



MEDICAL DEFENSE AND HEALTH LAW

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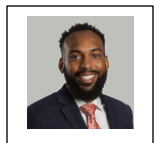
Bellwether cases did not exist when the IADC was founded a century ago, but they have become a critical part of defending mass tort litigation in the United States, for both domestic and foreign corporate defendants. This article will update you on the ins and outs of the bellwether opioid trials which has become “bet the company” litigation for many pharmaceutical companies and other defendants. Using opioids as an example, we will discuss best strategies for preparing for bellwether cases.

Opioid Litigation and Future of Bellwether Litigation

ABOUT THE AUTHORS



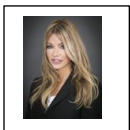
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ABOUT THE COMMITTEE

The Medical Defense and Health Law Committee serves all members who represent physicians, hospitals and other healthcare providers and entities in medical malpractice actions. The Committee added a subcommittee for nursing home defense. Committee members publish monthly newsletters and *Journal* articles and present educational seminars for the IADC membership at large. Members also regularly present committee meeting seminars on matters of current interest, which includes open discussion and input from members at the meeting. Committee members share and exchange information regarding experts, new plaintiff theories, discovery issues and strategy at meetings and via newsletters and e-mail. Learn more about the Committee at www.iadclaw.org. To contribute a newsletter article contact:



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The International Association of Defense Counsel serves a distinguished, invitation-only membership of corporate and insurance defense lawyers. The IADC dedicates itself to enhancing the development of skills, professionalism and camaraderie in the practice of law in order to serve and benefit the civil justice system, the legal profession, society and our members.

The advent and pervasive nature of mass tort litigation over the course of the last 25 years has increasingly led to consideration of alternative methods of managing broad-based litigation frequently involving hundreds, if not thousands of individual claims. Chief among these has been the use of multidistrict litigation (“MDL”), in which related cases are consolidated into one federal forum.¹ Procedurally, mass tort MDL litigation frequently then involved what are known as “bellwether trials,” with the term “bellwether” based on the historical “belling” a “wether” sheep that was intended to lead a shepherded flock of sheep.² A select number of bellwether cases are drawn from the broad expanse of consolidated MDL cases, and scheduled for several trials that are intended to provide both plaintiffs and the defendants generally an opportunity to test legal theories, evaluate expert testimony, assess the quality and effectiveness of testimony and evidence, and gain some global perspective as to how individual cases would generally be tried. The intent thereafter is for the results of bellwether trials to provide litigants with some basis to assess the value of individual claims, oftentimes to lead to mass

settlements with a basis for settlement dollar allocation.³

Bellwether trials can also allow for the preparation of “trial packages” that oftentimes include databases of extensive discovery materials, background information, deposition and trial testimony, biographies of potential witnesses, prior rulings, and organized sets of evidentiary material.⁴ Bellwether trials also allow for some input on the part of both plaintiffs and defendants in the type of cases to be tried, organizing what would be otherwise inefficient and costly fact and expert discovery, and allowing adverse litigants to have some control over which specific cases are tried in what order. For example, in currently-pending hernia mesh mass tort litigation, MDL venued in the Northern District of Georgia has relieved the parties of any Initial Disclosure requirement, and gave the parties the ability to each select twelve (12) cases from the pool of all pending cases to be subject to discovery; from that pool of 24 cases, the plaintiffs and defendants will then choose five cases each to be tried, which will then (and only then) be subject to expert discovery.⁵ From there, the parties can then submit to the Court their respective

¹ See *In re Zyprexa Prods. Liabl. Litig.*, 238 F.R.D. 539 (E.D.N.Y. 2006); *In re Fosamax Production Liab. Litig.*, 248 F.R.D. 389 (S.D.N.Y. 2008); see also Eldon E. Fallon, Jeremy T. Grabill & Robert Pitard Wynne, *Bellwether Trials in Multidistrict Litigation*, 82 TULANE LAW REVIEW, 2323(2008).

² *In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1019 (5th Cir. 1997).

