

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

IN RE: AMERICAN MEDICAL SYSTEMS  
PELVIC REPAIR SYSTEM  
PRODUCTS LIABILITY LITIGATION

MDL NO. 2325

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THIS DOCUMENT RELATES TO ALL CASES

**AMERICAN MEDICAL SYSTEMS' MEMORANDUM  
IN SUPPORT OF POP BELLWETHER PICKS**

At a conference in New York last month, Judge Richard Kramer of the San Francisco Superior Court (speaking on a panel of mostly federal court judges regarding Bellwether Trials) drew some laughter when he put the bellwether process in a unique light.

As this Court is aware, the etymology of the word “bellwether” refers to a neutered ram (a wether) with a large bell around its neck, responsible for keeping a flock of sheep together. In Judge Kramer’s words, the bellwether helps the flock “stay in line and follow him, so that there are no stragglers off doing their own thing, and they all go home together at the end of the day.” Judge Kramer drew the analogy to a bellwether case, adding that like the ram, it is very important that a bellwether case is not a “sexy” case – in other words, that it has no facts that would make it an outlier case or make it more favorable for one side or the other. He continued with the analogy, saying it was also important that the “other sheep don’t know that the wether isn’t sexy anymore” so that they continue to follow him and stay “with the flock” and so they can all “go home at the same time.”

Leading lights of the federal bench have similarly outlined the characteristics a bellwether case must have to make it representative, noting that:

[I]f Bellwether trials are to serve their twin goals as informative indicators of future trends and catalysts for an ultimate resolution, the transferee court and the attorney must carefully construct the trial-selection process. Ideally, the trial-selection process should accurately reflect the individual categories of cases that comprise the MDL in toto, illustrate the likelihood of success and measure of damages within each respective category, and illuminate the forensic and practical challenges of presenting certain types of cases to a jury. Any trial selection process that strays from this path will likely resolve only a few independent cases and have a limited global impact.

Hon. Eldon E. Fallon, *Bellwether Trials in Multidistrict Litigation*, 82 Tul. L. Rev. 2323, 2344 (June 2008).

Chief Judge Herndon in the Southern District of Illinois similarly opined:

“Little credibility will be attached to this process, and it will be a waste of everyone’s time and resources, if cases are selected which do not accurately reflect the **run-of-the-mill case**. If the very best case is selected, the defense will not base any settlement value on it as an outlier.

*See* Amended Case Management Order No. 24, Bellwether Trial Selection Plan, dated October 13, 2010, as filed in *In re: Yasmin and Yaz (Drospirenone) Mkt, Sales Practices and Prods. Liab. Litig.*, MDL No. 2100, 3:09-md-02100-DRH-PMP (S.D. Ill. 2010).

In going through the six potential POP bellwethers for the AMS August trial and making its recommendations, AMS has tried to keep true to this idea of a representative bellwether case. AMS anticipates that the parties will recommend a different number of cases to work up for the one POP trial in August due to the fact that they could not agree on how many cases to present to the court at this stage (Defendants suggested two; Plaintiffs wanted four). In the end, the parties agreed to propose as many as they thought “right” for the August POP trial. In looking at the six cases, and for the reasons set out in more detail below, AMS worked more along the

lines of a jury process (i.e., deselection of inappropriate cases vs. selection of the best cases) and after striking the “sexy” cases, three were left: [REDACTED]. Two are AMS’ initial suggestions ([REDACTED]), and one is Plaintiffs’ initial selection ([REDACTED]). Below is the reasoning that led to AMS’ proposal to work up [REDACTED] for the POP bellwether trial in August.

**[REDACTED] And [REDACTED] Are Outlier Cases With The Type of “Sexy” Facts That Are Not Appropriate for Bellwether Trials**

[REDACTED] and [REDACTED] are cases that contain the “sexy” issues that Judges Kramer, Fallon, and Herndon warn against. [REDACTED] are the same cases that Plaintiffs picked over a year ago for their initial POP work ups ([REDACTED] is the exact same case Plaintiffs presented as their favorite POP case at the June 25, 2013 bellwether selection presentation) --- and both these picks were the LEAST representative picks from the bellwether pool inventory then, and still are now. Plaintiffs have nevertheless opted to put [REDACTED] forth again, despite the fact that at the June hearing, this Court decided that it was not satisfied with any of the picks the parties presented, including [REDACTED].<sup>1</sup> All three cases are so far afield from the “average run of the mill” POP case that to pick them for the first POP trials will force the parties to “stray” from the effectiveness of the bellwether process and accomplish the resolution of “only a few independent cases” which will “have a limited global impact.” See

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<sup>1</sup> At that hearing, Your Honor said to Ms. Fitzpatrick:

I’m going to pick a POP case. **I just don’t like yours.** I told you that I don’t know how representative that they are in the POP census or inventory or whatever you want to call it, but you’re going to get one. Whether it tells the defendants what they want to – you know, it may be a big verdict, but is it really going to inform things? I don’t know.

