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And the Verdict Is...: Recent Trends in Drug and Device Litigation

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Agenda

- Personal jurisdiction
- Preemption
- Innovator liability
- Duty to report adverse events
- Off-label use and other claims
- The Learned Intermediary Doctrine (LID)
- “The Third Man”

Personal Jurisdiction After *Bauman*

- Companies only subject to jurisdiction in states of incorporation or principal place of business – *Daimler AG v. Bauman*, 134 S.Ct. 746 (2014)
  - Exceptions not relevant to ordinarily operating companies
- Can manufacturers be dismissed from mass tort hellholes that do not qualify
  - Yes (Illinois, 2014 WL 3928240, and Oklahoma, CJ-13-299); no (California, 175 Cal.Rptr.3d 412)
- Multi-defendant cases become harder, except in plaintiff's home state
- Look for cases concerning nationwide class actions asserting state law
- Litigation tourism to defendant's principal place of business will increase; rest decline

Preemption – The Driver of Novel Causes of Action

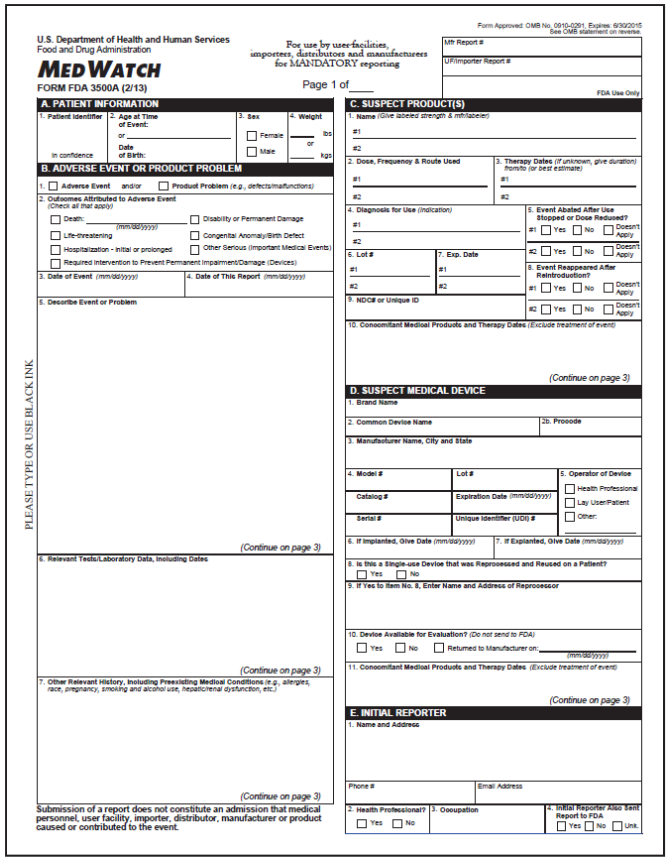
- In generic drugs – practically everything preempted
- In PMA medical devices – almost everything preempted except "parallel violation"

Innovator Liability

- Holding manufacturer of original drug, and drafter of original labeling, liable for defects in generic drug labels
- Scariest theory given size of generic market; Restatement Third § 9 is helpful for misrepresentation
  - Must be "in connection with the sale of a product"
- Federal courts are not supposed to predict expansion of expanded state law
  - Virtually every innovator liability claim in federal court has been rejected, except two *In re Darvocet*, 756 F.3d 917(6th Cir. 2014) (rejected for 22 states)
- State courts have been considerably harder
  - Supreme courts are split 1-1; Iowa (*Huck*, 850 N.W.2d 353, versus Alabama (*Weeks*, 2014 WL 4055813)
- State appellate courts are split 3-1 Florida, Louisiana and Minnesota versus California

Duty to Report Adverse Events

- Has gained currency in medical device cases – less in generics because based on warnings (cases in 2d, 5th, 6th, 7th, & 9th)
- Should be *Buckman* preempted, but courts have been reluctant
- Has causation problems
  - If dependent on FDA doing something different, a conflict exists with what FDA has already done. *Stengel*, 704 F.3d at 1234-35
  - Otherwise depends on prescriber somehow finding out about adverse events and acting differently


U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH
FORM FDA 3500A (2/13)

For use by user facilities, importers, distributors and manufacturers for MANDATORY reporting

