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Consolidated pharma cases: A rising tide lifts all boats

How plaintiffs' leadership in consolidated pharmaceutical cases can best protect the rights of all claimants

Cases involving injuries caused by prescription drugs are nearly always consolidated for pretrial proceedings. This serves a number of valid ends. For example: the discovery process is streamlined for plaintiffs; coordination among plaintiffs' counsel provides for economies of scale with respect to discovery against defendant; consistency can be achieved in rulings on critical dispositive motions, addressed to issues of general applicability.

In other ways, however, the process divests plaintiffs and their counsel of "ownership" of their case. This is because the task of developing the defendant's liability becomes, largely, the responsibility of a small group of lawyers appointed by the court, usually referred to as the "Plaintiff's Steering Committee" ("PSC"). Those attorneys who do not participate in the plaintiffs' leadership, but who represent claimants with cases transferred to the consolidated proceeding are, to some extent, sidelined until that proceeding ends and individual cases are remanded to the original jurisdiction.

In theory, this "wait and see" approach is reasonable. Arguably, a claimant can maximize recovery in consolidated drug cases by petitioning for remand at the appropriate time, and then leveraging a trial setting. But, as any practitioner with experience litigating pharmaceutical cases knows, this almost never happens. Indeed, few drug cases are ever tried in coordinated proceedings, and plaintiffs and their counsel are left to resolve their claims on the backs of whatever limited results are realized.

To be sure, there are examples of pharmaceutical Multidistrict Litigations ("MDL") in which so-called "bellwether" trials have achieved productive results (e.g., the recent *Vioxx* litigation). And courts in consolidated cases routinely invoke the specter of mass remands in order to motivate litigants. But all too

often, large drug cases are resolved without bellwether trials, and without any meaningful threat of large numbers of "post-remand" trials. This happens, principally, for two reasons: First, MDL courts and their state court counterparts are loathe to burden their brethren with trial cases. Second, there has been a persistent failure on behalf of the plaintiffs' leadership in consolidated pharmaceutical proceedings to convert the massive amount of evidence obtained during pretrial discovery into the sort of work product which would enable lawyers across the country to bring multiple complex drug cases to trial.

The solution to this problem lies not in rejecting the system of coordinated mass actions, but in working effectively within it. Consolidation of pharmaceutical cases is a fact of life for claimants and their counsel. There simply is no more efficient means for handling large numbers of claims involving the same product and – usually – nearly identical injuries. But in the absence of genuine trial pressure, truly equitable resolution of these cases is much harder to achieve. This article offers examples of ways in which the plaintiffs' leadership in consolidated drug cases can best discharge their obligation to claimants and their counsel, putting them on vastly improved footing when resolving these claims.

Consolidation and management of claims

Since the peak of the Bendectin litigation in the late 1980s and early 1990s, there have been scores of consolidated actions involving drug products, ranging in size from the massive *Vioxx* litigation – with more than 50,000 claims – to cases with relatively small numbers of plaintiffs, involving drugs like Zicam and the Nuvaring contraceptive device. The

primary claim in all these cases is strict products liability failure to warn; that is, the manufacturer failed to warn prescribing physicians about a risk, or risks, of the drug, about which it knew or should have known. These cases have had wide-ranging effects: exerting enormous influence on drug manufacturers in a way that has benefitted patients; producing seminal U.S. Supreme Court decisions, (See, e.g., *Wyeth v. Levine* (2009) 555 U.S. 555 and *Daubert v. Merrell Dow Pharmaceuticals* (1993) 509 U.S. 579) and, in some cases, inundating court systems across the country with tens of thousands of claims.

Because jurisdiction in many, if not most, drug cases is founded on diversity, the lion's share are filed in, or ultimately removed to, the federal courts. When two or more cases involving the same drug and similar injuries are pending in more than one district court, the Judicial Panel on Multidistrict Litigation can transfer them to a single federal district court (transferee court), for centralized pretrial proceedings. (See 28 U.S.C. § 1407(a).) In cases of this sort, centralization under section 1407 is generally considered to be necessary to eliminate duplicative discovery, prevent inconsistent pretrial rulings and conserve the resources of the parties, their counsel and the judiciary. (*In re Express Scripts, Inc., Pharmacy Benefits Mgmt. Litig.* (J.P.M.L. 2005) 368 F. Supp. 2d 1356, 1357.)

