

## **Drug or Medical Device Injuries: Litigating Joint Med Mal and Product Liability Claims**

Navigating Complexities of Choice of Forum, Choice of Parties,  
Standards of Care, Causation, Defenses, Settlement and Damages

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WEDNESDAY, OCTOBER 23, 2013

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

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Today's faculty features:

Jessica Cabral Odom, Attorney, Greenberg Traurig, Atlanta

Scott Campbell, Attorney, Shiver Hamilton, Atlanta

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# Joint Medical Malpractice & Product Liability Webinar

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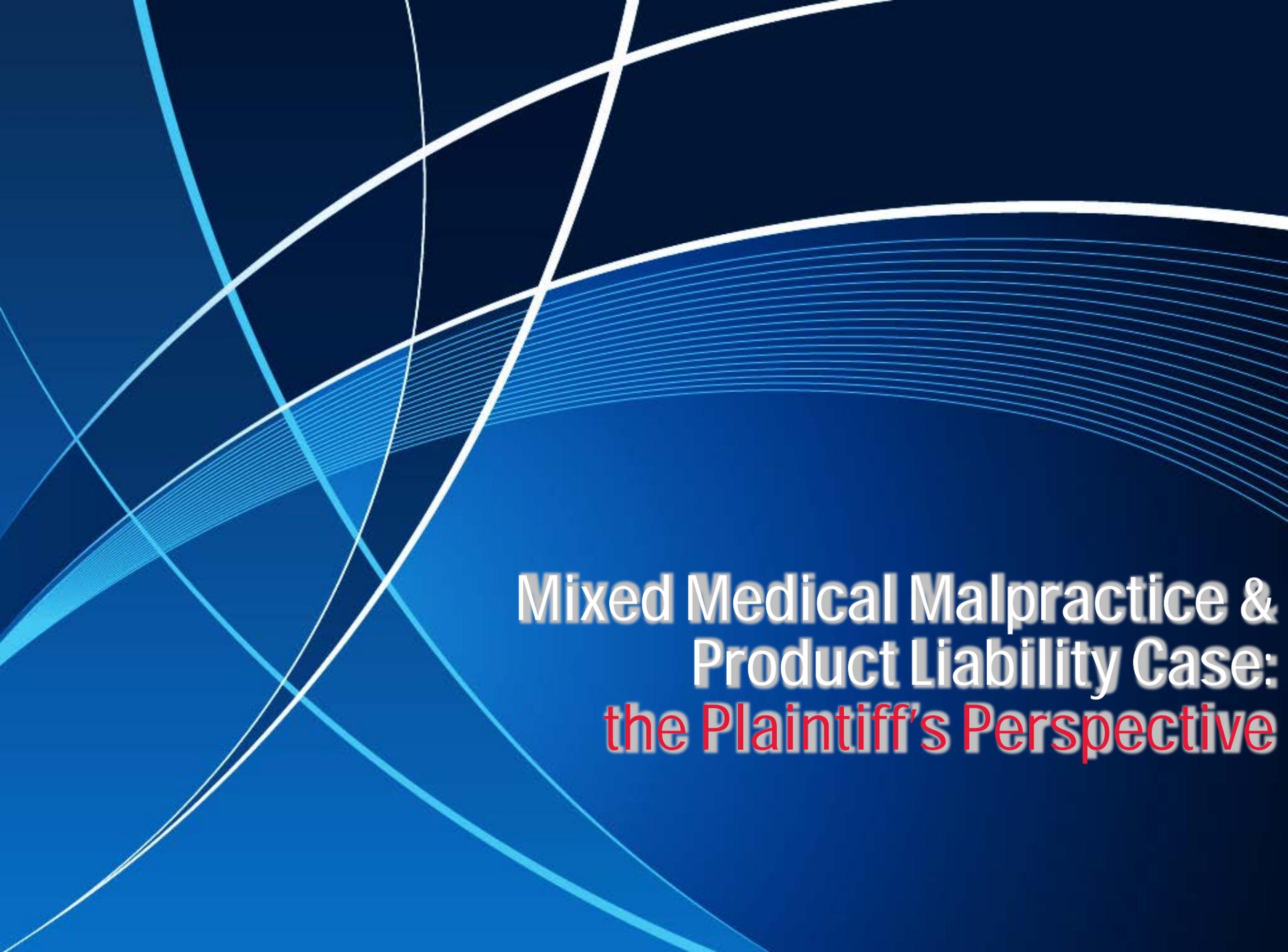
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SHIVER | HAMILTON  
Attorneys and Counselors

# Introduction & Agenda

1. Introduction
2. Mixed Medical Malpractice and Product Liability Case: the Plaintiff's Perspective
3. Mixed Medical Malpractice and Product Liability Case: the Defense Perspective
4. Unique Legal Issues to an Action Involving Both Claims
  - a. Jurisdiction Issues
  - b. Learned Intermediary Doctrine
5. Hot Topics
  - a. Preemption
  - b. Social Media
6. Q&A and Discussion

