. In June 2017, Mr. Stinson underwent a subsequent operation and his PerFix Plug was removed. His physician noted "we were able to find a large ball approximately 2.5 cm in diameter of rolled up mesh next to the

pubic tubercle." After the PerFix Plug was removed, the resulting recurrent hernia was repaired with a flat sheet of Bard Mesh.

Both Miller and Stinson allege pain, which is the most common type of alleged injury in inguinal cases in this MDL. Miller, however, does allege other alleged injuries such as nerve irritation and contracture that are not seen in Stinson. Stinson alleges that his PerFix Plug rolled up. Because this is not a common type of alleged injury (or understandable given the product design), Bard does not have any data points on it. The other alleged injuries in Miller do make up a combined 11% of the alleged injuries claimed in inguinal cases in the MDL making it more representative than Stinson. This is the reason Bard selected Miller over Stinson.

CONCLUSION

The three cases that Bard recommends for the Bellwether Trial Cases are representative of the broader range of cases in the MDL, and thus can provide the parties and Court with information on the strengths and weaknesses of various claims and defenses. Bard believes that these cases, along with the order in which these cases are to be tried, will help 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: January 13, 2020

/s/ Michael K. Brown

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CERTIFICATE OF SERVICE

I hereby certify that on January 13, 2020, 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/ Michael K. Brown
Michael K. Brown