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:
ALL CASES

DEFENDANTS C. R. BARD, INC. AND DAVOL INC.'S REPLY BRIEF REGARDING THE LACK OF REPRESENTATIVENESS OF *STINSON* AND *BRYAN*

I. INTRODUCTION

Contrary to the PSC's contention, Bard is not simply rehashing the same arguments it previously made with respect to the representativeness of the third and fourth bellwether trial cases. Rather, Bard is challenging the representativeness of *Stinson* and *Bryan* based on *recent* and *ongoing* developments in these cases that involve heightened allegations and injuries that are uncommon across the MDL. The PSC's Opposition attempts to ignore this reality through a distorted retelling of the facts and an unnecessary amount of vitriol.

First, nothing about the history of selecting bellwether cases in this MDL precludes Bard from raising its current challenges, the PSC's mischaracterization of that history notwithstanding. Indeed, the Court's orders, which Bard quoted and the PSC ignored, make clear that the bellwether cases and overall plan could change to suit the interests of justice resulting in the replacement of non-representative trial cases. In Case Management Order ("CMO") No. 10, the Court explicitly noted that it may amend the bellwether process and/or

bellwether case selections in the future "to ensure the integrity of the bellwether process" and/or serve "the interest of justice." CMO No. 10, ECF No. 62, at 2-3. The need to replace *Miller* because the plaintiff terminated his relationship with his PSC counsel set these issues in motion. Bard made clear that *Bryan* was being selected as a replacement for *Miller* to maintain the balance of products at issue, consistent with the scope of generic discovery, even though it had not made it to the Bellwether Trial Pool and there was some uncertainty about the plaintiff's then-current status. Bard also noted that Mr. Bryan's alleged injury, pain, was common to 81.2% of all claimants in the MDL. Bard expressly reserved its right to propose a different case if a material change occurred. *See* Bard's Dec. 28, 2021, Letter sent via email to the Court. Previously, the PSC had challenged *Miller* as a representative case, claiming it involved too low damages and atypical medical facts. Bard challenged *Stinson* in response, contending *Miller* was more representative at that time than *Stinson* was at that time. A new challenge years later, after the circumstances have dramatically changed, is what the Court and the parties envisioned.

Second, the PSC argues, without support, that *Stinson* and *Bryan* remain representative, despite the plaintiffs' ongoing medical treatment and heightened injuries. They double down that *Stinson's* surgery and the specter of a similar surgery in *Bryan* would change nothing. The PSC is wrong. When *Stinson* and *Bryan* were selected as bellwether cases they involved allegations of pain, the most common alleged complication in this MDL, and each also involved a single explant of *one* of the four most commonly alleged devices in this MDL. Now, however, the alleged injuries have morphed into something fundamentally different. Specifically, Mr. Stinson has had, and Mr. Bryan is apparently likely to have, one of his testicles removed. While the PSC claims that 4.4% of the PerFix Plug cases involve an orchiectomy—and do not dispute the number is 1% for all cases—this small percentage undercuts, not supports, the

representativeness of *Stinson* and *Bryan*. Additionally, Mr. Stinson has now had two Bard hernia devices removed and, regardless of whether Mr. Stinson intends to make a formal claim for his Bard Mesh, the reality is that that the second device is so intricately intertwined with his recent injuries that it will inevitably end up on trial right alongside the PerFix Plug.

As it stands now, *Stinson* is a fundamentally different case than it was at any point from its selection for the Bellwether Discovery Pool until late 2022. It appears that *Bryan*, based on seeking surgical intervention after years of no medical care for any groin or testicle pain, will follow the same path. As the PSC has recently recognized, whether a plaintiff has recent medical records that match with the claims of on-going injuries being made in the lawsuit can make or break a trial. In a recent interview, one of the members of the PSC reported that the PSC believed that the plaintiff lost *Johns* because the plaintiff in that case failed to seek medical care leading up to trial. As a result, the PSC has altered its litigation strategy and is now recommending that plaintiffs seek further treatment (in an attempt to bolster their chances at trial). The PSC cannot, on the one hand, argue that heightened injuries—particularly ones like those at issue here—have no bearing on the outcome of a case, while also implementing a new trial strategy that hinges on plaintiffs undergoing further medical treatment.

