IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	Civil Action No. 3:16-md-2738-FLW-LHG MDL No. 2738 PROPOSED TRIAL PLAN SUBMISSION

The Parties submit their respective proposals for the next steps in the process of working up cases for trial.

PLAINTIFFS' POSITION:

I. Bellwether Trial Cases Should Be Representative

Bellwether trials should produce reliable information about cases pending within the MDL in order to enhance the prospects of settlement or resolving common issues or claims.[1] Bellwether trials should assist the parties and the Court in identifying and evaluating the strengths and weaknesses of the litigation.[2] Moreover, Bellwether trials should be suitable to assist the Plaintiffs' Steering Committee (PSC) in developing a trial package that can be used in cases that are remanded to transferor courts (or "remand jurisdictions" if filed directly in the MDL). The PSC is developing a trial package that will include key documents, scientific literature, expert reports, depositions,[3] deposition designations, exhibit lists, and briefing on dispositive motions and motions in limine.

[1] Whitney, Melissa J., "Bellwether Trials in MDL Proceedings, A Guide for Transferee Judges," Fed. Judicial Ctr. And JPML 3 (2019) (quoting *In re* Chevron U.S.A., 109 F.3d 1016, 1019 (5th Cir. 1997)); *see also* Wolfson, Hon. Freda L. (U.S.D.J.), et al., "Multidistrict Litigation in Federal Court," New Jersey Mass Torts & Class Actions Treatise 39-54 (2020).

[2] Fallon, Hon. Eldon E., et al., "Bellwether Trials in Multidistrict Litigation," 82 Tulane L. Rev. 2323, 2338 (2008).

[3] Depositions would include additional case-specific fact witnesses and healthcare providers as needed, expert depositions, and depositions of relevant retailers.

In order for the bellwether process to be most effective, the cases selected for trial should be representative of other cases filed in the MDL. The key characteristics that should guide the Court's evaluation of representative cases and the selection of potential bellwether trial(s) are:

1. Disease:
    a. All cases considered should involve a plaintiff alleging epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer (together, "epithelial ovarian cancer" or EOC). These diseases are considered to be the same entity as they share similar risk factors and pathogenesis.[4] EOC accounts for approximately 90% of ovarian cancers.[5]

    b. Subtype: Epithelial ovarian cancer (EOC) includes the following histological subtypes: serous, endometrioid, clear cell, mucinous, undifferentiated, and borderline. The serous subtype is by far the most common type.

2. Product Usage: Plaintiffs' claims primarily involve the genital application of talcum powder following puberty, though most plaintiffs' exposure began as an infant during diapering. Cases considered for bellwether trials should involve plaintiffs who regularly applied talcum powder in the genital area following puberty.

3. Risk Factors: The following risk factors are generally accepted for EOC: inherited genetic mutations (such as BRCA1 or BRCA2); family history of a 1st degree relative with ovarian cancer, breast, or colon cancer; age; lifetime ovulations; endometriosis (endometrioid and clear cell subtypes only); pelvic inflammatory disease; obesity; polycystic ovarian disease; talcum powder;

[4] Levanon, Keren, Christopher Crum, and Ronny Drapkin. 2008. "New Insights Into the Pathogenesis of Serous Ovarian Cancer and Its Clinical Impact." *Journal of Clinical Oncology* 26 (32): 5284–93. https://doi.org/10.1200/JCO.2008.18.1107.

[5] Kaplan BY, Markman MA, and Eifel PJ: Ovarian Cancer, Peritoneal Carcinoma and Fallopian Tube Carcinoma. In: DeVita VT Jr, Hellman S, Rosenberg SA, ed. *Cancer: Principles and Practice of Oncology*. 7th ed. Philadelphia, Pa: Lippincott Williams & Wilkins, 2005, 1364.

and smoking (mucinous subtype only).[6] The first bellwether trial should not include a plaintiff who tests positive for a BRCA mutation.

4. Living or Deceased: Another factor is the plaintiff's ability to share in-person testimony describing her practice of using Johnson's talcum powder products and her experience with ovarian cancer, its treatment, and the effects of both on her physical and emotional health, her ability to participate in work and daily activities, and her outlook for the future. The first bellwether trial should involve a living plaintiff who can testify to her practice of using Johnson's talcum powder products.

