Random Selection Is Best For MDL Bellwether Trials

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In many mass tort litigations, where trying the claims of every plaintiff is impractical, courts and litigants have struggled with how to identify plaintiffs for early trials, often referred to as bellwether trials, that give the parties useful information about other plaintiffs in the docket. With some minor variations, courts generally either allow the parties to select cases they regard as representative, or the court (or parties) selects cases randomly, with the expectation that a random selection will more truly reflect the docket as a whole than party selections. Although the Manual For Complex Litigation endorses random selection,[1] courts in a number of recent mass tort litigations have allowed the parties to select plaintiffs who will be eligible for initial trials.[2]

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Until recently, many of litigants' arguments about the relative merits of party selection versus random selection have been theoretical and rhetorical, rather than empirical. Parties claim that their preferred method will lead to a more "representative" sample and identify potential problems with alternative selection methods, but there has been no empirical evidence that one method is superior to another in selecting cases that are more like other cases in the litigation.

Analysis of Party and Random Selections in Bextra and Celebrex Litigation

To address this gap, in a recent article published in the Akron Law Review,[3] we analyzed the selection methods used in the Bextra and Celebrex product liability litigations, in which the primary alleged injuries were cardiovascular and in which bellwether plaintiffs were a mix of party and random selections. Our analysis found that the plaintiffs' selections differed significantly from the random selections — which we anticipated — whereas the defense selections unexpectedly did not. Our results not only confirmed that party selections can produce samples that differ from the remaining cases and thus do not serve as an appropriate basis for extrapolation, but also called into question whether the bias introduced by party selection unfairly disadvantages defendants.

There were two limitations of our analysis. First, it is possible that something about the distribution in the general population of the primary injuries alleged in the Bextra and Celebrex litigations — heart attacks, strokes and cardiovascular-related deaths — affected the composition of the docket and our results, and we could not exclude the possibility that a different type of injury would yield different

results. Second, due to the number of plaintiffs in the dockets, we only analyzed the plaintiffs selected for the discovery pools in the Bextra and Celebrex litigations, not the entire docket.

Thus, while we showed that the plaintiff selections (but not the defense selections) differed significantly from the random selections, we could not compare the strength of the cases selected with the various methods to the average strength of the entire docket. In other words, we could not show that the random selections were more representative of the docket as a whole than the party selections.

Analysis of Bellwether Plaintiffs in the Chantix Litigation

In light of those limitations, we performed a similar analysis of plaintiffs the parties selected for the discovery pool in the Chantix multidistrict product liability litigation, in which the primary alleged injuries were neuropsychiatric (completed suicides, attempted suicides and other neuropsychiatric injuries, such as depression, suicidal ideation and aggression). Unlike our Bextra/Celebrex analysis, we were able to analyze the entire Chantix docket to assess the relative strengths of plaintiff selections and defense selections against the docket as a whole.

Below we present our methods, results and conclusions. As in the Bextra/Celebrex litigation, we conclude that party selections, particularly plaintiffs' selections, yield unrepresentative plaintiffs. Unlike the Bextra/Celebrex litigation, however, our ability to review the entire docket enabled us to draw a broader conclusion: that random selection is more likely than party selection to yield plaintiffs whose claims are similar to the remainder of the docket.

Background

In the Chantix MDL, the parties each selected 14 plaintiffs (for a total of 28 plaintiffs) for a discovery pool. The only plaintiffs eligible for selection were those who alleged neuropsychiatric injuries and filed complaints and completed a plaintiff fact sheet by a particular date. The court required a specific number of plaintiffs in each of three categories: (1) completed suicides (four plaintiffs selected by each side), (2) attempted suicides (three cases each) and (3) other neuropsychiatric injuries, such as suicidal ideation or depression (seven cases each). The litigants did not select any plaintiffs randomly.[4]

Methods

To evaluate the cases, we used a systematic, objective and quantitative model. We ranked each case in the docket on a scale of 0.5 to 100 points, using variables such as: (1) the nature of the injury; (2) the labeling period during which the plaintiff first took Chantix; (3) whether the plaintiff first suffered an injury within a certain period of time after the plaintiff last took Chantix; (4) whether the plaintiff filed suit within the applicable statute of limitations; and (5) whether the plaintiff resided in a state that preempts personal injury claims involving U.S. Food and Drug Administration-approved medications. Our model did not include a variable for pre-existing risk factors for psychiatric illness due to the complexity such a variable would have added.