Page 1 of ___

A. PATIENT INFORMATION

B. ADVERSE EVENT OR PRODUCT PROBLEM

C. SUSPECT PRODUCT(S)

D. SUSPECT MEDICAL DEVICE

E. INITIAL REPORTER

PLEASE TYPE OR USE BLACK INK

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

Off-Label Use Claims

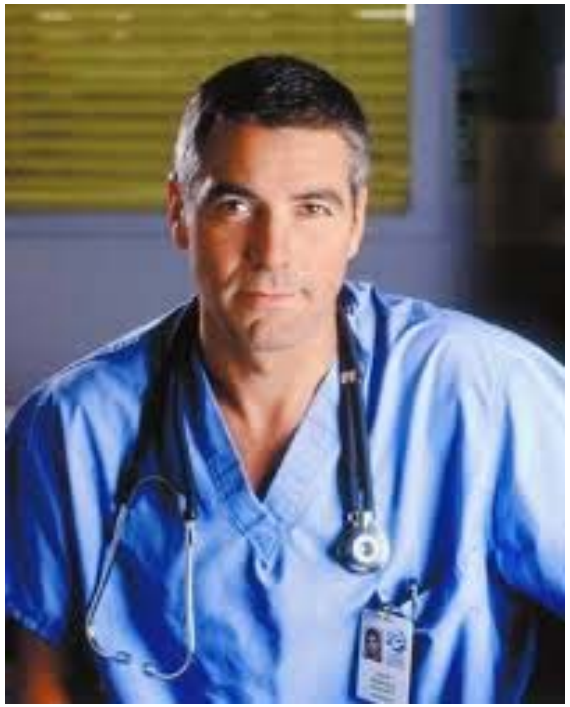
- In preemption cases, plaintiffs will emphasize off-label use
- Plaintiffs argue that preemption can't exist where FDA hasn't reviewed use. *Ramirez*, 961 F. Supp.2d at 995-1000
- Fallback is to argue there should be warnings about off-label use that FDA never reviewed
  - FDA pre-approval required for off-label warnings. 21 C.F.R. § 201.57(c)(6)(i) (drugs); 21 C.F.R. 814.82(a) (devices)
- Illegal off-label promotion that is also false can be parallel claim. Most common type of claim.
- State-law restrictions on negligence per se claims
  - Failure to have a license not usually negligence per se
  - Regulations sometimes not negligence per se

Other Claims

- Manufacturing defect claims based on generalized GMPs
  - Delaying action, when plaintiff forced to specify almost always diverges from FDA. *Pinsonneault*, 2014 WL 2879754, at *8-10
- Duty to update warnings
  - Generic drug specific – not many instances – causation problems since periods usually short, and don't match plaintiff's facts
- Parallel misbranding claims; sometimes dressed up as "adulteration"
  - Dictum in *Bartlett* not addressing adulteration claims; state negligence per se? *Lashley*, 750 F.3d at 476-77 (held preempted); but see *Yazmin*, 2014 WL 1632149, at *10 (allowed to survive)

The Learned Intermediary Doctrine in 2014 – Alive and Well

- Prescription drug and medical device manufacturers satisfy their duty to warn if they provide adequate warnings to prescribing physicians – not to patients.
- A plaintiff has to prove (1) that the warnings were inadequate and (2) that different or additional information in the warnings would have resulted in the physician making a different treating decision.



The Practical Impact

- A defendant can cut off liability with evidence that the warnings were adequate
- A defendant can cut off liability with evidence that
  - The prescribing physicians had independent knowledge of the risks that allegedly befell the plaintiffs
  - The prescribing physicians would have made the same decisions even if they had different or additional information
  - The prescribing physicians did not review the labeling, so different or additional information would not have mattered anyway
- *e.g.*, *Higgins v. Forest Labs.*, No. 5:07-cv-00054, 2014 Dist. LEXIS 124745 (W.D. Va. Sept. 8, 2014)

Frontal Attacks on the Learned Intermediary Doctrine

- Have generally not worked well
- *Hanhan v. Johnson & Johnson*, No. 1:11-oe-40007, 2013 WL 5939720 (N.D. Ohio Nov. 5, 2013 (rejecting exception for oral contraceptives)
- *Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4059214 (S.D. W. Va. Aug. 18, 2014 (rejecting argument that LID "does not apply" where the plaintiff alleged inadequate warnings)

Frontal Attacks on the Learned Intermediary Doctrine (cont.)

- "It does not withstand scrutiny to say that the learned intermediary doctrine suddenly becomes inapplicable when a plaintiff alleges that warnings are inadequate. If the learned intermediary doctrine became inapplicable when a plaintiff alleged that warnings were inadequate, the doctrine would never operate in California. Plaintiffs could simply plead around the doctrine by alleging inadequate warnings—which they must necessarily do to state a claim for failure to warn. . . .