Third, the PSC contends that Bard's request to have *Stinson* and *Bryan* replaced as bellwether trial cases is nothing more than a strategic ploy to try cases with "minor injuries and/or relatively low damages."[1] *See* PSC's Opp'n, ECF No. 251, at 2. The Court has

[1] The PSC also claims that Bard has been aware that Mr. Stinson and Mr. Bryan would need surgery "for years" and, for "tactical reasons," deliberately waited until the trials in these cases were reset (again) to raise objections to the cases' representativeness. *See* PSC's Opp'n, ECF No. 251, at 3. While Bard knew that these plaintiffs had some complaints of post-explant symptoms—which generally continued from pre-implant and had not been the subject of on-going medical care for several years—it could not and did not know that Mr. Stinson and/or Mr. Bryan would seek and receive additional surgery with their respective trials approaching. As the Court recognized in connection with moving the *Stinson* trial, another surgery near trial is a big deal and, certainly, a surgery that involves removing a testicle along with a second device is a game changer. Bard had no reason before late 2022 to expect that Mr.

recognized and Bard has repeatedly cooperated with the need to try representative cases to obtain verdicts that can provide meaningful information about the MDL *as a whole*. It so happens that the overwhelming majority of MDL cases involve "minor injuries and/or relatively low damages." Before the recent prospect of an additional surgery, this covered *Bryan* and *Stinson*. It was certainly the case that both were fundamentally chronic pain cases and that pain is the most common claimed injury, particularly among inguinal cases.[2] Now, however, the facts of and issues in *Stinson* and *Bryan* are no longer representative of a large (or even moderate) number of cases in the MDL. The PSC's insistence that these cases proceed to trial is nothing more than an attempt to inflate the value of their inventory by litigating two outlier cases that involve (or will involve) an extremely rare, but severe, injury. That is the true gamesmanship here.

Fourth, the PSC contends that working up a small number new cases for trial "is a herculean task that will take years." *See* PSC's Opp'n, ECF No. 251, at 8. This position contradicts the PSC's previous representation to the Court that it would take only ***six or seven months*** to work up a "handful" of cases for bellwether trials. *See* PSC's Brief on the Selection of the Fourth Bellwether Trial Case, ECF No. 344, at 3. Setting aside the PSC's inconsistent positions, the amount of additional work and the time it would take to work up cases for trial as outlined in Bard's proposal is not significantly greater than the time that will be required to get *Stinson* and *Bryan* ready for trial given their recent and expected care. Moreover, Bard's

Stinson might have another surgery before trial and certainly had no indication that he would have a testicle removed. That Mr. Bryan might follow Mr. Stinson's suit has become apparent in the last few weeks, but was not apparent when the case was substituted in as the fourth bellwether trial over the PSC's objection.

[2] Recurrence is the second most commonly alleged injury (67%), adhesions is the third (57%), and infection is the fourth (27%). As such, the bellwether cases tried in this MDL should consist of plaintiffs with one or more of these four alleged injuries, which is how the trial cases were set up originally.

proposal would maintain the integrity of the bellwether process by ensuring that the cases that are tried are actually representative of a large swath of cases in the MDL.

II. ARGUMENT

A. The Court's Orders Contemplate Changes To The Bellwether Selections To Maintain The Integrity Of The Process And Serve The Interests Of Justice

According to the PSC, Bard should be precluded from challenging the representativeness of *Stinson* and *Bryan* because the parties previously lodged unsuccessful challenges to various cases. Nothing in the Court's orders (which the PSC did not cite or reference) supports this fallacy. Since the inception of the bellwether process in 2018, the Court and the parties have contemplated the possibility that circumstances might arise that would necessitate modifications to the bellwether process and/or bellwether case selections. For instance, in CMO No. 10, the Court explained that amendments to the bellwether procedure and/or case selections might be required "to ensure the integrity of the bellwether process" and/or serve "the interest of justice." CMO No. 10, ECF No. 62, at 2-3. Such modifications were first necessary when the plaintiff in *Miller* fired a member of the PSC and Bard was forced to find a replacement bellwether trial case. In choosing *Bryan*, Bard made clear that its intent was to maintain the balance of devices at issue, consistent with the scope of generic discovery, even though the case was not in the Bellwether Trial Pool and there was uncertainty about the plaintiff's then current medical status.