We compared the mean scores and standard deviations for the plaintiffs' selections and the defense selections to the docket as a whole. We also performed tests of statistical significance to assess the likelihood that any observed differences between the party selections and the entire docket were due to the play of chance as opposed to a systematic bias.

We wanted to ensure that our results were not skewed by the presence in the docket of cases involving:

(1) nonneuropsychiatric injuries; (2) residents of Michigan and Texas, which preempt personal injury lawsuits involving FDA-approved medications[5]; or (3) plaintiffs whose first prescription occurred after the FDA implemented a boxed warning on the Chantix label, which the MDL court ruled was adequate as a matter of law.[6] Cases involving nonneuropsychiatric injuries were not eligible for the discovery pool, and we placed substantially lower values on the Michigan/Texas plaintiffs and postboxed warning plaintiffs in our model. We therefore conducted a sensitivity analysis excluding those groups of plaintiffs from our analysis of the rest of the docket.

We also wanted to evaluate whether random sampling would yield results that were closer to the docket as a whole than the parties' selections, although the scientific literature is replete with articles explaining that samples drawn randomly from a population are more likely to be representative of the population than other methods.[7] We also wanted to see how many plaintiffs one would have to select randomly in order to have a high degree of confidence that the sample would be more representative of the docket as a whole than party selections. We therefore drew random samples from the entire docket — one set of 10 random samples consisting of 14 plaintiffs each, and four sets of 10,000 random samples consisting of seven, 14, 21 and 28 plaintiffs — and compared the average strength of those random samples to see whether those samples were closer to the entire docket than the parties' selections.

Results: Party Selections vs. Entire Docket

As we expected, the plaintiffs' selections did, in fact, differ from the docket as a whole. The mean score for the entire docket was 15.57, with a standard deviation of 21.14. The mean score for the plaintiffs' selections was 32.54 — more than twice as high as the mean for the docket — with a standard deviation of 37.24. The difference between the plaintiffs' mean and the docket mean was not statistically significant (p=0.11) (i.e., we could not reject the hypothesis that the plaintiffs' mean is equal to the docket mean), likely due to the small sample size and the high variability within the plaintiffs' sample. That variability is due in part to the court's requirement that each side pick a certain number of plaintiffs within certain injury categories.

The defense selections also differed from the entire docket. Yet the difference was not as one might expect — that defense selections at least would be numerically weaker (if not significantly weaker) than the average case in the docket. Rather, the Chantix defense selections were stronger than the average case in the docket, by nearly 50 percent. (That likely was an artifact of the court's injury category requirements, which required the parties to select a disproportionate number of suicides.) The mean score for the defense selection was 23.32, with a standard deviation of 28.29. The results were not statistically significant (p=0.32), which suggests that the difference fell within the range of random variation. When we performed our sensitivity analysis excluding nonneuropsychiatric injuries, Michigan and Texas residents and postboxed warning plaintiffs, our results did not change materially. The mean score for the docket excluding such plaintiffs was 19.93, with a standard deviation of 23.11. The mean scores for party selections compared to the entire docket are displayed in Figure 1.

Figure 1 – Mean Scores for Party Selections Compared to Entire Docket

Selection Method	Entire Docket	Plaintiffs	Pfizer
No. Plaintiffs	2,708	14	14
Mean Score	15.57	32.54	23.32
Standard Deviation	21.14	37.24	28.29
P-Value (relative to entire docket)	—	0.11	0.32

Ten Random Samples of 14 Plaintiffs

In contrast to the party selection methods, random samples yielded results that were closer to the average case in the docket. The mean score for the 10 samples of 14 randomly selected plaintiffs was 14.19; those samples ranged from means of 6.93 to 24.36. Every single one of those random samples had a mean score that was closer to the overall docket mean score than the plaintiffs' selections, and all but one of those random samples had a mean score that was closer to the overall docket mean score than the defense selections.

Ten Thousand Random Samples of Seven, 14, 21 and 28 Plaintiffs

When we evaluated the mean scores of 10,000 random samples of varying size, we saw a similar pattern: the random samples consistently had mean scores that were closer to the docket as a whole than the parties' selections. The difference was more pronounced for the plaintiffs' selections; random samples consisting of 28 plaintiffs — the size of the pool the court ordered the parties to select — were closer to the docket mean than the plaintiffs' selections 99.98 percent of the time, out of 10,000 samples.

