

Overcoming Tensions between Drug/Device Defendants and Treating Physicians

Wednesday, June 18, 2014

Presented By the IADC Drug, Device and Biotechnology Committee and Medical Defense and Health Law
Committee

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Type your questions for presenters here in the Q&A Pod

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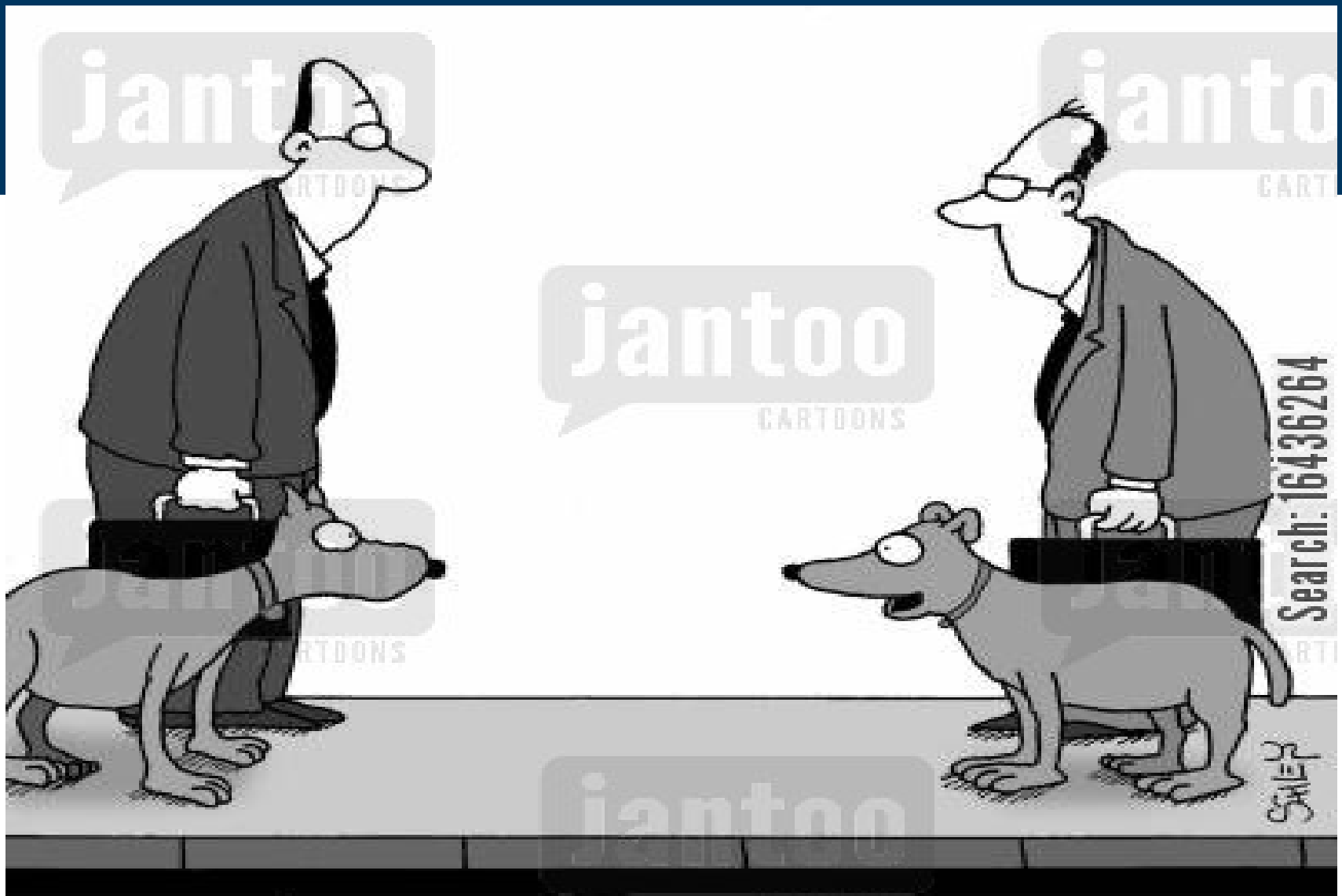
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Introduction – Imagine This Scenario

- A Products Liability case combined with a Medical Malpractice action
 - The Treating Physician is also a Defendant
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Plaintiff's Goal is to Create Tension