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**Mixed Medical Malpractice &  
Product Liability Case:  
the Plaintiff's Perspective**

# Mixed Medical Malpractice & Product Liability Case: *the Plaintiff's Perspective*

- Do I take the case?
  - *You have a choice, be methodical and selective.*
  
- Took the case, now what?
  - *You get a head-start, take advantage of it.*

# Mixed Medical Malpractice & Product Liability Case: *the Plaintiff's Perspective*

- Do I take the case?
  - *You have a choice, be methodical and selective.*
  
- Took the case, now what?
  - *You get a head-start, take advantage of it.*

# Do I take the case?

- (1) Is claim potentially time barred?
  - *Multiple SOLs and SORs may be in play*
- (2) Is claim potentially preempted?
  - *PMA or 510K - brand or generic*
- (3) What is the drug or device?
  - *Intended use, any known issues*
- (4) What are potential claims?
  - *Manufacturing defect, failure to warn, off-label promotion, breach of warranty, med mal*
- (5) Who are potential defendants?
  - *Manufacturer, distributor, sales rep, doctor*
- (6) Where does venue and jurisdiction lie?
  - *County, state, federal*
- (7) Are you sufficiently familiar with field of play?
  - *Medical issues and regulatory framework*
- (8) Is claim economically viable?
  - *Damages/economies of scale*

# Do I take the case?

- (1) Is claim potentially time barred?
  - *Multiple SOLs and SORs may be in play*
    - ❖ Act quickly
      - immediately
    - ❖ Vary by state
      - Check statute and case law
    - ❖ Assess nature of claim
      - med-mal, product liability, wrongful death
    - ❖ Assess potential avenues for tolling
      - notice, fraud

# Do I take the case?

- (2) Is claim potentially preempted?
  - *PMA or 510K*
    - ❖ PMA - FDA Approved - a finding of safety and effectiveness
      - Doesn't mean all claims preempted, but most likely will be
    - ❖ 510k - FDA Cleared - a finding of substantial equivalence
      - Preemption not a concern
  - *Brand or generic*
    - ❖ Generic - failure to warn claim preempted

# Do I take the case?

- (3) What is the drug or device?
  - *Intended use, any known issues*
    - ❖ Educate yourself
    - ❖ Manufacturer website,
      - read DFU and marketing materials
    - ❖ FDA website
      - MAUDE database
      - medical device safety communications
      - List of recalls
    - ❖ PDR
    - ❖ Google
    - ❖ Periodicals
    - ❖ Journals
    - ❖ Attorney advertisements

# Do I take the case?

- (4) What are potential claims?
  - *Manufacturing defect, failure to warn, off-label promotion, breach of warranty, med mal*
    - ❖ What happened?
    - ❖ Who was involved?
    - ❖ Did device malfunction?
    - ❖ What does DFU say?
    - ❖ What are indications for use?
    - ❖ What contraindications, warning, cautions provided?
    - ❖ What do marketing materials say?

# Do I take the case?

- (5) Who are potential defendants?
  - *Manufacturer, distributor, sales rep, doctor*
    - ❖ Manufactured: when, by whom where?
    - ❖ Distributed: when, how, by whom, exclusive?
    - ❖ Was a sales rep involved and who employed him?
    - ❖ What was doctor's role?
      - Potentially misused?
        - » Training?
      - Potentially used off-label?
        - » Marketing?
      - Potentially defective?
      - Key witness regardless
    - ❖ Facility's role?

# Do I take the case?

- (6) Where does venue and jurisdiction lie?
  - *County, state, federal*
    - ❖ Within state are multiple counties options?
      - Residency of sales rep, doctor, facility
    - ❖ Is sticking in state court likely?
      - Resident defendant
    - ❖ Potential jury pool
    - ❖ Concern about Twombly or preemption motion
    - ❖ Potential judges
    - ❖ Potential time frame
    - ❖ MDL

# Do I take the case?

- (7) Are you sufficiently familiar with field of play?
  - *Medical issues and regulatory framework*
    - ❖ Anyone can learn, but are you willing to and is your client best served by you doing so?
    - ❖ Need to understand the medicine
      - Bad result doesn't equal malpractice
      - Obtain expert insight early
    - ❖ Need to understand the regulatory framework
      - Some claims preempted
      - Can provide support for other claims
      - Source for documentary evidence
      - Expert support beneficial

# Do I take the case?

- (8) Is claim economically viable?
  - *Damages/economies of scale*
    - ❖ Case wont be cheap
      - Do damages support investment?
    - ❖ If questionable, is someone else handling similar cases
      - Possible to team-up or spread costs out across multiple cases?