  Even where a plaintiff *proves* that warnings were inadequate, the learned intermediary doctrine still applies. A plaintiff must prove that inadequate warnings altered the prescribing physician's decision to prescribe. Anything to the contrary would violate the California Supreme Court's clear holding that 'the duty to warn runs to the physician, not to the patient.'"

  -- *Sanchez*, 2014 WL 4059214, at *4

End Runs on the Learned Intermediary Doctrine

- Shift the focus to the plaintiff – courts have gone both ways
- Compare…
  - *Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, No. 3:09-oe-400023, 2014 WL 1369466 (N.D. Ohio Apr. 7, 2014)
  - *Luttrell v. Novartis Pharmaceuticals Corp.*, 555 Fed. Appx. 710 (9th Cir. Feb. 20, 2014)
- with…
  - *Guenther v. Novartis Pharmaceuticals Corp.*, 990 F. Supp. 2d 1299 (M.D. Fla. 2014)
  - *Payne v. Novartis Pharmaceuticals Corp.*, No. 13-6266, 2014 WL 4056889 (6th Cir. Aug. 18, 2014)

End Runs on the Learned Intermediary Doctrine (cont.)

- Manipulating the physician's testimony with hypothetical questions ("Doctor, if you had known . . . ?")
- But assumptions can be challenged.
  - *Boehm v. Eli Lilly & Co.*, 747 F.3d 501 (8th Cir. 2014)

End Runs on the Learned Intermediary Doctrine (cont.)

- Pleading around the LID
  - Pleading claims other than failure-to-warn
  - Design defect, manufacturing defect, fraud/misrepresentation, consumer remedies
- Not all that effective
  - Failure to warn is still the principal basis for potential liability
  - Many claims are failure-to-warn claims in disguise

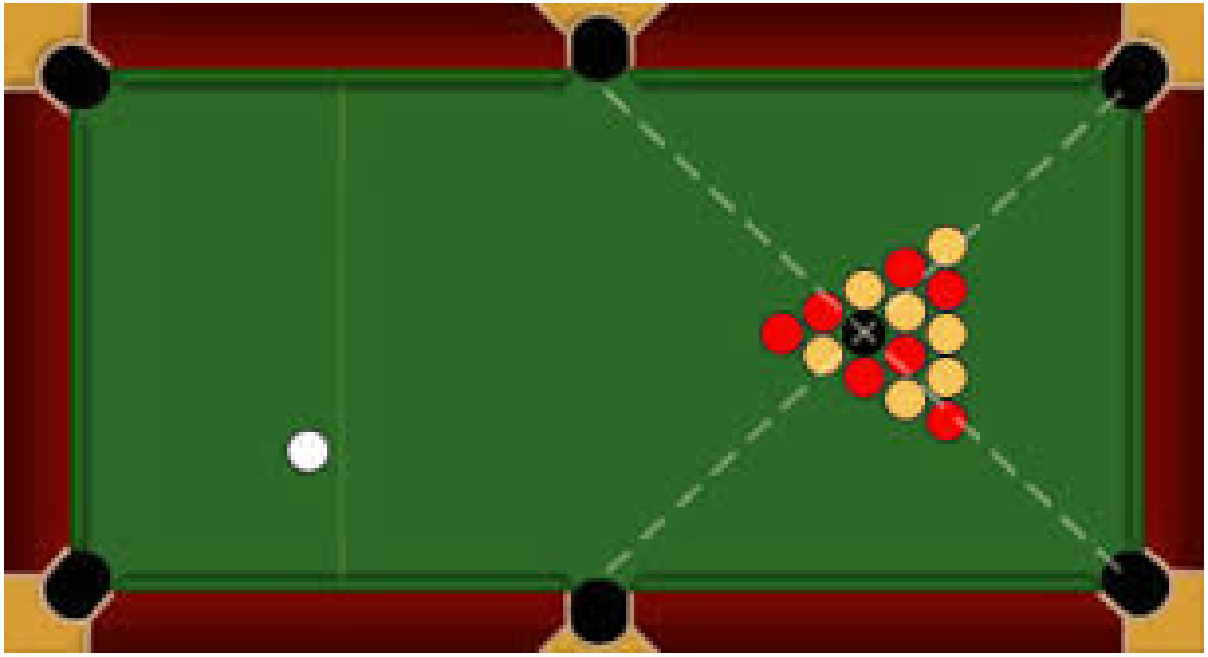
Trends in the Learned Intermediary Doctrine