- Benefits of finger pointing include:
 - √ Less work for plaintiff's attorney
 - √ Get one defendant to sell out the others
 - √ Juries get to choose both defendants, or choose the one they like least
 - √ Can drive up settlement or verdict by adding "heat" to the case
 - But when the physicians and the manufacturer work together:
 - √ Burden is shifted back to Plaintiff to establish liability and causation
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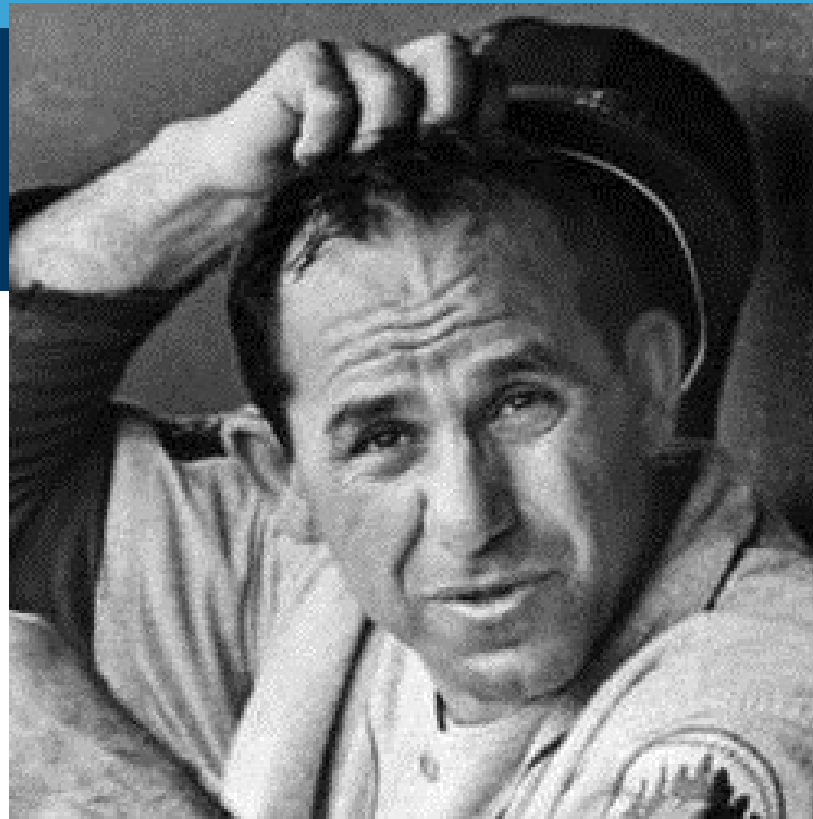


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LET'S GO AND CHASE SOME CATS WHILE
OUR LAWYERS BITE EACH OTHER!

Imagining The Scenarios

- **4 scenarios can arise and 3 of them are detrimental:**
 1. Plaintiff vigorously pursues the case against both the doctor and the manufacturer. The doctor and manufacturer each defend the case by casting blame on each other.
 2. Plaintiff primarily pursues the case against the doctor and forms an alliance with the manufacturer, in exchange for leniency/dismissal.
 3. Plaintiff primarily pursues the case against the deep pocketed manufacturer and forms an alliance with the doctor, in exchange for leniency/dismissal.
 4. The doctor and manufacturer stand shoulder to shoulder and defend on common ground.
-



“If you don’t know where you are going, you might wind up someplace else.”

- Yogi Berra

Perspective of the Doctor-Defendant

- *Internal Investigation Steps:*
 1. Obtain all communications between the manufacturer and your physician client (“Dear Doctor” letters, product pamphlets, training materials, etc.)
 2. Identify all manufacturer’s representatives that have interacted with your client
 3. Was the representative present at the incident in question?
 4. Has your client ever reported an adverse event to the manufacturer regarding the particular drug/device at issue?
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Perspective of the Doctor-Defendant

■ *External Investigation Steps:*

1. Obtain a copy of the product manual, package insert, and other published materials.

- Did your client read it?
- If not, how did your client learn about how to use the product?

2. Talk with the manufacturer's counsel.

- Layers of counsel
- What information will they say was given to your client?

3. Review outside medical references

- Has the PDR changed?
 - Has a “black box” warning been implemented?
 - FDA warnings?
 - Product recall?
-

Perspective of the Doctor-Defendant



RED FLAG SITUATIONS:

- **Manufacturer harming your defense can be inadvertent or intentional**
 - **Similarly situated “causation” experts**
 - **Poorly prepared 30(b)(5) and (6) representatives**
-

Perspective of the Doctor-Defendant

- *Collaboration/Commitment:*
 - Understand manufacturer's position
 - Gain a commitment (be it supportive or unsupportive):
 - ❖ Can the manufacturer support your doctor?
 - ❖ If not, can the manufacturer agree to stay away from the standard of care?
 - ❖ Agree to defer to clinical judgment?
 - In turn, can your doctor support the device/drug?
 - Joint selection of causation witnesses
-

Perspective of the Doctor-Defendant

Litigation Consequences

- Increased settlements and verdicts

Market Share/Economic Consequences

- Physician pushback as a result of manufacturer's tactics
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Perspective of the Doctor-Defendant

The Doctor Deposition

- Plaintiff's counsel infuses the doctor depositions with internal company documents, to create doubt in the doctor's mind about the manufacturer and product.
 - Doctors do not usually want to testify against their patients, but the manufacturer often times wants to drag the doctor into the legal battle.
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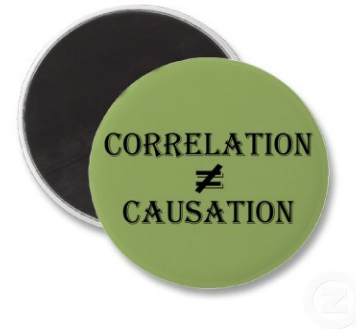
Perspective of the Drug/Device Manufacturer

- *In Pharmaceutical Mass Torts, the Focus is:*

“Bad Company” Story (Plaintiffs)



v.