The 28-plaintiff random selections also were closer to the docket mean than the defense selections 94.95 percent of the time. And the random samples did not need to consist of 28 plaintiffs for that pattern to hold true. Even when we reduced the random sample size to seven plaintiffs, the random selections were closer to the docket mean than the plaintiffs' selections 96.79 percent of the time and closer to the docket mean than the defense selections 67.64 percent of the time, as reflected in Figure 3.

Figure 3 – Percentage of Random Samples (Out of 10,000) That Had Means Closer to the Docket Mean Than Party Selections (by Sample Size)

Party Selection	Sample Size			
	28	21	14	7
Plaintiff	99.98%	99.93%	99.41%	96.79%
Pfizer	94.95%	91.39%	83.54%	67.64%

Random samples of as few as seven plaintiffs consistently outperformed the parties' selections in yielding plaintiffs with mean scores that were closer to the docket as a whole, although larger random samples (up to 28 plaintiffs) performed slightly better than the smaller random samples. Had we used a random sample of 28 plaintiffs, we would have yielded a sample that was within five points of the docket mean 79.7 percent of the time, and we would have yielded a sample as extreme as the plaintiffs' mean less than 0.1 percent of the time.

Conclusions

As with our Bextra/Celebrex analysis, our results confirm that plaintiffs' selections differ from the remaining cases and thus do not serve as an appropriate basis for extrapolating the results of bellwether trials to the rest of the docket. Because the defense selections were much closer to the docket as a whole, our analysis also provides further evidence that party selection is unfair to defendants, particularly when a court imposes specific injury categories as part of the selection process.

Our current analysis also extends our Bextra/Celebrex findings to a docket with a different set of injuries, addressing one limitation of our earlier findings. And rather than simply comparing selection methods to each other, our current analysis also enabled us to demonstrate that random selections — even relatively small random samples — are superior in yielding plaintiffs who are representative of the remainder of the docket. Moreover, while critics of random selection claim that random samples might yield outlier groups of plaintiffs, our analysis showed that random selection is extremely unlikely to result in samples that are outliers, particularly to the same degree as plaintiffs' selections.

If a party selection process both produces unrepresentative early trial candidates and disadvantages one party disproportionately, then such a process cannot fulfill the fairness and information-gathering purposes of bellwether trials. The inadequacies of party selection are particularly troubling when compared to random selection, which yields representative plaintiffs, is fair to both sides, and also produces valuable information for courts and litigants. With this additional empirical evidence, we continue to urge courts to employ random selection procedures where possible.

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[1] MANUAL FOR COMPLEX LITIGATION (FOURTH) § 22.315 (2004).

[2] See, e.g., In re: Lipitor (Atorvastatin Calcium) Marketing, Sales Practices & Prods. Liab. Litig., MDL No. 2:14-mn-02502-RMG, Case Management Order No. 6, at 3 (D.S.C. May 16, 2014) (providing for parties to select cases to be part of a discovery pool from which the first cases would be tried); In re Am. Med. Sys., Inc. Pelvic Repair Sys. Prods. Liab. Litig., MDL No. 2325, Pretrial Order No. 37, at 1 (S.D. W. Va. Jan. 18, 2013) (ordering plaintiff and defendant each to select 15 plaintiffs for a pool of potential bellwether

plaintiffs).

[3] Loren H. Brown, Matthew A. Holian, & Arindam Ghosh, Bellwether Trial Selection in Multi-District Litigation: Empirical Evidence in Favor of Random Selection, 47 AKRON L. REV. 663 (2014).

[4] Pretrial Order No. 9: Selection of Bellwether Plaintiffs for Discovery and Trial, Doc. No. 206, In re: Chantix (Var-enicline) Prods. Liab. Litig., MDL No. 2092, Mar. 10, 2011, ¶¶ 3(a), 3(d).

[5] See Mich. Comp. Laws Ann. § 600.2946(5); Tex. Civ. Prac. & Rem. Code Ann. § 82.007(a).

[6] See In re Chantix (Varenicline) Prods. Liab. Litig., 881 F. Supp. 2d 1333, 1343 (N.D. Ala. 2012).

[7] See, e.g., STEVEN K. THOMPSON, SAMPLING 3-4, 6, 8, 11-37 (3d ed. 2012); BERNARD ROSNER, FUNDAMENTALS OF BIOSTATISTICS 167-77 (6th ed. 2006).