In addition, the PSC had challenged *Miller* as a bellwether trial case, claiming that it involved too low damages and atypical medical circumstances, and Bard challenged *Stinson* as less representative than *Miller* was *at that time* in response. Despite these dueling challenges, the Court selected both cases as bellwether trial cases. The Court's determination (years ago) that *Stinson* and *Miller* were representative also does not preclude Bard from challenging the representativeness of *Stinson* and *Bryan* cases now, after their facts and issues have changed

significantly.[3] While Bard acknowledges that attempts to modify the bellwether selection process should be done sparingly and only when necessary, the current circumstances in both cases have changed to such a degree that permitting the cases to proceed to trial would undermine the integrity of the bellwether process. This was the exact sort of situation requiring modification that was contemplated by the Court's orders.

B. *Stinson* And *Bryan* Are Not Representative And Nothing In The PSC's Opposition Demonstrates Otherwise

The PSC argues, without support, that *Stinson* and *Bryan* remain representative, despite the plaintiffs' ongoing medical treatment and ongoing injuries. When *Stinson* and *Bryan* were selected as bellwether cases, they each involved allegations of pain—the most commonly alleged injury in this MDL. Each case also involved *one* of the four most commonly alleged devices in the MDL. Now, however, these cases involve or are expected to involve injuries and allegations that are no longer common to a large number of cases. Specifically, Mr. Stinson has had, and Mr. Bryan is apparently likely to have, one of his testicles removed. And although the PSC claims that 4.4% of the PerFix Plug cases involve the removal of a testicle (and do not dispute that only 1% of all cases in the MDL involve this alleged injury, as Bard asserted in its brief), this small percentage, if credited, undercuts, not supports, the representativeness of *Stinson* and *Bryan*.[4] As such, allowing these cases to proceed to trial would result in a jury verdict that would undermine the purposes of the bellwether process by rendering verdicts that would be

[3] The level of injuries and damages at issue in *Miller* at that time was similar to *Bryan* when Bard was forced to pick a replacement for *Miller*.

[4] The PSC's representation that "at least 75% of inguinal cases in the bellwether discovery pool have undergone and/or may undergo an orchiectomy" is simply absurd. *See* PSC's Opp'n, ECF No. 251, at 6. There is no support that this overstated guess would apply to the larger volume of cases—the number is not borne out by the information received by plaintiffs in this MDL, nor is it supported in the literature. Instead, it is a reflection of how the PSC picked unrepresentative inguinal cases from the start and has now urged plaintiffs to get second opinions as trials approach.

informative as to only 1% of total cases in the MDL, and less than 5% of PerFix Plug cases.[5] *See In re Welding Fume Prods. Liab. Litig.*, No. 1:03-CV-17000, 2007 U.S. Dist. LEXIS 41681, *19 n.3 (N.D. Ohio June 6, 2007) ("[T]he purpose of a series of bellwether trials is to 'produce a sufficient number of ***representative verdicts***' to 'enable the parties and the Court to determine the nature and strength of the claims, whether they can fairly be developed and litigated ***on a group basis***, and what range of values the cases may have if resolution is attempted ***on a group basis***.'") (quoting Manual for Complex Litigation Fourth §22.315 at 360 (2004)) (emphasis added). Further, not only are claims of an orchiectomy uncommon in the MDL, the literature supports that this complication is rarely, if ever, reported in the literature. *See, e.g.*, Millikan, K. W. & Doolas, A., *A long-term evaluation of the modified mesh-plug hernioplasty in over 2,000 patients*, Hernia (2007) (study involving 2,000 patients followed for an average of six years and not a single report of an orchiectomy).

Additionally, Mr. Stinson has now had two Bard hernia devices removed—a PerFix Plug and a Bard Mesh. While the PSC has represented that Mr. Stinson does not intend to make a claim for the Bard Mesh, it does intend to present evidence that the Bard Mesh and PerFix Plug are made from the same material and that Mr. Stinson's reaction to the Bard Mesh supports his claim as to the PerFix Plug. The evidence regarding the explant of Mr. Stinson's Bard Mesh, however, is not as straightforward as the PSC suggests. Mr. Stinson's medical records do not show merely that Mr. Stinson's Bard Mesh was removed—it shows that the mesh was wrapped along the length of Mr. Stinson's spermatic cord *such that the Bard Mesh could not be removed unless Mr. Stinson's testicle and spermatic cord were also removed*. In other words, the Bard Mesh is so intimately connected to Mr. Stinson's recent enhanced injuries that the jury will

[5] In now-pending cases involving the 3DMax, only 3% of cases involve even an allegation of an orchiectomy.

inevitably link the removal of Mr. Stinson's testicle and spermatic cord to that device, regardless of whether or not Mr. Stinson makes a formal claim for it. As a result, if *Stinson* is tried and the jury returns a verdict for the plaintiff, it will be impossible to determine which device was the basis of the jury's liability determination. In short, *Stinson* is a fundamentally different case than it was at any point from its selection for the Bellwether Discovery Pool until late 2022. And it appears that *Bryan* will follow the same trajectory.