# Mixed Medical Malpractice & Product Liability Case: **the Plaintiff's Perspective**

- Do I take the case?
  - *You have a choice, be methodical and selective.*
  
- Took the case, now what?
  - *You get a head-start, take advantage of it.*

# Took the case, now what?

- (1) Thoroughly review info available on-line
  - *Manufacturer, FDA, journals, newspapers*
- (2) Request medical records and bills
  - *From physician, facility, subsequent treaters*
- (3) Request regulatory documents
  - *510k, PMA, NDA, ANDA*
- (4) Notify potential defendants
  - *Put them on notice*
- (5) Inspect device
  - *Confirm product ID*
- (6) Meet with prescribing or implanting physician
  - *The learned intermediary*
- (7) Assess end-game for one or both claims
  - *Demand, mediation, suit, MDL*
- (8) Litigate
  - *Fill in the gaps*

# Took the case, now what?

- (1) Thoroughly review info available on-line
  - *Manufacturer, FDA, journals, newspapers*
    - ❖ Websites great way to obtain initial education as to issues as well as potential defenses
      - What is the general state of knowledge?
      - Did the doctor act in accordance with it?
    - ❖ Set up Google alert
      - Good way to stay abreast of developments
    - ❖ Any FDA alerts issued
      - Build timeline, substantiate notice
    - ❖ Any recalls
      - Confirm defects
    - ❖ Assess MAUDE database thoroughly
      - Is your client's case reflected

# Took the case, now what?

- (2) Request medical records and bills
  - *From physician, facility, subsequent treaters*
    - ❖ Obtaining prompt expert review if considering medical malpractice case
    - ❖ Review with eye towards
      - Developing chronology
      - Establishing liability
      - Establishing product ID
      - Identifying potentially helpful witnesses
      - Identifying potentially harmful witnesses
      - Assessing damages

# Took the case, now what?

- (3) Request regulatory records
  - *510k, PMA, NDA, ANDA*
    - ❖ Will include materials submitted by manufacturer pre-market
      - Provides insight as to what was done pre-market
      - Will indicate how product was being marketed
    - ❖ Will include correspondence between manufacturer and FDA
      - May indicate limitations on clearance or approval
      - May show potential concerns regarding certain use of product

# Took the case, now what?

- (4) Notify potential defendants
  - *Put them on notice*
    - ❖ Notify insurance
    - ❖ Preserve evidence
      - Determine where product is and notify whomever is in possession of it

# Took the case, now what?

- (5) Inspect device
  - *Confirm product ID*
    - ❖ Labeling
    - ❖ Packaging
    - ❖ Lot number
    - ❖ Appearance
    - ❖ Any apparent defects?
    - ❖ Any chain of custody issues?
    - ❖ Any potential spoliation?

# Took the case, now what?

- (6) Meet with prescribing or implanting physician
  - *The learned intermediary*
    - ❖ Why did he elect to use device
    - ❖ Did he act in accordance with the standard of care in using the device as he did
    - ❖ What information was he provided by manufacturer or distributor
    - ❖ Did he interact with sales rep
    - ❖ Would he had acted differently if he had been provided additional information or an alternative warning
    - ❖ Did the device function as intended
    - ❖ Thoughts on damages, long-term implications

# Took the case, now what?

- (7) Assess end-game for one or both claims
  - *Demand, mediation, suit, MDL*
    - ❖ Pre-suit requirements
      - Vary by state
    - ❖ Expert issues
      - May need affidavit
    - ❖ Additional avenues for investigation
      - Other treaters
      - Individuals identified in regulatory documents
    - ❖ Additional avenues for substantiating damages
      - Friends & family, subsequent treaters

# Took the case, now what?

- (8) Litigate

- *Fill in the gaps*

- ❖ Immediately serve pointed discovery seeking information from defendants not available pre-suit

