MEALEY'S LITIGATION REPORT

Propulsid

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Propulsid: Causes Of Action And Initial Discovery

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Commentary

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Preparing To File A Propulsid Lawsuit

A. Selection Of Plaintiffs

The first consideration is how to select your plaintiffs for petitions and whether to file your lawsuit as one of the following:

(i) *Single Plaintiff Case*
A single plaintiff case is an expensive proposition because that plaintiff must bear the entire cost of case presentation alone. For pharmaceutical cases, since they are so discovery intensive, that could run in the hundreds of thousands of dollars before trial even starts. In addition, the lawyer must put on an entire general liability case at trial for a single plaintiff. This could take more than a week of testimony and would be applicable only to that plaintiff. A solo plaintiff petition is most appropriate for serious injury cases since that plaintiff's specific case strengths and weaknesses could easily stand by itself without any assistance from other plaintiffs.

(ii) *Member Of Medical Monitoring Class Action*
The filing, certification and notification requirements of a class action can be overwhelming to a small firm. However, there are already several medical monitoring class actions on file. Should one of those be certified, your plaintiff could be eligible for inclusion. This option is best exercised for "exposure only" plaintiffs or plaintiffs who were exposed to Propulsid but currently have no obvious or known reaction to the drug. A medical monitoring class should provide some medical testing and treatment protection into the future for the class members.

(iii) *Member Of Personal Injury Class Action*
A personal injury class is best for plaintiffs who manifested small or insignificant injuries after exposure to Propulsid. A class action is not, by its nature, designed to effectively deal with large damage cases. It is best suited to plaintiffs with modest damages.

(iv) *Consolidated Filing On Behalf Of Multiple Plaintiffs*
The most effective and economical strategy is to group similarly injured plaintiffs into one consolidated petition in a single county. This is not a class action but a single consolidated action where each plaintiff shares common issues of law and fact. A consolidated petition allows the lawyer to effectively share the costs of prosecution among multiple plaintiffs and is a judicially economic way to try mass tort cases. There is a tremendous advantage at trial to be able to present a single liability case to the jury followed by more than one case specific causation evidence. The individual weakness of each case becomes offset by the strength of the combined presentation. However, in order to file a consolidated petition, a law firm must have multiple clients who meet the jurisdiction and venue requirements for that county. This simple fact has led to many "joint venture" deals between neighboring firms as they seek to consolidate plaintiffs into single petitions.

B. Selection Of Defendants

(i) *Manufacturing Defendants*
The Pharmaceutical Manufacturing Defendant will naturally be a named defendant. This will include their parent company entity, if appropriate. You should research the Defendants' registered agent for service in your jurisdiction to make sure that you effectuate proper service. For Propulsid, you should naturally include Janssen Pharmaceutica and Johnson & Johnson.

(ii) *Prescribing Physician*
Whether you sue the plaintiff's doctor requires an analysis of the individual fact pattern to assess physician culpability. The "Learned Intermediary" doctrine purports to grant a drug manufacturer immunity from liability if the manufacturer appropriately and adequately warns the prescribing physician about the potentially harmful effects of a drug. The manufacturer has no duty to warn the ultimate user. Depending on your state's interpretation, the "learned intermediary doctrine" can severely limit a drug company's responsibility if the prescribing physician failed to warn the user of any known side effects the drug may have caused. If the physician had the opportunity to warn the user of a potential side effect (and did not), the physician should be included as an in-state Defendant in the lawsuit to establish all links in the chain of liability.

Secondly, in some cases, the patient will have come into the physician's office with complaints about their adverse reaction to the drug. If the physician did not promptly remove the patient from the drug or correctly diagnose the adverse event, the physician could be culpable as the patient's symptoms became worse or were not promptly treated.

(iii) *Pharmacy / Pharmacist*
Depending on the laws of your state, a pharmacy may assume liability based on their own actions such as an inadequate (and incomplete) discussion of the drug's

risks with the user. In addition, some states consider pharmacies as suppliers in the chain of commerce for strict product liability causes of action. To maintain in-state jurisdiction, you will need to name the individual pharmacist who filled the prescription since most pharmacy chains are incorporated in Delaware. The individual pharmacist or head pharmacist will typically be an in-state resident.

