

**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 ACTIONS**

**PLAINTIFFS' STEERING COMMITTEE'S BRIEF ON THE SELECTION OF THE
FOURTH BELLWETHER TRIAL CASE¹**

The Plaintiffs' Steering Committee ("PSC") submits this brief in response to the Court's directive at the February 2, 2021 Case Management Conference ("CMC") and in further support that: (1) *Stinson* remain the third bellwether case—as previously ordered by the Court—and should proceed to trial as already determined; and (2) require Defendants to pick the fourth trial case, which they are entitled to do, from a larger pool of cases at a later date, because the proposed case by Defendants is an outlier case due to its unique set of facts and unrepresentative nature.

As outlined below, this position is consistent with the history behind the overall bellwether process in this MDL.

¹ Both parties have briefed these same bellwether selection issues in the past. *See* ECF Nos. 298, 299, 307, 308, 343, 344. As such, the majority of the arguments that the PSC will raise in this brief have been previously brought to the Court's and Defendants' attention. This is merely another attempt by Defendants to argue why *Miller*, a non-representative outlier case, should be selected as a bellwether trial case and a sudden attempt to undue the Court's prior ruling and remove *Stinson* from the bellwether trial pool. It is not the PSC's intention to re-raise facts and arguments it previously outlined in great detail in its briefs filed on: (1) January 13, 2020 (ECF No. 298); (2) January 21, 2020 (ECF No. 308); and (3) February 12, 2020 (ECF No. 344). Nor is it the PSC's intention to ignore the Bellwether Selection Order issued by this Court on January 24, 2020 (ECF No. 318). To that end, the PSC respectfully re-urges the arguments in its prior briefing and incorporates the same as if fully set forth herein.

I. INTRODUCTION

The parties began the bellwether selection process in 2018. First, the parties engaged in extensive and protracted negotiations for a bellwether process, which was ultimately memorialized by the Court in Case Management Order (“CMO”) No. 10 on November 20, 2018. CMO No. 10 delineated, in great detail, exactly how the bellwether cases would be chosen for trial. Specifically, each party had until January 31, 2019 to identify six representative plaintiff candidates, for a total of twelve cases to be worked up for case-specific discovery. *See* ECF No. 62 at 1–2. Following case-specific discovery, each party would identify three cases for trial consideration, for a total of six potential bellwether trial cases. *Id.* at 2. Lastly, following briefing by the parties, the Court would ultimately select three cases that will proceed to trial. *Id.* at 2–3. CMO No. 10 also outlined that additional cases may be selected for trial and that future CMOs would detail those case(s), criteria, and schedule(s). *Id.* at 3.

On July 12, 2019, in accordance with CMO. No. 10, the parties each selected three cases from the pool of twelve potential bellwether cases. *See* ECF No. 125. On January 13, 2020, upon completion of Core Discovery of the six cases, the parties filed their respective briefs setting forth which three cases were most representative and should be selected for trial. *See* ECF Nos. 298 and 299, the PSC and defense briefs, respectively.

Then, at the January 13, 2020 CMC, the Court indicated that it would make the bellwether process more fair to have four, instead of three, bellwether cases go to trial, with the fourth trial being scheduled a year away.² The Court highlighted that, with four trials, each party will select two trial cases, and whichever party tries its selection first will also choose the fourth trial plaintiff.³

On January 21, 2020, the parties filed additional briefing in response to each other’s

² *See* 1/13/2020 CMC Tr. 63:21-63:25.

³ *Id.* at 65:9-65:13.

bellwether proposals. *See* ECF Nos. 307, 308 (the defense and the PSC briefs, respectively). In its response, the PSC, keeping in mind the Court's guidance and directive regarding the fourth trial, and in the spirit of compromise, ceded the first trial to the Ventralight ST case proposed by Defendants, the *Johns* case. This ensured that the PSC's most representative selections were tried second and third (*Milanesi* and *Stinson*, respectively), and confirmed that the fourth case **would be chosen by Defendants at a later date**. *See* ECF No. 308 (emphasis added).