³ See, *supra* note 1 at 2337-2342; *Chevron*, 109 F.3d at 1019 (“[i]f a representative group of claimants are

tried to verdict, the results of such trials can be beneficial for litigants who desire to settle such claims by providing information on the value of the cases as reflected by the jury verdicts”).

⁴ See, *supra*, note 1 at 2339.

⁵ See Practice and Procedure Order No. 13, *In re Ethicon Physiomes Mesh Flexible Composite Hernia Mesh Prod. Liab. Litig.*, MDL Docket No. 2782, 1:17-md-02782-RWS.

proposed schedule of trials, with the Court determining the manner of trial, order of selection of plaintiffs for trial, and timing of trial.⁶

While such bellwether results would appear to support use of bellwether in all manner of mass tort litigation, the MDL and associated bellwether procedure is not without its detractors. First, the concept of collective resolution of what are, at heart, individual cases of liability, is seen by many plaintiffs' counsel (and some defense counsel) as robbing their individual claimants of the opportunity to present their claims to a jury of their peers and the "realistic treat ... trial provides."⁷ Another concern is that MDL and bellwether trials effectively compel litigants to participate and give up their right to jury assessment of damages, as opposed to lawyers; in such cases, participants in MDL are likely recognizing that the chance of their case being tried among the thousands being litigated is slim.⁸ Other criticisms include the potential for systemic bias to affect trial outcomes, jury awards, and related post-verdict settlements given that one set of jurors in one venue is often deciding the outcome of bellwether cases.⁹

In the past several years even more complications have arisen, most notably in the pelvic repair system litigation venued in the Southern District of West Virginia.¹⁰ In that case, the Court set up a bellwether trial scheme similar to that discussed earlier in the Georgia mesh case, where the adverse parties could select a number of claims among the total claims pending for trial.¹¹ Four bellwether cases were selected for trial, only to be voluntarily dismissed by the plaintiff with prejudice, along with 20 other cases in the discovery pool, leaving only six cases remaining.¹² From there, the plaintiffs' counsel moved to withdraw from the remaining six cases rather than file summary judgment oppositions.¹³ The MDL Court, as a result, decided to scrap the bellwether process entirely, ordering discovery in 250 cases in a first step to remanding them back to their transferor districts for trial.¹⁴

In the pharmaceutical realm, the bellwether trials involving Vioxx conducted in the late 2000s are a perfect example of the bellwether process.¹⁵ In the Vioxx cases the MDL Court conducted six trials (one of the six cases was retried after a hung jury in the first MDL trial) resulting in five verdicts for

⁶ See *id.*

⁷ See Alexandra D. Lahav, *Bellwether Trials*, 76 THE GEORGE WASHINGTON LAW REVIEW 576, 578 (2008).

⁸ See *id.* at 592-93.

⁹ See, *supra*, note 9 at 594.

¹⁰ *In re Cook Medical, Inc. Pelvic Repair System Prods. Liabl. Litig.*, MDL No. 2440.

¹¹ See Pretrial Order #59, *In re Cook Medical, Inc. Pelvic Repair System Prods. Liabl. Litig.*, MDL No. 2440, 2015 WL 3385719 (S.D. W. Va. May 19, 2015).

¹² Steven Boranian, *Is This a Crack In The Bellwether?*, Drug & Device Law, May 29, 2015, <https://www.druganddevicelawblog.com/2015/05/is-this-crack-in-bellwether.html>, last accessed Nov. 27, 2019.

¹³ *Id.*

¹⁴ See *id.*

¹⁵ See *In re Vioxx Prods. Liabl. Litig.*, 360 F. Supp. 2d 776 (E.D. La. 2007).