- Determine who knew what when and who said what to whom

- ❖ Educate client

- *Be prepared for a fight through trial*

- ❖ Witness heavy

- ❖ Document intensive

- Do your due diligence pre-suit

# Mixed Medical Malpractice & Product Liability Case: *the Plaintiff's Perspective*

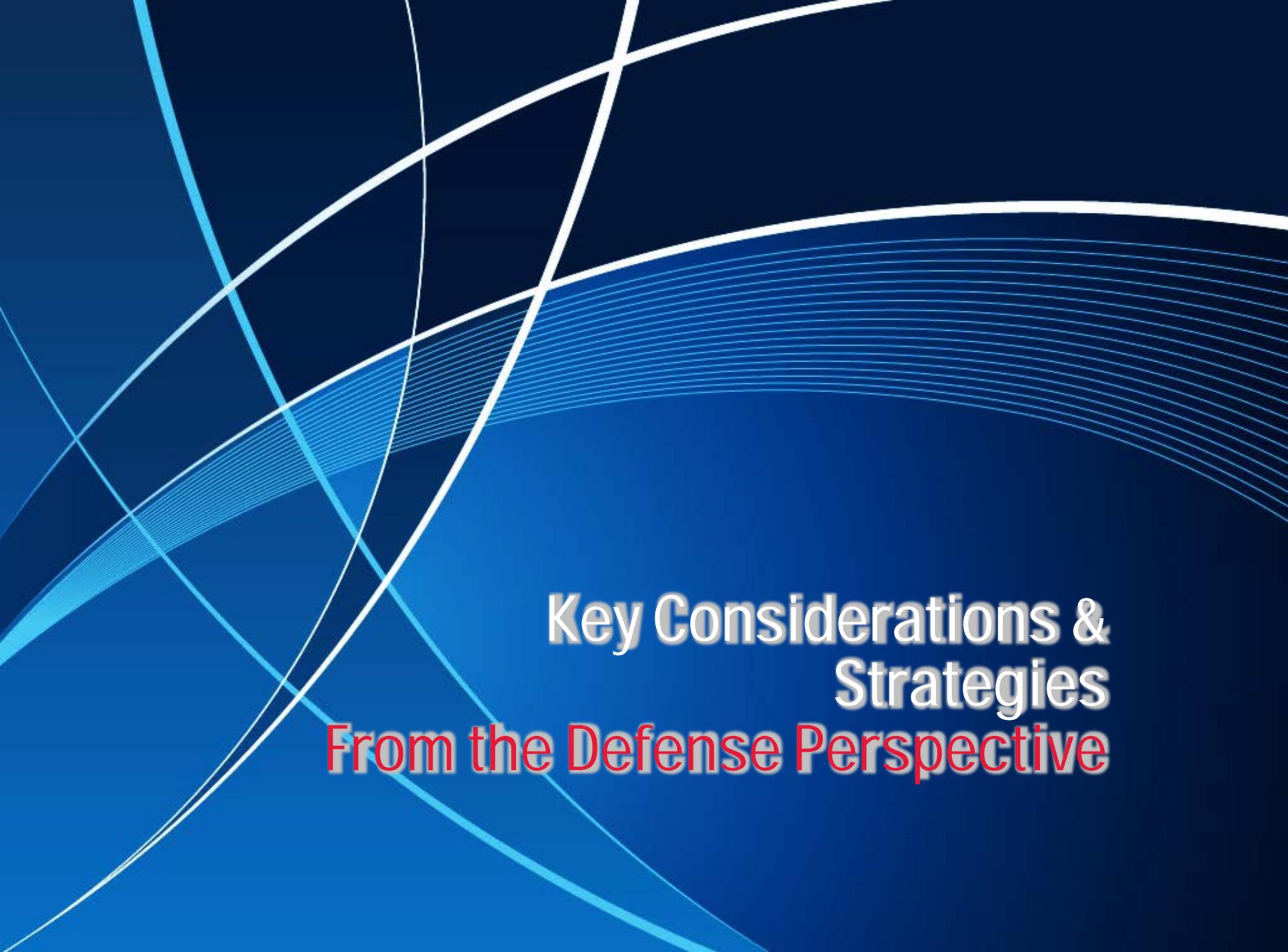
- Do I take the case?
  - *Only after careful assessment and deliberation.*
  
- Took the case, now what?
  - *Educate yourself, confirm target(s), and strategically proceed.*

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**Mixed Medical Malpractice &  
Product Liability Case:  
the Defense Perspective**

# Defense Perspective

- Key Considerations and Strategies
- Unique Legal Issues
- Hot Topics



**Key Considerations &  
Strategies  
From the Defense Perspective**

# Co-Defendant Strategy

- Consider advantages and disadvantages of pointing the finger at the co-Defendant
- Is a co-defense agreement an option?
- Even if the physician is not a named defendant, he or she will be an important witness

# Know Your Jurisdiction

- Each jurisdiction has specific case law and statutes that may apply to a mixed medical malpractice and product liability case.
  
- Educate yourself on that particular jurisdiction
  - *Procedural hoops*
  
  - *Unique defenses*
  
  - *Removal/Fraudulent Joinder law*
  
  - *Application of evidentiary rules on product liability defendants*
  
  - *Apportionment specific to medical malpractice defendants versus product liability defendants*

# Evaluate Key Affirmative Defenses Early

- Federal Preemption under *Riegel*, *Mensing*, *Bartlett* and *Buckman*
- Learned Intermediary Doctrine
- Product ID (not our product)
- Assumption of the Risk
- Informed Consent
- Failure to Mitigate
- Unforeseeable Idiosyncratic Reaction
- Intervening, Superseding Causes
- Contributory/Comparative Negligence
- Comment K of Section 402(A) of Restatement of Torts
- Statute of Limitations/Repose
- Improper Jurisdiction/Forum Non Conveniens
- Iqbal/Twombly
- No injury - “Fear Of” Claims/Medical Monitoring

# To Remove or Not to Remove

- Manufacturers will generally prefer to remove the case to federal court.
  - *Wider jury pool*
  - *Less likely to be home-cooked*
- Physician may prefer to stay in state court.
  - *Home field advantage*
  - *Or, even if the physician is not opposed to removal, may not be aggressive in removing the case.*
  - *Manufacturer will have to take lead on removing case.*

# Learn Key Documents

- PMA or 510(k) file, letters, application, reports, supplements for devices
- ANDA or NDA files for pharma
- FDA correspondence, notices
- “Dear Doctor” letters
- Documents related to any CAPA, field actions, recalls, withdrawals
- Design history file
- Risk Analysis
- Manufacturing records/Traceability/Travelers/Lot History
- All Labeling
  - *IFU - Instructions for Use*
  - *Outer Packaging*
  - *Package Inserts*
  - *Medication Guide (given to patients)*