II. Census Data from Phase One and Phase Two Cases

In Phase One, Plaintiffs submitted Plaintiff Profile Forms in 967 cases. There are 30 Phase Two or Discovery Pool cases. Key characteristics of these cases are as follows, with the most common types of cases shaded blue:

Key Characteristic	Phase One (PPF) (n = 967)	%	Phase Two (Discovery Pool) (n = 30)	%
Disease				
Epithelial Ovarian Cancer (EOC)	929	96.07%	30	100%
Subtype:				
Serous	625	61.89%	21	70.00%
Endometrioid	135	14.53%	6	20.00%
Clear Cell	51	5.49%	3	10.00%
Mucinous	37	3.98%	0	0.00%
Undifferentiated	12	1.29%	0	0.00%
Unknown	119	12.81%	0	0.00%
Age at Diagnosis:				
0-20 years	7	0.72%	0	0.00%
21-30 years	40	4.14%	0	0.00%
31-40 years	102	10.55%	0	0.00%
41-50 years	217	22.44%	5	16.67%
51-60 years	302	31.23%	15	50.00%
61-70 years	192	19.86%	7	23.33%
71-80 years	80	8.27%	3	10.00%
81+ years	14	1.45%	0	0.00%

[6] Mallen, Adrianne R., Mary K. Townsend, and Shelley S. Tworoger. "Risk Factors for Ovarian Carcinoma." *Hematology/Oncology Clinics of North America,* September 2018.

Unknown	13	1.34%	0	0.00%
Plaintiff Status				
Living	635	65.67%	21	70.00%
Deceased	332	34.33%	9	30.00%
Product Usage (JBP)				
≤ 10 years	52	5.53%	2	6.67%
11-20 years	108	11.48%	2	6.67%
21-30 years	164	17.43%	4	13.33%
31-40 years	203	21.57%	9	30.00%
41-50 years	196	20.83%	10	33.33%
51+ years	212	22.53%	2	6.67%
Unknown	6	0.64%	0	0.00%
Genetic Risk Factor (BRCA)				
No Genetic Testing	510	52.74%	8	26.67%
Blank	31	3.21%	0	
Genetic Testing Completed	426	44.05%	22	73.33%
Negative	359	84.27%	21	95.45%
Positive	44	12.26%	1	4.54%
Unknown	23	2.38%	0	

The census data for the Phase One and Phase Two cases is remarkably consistent across key categories. Based on this data, a representative case involves a plaintiff with epithelial ovarian cancer with the following characteristics:

Subtype	Serous
Age at diagnosis	41-60 years of age
Plaintiff status	Living
Product Usage	31-50 years
Genetic Testing (BRCA)	Negative

III. Selection Process for Bellwether Trial(s)

In keeping with the principles and data outlined above, Plaintiffs propose the following Bellwether Trial selection process. First, Plaintiffs shall select three representative cases from the pool of 30 Phase Two cases and Defendants shall select three representative cases from the pool of 30 Phase Two cases, for a total of six representative cases. Following the selection of six representative cases, each side will be permitted to exercise one strike, leaving four cases for trial consideration.

Thereafter, the parties will proceed with work-up of the four cases to include additional fact depositions as needed, expert disclosures and discovery, and motion practice. Upon the completion of the trial preparation process, the parties will alternate case selection from the remaining four cases with the Plaintiff afforded the opportunity to select the first trial case.

IV. Plaintiffs' Response to Defendants' Proposal

As the Court will recall, Phase One cases were selected randomly. Phase Two cases were selected as follows: 10 by Plaintiffs; 10 by Defendants; and 10 randomly. Plaintiffs have had little control over the cases to be selected. The demographics of both the Phase One and Phase Two cases are very consistent. Representative cases involve epithelial ovarian cancer with serous subtype; diagnosis between the ages of 41-60; living; product usage of between 31 and 50 years; and negative genetic testing.

In addition to those characteristics, other considerations are important in selecting a bellwether case such as the applicable state law and the law firm that represents the plaintiff. For example, if the applicable state law would result in the application of "but for" causation or a product liability theory that is out-of-step with a majority of jurisdictions in the country, the trial of the case would have limited usefulness in evaluating the strengths and weaknesses of the cases in the MDL. If the plaintiff is represented by a solo practitioner or smaller firm, it may be more difficult for the firm to make a robust presentation of the case. Because the evaluation of state law and law firms representing the clients necessarily involves the weighing of the merits of the case and the strength of the parties, Plaintiffs believe it is more appropriate not to put the Court in the position of selecting trial cases.