Merck, the manufacturer of Vioxx. One of those Merck verdicts was set aside later and not retried. Trials also were conducted in Texas, New Jersey, Illinois, and California state courts.¹⁶ In sum, by the end of November 2007, juries in federal and state courts had decided for Merck 12 times and for plaintiff five times.¹⁷ One Merck verdict was set aside and not retried, and another Merck verdict was set aside and retried, leading to one of the five plaintiff verdicts.¹⁸ There were also two unresolved mistrials. Merck filed appeals or sought review in each of the five cases with plaintiff's verdicts; two of the five plaintiff verdicts later would be reversed on appeal for insufficient evidence, and judgment entered for Merck.¹⁹ Merck engaged in substantive settlement discussions, ultimately entering into a settlement agreement with plaintiffs' counsel in November 2007 to resolve Vioxx personal injury claims in federal and state court jurisdictions.²⁰

State court proceedings can also serve as "implicit" bellwethers. State court cases brought by state and local governments seeking compensation under state statutes will frequently involve litigation of fact and expert issues that have potentially broad application to similar cases that may be brought in other state jurisdictions, and

counsel will frequently look to state court decisions such as Oklahoma's to build their own "trial package" for use in other states. Notwithstanding criticisms of the bellwether procedure, both explicit bellwether litigation in the MDL context and implicit bellwether litigation in the context of state lawsuits are likely here to stay in mass tort litigation. Nowhere is that more apparent in the last ten years than the advent of mass tort litigation involving opioid pain medication. Following introduction and widespread use of both immediate and extended release opioids, including OxyContin, Morphine, Fentanyl and others, in the United States from the mid-1990s through the present, issues have arisen regarding the known addictive properties of opioids, their long-term use to treat non-cancer chronic pain, and their use for periods longer than seven (7) days following surgical procedures. The Food and Drug Administration as recently as February 26, 2019, identified the "opioid crisis" as it has come to be known in the media as "one of the largest and most complex public health tragedies that our nation has ever faced."²¹

As a result, practitioners, hospitals, hospital systems, pharmacies, and major pharmaceutical companies have faced cases alleging injury from opioids on an individual

¹⁶ See, e.g., *In re Vioxx Prods. Liabl. Litig.*, 239 F.R.D. 450, 452 n. 4 (E.D. La. 2006).

¹⁷ Mary E. Bartkus, *The Cost to Society of Pharmaceutical Mass Tort Litigation*, Presented for The Foundation for Law, Justice, and Society, Oxford, England (June 11, 2019).

¹⁸ See *id.*

¹⁹ See *id.*

²⁰ See, *supra*, note 1 at 2335-2336 (citing Heather Won Tesoriero, Sarah Rubenstein & Jamie Heller, *Merck's Tactics Largely Vindicated as It Reaches Big Vioxx Settlement*, WALL ST. J. Nov. 10, 2007 at A1).

²¹ <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-2019-policy-and-regulatory-agenda-continued>, last accessed Nov. 27, 2019.

and class basis. State and local government cases seek to recover costs they associate with increased health care and substance abuse treatment expenditures, with associated expenses estimated at over \$19.6 billion nationally.²² Following mass tort action plans previously seen in the context of tobacco litigation, state Attorneys General and private litigants have filed thousands of opioid-related lawsuits in the last 20 years, seeking to recover compensation for private litigants, or a means of funding opioid treatment and related costs for public plaintiffs.

For purposes of this article, we will review and discuss two cases that have had recent developments and provide some insight into the potential bellwether effects of opioid litigation. The two cases include the recent Oklahoma state court trial brought by the State of Oklahoma,²³ as well as the pending MDL litigation venued in the Northern District of Ohio.²⁴ The former case is representative of an implicit bellwether, while the latter represents the more formal, MDL-based explicit bellwether process.

An implicit bellwether case was in Cleveland County, Oklahoma leaves us with some

important lessons. The case commenced on June 7, 2017, following a similar but slightly more expedited timeline as federal opioid litigation. The Attorney General of Oklahoma brought the action on behalf of the State of Oklahoma, alleging opioid manufacturers, among others, created a public nuisance under Oklahoma state law.²⁵ The case proceeded to trial, and on August 27, 2019, Judge Thad Balkman issued a ruling finding for the State, awarding \$572 Million dollars for an abatement of the opioid damage to the state.²⁶ In his ruling, Judge Balkman made several factual findings that have broad application beyond Oklahoma, confirming the existence of an “opioid crisis.”