(iv) *Drug Supplier*
If the drug supplier for your client's pharmacy is an in-state resident, strict product liability laws on supplier liability should be analyzed.

C. Selecting Venue

The next decision is whether to file the lawsuit in state or federal court. Since the federal court cases are subject to the Multi-District Litigation Automatic Transfer Statute, a decision to file in federal court requires a good understanding of the MDL issues.

(i) *State Court*
There are clear advantages to prosecuting your case in state court including retaining control over your own case, potential to get a quick trial setting and better trial atmosphere with a state court jury. To retain your case in state court, you will need to name an in-state defendant and fight any attempt at removal. Should the Defendants file for removal, you must seek and get a remand decision from the local federal court within 45 days. After 45 days, the Automatic Transfer Statute will take effect and your case will be moved to New Orleans. After 45 days, only the MDL judge can grant a remand and your opportunity to get a hearing is limited, may require a trip to New Orleans and involve substantial delay. To get a prompt ruling from your local federal court will require you to file an immediate remand motion and waive your right to a reply brief. Only with quick action, can you accomplish a remand in the short time before transfer.

(ii) *Federal Court / MDL*
The MDL brings with it many unique issues that must be properly assessed before you make the decision to file your case in federal court.

Advantages Of MDL

- It is significantly less expensive to prosecute your individual cases since the MDL lawyers conduct all of the general liability discovery and cover all costs and expenses for general liability case development. Since drug cases are very expensive to prosecute, this is a major advantage, and may be well worth the low MDL assessment.

- You will not have to work as hard on developing your cases for trial because the general liability discovery will be done by MDL lawyers.

- There is potential of Global Settlement in connection with the MDL.

Disadvantages Of MDL

- You lose control over your own cases. You will probably have no contact with the MDL judge and must rely on unknown lawyers to adequately represent your clients' interests before the judge.

- MDL cases typically take significantly longer from start to completion than state court cases. It can take as much as 3-4 years before cases are remanded for trial.

- Historically, MDL cases received less money in settlements because they were often settled later than state court cases when the settlement values are already deflated.

- When your case is returned for trial, you end up in your local federal court for trial which may be a more conservative forum that your state court.

D. Causes Of Action

The following causes of action are recommended depending on your jurisdiction:

Negligence:	Negligence Negligence per se based upon violations of federal law (CFR) Gross Negligence
Strict Product Liability:	Defective product Defective marketing and promotion Failure to adequately warn Breach of express & Implied warranty
Fraud:	Intentional Misrepresentations Negligent Misrepresentations Fraud Fraudulent concealment
Intentional Torts:	Pled in jurisdictions where there are statutory caps on damages and the caps do not apply to intentional torts Battery Intentional Infliction of Emotional Distress
Damages:	Compensatory Punitive/Exemplary

Initial Discovery

The Defendants will likely try to delay the start of initial discovery as long as possible. They will use a myriad of excuses to stop or postpone discovery including arguments about how difficult it is to review the large number of documents involved in a mass tort as well as their inability to coordinate depositions when facing a significant number of lawsuits. The best response is one of persistent determination. If you push them long enough — and hard enough — they will eventually be forced to move forward on

your cases. This determination will also place you firmly on their radar screen, where you need to be to get their attention for settlement purposes.

1. ***Requests For Production***

Besides the standard requests for production concerning expert reports and insurance coverage, there are several groups of documents that you need which are unique to pharmaceutical cases:

- The entire Investigational New Drug Application (IND) and New Drug Application (NDA) including all documents submitted to the FDA in support of such application. These documents should involve 70-100 banker boxes of animal studies, clinical trial data and safety summaries.