# Learn Key Documents

- Patient Brochures, Videos
- Advertising and Marketing
- PDR publication for pharma
- Medical Literature/Packets
  - *Given to MDs*
  - *Cited or referenced to FDA or in labeling*
- Training Materials and Presentations
  - *Sales Reps*
  - *Implanting MDs*
- Product Complaint Files
- SOPs regarding MDR reporting, complaint handling
- Plaintiff specific records
  - *Claim file*
  - *Medwatch*
  - *Registration records*
  - *Invoices/Sales records*
  - *Device testing, analysis, reports, protocols*
  - *Audio recordings with customer care*
- MD specific records (for implanting/explanting MD)

# Producing Documents

- Coordination with client
- Protective Order for Proprietary and Confidential Documents
  - *Single Tier*
  - *Two-Tier for Attorneys' Eyes Only*
  - *Check local rules, standing orders*
- Relevancy redactions
- Redactions required - Other patients' HIPAA Protected Health Information

# Handling of Key Witnesses

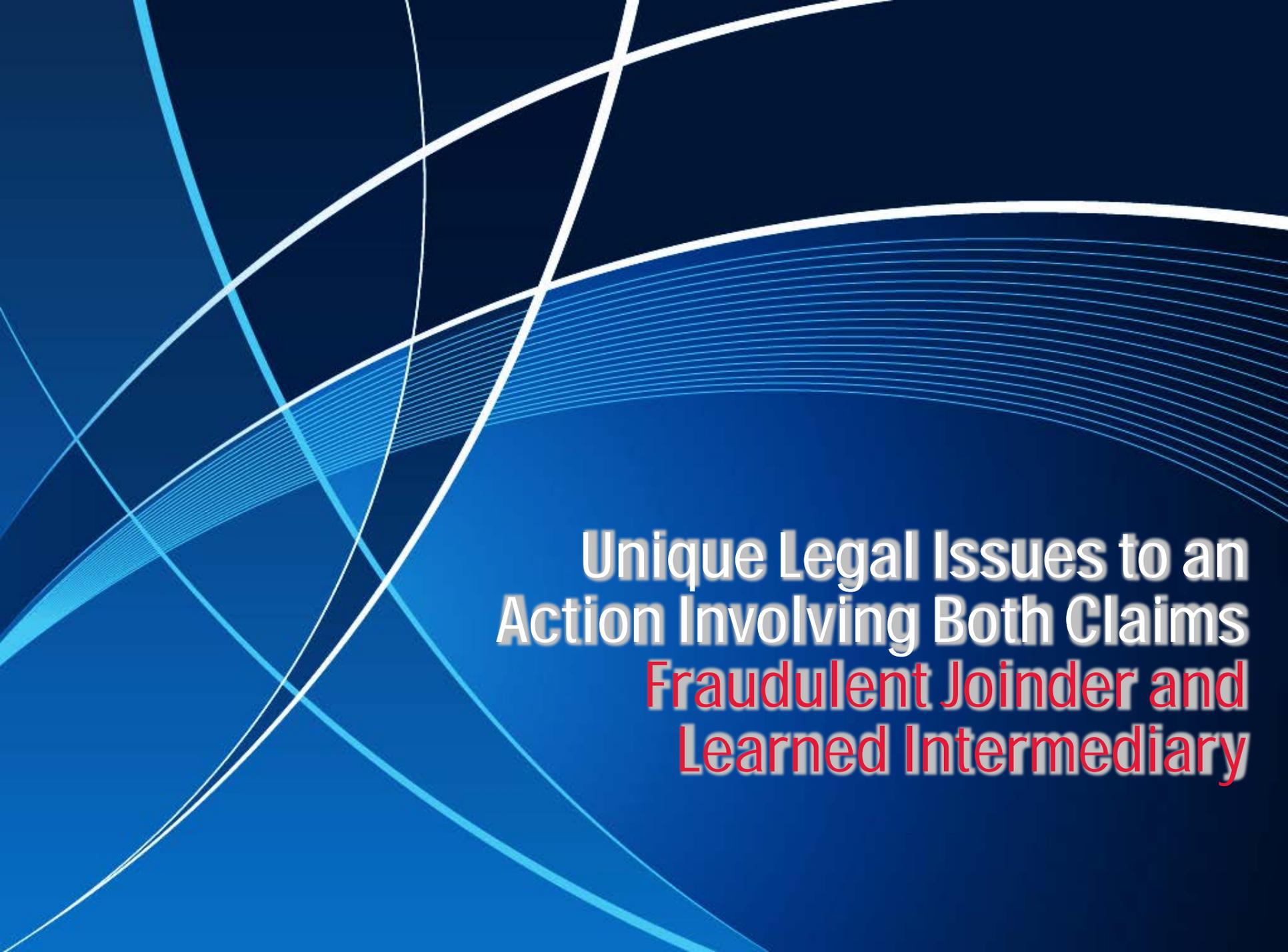
- Sales Representatives/Marketing Personnel
  - *Where they interacted directly with the prescribing doctor or patient, their depositions are key events in the case.*
  - *Extensive preparation and "handling" are the key to success.*
  