Importantly, On January 24, 2020, the Court issued CMO No. 25, which set forth the order of the first four bellwether trials: (1) *Johns*; (2) *Milanesi*; (3) *Stinson*; and (4) Defendant Pick TBD. *See* ECF No. 318.

The same CMO outlined a very specific procedure that both parties had to follow if they wish to raise *any objections* to the Court's bellwether selections. In fact, the parties had until 12:00 p.m. EST on January 27, 2020 to file a written response, of no more than 5 pages, if they objected to the Court's selections. *Id.* at 4. Significantly, Defendants never filed any written responses objecting to *Stinson* being selected as the third bellwether trial.

Instead, on February 12, 2020, both parties filed briefing regarding Defendants' selection of the fourth bellwether case. In its briefing, the PSC outlined why *Miller* should not be the fourth trial case, as it is not representative and will not advance the litigation because there is limited information that would be learned from it that would apply to other cases in the MDL. *See PSC's Br. Regarding the Selection of the Fourth Bellwether Trial*, (ECF No. 344) at 2–3, n.3. The PSC also proposed that Defendants select the fourth bellwether case following the second and/or third trial, so that their selection is based on prior bellwether cases' dispositive rulings, pre-trial evidentiary rulings, and trial results. *Id.* at 3–4. However, unlike the first three trials that the Court memorialized in CMO No. 25, an Order identifying the fourth trial case and the date of the fourth

trial has not yet been issued.

Accordingly, the representation by Defendants at the February 2, 2021 CMC, that *Miller*, just like *Stinson*, was “set in stone”⁴ as a bellwether trial, is simply wrong. Similarly, Defendants’ claims that this was the first time they “heard that anybody from the plaintiffs’ side has a concern about *Miller*,”⁵ is, at best, a forgetful moment by defense counsel. To be sure, it has been the PSC’s consistent position in all of its bellwether briefing that *Miller* is not a representative case and should not, under any circumstances, be considered as a trial case. *See* ECF No. 299 at 3, 9, 10. (“Mr. Miller’s case presents *the most plaintiff-specific circumstances* and non-representativeness, making *Miller* unfit to be an initial bellwether trial); *see also*, ECF No. 308 at 4–5 (emphasizing that litigating Mr. Miller’s case will unnecessarily waste the Court’s resources and that it “should be excluded as a bellwether trial altogether.”); *see also* ECF No. 344 at 2–3 (“selecting the *Miller* case, which the PSC understands is Defendants’ preference, would not be instructive or efficient.”).

As discussed in detail below, it is still the PSC’s position that selecting for trial *Miller* as the fourth bellwether trial will result in an enormous waste of the parties’ resources as well as both the Court’s and the parties’ time. *Miller* simply would not be informative due to its unique and complicated case-specific facts. *Miller* would do nothing to inform the Court or the parties on cross-cutting issues relevant to large swaths of cases in this MDL.

II. SELECTION OF REPRESENTATIVE BELLWETHER CASES FOR TRIAL

As the Court is well-aware, the ultimate goal of the bellwether case selection process is to identify cases that can: (a) address as many common issues as possible; (b) be representative of multiple issues across many cases; and (c) deliver judicial rulings and a jury verdict that both sides

⁴ *See* 2/2/2021 CMC Tr. 23:23-23:25.

⁵ *Id.* at 24:22-24:23.

can view as instructive in fashioning a resolution of the MDL or for judge's on remand to use if the cases are all sent to their original jurisdiction for trials. The underlying purpose of bellwether workups and then trials is to provide the parties—and the Court—with helpful information regarding the strengths and weaknesses of the claims and defenses, as well as case values through verdicts.