Transcript of 06/25/12 Bellwether Hearing at 73 (emphasis added).



Fallon, "*Bellwether Trials in Multidistrict Litigation*", supra.<sup>2</sup> For example [REDACTED],

[REDACTED] have all had two explants, which puts them in the **outlier position of**

**all POP bellwether plaintiffs**, claiming the most serious level of damages (less than one third

of the bellwether pool). According to medical records and deposition testimony, both [REDACTED]

[REDACTED] are **contemplating a third explant procedure**, which would put them in a tiny

slice of the inventory (a few percent of the pool). To allow the most serious injury cases to go

first as "representative" of the entire inventory would be completely inappropriate to the goal of

bellwether trials.<sup>3</sup> Other outlier facts are as follows:

- [REDACTED]'s implanter, Dr. [REDACTED], experienced a 50% complication rate with his pelvic mesh surgeries – **five to ten times the average rate of complications seen by surgeons**. [REDACTED] dep. at 96, 157.
- [REDACTED] had a complex medical history which includes pelvic inflammatory disease, removal of an ovary **at age 21**, and diagnoses of multiple prolapses, including a rectocele, enterocele, cystocele and uterine prolapse.
- [REDACTED] had a very early implant (2005), much earlier than the vast majority of the bellwether pool (less than 10% had implants this early).
- [REDACTED] initial problems were a result of a suture (not the mesh product) coming out through her vagina which her doctor decided not to replace. He instead left the unsutured incision to heal on its own. The resulting wound created the initial exposure of mesh. The doctor testified he chose not to repair the suture, and later

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<sup>2</sup> For the same reasons, AMS also will not put forward the [REDACTED] case, an initial AMS pick. That Plaintiff had a second explant removal in December (after AMS chose to work the case up), the details of which are still unknown at this time, as no medical records from that surgery have been produced. Ms. [REDACTED] further testified that she is preparing for a third possible surgery, which puts her in a very small minority of cases. Plaintiffs claim that Ms. [REDACTED]'s implant failed because one of the fixation tips for a rear arm of the Elevate Anterior was not anchored in the implant location identified in the Instructions For Use. Assuming that the Plaintiff's claim is a defect in the fixation tip that caused it to come loose post-implant, this would not be representative of the inventory in any way.

<sup>3</sup> AMS has attached a summary chart of the six potential picks for ease of reference as Ex. A.



reduced his medical bills associated with the procedure accordingly.

- [REDACTED] implant (Apogee only) is by far the least common implant in the bellwether pool (only 3% of all POP cases fall in this category).
- In addition to mesh repairs, [REDACTED] surgery included two non-mesh procedures, a concomitant vault repair and a perineoplasty, which distinguishes her from the majority of the bellwether pool.
- [REDACTED] implanting doctor testified that prior to his deposition, [REDACTED] attorneys told him “how to answer the questions and behave, basically.” Detty Dep. at p. 168.
- [REDACTED] was fired from her employment in 2012 for forging/altering the return to work date on the release that her explanter, [REDACTED], gave her following the explant. [REDACTED] dep. at 152.
- [REDACTED] is an extraordinarily sympathetic plaintiff, experiencing chronic depression relating to the traumatic death of her husband and son in a motor vehicle accident in 1998. [REDACTED] dep. at 155.

In addition to these outlier facts, both [REDACTED] and [REDACTED] hail from states that have the smallest number of plaintiffs from the bellwether pool: [REDACTED] from Montana (only 7 bellwether pool plaintiffs) and [REDACTED] from Ohio, which has fewer bellwether pool plaintiffs than California ([REDACTED]), Arizona ([REDACTED]), or Michigan ([REDACTED]).

