









RX for the Defense

The Newsletter of the Drug and Medical Device Committee

7/1/2016 Volume 24 Issue 3

In this Issue

From The Chair

From the Editor

The Preemption Defense in Innovator Failure to Warn Cases: When FDA Inaction Isn't Enough Don't Take It for Granted: Centralization by the

JPML Is No Longer Automatic

Mobile Health Devices in Canada: A Game of Regulatory Catch-up





#1 in End-to-End eDiscovery

National Law Journal, 2016

www.CDSLegal.com

Join a Committee

Committee Leadership



Committee Chair
J. Carter Thompson, Jr.
Baker Donelson
cthompson@bakerdonelson.com

Don't Take It for Granted: Centralization by the JPML Is No Longer Automatic

by Kevin Hara



Over the past decade, the Judicial Panel on Multidistrict Litigation ("JPML" or "Panel") has increasingly denied motions for centralization, rather than simply granting such requests, which had been almost a certainty more than 10 years ago. In 2015, the JPML denied more centralization motions (36) than it granted (33), the first time ever that denials have surpassed the number of motions granted. While this article considers all types of cases, it

is predominately focused on products liability actions, and strategy for opposing centralization

The JPML is authorized to transfer civil actions pending in more than one district and involving one or more common questions of fact for coordinated pretrial proceedings upon the determination that transfer "will be for the convenience of the parties and witnesses and will promote the just and efficient conduct of such actions." See Manual for Complex Litigation, Fourth, § 20.31 (2004). Although the JPML still grants many motions for coordination, centralization can no longer be taken for granted.

From 2006-2015, the JPML has considered steadily fewer centralization motions, at the same time denying a greater number requests. For instance, the numbers of motions filed has sharply declined, from 121 motions for centralization (including cases of all types) in 2009, to only 82 in 2015, a decrease of nearly 30%. See JPML Calendar Year Statistics January-December 2015. By contrast, the denials have increased; while the JPML denied only 4 out of 74 centralization motions in 2006, or 5%, it denied many more – almost 44% in 2015. *Id.* In analyzing this trend, three factors recur in the denied motions: 1) a small number of cases at the time of the request; 2) lack of uniformity among actions, and/or where the cases are not suited for consolidation; and 3) the predominance of individual issues. The JPML has denied centralization motions in actions having at least one, or more often, a combination of these factors, and in opposing such a motion, counsel should be prepared to demonstrate the existence of the criteria above.

Small Number of Actions

The JPML has emphasized that "where only a minimal number of actions are involved, the moving party generally bears a heavier burden of demonstrating the need for centralization." See In Re: Transocean Ltd. Sec. Litig. (No. II) (MDL 2201), 753 F. Supp.2d 1373, 1374 (J.P.M.L. Nov. 30, 2010) (denying motion to centralize two actions involving allegations of securities fraud). Not surprisingly, the JPML is more likely to rule that centralization is unnecessary where there are a small number of actions, and the promise of a greater number of future actions will not prevent denial. In Re: Intuitive Surgical, Inc., Da Vinci Robotic Surgical Sys. Prods. Liab. Litig., (MDL 2381), 883 F. Supp.2d 1339, 1340 (J.P.M.L. Aug. 3, 2012) (denying centralization, noting that "[w]hile proponents maintain that this litigation may encompass "hundreds" of cases or "over a thousand" cases, we are presented with, at most, five actions."); In Re: Mirena lus Levonorgestrel-Related Prods. Liab. Litig., (MDL 2559), 38 F. Supp.3d 1380, 1380-1381 (J.P.M.L. Aug. 12, 2014) (Mirena II) (denying motion stating that "the mere possibility of additional actions" did not warrant centralization). Some other recent examples of such decisions include: In Re: Forcefield Energy, Inc., Securities & Derivative Litig., (MDL 2655), --- F.Supp.3d ----, 2015 WL 6081431 (J.P.M.L. Oct. 13, 2015) (centralization motion denied for 5 securities fraud actions where they were 'pending in adjacent districts and involve[d] only a small number of counsel and judges"); In Re: Caribbean Cruise Line, Inc., Tel. Consumer Prot. Act (TCPA) Litig. (MDL 2604), 89 F. Supp.3d 1356, 1357 (JPML Feb. 6, 2015) (rejecting





Vice Chair Sara J. Gourley Sidley Austin LLP gourley@sidley.com



Newsletter Editor Kimberly L. Beck Ulmer & Berne LLP kbeck@ulmer.com

Click to view entire Leadership

Upcoming Seminar



Don't forget to bring a colleague with you—group discounts are available! Call DRI Customer Service at 312.795.1101 for more information.