As such, cases with the most representative issues (and facts), that can be applied to many other cases should be selected as being most instructive to the litigation as a whole. *See, e.g.*, Manual for Complex Litigation, Fourth, §22.315 (2004) (for test cases to produce reliable information about other cases, the specific plaintiffs and their claims should be **representative** of the range of cases). Similarly, this Court recently underscored the need for representative cases in order to move the litigation forward.⁶

Conversely, selecting bellwether cases with highly specific and unique facts, like *Miller*, could lead to early dismissal that will not be instructive or relevant to larger group of plaintiffs in this MDL. As the PSC previously set forth in its original briefing related to the proposed selection by the defense of the *Miller* case, Mr. Miller has an extremely complicated and unique medical history. His past medical history is significant for many medical conditions, including, heart attack, stroke, cardiac arrhythmia, lung disease, seizures, Chiari malformation, coronary artery disease, that render his case highly atypical. Similarly, Mr. Miller's surgical history is replete with numerous invasive procedures, including, brain surgery, six spinal surgeries, percutaneous transluminal coronary angioplasty and coronary artery bypass grafting, that further complicate this case. A case with so many co-morbidities and unique case specific issues, such as this, that may be disposed of through summary judgment or other ruling or facts that a jury might seize on (good

⁶ *See* 2/2/2021 CMC Tr. 22:1-22:4.

or bad) will not advance the purposes of the bellwether process or provide any guidance about the issues in the majority of cases. Such cases are inefficient to pursue if the goal is to learn as much as possible on cross-cutting issues that can be applied to as many cases as possible, unnecessarily waste the Court's resources, and cost the parties significant time and resources for an outlier case.

Selecting representative trial cases will ultimately guide the parties to facilitate an appropriate resolution. Indeed, such guidance is especially important given the unprecedented circumstances surrounding the COVID-19 pandemic and the resulting delays. In the past year, this Court has gone to great length to continually move this litigation forward and not let the ongoing health crisis halt advancing this MDL. However, despite the Court's and the parties' best efforts, all the bellwether trials have been postponed multiple times, thereby delaying the outcomes of the trials and all that would be learned from those trials. Therefore, a coveted trial spot should be reserved for a case that the parties can truly learn from; and the *Miller* case is, respectfully, not that case.

As such, the PSC respectfully submits that Defendants should be precluded from striking *Stinson* as the third trial case and from selecting *Miller* as the fourth trial case. And, because the fourth bellwether trial will tentatively go forward more than a year from now, Defendants should select the fourth bellwether case from a larger and a more diverse pool of representative cases⁷ *after* the parties have all the dispositive, pretrial evidentiary, and jury results from the first one or two already selected bellwether trials.

III. STINSON SHOULD REMAIN THE THIRD CASE TRIED AS ALREADY DECIDED AND ORDERED BY THIS COURT

It is without dispute that the Court has already decided that the *Stinson* case would be the

⁷ As the PSC has previously suggested, given the non-representativeness of *Miller*, selection of the fourth case from the larger Bellwether Discovery Pool (where discovery has been substantially completed), or possibly elsewhere, will better serve the goals of a bellwether trial.

third bellwether trial case in this MDL. *See* CMO 25. Importantly, CMO 25 also set forth that if Defendants had any objections to *Stinson* being tried as a bellwether, they needed to have been filed within the time provided in CMO 25, not raised over a year later.

Instead, for over a year, Defendants expended their own and the PSC's time and resources preparing the *Stinson* case for trial without voicing any concerns regarding its representativeness before declaring, at the February 2, 2021 CMC, that the *Stinson* case is not representative and requesting briefing on same despite the deadlines in CMO 25 having expired and as an apparent a knee-jerk reaction when the PSC maintained its objection to the selection of *Miller* as the fourth bellwether trial case (the briefing of same which remained *sub judice*).

The PSC submits that Defendants' belated challenge of *Stinson*'s representativeness should be rejected. The PSC respectfully submits, that CMO 25 should not be amended, and the proper vehicle to do so would be a motion to alter or amend the Court's Order. Moreover, allowing Defendants to defy an Order, that the Court issued more than a year ago, by suddenly seeing to strike *Stinson* from the bellwether trial pool under the pretenses of unrepresentativeness and/or forgetfulness of the Court's prior Orders selecting it and setting deadlines to challenge it, would not only irreparably harm all plaintiffs and cause additional delays but would set a dangerous precedent that would negatively impact the resolution of this MDL.