As a result, the Oklahoma case serves as something of an “implicit” bellwether – occurring outside the confines of your garden-variety MDL bellwether, but with similar potential effects, including review and enumeration of factual issues with potential universal application. Certainly plaintiffs’ attorneys across the country and perhaps globally, will attempt to use Judge Balkman’s opinion in other pending cases, holding out a jurist’s conclusions at the end

²² Curtis Florence, Feijun Luo, Likang Xu, and Chao Zhou, *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States*, 2013, *Med Care* 2016 Oct; 54(1): 901-906, at <https://www.ncbi.nlm.nih.gov/pubmed/27623005>.

²³ *State of Oklahoma, ex rel., Mike Hunter, Attorney General of Oklahoma v. Purdue Pharma, L.P., et al.*, 2019 WL 4059721 (Okl. Dist. 2019).

²⁴ *In Re National Prescription Opiate Litigation*, MDL 2804, Case No. 1:17-md-2804, United States District Court, Northern District of Ohio, Eastern Division.

²⁵ *State of Oklahoma, ex rel., Mike Hunter, Attorney General of Oklahoma v. Purdue Pharma, L.P., et al.*, 2019 WL 4059721 (Okl. Dist. 2019)

²⁶ The Court’s judgment was later reduced by \$107 million, leaving a current judgment of \$465 million with an issue remaining as to a credit for the previous settlements. Both the State and Johnson and Johnson are appealing.

of hearing volumes of evidence as instructive if not dispositive.

Bellwethers Going Forward

It appears that bellwethers – albeit in various forms and structures – are here to stay. The mere scale of mass tort litigation, and the ongoing and supported use of MDL effectively renders bellwethers a reasonably anticipate approach if not outright necessity. The volume of mass tort cases, be it opioid cases, mesh cases, or talc cases, neither plaintiff nor defense litigants can take all cases to trial, and courts are ill-equipped to manage voluminous and otherwise repetitive discovery. Plaintiffs will potentially less high-value claims as compared to better-financed claims with broader appeal will continue to see bellwethers as the best vehicle to extract settlement monies, while mass tort plaintiffs’ attorneys will continue to view bellwethers as a means to assess and identify their best cases, test legal theories, and ultimately reap the rewards of trial – even if there are adverse verdicts – by likely securing total or partial settlements on behalf of all litigants. Defendants, for that matter, appear to recognize that bellwethers in the MDL context likely serve a purpose in clarifying legal issues in furtherance of settlement of the broader group of cases transferred to MDL, hence the Northern District of Ohio’s recognition of a “settlement track” and “trial track.”

The ramifications of the Oklahoma state court case, at least domestically, is harder to

gauge. As a bench trial, the lawsuit does not provide a great deal of direction as to how a jury may assess similar claims and is focused on application of a specific Oklahoma statute; however, Judge Balkman’s decision interpreting Oklahoma law (assuming no reversal on appeal) certainly resolves questions of law regarding Oklahoma statutory interpretation, and his findings of fact will inevitably serve to provide plaintiffs with a “cookbook” on presentation of certain facts relevant to the presentation of opioid claims.

As corporate litigants continue to face mass tort claims, including remaining opioid claims, hernia mesh claims, glyphosate-related cancer claims, and talc claims alleging ovarian cancer, the merits of and best ways to approach and participate in bellwether schemes must be carefully evaluated and considered. The potential benefits of bellwethers in terms of settlement may provide some cost certainty for litigants, but must be balanced against the utility of a trial on the merits of one or more bellwether claims sufficient to stave off future lawsuits or resolve potential claims both domestic and international. In-house corporate officers must work closely with outside counsel to assess the universality of claims brought by various types of litigants, and determine the best way to approach courts in the MDL setting with respect to categorizing cases and identifying how bellwether litigation should proceed. Opioid cases provide concrete examples of the benefits and challenges of both explicit and implicit bellwethers and



the organization and results of each serve to inform both in-house and outside counsel on best practices in comparable mass tort cases.

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