As the PSC has recently recognized, whether a plaintiff has recent medical records that match with the claims of on-going injuries being made in the lawsuit can make or break a trial. In a recent interview, one of the members of the PSC reported that the PSC believed that the plaintiff in *Johns* lost because he failed to seek medical care leading up to trial. *See*, *Hernia Mesh Litigation Updates with Kelsey Stokes*, Case Works, May 8, 2023, available at https://yourcaseworks.com/status-of-hernia-mesh-litigation/, at 8:10-9:16. She also explained that the jury provided feedback after trial that it could not find for the plaintiff because it did not believe that the plaintiff was injured. *Id*. at 9:49-10:18. As a result, the PSC has altered its litigation strategy and is now recommending that plaintiffs seek additional medical treatment, in an attempt to strengthen the strength of their claims at trial.[6] *Id*. at 8:10-9:16. The PSC cannot, on the one hand, argue that heightened injuries—particularly ones like those now at issue in *Stinson* and, likely, *Bryan*, have no bearing on the outcome of a case—while also implementing a new trial strategy that hinges on plaintiffs undergoing further medical treatment. Nor can they reasonably claim that an additional surgery changes nothing, when that surgery resulted in a

[6] Notably, in 2019, the FTC issued a press release regarding attorney advertising that solicits clients for personal injury lawsuits against drug manufacturers in which the FTC reported that there were consumers were making medical decisions, including discontinuing medications they had been prescribed, based off information provided in the ads. *See* FTC Flags Potentially Unlawful TV Ads for Prescription Drug Lawsuits, Federal Trade Commission, Sept. 24, 2019, available at https://www.ftc.gov/news-events/news/press-releases/2019/09/ftc-flags-potentially-unlawful-tv-ads-prescription-drug-lawsuits.

significant injury and implicates a second device.

Additionally, the PSC's claim that *Stinson* is even ***more representative*** now because its more significant injuries and potential damages will instruct both sides on how to assess the values of cases "with more expansive injuries and larger damages" is nonsensical. *See* PSC's Opp'n, ECF No. 251, at 6-7. This MDL does not involve a significant number of cases with "expansive injuries and larger damages." Rather, the majority of cases involve allegations of "minor injuries," like pain and recurrence. *See, e.g., id*. at 3-4 (conceding that pain is a minor injury with low damages). Because cases with expansive injuries, like *Stinson* is now and *Bryan* (likely) will be, involve the most severely injured plaintiffs and would not facilitate settlement of all (or even a significant number of) cases, they are not appropriate bellwether trial cases. *See In re E.I. du Pont de Nemours & Co. C-8 Personal Injury Litig*., 529 F. Supp. 3d 720, 740 (S.D. Ohio 2021). ("Bellwether plaintiffs are ***purposefully selected to exclude the most severely injured plaintiffs because it would frustrate the bellwether procedure's purpose***. That is, the need to try multiple bellwether cases to facilitate settlement of all cases in an important component of the handling an MDL.") (emphasis added).

C. Proceeding With *Stinson* And *Bryan* As Bellwether Trial Cases Would Undermine the Integrity Of The Bellwether Process And Serve Only To Inflate The Value Of The Inventory Of Cases In The MDL

The PSC accuses Bard of seeking to replace *Stinson* and *Bryan* for the sole purpose of gaining a strategic advantage by "trying cases involving low damages and minor injuries." *See* PSC's Opp'n, ECF No. 251, at 3-4. The PSC is mistaken. Bard's purpose for seeking to replace *Stinson* and *Brian* is to ensure that the bellwether trial cases involve facts and issues, including alleged injuries, common to a significant number of cases in the MDL. This goal is in accordance with the Court's expressed intent of trying representative cases to obtain verdicts that can provide meaningful information about the MDL as a whole. *See, e.g*., 2/4/2021 CMC Tr.,

ECF No. 477, at 23:14-18 & 26:12-16. Because the vast majority of plaintiffs in the MDL allege "minor injuries," such as pain, recurrence, adhesions, and infection, it is only logical that the bellwether trial cases consist of plaintiffs with one or more of these four alleged injuries.