- Applications submitted by Defendants, or on behalf of Defendants, to sell, register or market Propulsid in any country other than the United States of America;

- All FDA Contact sheets or similar form which evidences contact between any agent of the Defendants and any employee of the Food & Drug Administration;

- All E-mails concerning, related to or in reference to Propulsid;

- All package inserts and "Dear Doctor" or "Dear Healthcare Professional" letters including ***(and most importantly)*** all drafts of such, all minutes from meetings in which revisions or amendments of such were discussed, as well as all editions or notations made concerning same;

- All Post Marketing Surveillance documents including all Medwatch forms, all Adverse Drug Experience reports as well as corresponding documentation, correspondence and memorandum relating to adverse experiences reported to Defendants concerning Propulsid;

- Marketing materials including copies of all Direct to Consumer (DTC) advertisements;

- All promotional materials or items concerning Propulsid;

- All documents which reflect a sales calls made by any agent or employee of Defendants to any physician where Propulsid was discussed, questioned or mentioned including such sales person or detail person's notes, memorandum and recordings of such interaction.

2. ***Protective Orders***

The Defendants will typically demand a strict protective order before they will allow you access to any documents. The protective order permits the Defendants to stamp, at their unilateral discretion, any document as confidential and then substantially limit your ability to freely use such document because of the confidential designation. Beware of a common trick — the Defendants will often use a large, obstructive "Confidential" stamp which runs diagonally across the entire face of the document. This is more than an inch wide and substantially disfigures the page. The stamp makes the docu-

ment difficult to read (especially when it is photocopied) and is so distracting as to make the document impossible to use before a jury. The Defendants will argue that this type of stamp must be used to prevent lawyers from merely removing confidential designations from the margins and disseminating the documents anyway. The strongest argument in response to the Defendants' proposed stamp is that it interferes with current word recognition scanning software. The diagonal presence of letters prevents you from being able to scan in the documents and word search with recognition software. Many judges will prevent such a mark in light of that argument.

A decision whether to sign the proposed order, or litigate the issue, can only be made after you analyze your state's case law on protective orders.

3. Corporate Representative Depositions

The first round of depositions usually involves corporate representatives from a variety of departments including:

Research & Development — who were involved in the initial development of the drug as well as the animal studies during the IND.

Clinical Trial Department — the managers who supervised and collated the human clinical trials during late stage drug development.

Regulatory Department — responsible for getting the drug approved at the FDA.

Safety Surveillance — Supervisors of the Post Marketing Surveillance Department who are responsible for all Medwatch and Adverse Drug Experience reports.

Medical Monitor — the medical doctor responsible for review of all medical and safety concerns concerning the Propulsid project.

Labelling — people responsible for the drafting, creation and amending of the package inserts and corresponding "Dear Doctor" letters.

Marketing — responsible for drafting and creation of all marketing, promotional and advertising materials.

These depositions will provide a general liability framework upon which more specific and in-depth questions can be developed. The MDL general liability lawyers will complete these general depositions, but their timing may not work with your state court trial setting. If you are fast tracked for trial, you may need to schedule these depositions yourself. You can use general corporate representative deposition notices or, once you review the documents, you will be able to name specific people who were clearly responsible in different department.

4. Sales Representatives / Detail People Depositions

Interrogatories to both the manufacturing defendant and the prescribing physician should ask for the identity of all detail people or sales representatives who called on the plaintiff's doctor. These people are prime deponents and can provide useful information about what representations were made to the plaintiff's doctor.

5. Prescribing Physician Discovery & Depositions

To beat the learned intermediary doctrine, the prescribing physician must be questioned on the following topics:

(a) The physician's typical practice of informed consent concerning prescription medications, i.e. does the doctor tell patients all risks of drugs, some risks or generally make the risk/benefit analysis himself or herself from a medical point of view and relay none of the risks to the patients directly;

(b) The physician's reliance on manufacturer representations — Does he or she in fact read package inserts and Dear Doctor letters or are they automatically filed or destroyed by the staff? Does the physician refer to the PDR when prescribing medications?

(c) The physician's memory of detail personnel representations. Did he or she address specific concerns with the detail people and what were their assurances?

(d) Had the physician known the truth about the clinical trial data/post marketing surveillance statistics, is there no class of patients — in the doctor's opinion — that would have been appropriate for that level of risk in relation to the benefit. (This is the key question that must be addressed to beat the learned intermediary doctrine). ■