- Prescribing and Treating Physicians
  - *These depositions are always critical and can make or break a case.*
  - *Their testimony is critical to learned intermediary defense.*
  - *Treating physicians are perceived as neutral by the jury, unless a defendant - Causation opinions are key*
  - *Treating physician may also be a named co-defendant, and may be tempted to finger-point at the company.*

# Expert Selection and Retention

- Types of Experts Relied on by Defense:
  - *FDA/Regulatory*
  - *Engineering/Device Experts*
  - *Physician: Prescriber, Causation, Damages/Treatment*
  - *Epidemiologist*
  - *Pharmacologist/Toxicologist*
  - *Pathologist or other Expert in the alleged injury, condition, or diseases at issue*
  - *Warnings or Human Factors*
  - *Damages*

# Expert Selection and Retention

- Strategies for Selecting and Retaining Experts:
  - *Rely on both internal and external experts*
  - *Use a mix of local and national experts*
  - *Avoid experts who are "overused"*
  - *Watch expert costs and ask for budget in advance*
  - *Work with client to identify key opinion leaders*
  - *Be careful of experts who have served as consultants to client or who have been paid by client for studies, seminars, etc.*



**Unique Legal Issues to an  
Action Involving Both Claims  
Fraudulent Joinder and  
Learned Intermediary**

# Fraudulent Joinder

- Closely examine the allegations against the forum defendants.
- This scenario brings with it the threat of inconsistent rulings and accelerated state court dockets.
- One tool defense counsel has available to it in this situation is the doctrine of fraudulent joinder.

# Fraudulent Joinder - Considerations

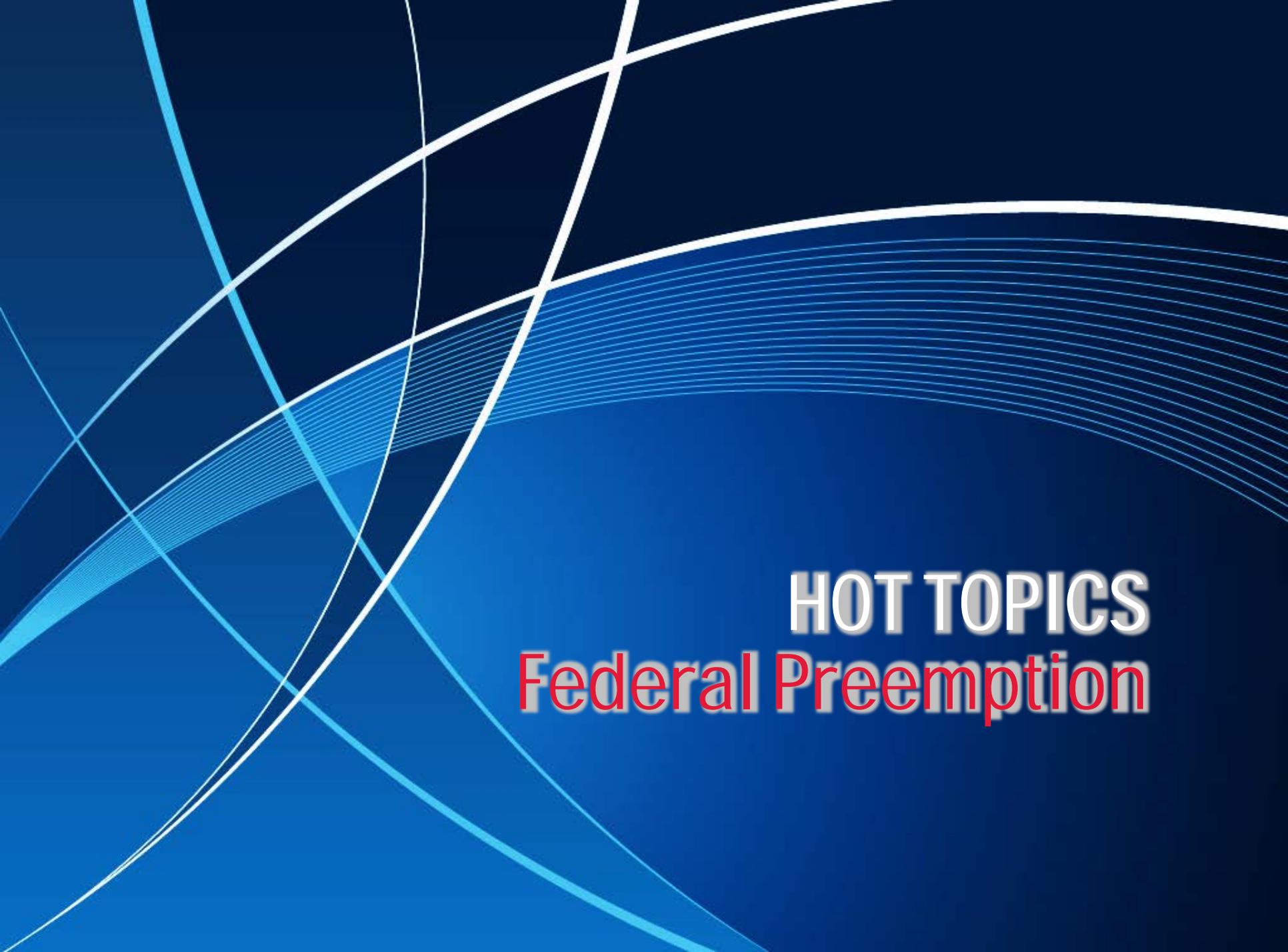
- Carefully examine the complaint for allegations against the forum physician or hospital defendant and consider:
  - *Do the allegations meet pleading requirements?*
  - *Have all state requirements for a medical malpractice been met, i.e. affidavit?*
  - *Are the allegations true medical malpractice allegations against physician or hospital?*
  - *Would the claims against the physician or hospital be barred by state or federal law?*