Alternative or No Causation (Defendants)

Perspective of the Drug/Device Manufacturer



Expert Causation Testimony from **Compensated Experts** is Important, BUT Testimony from **the Treating Physician** is Key:



Don't be afraid, but it can help the **Plaintiff**:

- ✓ Show the Existence of a Claimed Disease
 - ✓ Support claims for Pain and Suffering
 - ✓ Demonstrate they sought treatment for the injury
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Perspective of the Drug/Device Manufacturer

- *Testimony from the Treating Physician is Key:*

It can help the **Defendant**:

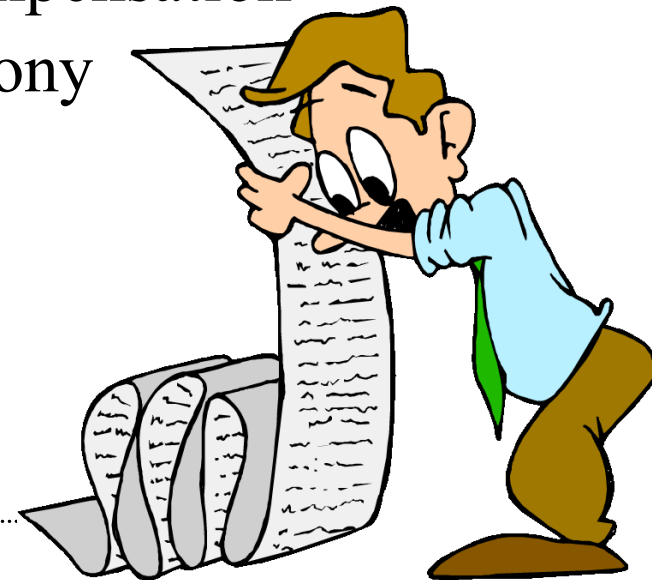
- ✓ Demonstrate No Causation or Alternative Causation
 - ✓ Confirm Warnings Defense
 - ✓ Support a Statute of Limitations Defense
 - ✓ Refute Severity of Plaintiff's Claim
- **Cooperation is Key:**
 - Work Together With Doctors
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Perspective of the Drug/Device Manufacturer

- **FRCP Requirements -- Paid Experts Must Provide:**

- ✓ A signed report (which includes all opinions being offered, the facts and data that support them, and any exhibits being used to summarize them)
- ✓ Their Qualifications
- ✓ A financial statement listing the compensation to be paid for their report and testimony



Perspective of the Drug/Device Manufacturer

- ***Old* FRCP Rules -- Treating Doctors Have To Provide:**
 - ❖ **NOTHING!** (as long their testimony was limited to opinions or inferences within the course of treating the particular patient who was the plaintiff in the case)



- ❖ **BUT...** many courts prevented the treating physician from providing causation testimony
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Perspective of the Drug/Device Manufacturer

- **New Amendment to the FRCP -- Rule 26(a)(2)(C) (Dec. 2010)**
 - Enacted to address concerns that parties were trying to satisfy their causation burden through undisclosed experts.
 - **Now**, a party wishing to present any testimony from non-retained experts (such as treating physicians), must file a disclosure which includes:
 - ✓ The subject matter on which the witness is expected to present evidence, and
 - ✓ A summary of facts and opinions the witness is expected to testify to
 - Example: *Schutter v. Wyeth* (N.D. Ill., 2011)
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Perspective of the Drug/Device Manufacturer

- **Effect of New FRCP Requirements:**

1. Defendants can seek to elicit favorable alternative cause or no causation testimony from the treating physician.
 2. If defendant is successful, plaintiffs would have to obtain testimony that the doctor formed his or her opinions outside the course of the plaintiff's treatment.
 3. If plaintiff is successful, defendants must seriously consider having the doctor prepare a full expert report in order to guarantee that the doctor can favorably testify at trial on the key causation issue.
 4. Conversely, if the plaintiff develops favorable causation testimony, defendants must be guided by the rules in seeking to exclude the testimony of the treating physician while at the same time attempting to remain aligned with their co-defendant.
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Perspective of the Drug/Device Manufacturer

- **Tools for Getting Over the Admissibility Hurdle, or Challenging Admissibility:**
 - ✓ Straight forward phrases about “care and treatment”
 - ✓ Foundational Daubert methodology questions
 - ✓ Work with co-counsel (or the doctor, where permitted), to flush out potential problems on key issues in advance of the deposition
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Strategies for Avoiding Finger-Pointing and Working Together

- 1. Make Early Contact with Co-Defense Counsel:** Determine who is making the decisions on the other side
 - 2. Develop Common Ground For Defenses:**
 - ✓ Manufacturer stands behind its device/drug
 - ✓ Deference to doctor's clinical judgment
 - 3. Jointly Select Causation Experts, if similarly situated**
 - 4. Consider a Joint Defense Agreement**
 - 5. Beware the Indemnity Agreement**
-

Questions for Presenters?



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