DRI Publications



FDA Basics for the Drug and Medical Device Lawver



Defense Practitioner's Guide to MSP Issues

DRI Social Links









centralization request where there were only four actions "already . . . being managed in an orderly and efficient manner, and the issues presented [were] not unusually complex"); In Re: Waggin' Train Chicken Jerky Pet Treat Prods. Liab. Litig., (MDL 2392), 893 F. Supp.2d 1357, 1358 (J.P.M.L. Sept. 28, 2012) (request for centralization denied for three actions involving alleged contamination of dog treats, because of "lack of complexity, [and] the small number of involved actions," and counsel); Thus, where relatively few actions are involved, the JPML has is increasingly declined to consolidate such cases, and the assurance of more actions will not increase the likelihood of centralization, as in In Re: Intuitive Surgical. Inc.

Centralization Unnecessary Due to Procedural Posture/Lackof Necessity

Another factor that has led the JPML to deny motions for consolidation is the varying procedural posture and/or suitability of the cases for formal centralization. For instance, in situations involving only a few cases and counsel, such as In Re: Forcefield Energy, Inc., and In Re: Caribbean Cruise Line, Inc., the feasibility of informal procedures for case management may be preferable to court intervention, making such actions unsuitable for consolidation. In other actions, the JPML has determined that centralization would not be efficient because the actions are at different stages, making formal coordination of discovery and pretrial procedures impractical.

One recent example is particularly interesting because the JPML twice rejected plaintiffs' attempt to centralize actions involving the prescription pharmaceutical Cymbalta, in December 2014 and again in October 2015. See In Re: Cymbalta (Duloxetine) Prods. Liab. Litig. (No. II) (MDL 2662), --- F. Supp.3d ----, 2015 WL 5936936 at *1-2 (Oct. 9, 2015) (Cymbalta II); In Re: Cymbalta (Duloxetine) Products Liab. Litig., (MDL 2576), 65 F. Supp.3d 1393, 1394 (J.P.M.L. Dec. 10, 2014) (Cymbalta I). In denying centralization again, the JPML ruled that "there ha [d] been no "significant change in circumstances" since 2014, because the cases remained "at substantially different procedural stages," with some actions awaiting case management orders and others approaching the discovery cutoff. Cymbalta II, 2015 WL 5936936 at *1. The Panel also found that common discovery had advanced substantially, with only four plaintiffs' firms and one primary defense counsel, making informal coordination efforts by the parties and courts practicable. Id. at *2. As in Cymbalta II, the Panel had previously ruled that "informal coordination with respect to the remaining common discovery, as well as other pretrial matters, should be practicable." *Cymbalta I*, 65 F. Supp.3d at 1394 (denying motion to centralize 25 actions involving Cymbalta, because "the procedural posture of the actions varie[d] significantly," two firms represented the constituent plaintiffs, and "informal coordination" discovery and pretrial matters was possible).

Other actions in which the JPML has found that centralization would not be beneficial for similar reasons include: In Re: Clean Water Rule: Definition of Waters of The United States (MDL 2663), 2015 U.S. Dist. LEXIS 140117 (J.P.M.L. Oct. 13, 2015) (declining centralization where discovery would be "minimal," and "would be problematic due to their procedural posture," as a result of conflicting rulings by different courts.); In Re: Uponor F1960 Plumbing Fittings Prods. Liab. Litig., (MDL 2393), 895 F. Supp.2d 1346, 1347-1348 (J.P.M.L. Sept. 27, 2012) (request for centralization denied for actions involving alleged defects in plumbing fittings, citing "potential inefficiencies and inconvenience associated with centralizing this litigation," because actions were in "distinct procedural postures"). Therefore, where the cases are not suited for consolidation, because alternative means of coordination are possible or the circumstances do not warrant centralization, the JPML may deny the motion.

Predominance of Individual Issues

The third major factor that has led the JPML to deny requests for centralization is predominance of individual issues, especially with regard to liability and causation. This issue has been a long-standing and practical reason that the Panel has refused to grant such motions.

Most recently, the JPML refused to consolidate nine actions in part due to the fact intensive inquiries necessary with respect to each claim against several different defendants in In Re: Cordarone (Amiodarone Hydrochloride) Marketing, Sales Practices, and Prods. Liab. Litig., (MDL 2706), --- F. Supp.3d ---- 2016 WL 3101841 (J.P.M.L. June 2, 2016). There, the JPML denied the motion to centralize nine actions involving allegations of unlawful off-label promotion of a heart rhythm drug, finding that the need for case specific discovery "appears to mandate a unique inquiry, given that the subject drug was manufactured by one of several of the Generic Defendants and dispensed at different times and at different locations." Id. at *4. The Panel therefore concluded that "centralization would not achieve significant efficiencies," due to the individualize inquiries. Id.