Plaintiffs seek an order from the Court directing the parties to select representative cases from the Phase Two cases for the Bellwether Pool and then allowing the parties to select the trial cases. Because the Plaintiff bears the burden of proof, the Plaintiffs should select the first trial case; Defendants the second. This process is consistent with *In re* Actos *(Pioglitazone) Prods. Liab. Litig*. (MDL No. 2299) (W.D. La.), Scheduling Order: Pilot Bellwether Program (First Trial) (Feb. 19, 2013); *see In re Fosamax Prods. Liab. Litig.* (MDL No. 1789) (S.D.N.Y.) (Case Management Order No. 9) (Jan. 31, 2007); *see also In re: Zofran Prod. Liab. Litig.*, MDL No. 2657, MDL Order No. 33 (April 16, 2019) (plaintiff-selected case to be tried first). Plaintiffs believe that this approach will be most useful in reaching "the

ultimate goal . . . . to obtain representative data to assist with global settlement or move the MDL proceeding forward efficiently."[7]

DEFENDANTS' POSITION:

The Defendants propose that the Court narrow down the current pool of 30 cases to eight cases that would be fully worked up for trial and subject to dispositive motions. We further propose that four of those cases be selected randomly from the bucket of high-grade serous cases and four be selected randomly from the other cases, as detailed below. Alternatively, a party selection and striking process is proposed if the Court is not inclined to use a random selection process. Either way, the final selection of the cases to be tried and in what order should be made by the Court after resolution of any dispositive motions and after review of individual case submissions by the parties. Part I of this submission sets out the defense proposal for selection of cases to proceed to the next level of work-up and ultimately trial. Part 2 discusses motions that can be made simultaneously after some further discovery.

I. Narrowing the Pool

The parties started with a pool of 1,000 randomly selected cases. Sixty-nine (7%) of those were subsequently dismissed voluntarily or by motion. After the pool was narrowed to 30 cases (ten plaintiff picks, ten defense picks and ten random picks), 18 (60%) of those cases were replaced due to refusal to waive *Lexecon* (16) or dismissal with prejudice (2). This has resulted in a skewed sampling of cases.

Most notably, in the initial pool of cases, known high-grade serous cases comprise just 34 percent, whereas in the current group of 30 cases, those cases comprise 60 percent, as depicted in the figure below. (12% (114) of the 1,000 plaintiffs did not indicate a subtype on their fact sheets; another 21% (195) didn't know whether their serous diagnosis was high grade or low grade, an important distinction as these are two different diseases).

Figure 1. Subtypes

	Pool of 1,000 (now 931) Cases	Current Discovery Pool of 30 Cases	Pool of 17 Cases selected for inclusion and then removed by the plaintiffs[8]
Known High-Grade Serous	34% (316)	63% (19)	35% (6)
Unknown or Other Subtypes	66% (615)	37% (11)	65% (11)

Figure 2.

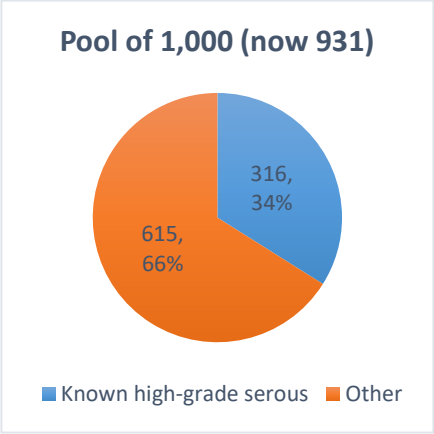


Figure 3.

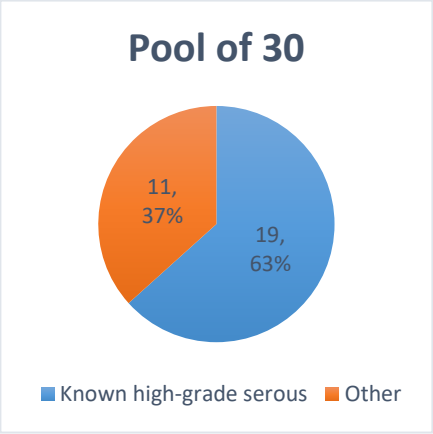
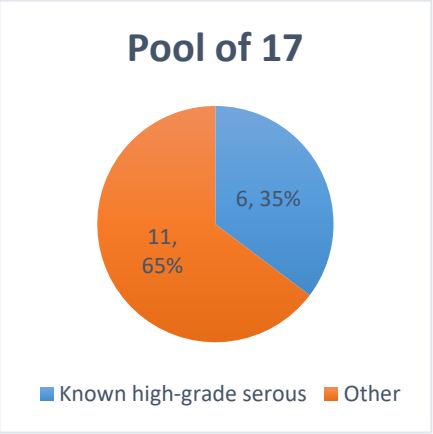


Figure 4.