#### **The Bellwether Selections Should Reflect The Inventory Of Cases As A Whole**

A bellwether trial is most effective when it can accurately inform future trends and effectuate an ultimate culmination to the litigation; therefore, it is imperative to know what types of cases comprise the MDL.

Fallon, *Bellwether Trials in Multidistrict Litigation*, *supra*.

At the beginning of this bellwether process, AMS pointed out in several briefs that, despite the fact that this Court decided that it would not try multi product cases in a bellwether

trial, Plaintiffs nominated mostly multi product POP cases. AMS lost that fight, and is prepared to move on. AMS now urges this Court to consider the make up of the bellwether pool in deciding which multi product cases should be tried. The POP inventory is quite small compared to the inventory as a whole. Even when the multiple product POP cases and the combination product POP/SUI cases are added to the single product POP cases, the bellwether pool inventory is still less than a third of all pending cases. In addition, the POP inventory is made up overwhelmingly of combination POP/SUI cases (only about a quarter of the POP cases do not also involve an SUI product). Thus, when trying multiple product POP cases, it makes the most sense to include a combination POP/SUI case (in this instance, [REDACTED], the only case of the six potential picks that falls into this category). After taking [REDACTED] out of the potential bellwethers, the cases that are left are: (a) a combination POP/SUI case ([REDACTED]); (b) a single product Elevate case ([REDACTED]) and (c) a combination Apogee/Perigee case ([REDACTED]). There is some symmetry to this line up, because those three cases represent the three combinations of POP bellwethers available to the Court.

AMS is not recommending that the three remaining cases be placed in any particular trial order at this time. Discovery is still ongoing in the cases, and seven months stand between now and trial. Instead, AMS suggests that the parties brief the issue of trial order sometime in May, three months in advance of trial, when the discovery is complete.

Accordingly, in no particular order, here are facts from each of the three cases that show how they are representative cases:

[REDACTED]

- Ms. [REDACTED] complains of long term pain and dyspareunia, the most common complaints among the POP plaintiffs, as well as vaginal bleeding, chronic constipation, urinary tract infections,

pelvic and vaginal pain, frequent urination and urge incontinence (also common complaints).

- Married 40 years, she is the only one of the three Plaintiffs with a consortium claim (the majority of the bellwether pool plaintiffs are married).<sup>4</sup>
- She had a POP product (Elevate) implanted as well as an SUI product (Monarc), which as noted above, puts her case in the vast majority of POP cases: combination POP/SUI.
- Most of the plaintiffs in the POP inventory had implants in 2009 and 2010; [REDACTED] was in 2009.
- She is from Arizona, which has the second most POP bellwether plaintiffs.

[REDACTED]

- Ms. [REDACTED] was 58 at the time of implant, and the largest number of plaintiffs in the pool were between 50 and 59.
- She had an Elevate anterior product implanted, the product that the vast majority of the bellwether POP plaintiffs used.
- She has had one explant surgery; of those bellwether plaintiffs with explants, more than twice the number of plaintiffs had only one explant versus those who had two or more.
- She complains of pain, extrusion, dyspareunia, infection and urge incontinence, which are very common complaints among the bellwether pool.
- Ms. [REDACTED] is from California, which has the most POP bellwether plaintiffs.

[REDACTED]

- Ms. [REDACTED] had an Apogee and Perigee implanted in 2006 (both AMS products); although there are very few Apogee cases in the inventory, there are twice as many Perigee cases. (The vast

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<sup>4</sup> [REDACTED] also has a consortium claim, but is unrepresentative for other reasons as stated above.



majority of the cases, as noted above, involve Elevate). Because she also had a Perigee, Ms. [REDACTED] is more representative than someone like Ms. [REDACTED].

- Ms. [REDACTED] had one explant surgery in 2011; as noted above, this is far more common in the bellwether pool than two or more explants.
- She complains of extrusion, infection, abscess, pain, dyspareunia and vaginal scarring ... all common complaints.
- She is from Michigan, which has the third most POP bellwether plaintiffs.

In sum, three of the six possible bellwether cases are such outliers that this Court should not even consider them for bellwether selection. Of the three remaining cases, AMS believes it is too soon to order the cases for trial, but would suggest that the Court do so in May, after discovery is completed.

As the Court can see here, none of these cases is a “perfect” case, nor is any one of them particularly favorable to defendants. Accordingly, AMS requests that this Court narrow the POP trial pool down at this time to [REDACTED].

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