Notwithstanding, as the PSC advanced over a year ago, Mr. Stinson's age, general health, mesh implant, and injuries are common to many plaintiffs in this MDL and the case should be a bellwether trial case. By way of example, Mr. Stinson was of average age and physical condition when he was implanted with the PerFix Plug, one of the most common devices in this litigation, and when he suffered his mesh-related injuries. Just like most similarly situated individuals who filed an action in this MDL, Mr. Stinson is not in perfect physical health. However, he does not

suffer from any unique comorbidities that could potentially complicate the bellwether trial and/or confuse the jury.

Indeed, the injuries Mr. Stinson suffered as the result of his inguinal mesh implant, including chronic pain necessitating months of nerve block injections and then surgical explanation of the mesh, are very common with PerFix Plug implants. Accordingly, *Stinson* does not involve any unique questions that would render the case non-representative.

Notably, *Stinson* is the only bellwether case, currently scheduled to be tried, that has a gross specimen of the explanted mesh along with Scanning Electron Microscopy (SEM) imaging studies that were done on the specimen in preparation for trial. Having access to the explanted mesh specimen and the pathology report enables both parties to present to the jury concrete evidence and expert witness testimony that is based on the actual explanted mesh at issue, and not based solely on animal studies, other patients' medical records and/or scientific literature.

Lastly, significant time and substantial resources have been expended to prepare this case for trial. Although on its own, time and resources expended is not determinative in selecting a bellwether trial case, this factor taken in the totality of the unique circumstances, further supports the PSC's position. Indeed, Defendants should not be allowed to prevent the *Stinson* case from being litigated *after* it has been fully worked up for trial simply because they are hesitant to try a case where the verdict may not be in their favor. This would cause undue delays and prejudice all plaintiffs who have to bear the costs associated with starting trial preparation anew.

IV. FOURTH BELLWETHER TRIAL

As noted at the outset, unlike the first three bellwether trials (*Johns*, *Milanesi* and *Stinson*) the fourth bellwether trial case was *never* set by the Court. CMO No. 25 (ECF No. 318) at 4.

The PSC submits that the fourth trial case—which Defendants will select—should be

selected after at least one of the bellwether trials is completed. And if Defendants are requesting that it be *Miller*, which was the position in their briefing, the Court should either deny the request with leave to re-submit or continue to hold the decision on selecting the fourth case in abeyance.

As noted above and in the PSC's prior briefing, Mr. Miller has an extremely complex medical history, which is significant for over 20 medical conditions⁸ that render his case atypical and unrepresentative. Further, Mr. Miller's injuries, the full extent of which is not yet known, are ongoing, as his hernia mesh has not been removed and is continually causing chronic pain. This further renders this case inappropriate as a bellwether.

Therefore, allowing Defendants to select *Miller*, would not provide meaningful guidance on any large sub-set of cases. Indeed, aside from Mr. Miller's unique medical history, a verdict in a 3DMax product-in-place case would, at most, be instructive to a handful of plaintiffs in the MDL because the majority of claims involve other types of polypropylene mesh products, most of which have already been explanted and/or revised. Simply put, because no parallels could be made from *Miller* to meaningfully resolve most other cases, selecting the *Miller* case will do nothing but waste valuable resources and time of the parties and Court and would needlessly prolong this litigation, resolution of which has already been unforeseeably delayed, by at least a year, due to the pandemic.

Conversely, not picking *Miller*, a non-representative case, and/or delaying the selection until there are more dispositive rulings, pre-trial evidentiary rulings, and trial results as well as considering whether allowing the defense to select the fourth bellwether trial case from an available, but less limited pool, would ensure that the fourth trial case will provide necessary guidance to the parties and the Court on how to best proceed with the remaining cases in the MDL.

⁸ Including, but not limited to, Chiari malformation necessitating brain surgery, stroke, seizures, six spinal surgeries, central serous chorioretinopathy, coronary artery disease with percutaneous transluminal coronary angioplasty and TAXUS stent, heart attack requiring coronary artery bypass grafting, cardiac arrhythmia, mild restrictive lung disease, vertigo, and major depressive disorder. See list of Mr. Miller's comorbidities attached hereto as Exhibit A.