Analogous procedures exist in a number of states. For example, in California, when multiple civil actions sharing a common question of fact or law are pending in different courts, the presiding judge of the court, or either party, may submit a petition for coordination to the Chairperson of the Judicial Council. The Chairperson may assign a judge to determine whether the actions are

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complex, and if so, whether coordination of the actions is appropriate. (Code Civ. Proc., § 404.) In the past decade, coordinated proceedings have been ordered in a number of pharmaceutical cases, including Vioxx, diet drugs, Yaz/Yasmin and Fosamax, to name a few. While state-level coordinated proceedings typically attract fewer cases than their federal counterparts, some have played significant roles. Indeed, state court trials in California, New Jersey and Texas provided significant momentum for plaintiffs in the *Vioxx* litigation.

One of the transferee court's earliest, and most critical, decisions is the appointment of supervising plaintiffs' counsel, or — typically — the Plaintiffs' Steering Committee ("PSC"). As Judge Eldon Fallon has observed, a PSC is necessary to create centralized leadership and control in litigations of this size. (*In re Vioxx Products Liab. Litig.* (E.D. La. Aug. 9, 2011) MDL 1657, 2011 WL 3563004.) The PSC assists all plaintiffs by overseeing discovery, communicating with other plaintiffs' lawyers, appearing before the court, attending status conferences, and preparing motions and responses regarding case-wide discovery matters. The PSC acts on behalf of, or in consultation with, Plaintiffs' Lead Counsel in the management of the litigation. (*In re Prempro Products Liab. Litig.* (E.D. Ark. Jan. 13, 2011) 4:03-CV-1507-WRW, 2011 WL 124188.)

The *Vioxx* litigation plaintiffs' trial package

In most consolidated drug cases, the plaintiffs' leadership performs an enormous amount of work. Even in the most haphazard MDL, millions of pages of documents are reviewed, scores of depositions are taken and numerous experts are developed. This work is critical to getting the litigation into a posture for either trials or resolution. But a single court can only do so much in terms of establishing benchmarks for the viability, and value, of plaintiffs' claims in large consolidated cases, no matter how many similarities individual cases may share. Bellwether trials can be helpful and informative, but they offer a minuscule

sample size of the extant cases. As such, the goal of the PSC should not simply be to grind through discovery, and shepherd plaintiffs' general theories past the inevitable *Daubert* and summary judgment motions, or even to try a handful of bellwether cases. Rather, in order to put the largest number of plaintiffs in the best position to achieve good results at the time of settlement, the PSC should prepare counsel across the country for trial. Regrettably, work product that achieves this objective is still the exception, not the rule.

There is, however, an analogue for this kind of work product in the form of the "trial package," produced by the *Vioxx* MDL PSC. This was an effort by the plaintiffs' leadership to deliver common benefit work product which would actually enable practitioners to try a case after remand. It was designed not simply as a repository for the detritus of more than five years of discovery, but as a tool with the trial of a pharmaceutical case firmly in mind. For just this reason, the trial package was organized along the lines of a trial notebook. While space prevents an in-depth examination of the entire package, a discussion of the following major sections offers an adequate introduction: Liability Case; Science Case; Case Presentation and Themes; Witnesses; and Cross Examination Modules.

In some measure, the PSC was able to deliver this product because of the way in which the litigation unfolded. When *Vioxx* was pulled from the market in September 2004, the litigation was already quite mature. A large number of cases had been pending in various state courts for more than two years, most in a consolidated proceeding before Judge Carol Higbee, in Atlantic City, New Jersey. By the time the MDL was ordered, before Judge Eldon Fallon in the Eastern District of Louisiana, a substantial amount of discovery had already been completed. This enabled the federal litigation to hit the ground running, with a bellwether trial beginning less than a year after the court's first hearing. (See *In re Vioxx Products Liab. Litig.*, MDL 1657, 2011 WL 3563004 (E.D. La. Aug. 9, 2011).)

• *Liability Case*

The liability section provided an overview of the *Vioxx* case, taking the user through most of the main themes, including: the development of the drug, as well as others in the same class; the competitive pressure that motivated Merck, the drug's manufacturer; the company's marketing blitz following FDA approval; the publication of key studies demonstrating the risks of *Vioxx*; and, finally, the withdrawal of the drug from the market. The liability section itself contained the following subsections:

• *Liability Playbook*

The playbook provided a narrative summary of the *Vioxx* liability case, with citations to exhibits, deposition testimony and relevant medical literature. The playbook functioned as an introduction to the case, comprehensively addressing all major issues, with specific references to evidence, including documents, deposition and medical literature. This enabled attorneys with limited previous exposure with the litigation to assimilate an enormous amount of complicated information relatively quickly and efficiently.