PDF Version

The prevalence of individual issues likewise led to JPML's denial of centralization (despite having formed an MDL for the same product involving different injuries in *In Re: Mirena IUD Prods. Liab. Litig.*, (MDL 2434), 938 F. Supp.2d 1355 (J.P.M.L. 2013) (*Mirena I*)) in *In Mirena II*, 38 F. Supp.3d at 1380-1381. Aside from rejecting "the mere possibility of additional actions," as discussed above, *Mirena II* also cited the "fact-intensive inquiry over whether each plaintiff was properly diagnosed," in light of the nonspecific injuries of headaches and vision problems, in denying the request. *Id.* The JPML cautioned that reliance on the creation of the prior *Mirena I* MDL was "misplaced," because that litigation involved "a far greater number of actions," and plaintiffs' counsel, making "[e]ffective voluntary coordination in that context . . . not feasible," in addition to the individual issues. *Id.* at 1381.

Hence, if individual issues outweigh the economies of centralization, the JPML has been reluctant to grant motions, as in the following examples: In Re: Electrolux Dryer Prods. Liab. Litig., (MDL 2477), 978 F. Supp.2d 1376, 1376-1377 (J.P.M.L. Oct. 16, 2013) (denying motion for centralization of 35 actions involving alleged defect in dryers causing fires, where litigation was "quite mature," with numerous jury verdicts, and due to predominance of "individualized facts concerning the circumstances of each fire, including installation, repair, and maintenance," over common issues); In Re: Qualitest Birth Control Prods. Liab. Litig., (MDL 2552), 38 F. Supp.3d 1388 (J.P.M.L. Aug. 12, 2014) (denying centralization for two actions involving contraceptive, ruling that "the individualized facts—particularly relating to whether each plaintiff received an improperly packaged Qualitest birth control product and whether she became pregnant as a result of taking the pills in the wrong order-will predominate over the common factual issues," notwithstanding the possibility of future actions); In Re: Chilean Nitrate Prods. Liab. Litig., (MDL 2237), 787 F. Supp.2d 1347 (J.P.M.L. May 20, 2011) (denying centralization request involving two actions in which municipalities claimed drinking water was contaminated by perchlorate, where there were "numerous individualized issues," including whether products were used in municipalities, dates and extent of application, other possible sources of contamination, and defendants' knowledge); In Re: American-Manufactured Drywall Prods. Liab. Litig., (MDL 2160), 716 F. Supp.2d 1367, 1368 (J.P.M.L. June 8, 2010) (motion denied in part due to "multiple individualized issues, including . . . liability and causation, that these actions appear to present," and availability of other methods to achieve efficiency in pretrial proceedings); In Re: Ambulatory Pain Pump-Chondrolysis Prods. Liab. Litig., (MDL 2139), 709 F.Supp.2d 1375, 1378 (J.P.M.L. Apr. 14, 2010) (denying centralization of 102 personal injury actions, where "individual issues of causation and liability . . . predominate, and remain likely to overwhelm any efficiencies that might-be-gained by, centralization," where pain pumps involved different sizes, volumes, duration, flow capacities, plaintiffs had individual medical histories, also noting actions were at "widely varying procedural stages.").

Conclusion

One may speculate that the increasing prevalence of small-case-number MDLs, at a time of decreasing overall number of consolidation requests, may be driven by plaintiff-side desire to advertise "multi-district litigation" to the public. Whatever the underlying forces may be, the JPML has plainly receded in the last decade from previous practice that overwhelmingly granted motions for centralization. There are three overarching factors that are common among the denials: 1) a small number of actions at the time that the motion is made; 2) the procedural posture and need for formal management of discovery and pretrial matters without formal consolidation; and 3) the existence of individual issues with regard to liability, injuries, causation. The fewer the actions, number of involved counsel, ability to informally manage common proceedings, and greater prevalence of individualized issues are all criteria that have tipped the balance in favor of the JPML denying motions for centralization. Defense counsel opposing centralization would be best served by demonstrating that the actions are not suited for coordination because of the existence of one or more of the above factors. While many product liability actions will involve individualized questions, this factor alone does not guarantee that a denial, but to the extent such issues can be shown to predominate over commonalities, the argument against centralization will be strengthened.

Kevin Hara is an associate of Reed Smith in San Francisco. Mr. Hara's focus is on life sciences product liability litigation. He has represented many major manufacturers of medical products, including numerous cardiac and orthopedic medical devices, and commonly used prescription medications.

Back

ENGAGE | CONNECT | GROW | LEARN | The DRI Community