# Learned Intermediary Doctrine

- Manufacturers discharge their duty to warn by providing warnings to the prescribing physicians, the “learned intermediary.”
- The treating physician has the sole responsibility for advising the patient of dangers associated with the use of the prescription product.
- Proximate Cause

# Learned Intermediary Doctrine

- Heeding Presumption
- If the doctor was aware of the risk alleged from some other sources, such as medical literature, then no proximate cause for failing to warn
- Exceptions to the learned intermediary doctrine recognized in some states.



**HOT TOPICS**  
**Federal Preemption**

# Federal Preemption

- Preemption is the principle that a federal law can and must supersede a state law that is inconsistent.
- 2 Types of Preemption:
  - *Express Preemption*
  - *Implied or Conflict Preemption*

# *Mensing*: Federal Preemption for Generic Drugs

- *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011)
- Because generic drug manufacturers cannot change the FDA required labeling of their drugs, state law claims that the labeling is inadequate would conflict with FDA regulations and are thus preempted.
- Failure to Warn claims preempted
- Plaintiffs' Efforts to Undermine *Mensing*
- No preemption protection for labeling claims as to branded drugs. *Wyeth v. Levine*, 555 U.S. 555 (2009)

# *Bartlett*: Federal Preemption for Generic Drugs

- *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S.Ct. 2466 (2013)
- Design defect claims against generic manufacturers preempted
- Failure to stop-selling claims preempted
- Footnote 4 - Misbranding claims

# Federal Preemption: *Buckman*

- *Buckman Co. v. Plaintiffs' Legal Committee*, 541 U.S. 341 (2001)
- No private right of action to enforce the FDCA
- Only FDA has the right to determine whether and when to take enforcement action.
- Applies to both medical device and pharmaceutical cases.

# Federal Preemption: *Riegel v. Medtronic, Inc.*

- FDA PMA process established federal requirements, therefore patient's New York common-law claims of negligence, strict liability, and implied warranty against manufacturer were preempted.
- Medical Device Amendments (MDA) preempt state law claims that are "different from, or in addition to, any requirement applicable...to the device under federal law § 360k(a)."
- State law common law claims regarding a PMA approved medical device are preempted.

# Preemption Motion Strategy

- Can you use a combination of preemption arguments?
- Mensing/Bartlett plus Buckman
- Iqbal/Twombly
- Failure to plead fraud
- Procedural arguments

# Preemption Tips

- *Learn to navigate the FDA website*
- *Stay up to date on preemption developments*
- *Drug and Device Law Blog -*
  - Preemption scorecards
- *Know what the case law says -*
  - Research all preemption decisions nationwide involving this or similar device or drug
  - Coordinate with client to make sure we understand preemption ruling history for this device/drug
- *Consider sending preemption letter early in case*

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**HOT TOPICS**  
**Social Media**

# Scope of Discovery

- Social networking posts are neither privileged nor protected by any right of privacy
- No fishing expeditions: No “generalized right to rummage at will through information that [the responding party] has limited from public view”
- Threshold showing that requested info is reasonably calculated to lead to discovery of admissible evidence

# Key Social Media Cases

- *Glazer v. Fireman's Fund Insurance Co.*, 2012 WL 1197167 (S.D.N.Y. Apr. 5, 2012)
- *Targonski v. City of Oak Ridge*, 2013 WL 436948 (E.D. Tenn. Feb. 5, 2013)
- *Bass v. Ms. Porter's School*, 2009 WL 3724968 (D. Conn. 2009)
- *Reid v. Ingerman Smith, LLP*, 2012 WL 6720752 (E.D.N.Y. Dec. 27, 2012)
- *Crispin v. Christian Audigier, Inc.*, 717 F. Supp. 2d 965 (C.D. Cal. 2010)
- *Mailhoit v. Home Depot U.S.A.*, 2012 WL 3939063 (C.D. Cal Sept. 7, 2012)
- *Howell v. The Buckeye Ranch, Inc.*, 2012 U.S. Dist. LEXIS 141368 (S.D. Oh. Oct. 1, 2012)
- *Tompkins v. Detroit Metropolitan Airport*, 278 F.R.D. 387 (E.D. Mich. 2012)