The differences between the current pool of 30 cases and the randomly chosen pool of 1,000 are at least in part explained by the fact that 60% of the original 30 cases were either dismissed by plaintiffs or were subject to revoked *Lexecon* waivers after selection, resulting in a discovery pool that does not reflect the overall MDL docket.

A. Random Selection Proposal

As noted above, defendants propose that the Court randomly select four cases from the following alleged high grade serous cancer cases in the discovery pool of 30:

[8] 18 cases were removed by the plaintiffs but there are no data on one of them.

1. Brown
2. Fisher
3. L. Hill
4. Judkins
5. Landreth
6. Lihani
7. Loreth
8. McClendon
9. Moore
10. Rabasca
11. Rausa
12. Sarver
13. Smith
14. Tunson
15. Ulrich
16. Vaul
17. C. Williams
18. Walton

In addition, defendants propose that the Court randomly select four cases from the following alleged non-high grade serous cancer cases in the discovery pool of 30:

1. Bondurant
2. Converse
3. Gallardo
4. T. Hill
5. Laddusaw
6. Kinberger
7. Newsome
8. Nixon
9. Orr
10. Skaggs
11. A. Williams

Excluded from the above lists is the *Rodgers* case. A review of the pathology in this case suggests that the primary cancer was gastric or pancreatobiliary which metastasized to the ovary. *The uniqueness of the pathologic diagnosis in this case requires that it be excluded.*

After the eight cases proceed through expert discovery and dispositive motions are ruled upon, we propose that the parties submit to the Court for each remaining case two-page statements about why each case is or is not the best candidate for trial, including a discussion of risk factors, family history, genetic testing and other characteristics, some of which are summarized in the data tables at the end of this proposal.

If a case in the pool of eight is dismissed by the plaintiffs at any point in this process, the defense will select a replacement. Given the wholesale removal of cases from the randomly selected discovery pool, this protection is necessary.

B. Alternative Party Selection Proposal

If the Court is not inclined to proceed on a random selection basis, the defense proposes in the alternative that each side pick four cases, at least one of which must be from the non-high grade serous list, for a total of eight cases. Each side will then strike one case from the list, leaving six cases to be worked up for trial through the dispositive motion stage.

After the six cases proceed through expert discovery and dispositive motions are ruled upon, the parties shall submit to the Court for each case two-page statements about why each case is or is not the best candidate for trial, including a discussion of risk factors, family history, genetic testing and other characteristics, some of which are summarized in the data tables at the end of this proposal.

If a case in the pool of six is dismissed by the plaintiffs at any point in this process, the defense will select a replacement. Given the wholesale removal of cases from the randomly selected discovery pool, this protection is necessary.

C. Comments on Plaintiffs' Proposal

The data show that contrary to the plaintiffs' position, the most common type of case in the MDL is ***not*** high grade serous (see figure 5 below). Whether a plaintiff is living or deceased should not be a determinative factor in case selection. The product usage information cannot fairly be characterized as "data" because it is purely subjective and self-serving. The genetic testing information cited by the plaintiffs must be viewed through the lens of the fact that more than half of the plaintiffs in the pool of 1,000 did not have genetic testing. Further, unless plaintiffs

are willing to dismiss with prejudice the cases of women who have tested positive for a BRCA mutation, those cases should be considered for trial.

The defense strongly objects to the concept that the plaintiffs unilaterally get to select the first case that will be tried. The Court and the parties should strive to try cases that have characteristics shared by other cases on the docket, not the cases that are most favorable to the plaintiffs.

II. Potential Motions

Because the cases are not fully worked up, we are not in a position to identify every motion we would seek to file, but the following reflects our initial thoughts.

A. We expect to file specific causation *Daubert* motions in all of the trial pool cases at the conclusion of expert discovery, although we obviously need to review plaintiffs' reports and depose their experts before finalizing our plans.

B. We expect to file general causation *Daubert* motions in cases involving subtypes that were not covered by the Court's prior *Daubert* ruling.

