

Non-IP Life Sciences Litigation

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Overview

- Techniques for dealing with parallel proceedings involving various government agencies (FDA, DOJ, FTC, and HHS)
- How to find, retain, and coordinate a multidisciplinary panel of experts
- How to utilize creative motion practice to pare down the number of cases and issues in MDL and consolidated state court proceedings

Impact of Parallel Proceedings

Potential for Positive or Negative Effects

- If a company moves quickly and strategically, parallel proceedings can have a positive impact on present and future litigation
- If a company fails to handle an investigation efficiently and effectively, it has the potential to take on a life of its own
- Resulting litigation can have serious economic and even criminal impact on the company and its executives

Techniques for Dealing with Parallel Proceedings

Examples of Parallel Proceedings

- FDA Regulatory Process
- Department of Justice/U.S. Attorney Investigations
- Qui Tam/False Claims Act/Whistleblower Investigations
- Congressional Investigations

Strategic Use of Parallel Proceedings

Checklist

- Immediately engage experienced outside litigation counsel
- Negotiate with government entity to establish a favorable process for the investigation
- Gather, review, and produce documents
- Interview current and former employees to establish narrative and identify in-house expertise
- Engage consulting experts to aid in understanding and presenting technical issues
- Develop and deliver a compelling presentation

Strategic Use of Parallel Proceedings

How to Positively Utilize Parallel Proceedings

- Be proactive
- Avoid a piecemeal approach
- Address concerns brought up by investigation to avoid civil or criminal litigation
 - Example: 483 Notice → Recall → Products liability litigation

Organizing a Multidisciplinary Panel of Experts

What experts will you need?

- Technical Experts
- Medical Experts
 - General v. Specific Causation
- Regulatory Experts
- Damages Experts
- Consulting Experts

Organizing a Multidisciplinary Panel of Experts

How do you find the best experts?

- Review academic journals and publications in the field
- Start early and lock down the leading experts in the field
- Understand the politics of the field (competing camps, affiliations, sponsorship, etc.)
- Focus on experts whose research is concentrated on the specific topic not just the general field
- Consider pulling in experts from other fields to creatively develop global opinions regarding the topic of interest

Getting the Most Out of Your Experts

Utilize your experts to:

- Understand the underlying technical and/or regulatory issues
- Aid in developing case theory and strategy
- Effectively respond to other side's expert opinions and prepare for depositions
- Identify weaknesses in other side's expert opinions and aid in preparing *Daubert* motions to exclude them
- Interface with government entities in parallel proceedings
- Effectively present opinions at trial

Getting the Most Out of Your Experts

Coordinating a large group of experts

- Develop expert opinions with an eye toward global positions
- Maintain coherent opinions across experts to avoid contradictions
- Have the experts read and respond to each other's reports to bolster opinions
- Facilitate discussions between experts

Getting the Most Out of Your Experts

Overcoming challenges in utilizing experts

- Busy schedules
 - Be upfront about time commitments
 - Be as flexible as possible in accommodating schedules
- Strong personalities
 - Utilize experts to develop opinions instead of shoe-horning
 - Select experts who are willing to engage in conversations with other experts in your panel

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Severing The Weakest Link In The Chain of Causation

- *Daubert* Motions
- Summary Judgment Motions
- Motions In Limine

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Daubert

I. Fresenius' Motion to Exclude Certain Statements in the Hakim Memo as Well as Plaintiffs' Experts' Opinions Based on those Statements

On November 4, 2011, Fresenius' Medical Office distributed an internal memorandum to medical directors and attending physicians at Fresenius clinics ("Hakim Memo"). Fresenius argues that the Plaintiffs' experts should not be permitted to render opinions based on the Hakim Memo because it serves as an unreliable, unsupported, and speculative foundation. Fresenius points to seven opinions that do not meet the standards for expert testimony:

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1. “The major cause of metabolic alkalosis in dialysis patients is inappropriately high dialysate total buffer concentration.” Hakim Memo (Exhibit 1 to Fresenius’ Motion), at 1.
2. “There are instances whereby the physicians’ bicarbonate prescriptions were kept the same when shifting to power [sic] concentrate (Granuflo [sic]) (failing to account for the additional 8 mEq/L of sodium acetate), thus exposing patients to a higher total buffer load than intended.” Hakim Memo (Exhibit 1 to Fresenius’ Motion), at 5.

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Daubert

3. “The bicarbonate prescription entered into the dialysis machine underestimates the total buffer that the patient receives from the dialysate – *by ~8 mEq/L in the case of dialysate prepared from Granuflo [sic] (powder) or by ~4 mEq/L in the case of dialysate prepared from NaturaLyte (liquid)* – since acetate is rapidly converted into bicarbonate by the liver.” Hakim Memo (Exhibit 1 to Fresenius’ Motion), at 1-2 (emphasis in original).

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6. “Over time, there has been a shift towards higher dialysate bicarbonate prescriptions accompanied by increasing serum bicarbonate levels before dialysis and presumably much higher post dialysis. This issue needs to be addressed urgently.” Hakim Memo (Exhibit 1 to Fresenius’ Motion), at 5.

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7. “The current analysis determined that: *‘borderline elevated pre-dialysis bicarbonate levels and overt alkalosis are significantly associated with 6 to 8 fold greater risk of CP arrest and sudden cardiac death in the dialysis facility.’*”
Hakim Memo (Exhibit 1 to Fresenius’ Motion), at 1 (italics and internal quotations in original).

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Fresenius' motion is **ALLOWED** because there are too many shortcomings in the support for the challenged findings to allow them to serve as a basis of other expert opinions.

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Contact us with your questions and comments.



Juanita Brooks
Principal
Fish & Richardson
brooks@fr.com
858-678-4377



Roger Denning
Principal
Fish & Richardson
denning@fr.com
858-678-4784



Christina Brown-Marshall
Associate
Fish & Richardson
brown-marshall@fr.com
404-724-2760