With respect to *Stinson* and *Bryan,* the cases originally involved allegations of pain, the most common alleged injury in this MDL. Now, however, the plaintiffs have undergone, or will undergo, significant additional medical treatment resulting in heightened alleged injuries common to only a small fraction of cases. As such, a verdict in these cases would not serve the overall goals of the bellwether process. *See In re Zimmer M/L Taper Hip Prosthesis*, MDL No. 2859, 2022 U.S. Dist. LEXIS 11866, *32 (S.D.N.Y. Jan. 21, 2022) ("In other words, bellwether cases should be 'representative' of the overarching issues within the overall MDL to aid the development of the parties' disputes and put a value on the litigation.") (citing *In re FEMA Trailer Formaldehyde Prod. Liab. Litig*., No. 092967, 2009 WL 3418128, at *3 (E.D. La. Oct. 14, 2009), *aff'd sub nom*. *In re FEMA Trailer Formaldehyde Prod. Liab. Litig*., 628 F.3d 157 (5th Cir. 2010) (finding one of "the principle goals of the bellwether process" is to select a plaintiff or plaintiffs "who can truly be representative ***of the whole mass of plaintiffs in the MDL***") (emphasis added)). While the PSC may hope to inflate the value of their inventory of cases by litigating two outlier cases that involve (or will involve) an alleged injury that is extremely severe, but also extremely rare, that is not the purpose of the bellwether process.

In short, there is no malintent on Bard's part in requesting substitution of *Stinson* and *Bryan*. Rather, the vast majority of cases in the MDL involve plaintiffs who are alleging minor injuries and cases involving those alleged injuries are the ones that will provide the most meaningful information to the parties at the Court. Those are the sort of cases that should be tried.

D. Selecting Replacement Bellwether Trial Cases Will Maintain The Integrity Of The Bellwether Process And Not Result In A Significant Amount Of Extra Work Or Delay

The PSC claims that working up a small number of cases "is a herculean task that will take years."[7] *See* PSC's Opp'n, ECF No. 251, at 8. This position stands in stark contrast to the PSC's prior representation to the Court that it would take only ***six or seven months*** to work up a "handful" of cases for trial. *See* PSC's Brief on the Selection of the Fourth Bellwether Trial Case, ECF No. 344, at 3. The PSC's exaggeration of this timeline is obvious. As detailed more fully in Bard's prior brief, the time it would take to prepare four new cases for trial would not significantly differ from the amount of time it will take to prepare *Stinson* and *Bryan*. *See* Bard's Brief, ECF No. 477, at 17-19. Mr. Stinson is still recovering from his surgery and none of the additional discovery, including multiple depositions, expert discovery, and motions practice, has even begun. Mr. Bryan is even further behind schedule, as he has only recently begun seeking additional medical care and the extent of additional treatment and timeline remain unknown. If the timeline of Mr. Stinson's medical course is any indication, Mr. Bryan will not be ready for trial until at least Spring 2024. Notably, the PSC acknowledges that no case-specific expert discovery and/or motions practice has been completed in *Bryan*, thus, rendering any potential delay even less of an issue in that case. *See* PSC's Opp'n, ECF No. 251, at 7. Contrarily, if *Stinson* and *Bryan* were replaced, the parties could immediately begin the process of proposing new cases and working them up for trial. Moreover, having two bellwether trials that actually represent common issues and facts would serve the purposes of

[7] The PSC also claims that Bard is attempting to deny Mr. Stinson his day in court by seeking substitution of his case. This position completely ignores the fundamental purpose of the bellwether process. The bellwether process is not about a single plaintiff having his or her case tried. Rather, it is to select a subset of cases with facts and issues common across the MDL such that the outcomes of those cases will enable the parties and the Court to make informed decisions about the *entire* MDL moving forward. Mr. Stinson will undoubtedly have his day in Court. But his individual right to trial should not override the right of the rest of the plaintiffs (many of whose case have

the bellwether process and result in valuable information for the parties and the Court.

III. CONCLUSION

For the reasons stated above, Bard respectfully requests that the Court find *Stinson* and *Bryan* not representative of the MDL and that it is in the interests of justice to replace them with cases that are more representative.

DATED: June 1, 2023

Respectfully Submitted,

/s/ Eric L Alexander

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been pending for years) to have bellwether trials that will benefit not only Mr. Stinson, but the MDL as a whole.

CERTIFICATE OF SERVICE

I hereby certify that on June 1, 2023, 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/ Eric L. Alexander
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