# Social Media – Just Another Flavor of ESI

- *Robinson v. Jones Lang Ams.*, 2012 U.S. Dist. LEXIS 123883
  - *Court bundled social media into ESI along with emails and text messages*
  - *Social media is simply another form of ESI*
- *E.E.O.C. v. Simply Storage Mgmt., LLC*, 270 F.R.D. 430 (S.D. Ind. 2010)
  - *Social media might provide information inconsistent with plaintiff's allegations*

# Bar Association Opinions

- New York State Bar Association Committee on Professional Ethics, Formal Opinion 843.
- Philadelphia Bar Association Opinion 2009-02.
- San Diego Bar Association Legal Ethics Opinion 2011-2.
- Association of the Bar of the City of New York, NYC Formal Opinion 2010-2.

# Example: *Lineberry v. Detroit Medical Ctr*

Evidence from social media was key in dismissal of Plaintiff's cause of action.

Facebook comments and photographs contradicted her claims.

2:11-cv-13752-LPZ-MKM Doc # 20 Filed 02/05/13 Pg 1 of 12 Pg ID 463

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MICHIGAN  
SOUTHERN DIVISION

CAROL LINEBERRY,

Plaintiff and Counter-Defendant,

Case No. 11-13752  
Hon. Lawrence P. Zatkoff

ESSICA RICHARDS, LAURA  
HEPARD, VALERIE GIBSON,  
and PAULETTE GRIFFIN,

Defendants,

and

DETROIT MEDICAL CENTER,

Defendant/Counter-Plaintiff.

## OPINION AND ORDER

AT A SESSION of said Court, held in the United States Courthouse,  
in the City of Port Huron, State of Michigan, on February 5, 2013

PRESENT: THE HONORABLE LAWRENCE P. ZATKOFF  
UNITED STATES DISTRICT JUDGE

### I. INTRODUCTION

This matter is before the Court on Defendants' Motion for Summary Judgment (Docket #2) with respect to Plaintiff's cause of action. The Motion has been fully briefed. The Court finds that the facts and legal arguments are adequately presented in the parties' papers such that the decisional process would not be significantly aided by oral argument. Therefore, pursuant to E.D. Mich. L.R. 1.1(f)(2), it is hereby ORDERED that the Motion be resolved on the briefs submitted. For the following reasons, Defendants' Motion for Summary Judgment is GRANTED.

# Discovery Tips

- Issue a preservation letter - data can change from minute to minute
- Factual predicate for why you are seeking information
- Do not ask for entire account information
- Narrowly tailor requests
- Do not ask for passwords

# Company Witnesses

- Social media research on your company witnesses
- Preparation for deposition and trial testimony
- Counsel witnesses on risks of social media going forward

# Expert Witnesses

- Tool for researching opposing experts
  - *YouTube*
  - *LinkedIn*
  - *Facebook*
  - *Twitter*
  - *Comments on blogs*
- Presentations and supporting materials
- Don't forget your experts

# Jury Selection Research

#	Name	Age	Gender	Occupation	Retired	Marital Status	Children	Social Media Results
1	Adkins, Amanda	55	F	Hospital Volunteer	N	M	3	Facebook Posted: "Why do I have to prese 'ONE' for english, when you're just going to transfer me to someone I can't understand anyway?!?"; Likes: The Federalist Papers
2	Barnes, Anne	29	F	X-Ray Technologist	N	M	0	Facebook. Likes Barack Obama, Tylenol, Fifty Shades of Gray. Pro-Choice
3	Boggs, Michael	19	M	College Student	N	S	0	Broadcasting drinking tendencies on Twitter. Bragging "I'm gonna be so drunk tonight."
4	Bogart, Bill	57	M	Farmer	Y	M	2	Found on Facebook. Likes hunting, shooting, fishing, football, camping. Country music fan. Anti-Gay Marriage. Pro drug testing for welfare recipients.
5	Bradley, Jon	20	M	Wal-Mart - Associate	N	S	?	Facebook, Obama is the Worst President Ever, Twitter account feed, reposts from Fox news, Donald Trump and Mitt Romney
6	Christian, Kelly	41	F	Mother, Homemaker	N	M	3	Facebook. Likes organic food, Office Depot, Pepsi, Cat lover. Twitter "Hate it when companies mislead us with labels so we think food is organic when it's not!"
7	Cruz, Henley	49	M	Truck Driver	Y	M	1	Has Facebook page; posts about upholding second amendment; has meme that says: "The purpose of the constitution is to limit the power of the federal government not the people."
8	Day, Jessica	32	F	Information Tech	N	M	2	An Atheist for President, MSNBC, Nerds do it better, Liberals on Parade, Hate Liberals? Bite Me., Paul Ryan Is a Douchebag