- The learned intermediary doctrine is alive and well
- Plaintiffs will continue to attempt to divert attention away from physicians and toward themselves
- Plaintiffs will continue to attempt to manipulate physician testimony

“The Third Man”

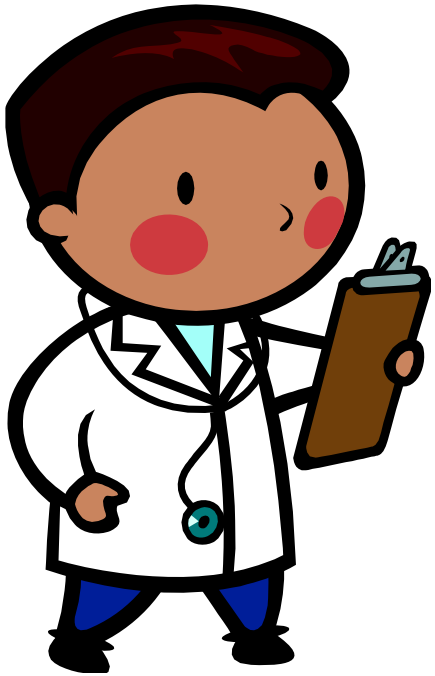
Who Is the Third Man and Why Is He Here?

- Plaintiffs
- Defendants
- Discovery
- Jurisdictional Effect
- Liability Effect
- Search for More Pockets



Doctors

Turner v. DePuy Orthopedics, Inc.,
2014 U.S. Dist. LEXIS 104081
(C.D. Cal. July 29, 2014)



- Failure to warn claim vs. doctor
- Mensing argument
- Doctor influence on labeling?
- Doctor was designer of medical device
- A “Product Champion”
- Case remanded

Pharmacists

Whiting v. Rite Aid Pharmacy,
2014 U.S. Dist. LEXIS 87354
(D. Utah, June 24, 2014)

- Pharmacists can be sued for malpractice and negligence
- Advice on suitability of non-prescription drug
- No Utah precedent
- Requires affirmative misrepresentations

Sales Representatives

Hutchens v. Smith & Nephew, Inc., 2014 U.S. Dist. LEXIS 116839 (N.D. Tex. Aug. 22, 2014)

- Fraudulent joinder?
- Applied Texas "fair notice" pleading
- Corporate agent liability
- Sales rep provided information
- Sales rep in the operating room

Publishers

King v. Solvay, S.A.,
2014 U.S. Dist. LEXIS 120284
(D. Colo., Aug. 28, 2014)

- *Qui tam*
- Anti-Kickback Statute Conspiracy… or Fraud?
- Third-party discovery

Hardin v. PDX, Inc.,
2014 WL 2768863
(Cal. Ct. App. June 19, 2014)

- SJS case
- Plaintiff sued publisher of pharmacy monograph
- Plaintiff also sued software company
- Good Samaritan liability (Rest. (Second) Torts § 324A)

Raw Materials Suppliers

- Biomaterials Access Assurance Act (21 USC §§ 1601-06)
- Implications for Jurisdiction

  In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig. (MDL) (S.D. W.Va.)

  - No fraudulent joinder
  - No federal question
  - Sanctions
  - Philadelphia CCP – Secant

Raw Materials Suppliers (cont.)

Bocock v. Med-Venture Tech. Corp.,
2013 U.S. Dist. LEXIS 135086
(S.D. Ind. Sept. 20, 2013)

- Permitted discovery
- Case transferred to MDL

- Implications for Liability
- MSDS

Third-Party Payers

In re Actiq Sales & Marketing Practices Litigation, 2014 U.S. Dist. LEXIS 984411 (E.D. Pa. July 21, 2014)

- Off-label painkillers
- *Daubert* re plaintiff economist expert
- Court permitted assumptions

Travelers Indemnity Co. v. Cephalon, Inc. 2014 U.S. Distr. LEXIS 95075 (E.D. Pa. July 14, 2014)

- More off-label painkillers
- *Twiqbal* applied
- Standing denied
- No ascertainable loss
- Case dismissed

Third-Party Payers (cont.)

Regional Council of Carpenters Welfare Fund v. Cephalon, Inc., 2014 U.S. Dist. LEXIS 69526 (E.D. Pa. May 21, 2014)

- RICO claim
- Off-label promotion of painkillers
- Rule 9(b) particularity

Questions?

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