This would also prevent the parties and the Court from wasting needless time and money⁹ of a case that represents a plaintiff with a significant number of co-morbidities and other factors that make his case non-representative and an outlier to the overall process.

Thus selecting, *Miller*, which the PSC understands is Defendants' preference because they feel that it will be an easy win for them, would not be instructive or efficient. Picking easy wins or any party's "best" case is not the purpose of the bellwether process and will not accomplish the Court's goal of advancing this MDL to a timely and fair resolution.

V. CONCLUSION

Because the cases selected for trial should be instructive and representative of other cases in the MDL, the PSC urges the Court to keep *Stinson* as the third bellwether trial case and disregard any argument to the contrary based on CMO No. 25 and because the time by which to challenge it has expired.

To this end, the PSC maintains its position that *Miller* is not representative, as its unique factual issues are not representative of the majority of inguinal cases pending in this MDL. Thus, because *Miller* was never selected as the fourth trial case and consistent with the *sub judice* briefing, the PSC maintains that a fourth trial case should be deferred and that Defendants should select a representative fourth bellwether case at a later date.

⁹ The *Miller* case has not yet been fully worked up for trial and no significant resources have been expended by either party. In fact, the parties agreed to postpone expert depositions until such time when a determination was made by the Court if *Miller* will proceed to trial.

Dated: February 23, 2021

Respectfully submitted,

/s/ David J. Butler

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CERTIFICATE OF SERVICE

I hereby certify that on this 23rd day of February 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/ David J. Butler
Plaintiffs' Liaison Counsel

EXHIBIT A

Ross Internal Medicine, PC
2611 S. 70th St. Suite A
Lincoln, NE 68506
Date: 04/04/14

Patient: Gregory Miller
DOB: [REDACTED]

PROBLEM LIST

1. Arnold-Chiari type 1 malformation – six spinal and 3 AVM surgeries – 4/1/93
2. Allergies: Ambien – hydrocodone – morphine – MSG – Stadol – sulfa – tramadol –
dilauded - cats
3. Bilateral rotator cuff surgeries – 1998/2000
4. Right knee arthroscopy x 2 for meniscal tear left and right knee
5. Colon polyp resection – 2001/2005/2014
6. Chronic headache and neck pain- migraines?
7. 6mm subcortical hemorrhage right parietal lobe decreased vision/balance 11/05
8. Central serous retinopathy versus macular degeneration-decreased vision
9. Coronary artery disease RCA with PTCA and TAXUS stent – 7/3/08
10. Recurrent vertigo and loss of balance - rare
11. Hypercholesterolemia - mixed
12. Mild anxiety and depression
13. Diverticulosis by colonoscopy – 9/05
14. Paroxysmal spells of acute weakness and fatigue
15. Mitral regurgitation by echo – 2005
16. Intermittent reflux esophageal symptoms
17. Insomnia
18. Right supraclavicular nodule tenderness
19. Right gynecomastia - Resolved
20. Mild Kyphoscoliosis
21. Bilateral varicose veins of lower extremities right greater than left

Ross Internal Medicine, PC
2611 S. 70th St. Suite A
Lincoln, NE 68506
Date: 04/04/14

Patient: Gregory Miller
DOB: [REDACTED]

22. Peripheral sensory neuropathy
23. Chronic sinusitis with history of surgery for cysts and polyps- 1983
24. Proteinuria- resolved
25. Decreased hearing in the lower frequency range
26. Hypogonadism
27. Vitamin D deficiency
28. Bilateral epididymal cysts right side greater than left
29. Fracture bone – fingers/foot/skull
30. Arthroscopy left knee-2000
31. Pneumonia
32. Chronic lower back pain
33. Right lower quadrant tenderness – secondary to hernia surgery
34. Tonsillectomy – 1983
35. Removal benign tumors right forearm
36. Bilateral carpal tunnel repair x2
37. Abnormal Romberg
38. Slightly elevated uric acid level – 10/15 normal
39. Multiple stable pulmonary nodules – 2008
40. Mild restrictive lung disease
41. Elevated homocysteine level
42. Hypertension
43. Cardiac arrhythmia