• *Cast of Characters*

As with any case involving a complex product — one developed, sold and studied for more than eight years — the *Vioxx* litigation encompassed scores of critical figures. While it was not necessary to immediately recall each and every one from memory, the trial package committee thought it necessary to provide salient information about a discrete universe of players, in a format that was readily accessible. The Cast of Characters included titles and descriptions — with information about relevant document production from Merck — for nearly one thousand key figures in the case, including: Merck employees; authors of scientific and medical literature; plaintiff and defense experts.

• *Vioxx Dictionary*

While drug cases can be remarkably straightforward, at least when distilled to their essential elements, they require attorneys to become conversant with a number of otherwise foreign subjects; including pharmacology, pharmaceutical

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regulation and wide-ranging medical topics. The Vioxx Dictionary provided definitions and context for hundreds of terms practitioners would encounter, particularly during case-specific discovery, such as U.S. Food & Drug Administration and Merck acronyms, medical jargon and Merck-specific terms.

• **Vioxx Timeline**

The timeline is a self-explanatory document, and provided a chronological graphic representation of critical events from the Vioxx life cycle, beginning with the invention of the molecule and early concerns about its safety, through the entire regulatory history, including post-marketing safety developments, up to and beyond the withdrawal of the drug from the market, with citation to exhibits as appropriate. Together with the liability playbook, the timeline offered a thorough introduction to the case, in an accessible format.

• **Science Case**

Drug cases can be overwhelming for practitioners because of the enormous amount of scientific evidence which has to be assimilated and explained to the jury. In order to present the case coherently, attorneys have to be conversant with the mechanism of action of the drug, both with respect to its indications and its adverse effects; they must understand the mechanism of the injury caused by the drug, as well as co-morbid conditions to which the defense will point as alternate causes of the plaintiff's injury; they have to be able to engage well-credentialed defense experts who will, if history is any guide, concoct Byzantine defenses with only a tenuous basis in science and medicine.

In the presentation of the science case, the trial package committee sought to provide an introduction to these sorts of critical subject matters. There were two principal documents: the Backgrounder and the Compendium. The Science Backgrounder was a comprehensive guide to the critical scientific issues in the case. For Vioxx, which belongs to the class of drugs which selectively inhibit the enzyme cyclooxygenase-2, this involved explanations of cyclooxygenase and selective inhibition of COX-2; the

proposed mechanism of action for adverse reactions to the drug, and early hypotheses regarding potential risk; the manufacturer's clinical trials, with particular attention paid to the critical VIGOR study and its aftermath; important label changes; and issues surrounding the withdrawal of the drug.

The Science Compendium was an introduction to the core medical literature, and contained detailed abstracts of key articles. At the same time, an exhaustive collection of the relevant collection of medical literature was provided, organized by topic and fully searchable. This enabled attorneys to access quickly a large body of literature to address specific points.

• **Case Presentation and Themes**

As discussed above, most MDLs ably conduct discovery against the defendant. And most eventually make available for plaintiffs at least some analysis of the documents in the case, usually in the form of what has come to be called a "theme grid." But unfortunately, it is uncommon for plaintiffs' leadership to provide a coherent general liability presentation that is actually ready for trial, in a genuine "plug and play" format, and this is a shame. Empowering lawyers around the country to push cases to trial would create enormous pressure, and redound to the benefit of all plaintiffs. What's more, this sort of work product is well within the means and abilities of most, if not all, PSCs now; indeed, because they are paid to provide this (via assessments on all cases in the consolidated litigation), it would seem they have an absolute obligation to do so.

In the past, the critical shortcoming of MDL work product has been the failure to bridge the gulf between, on the one hand, a database of thousands of "hot" documents, scores of purportedly critical liability depositions and reams of expert reports, and, on the other hand, the presentation of this material at trial. A mountain of data is assembled in order to convince the defendant to resolve claims fairly and adequately, but it is seldom put to widespread use. The Vioxx trial package committee sought to bridge the gap by offering more than a collection of

"hot" documents and endless deposition summaries. The end product, instead, was an actual road map to a Vioxx trial. The case presentation and themes section of the package nicely encapsulated this organizing principle, as demonstrated in its constituent sections:

• **Master Order of Proof**

The Master Order of Proof offered direction as to how the liability case should be presented at trial, with specific recommendations about which witnesses' videotaped depositions to play, together with the evidence to be offered through the witness. It provided thumbnail introductions for all liability and expert witnesses and detailed the elements of the plaintiff's case-in-chief which could be established through the witness.

• **Exhibit Database**

The exhibit database organized a core of approximately 5,000 liability documents, identified by the MDL Discovery Committee as "hot," "trial," and "reference," which were critical to the presentation, and preparation, of the plaintiff's case. The database permitted the user to search documents by theme, subtheme, date, Bates number, description, or text.