C. We expect to file a *Daubert* motion and accompanying summary judgment motion in the *Rodgers* case, discussed above, if plaintiffs pursue this case.

D. Statute of limitations and statute of repose motions. These motions are under consideration in a number of cases.

E. Inability to prove usage. There are several cases in which either: (1) the plaintiff has not produced admissible evidence of product usage with regularity in the perineal area, or (2) no witness has been deposed yet. Additional fact discovery may be required in these cases, but we expect to file disposition motions in some of them.

The defense proposes that after the pool of six cases is selected to move into the expert discovery phase, the parties meet and confer on a separate track for motions in the 24 cases not included in that final trial pool, including what additional discovery will be necessary.

III. Summary of Data from Plaintiff Fact Sheets As Submitted to MDL Centrality.

Figure 5. Subtypes

	Pool of 1,000 (now 931) Cases	Current Discovery Pool of 30 Cases	Pool of 17 Cases selected for inclusion and then removed by the plaintiffs[9]
High Grade	34% (316)	63% (19)	35% (6)
Clear Cell	5% (50)	10% (3)	6% (1)
Endometrioid	16% (145)	20% (6)	12% (2)
Low Grade	6% (56)	3% (1)	6% (1)
Mucinous	4% (34)	0% (0)	0% (0)
Serous (unsure high or low grade)	21% (195)	0%(0)	18% (3)
Undifferentiated	1% (13)	0% (0)	6% (1)
Multiple subtypes	<1% (8)	3% (1)	0% (0)
Unknown	12% (114)	0% (0)	18% (3)

Figure 6. Family History

	Pool of 1,000 (now 931) Cases	Current Discovery Pool of 30 Cases	Pool of 17 Cases selected for inclusion and then removed by the plaintiffs
Family history of breast or ovarian cancer	37% (346)	33% (10)	53% (9)

[9] 18 cases were removed by the plaintiffs but there are no data on one of them.

Figure 7. Have you ever been diagnosed with a BRCA1 or BRCA2 mutation?

	Pool of 1,000 (now 931) Cases	Current Discovery Pool of 30 Cases	Pool of 17 Cases selected for inclusion and then removed by the plaintiffs
Yes	5% (45)	3% (1)	0% (0)
No	84% (784)	97% (29)	88% (15)
Unknown	11% (102)	0% (0)	12% (2)

Figure 8. Genetic Testing

	Pool of 1,000 (now 931) Cases	Current Discovery Pool of 30 Cases	Pool of 17 Cases selected for inclusion and then removed by the plaintiffs
Had genetic testing	44% (412)	77% (23)	35% (6)
Did not have genetic testing	53% (492)	23% (7)	59% (10)
Left the question blank	3% (27)	0(0%)	6% (1)

Figure 9. Age at Diagnosis

	Pool of 1,000 (now 931) Cases	Current Discovery Pool of 30 Cases	Pool of 17 Cases selected for inclusion and then removed by the plaintiffs
Diagnosis before age 50	35% (323)	20% (6)	35% (6)
Diagnosis age 50-60	35% (328)	50% (15)	41% (7)
Diagnosis age 61-70	19% (178)	20% (6)	18% (3)
Diagnosis age over 70	7% (93)	10% (3)	6% (1)

	Pool of 1,000 (now 931) Cases	Current Discovery Pool of 30 Cases	Pool of 17 Cases selected for inclusion and then removed by the plaintiffs
Diagnosis age unknown	1% (9)	0% (0)	0% (0)

Figure 10. Tubal Ligation

	Pool of 1,000 (now 931) Cases	Current Discovery Pool of 30 Cases	Pool of 17 Cases selected for inclusion and then removed by the plaintiffs
Tubal ligation	25% (229)	30% (9)	6% (1)
No tubal ligation	73% (681)	70% (21)	88% (15)
Unkown	2% (21)	0% (0)	6% (1)

Figure 11. Date of Diagnosis

	Pool of 1,000 (now 931) Cases	Current Discovery Pool of 30 Cases	Pool of 17 Cases selected for inclusion and then removed by the plaintiffs
Diagnosed with cancer before 2013	50% (463)	30% (9)	41% (7)
Diagnosed with cancer 2013-2016	36% (337)	50% (15)	35% (6)
Diagnosed with cancer after 2016	13% (122)	20% (6)	24% (4)
No date of diagnosis provided	1% (9)	0% (0)	0% (0)

Respectfully submitted,

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