• **Exhibit Theme Grid and Exhibits**

By the end of the Vioxx litigation, Merck had produced in excess of 20 million pages of documents. More than 5,000 of these were coded as "reference" (that is, important to some element of the case) or higher. An enormous amount of effort was expended in reviewing, coding and describing these documents. This work was performed by attorneys across the country. In providing this work product to plaintiffs' counsel at large, it was critical to provide structure for the documents, or they would be lost in a sea of data. This was done using the theme grid. In many ways, this searchable database functioned as the framework for the story of liability. It imposed, if not a narrative structure, then certainly a coherence that enabled users to access the story of the Vioxx case.

While all coded documents were available in the complete trial package, approximately 1,500 of the "hottest" and most relevant were organized and

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searchable using the theme grid. All of these documents were subjectively coded, and short descriptions of each were provided, with links to complementary documents. But perhaps most important, all documents on the theme grid were categorized by themes and subthemes. For example, a key point in the plaintiff's case was Merck's motive to sell Vioxx aggressively even in the face of early concerns about the drug's safety. Documents relevant to this contention were organized under the general theme "Merck desperate for a blockbuster." Beneath this general theme were more focused subthemes such as: "Vioxx has to succeed against tough Celebrex competition"; "Products going off patent"; "Pipeline is thin"; and "Analysts are gloomy about Merck future." This organizational structure enabled litigators to quickly and easily assemble documents to prove an element of the case, or to interrogate a Merck defense.

• **Deposition Designations**

In previous iterations of MDL trial packages, videotaped depositions of key witnesses were provided, some with trial designations, but often these were of limited value. In *Vioxx*, we were able to go a step further because of the comparatively large number of trials that were completed before the trial package was disseminated. For all key liability witnesses (not just company employees, but third-party witnesses and experts — retained and independent), deposition and trial transcripts were provided, with exhibits. In addition, deposition designations from all trials were provided — together with the committee's recommended designation — and Merck's counter-designations, with previous rulings on admissibility from various courts. When used with the master order of proof, these "witness folders" enabled practitioners to assemble the majority of the general liability

case pretrial, mapping out beforehand a large portion of the evidence to be offered at trial, with a well-developed plan for how and when it would be offered into evidence.

• **Cross Examination Modules**

Of course, there is a limit to the number of variables in trial which can be controlled with pretrial preparation. While significant portions of the plaintiff's case-in-chief can be presented using videotaped deposition testimony, every pharmaceutical trial involves live cross examination of critical defense witnesses. These witnesses are almost always highly educated scientists and physicians, with broad experience in their respective fields, who are generally very well prepared for trial. Witnesses of this type consistently offer remarkably sophisticated defenses to liability, based on analyses of scientific data and convoluted pharmaceutical regulations. To better enable attorneys to engage these witnesses and defenses, at deposition and trial, the trial package contained witness folders for defendant employees and retained witnesses who could reasonably be expected to testify live at trial, complete with all depositions, transcripts of previous trial testimony, cross examination outlines and, where applicable, expert reports. In addition to these, folders were also provided for critical witnesses whose identities would change from case to case; such as case-specific experts, sales representatives, treating cardiologists (in heart attack cases) and prescribing physicians.

Similar to the witness folders, which were designed to help practitioners prepare for a live witness, the committee also supplied defense modules, to help counsel rebut common Merck defenses. These provided strategies for responses to defense claims pertaining to liability — e.g.: "We gave all relevant information to the FDA"; "Vioxx was no more dangerous

than any other drug in the class"; or "Hypotheses demonstrating the risks of Vioxx had been disproved." The modules contained narrative explanations of the Merck defense, explained the evidence relied upon by the company, and catalogued the evidence available to rebut the claims, including cites to deposition testimony, liability documents, medical literature, and other material.

Conclusion

Every Vioxx case presented significant plaintiff-specific issues. The signature injury — heart attack — has a host of co-morbid conditions, most of which were in play in every case. Merck's attorneys defended their client relentlessly, contesting every issue throughout the litigation. And yet, by consistently pushing individual cases to trial, the plaintiffs negotiated a settlement of nearly \$5 billion. In large measure, this was made possible by the development of a portable liability package. This is an example of one of the ways which plaintiffs' leadership cases can fulfill their obligations to claimants who — of necessity — rely on common-benefit work product. In fulfilling this obligation, these attorneys can keep the focus of these often unwieldy cases where it should be: on individual trials of strong cases. The more this approach is given precedence over indiscriminate mass settlements, the better the rights of all claimants can be protected.

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