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Thumbs Up and Thumbs Down: The Best and Worst Prescription Drug/Medical Device Decisions of 2014

Presented by:

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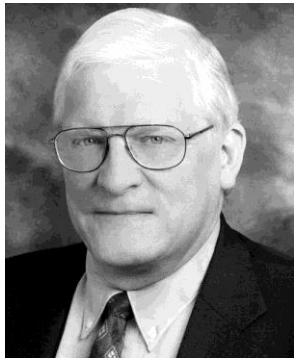
Presenters



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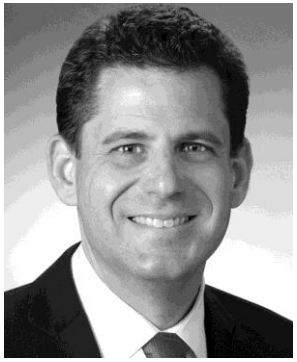

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BEST #1: *In re Darvocet, Darvon, and Propoxyphene Products Liability Litigation*, 756 F.3d 917 (6th Cir. 2014)

- Non-manufacturer “innovator liability” for generic drug warnings
- Most dangerous liability theory in prescription drug product litigation, as 80 percent of drugs are currently generic
- Biggest defeat for *Conte* liability ever
- Predicted law of 22 states; none would adopt, under any theory
- Including Illinois where rogue district court had allowed

WORST #1: *Wyeth v. Weeks*, 2014 WL 4055813 (Ala. Aug. 15, 2014)

- Innovator liability necessary after *Mensing*
- Discounts post-*Mensing* cases rejecting innovator liability
- Emphasizes FDA regulation and learned intermediary doctrine

BEST #2: *Caldwell v. Janssen Pharmaceutica, Inc.*, 144 So.3d 898 (La. 2014)

- Reversed $330 million verdict, ordered judgment for the defendants
- Risperidone DHCP letter with off-label statements re diabetes risk
- Louisiana (represented by contingent fee attorneys) sued manufacturer for fraudulent claims against state medical assistance program
- The statutes required “fraud” or “false statements” – *and there were none*

WORST #2: *Lance v. Wyeth*, 85 A.3d 434 (Pa. 2014)

- Pennsylvania is comment k across the board – no strict liability
- Traditional negligence hardly mattered
- Assumed truth of what was really a legal conclusion – an FDA-approved drug was so dangerous it could not be used safely by anyone
- Design defect liability without any alternative design
- Effectively a duty to remove from market
- Is theory limited to withdrawn drug – fen-phen?
- Is claim preempted?

BEST #3: *Huck v. Wyeth, Inc.*, 850 N.W.2d 353 (Iowa 2014)

- Rejects innovator liability, even after *Mensing*
- Specific production identification requirement trumps general Restatement (3d) Torts section 7
- No preemption of failure to update claim
- Plurality?

WORST #3: *In re Actos (Pioglitazone) Products Liability Litigation*, 2014 WL 4364832 (W.D. La. Sept. 2, 2014)

- Upheld $9 billion verdict
- Culmination of bad decisions
  - Lots of evidence re fraud on the FDA – why no preemption?
  - NDA holder and co-promoter blurred together
  - Does warning mean Warning?
  - Alleged spoliation
- Amount of verdict later reduced on motion for new trial

BEST #4: *Corber v. Xanodyne Pharmaceuticals, Inc.*, 771 F.3d 1218 (9th Cir. 2014) (en banc)

- CAFA removal jurisdiction okay
- Multiple complaints grouped together
  - Each fewer than 100 plaintiffs
  - Each including at least one non-diverse defendant
  - Same product
  - Coordination Petition filed
- “proposed to be tried jointly”
- Strike again litigation tourism

WORST #4: *Mississippi ex rel. Hood v. AU Optronics Corp.*, 134 S. Ct. 736 (U.S. 2014)

- Contingent fee lawsuits in name of state attorneys general are inherently mass actions
- But are they “mass actions” under CAFA, allowing removal to federal court?
- Supreme Court said “no”
- Nothing in CAFA allows looking behind the existence of a single plaintiff to unnamed persons
- Did not change existing law very much

BEST #5: *Drager v. PLIVA USA, Inc.*, 741 F.3d 470 (4th Cir. 2014)

- Best generic preemption decision of 2014
- First appellate court post-*Bartlett* to take functional approach
- If manufacturer can't be forced to change warnings or designs, or remove product from market claims, what can possibly be left?
- Whatever the test for defect, if the result is a duty to change design, claim is preempted
- No separate duty to test

WORST #5: *Hardin v. PDX, Inc.*, 173 Cal. Rptr. 3d 397 (Cal. App. 2014)

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

BEST #6: *Ortho-McNeil-Janssen Pharmaceutical, Inc. v. State of Arkansas*, 432 S.W.3d 563 (Ark. 2014)

- Reversed $1.2 billion state false claims act verdict
- Contingent fee case following warning letter re antipsychotic drugs
- Peculiar codification error
- Warning letter was inadmissible
  - Not a public record because of “special investigation” carve-out
  - Unduly prejudicial

WORST #6: *Payne v. Novartis Pharmaceutical Corp.*, 767 F.3d 526 (6th Cir. 2014)

- Prescriber says he would still have prescribed Aredia-Zometa
- But now he advises a dental exam because of osteonecrosis of the jaw (ONJ) risk
- Plaintiff escapes summary judgment with “speculative” testimony that she would have preferred cancer to ONJ

BEST #7: *Booker v. Johnson & Johnson*, ___ F. Supp.3d ___, 2014 WL 5113305 (N.D. Ohio Oct. 10, 2014)

- *Bartlett*: Supreme Court went out of its way to mention that design changes for both generic and branded drugs required FDA pre-approval
- Why would it do that except to point out that design preemption applies to all drugs?
- Eventually, a court would catch on
- *Booker* did in Ortho-Evra MDL – arguments thoroughly litigated
- State law demands immediate change to “safer” design – FDCA says not unless FDA allows
- Beginning of end for design defect claims in prescription drugs?

WORST #7: *Scott v. C. R. Bard, Inc.*, ___ Cal. Rptr.3d ___, 2014 WL 6475366 (Cal. App. Nov. 19, 2014)

- Affirmed judgment on negligence claims
- California has no strict liability for design defect – but what about negligence?
- Medical device manufacturer's duty to train surgeons
- Admissibility of post-surgery regulatory actions

BEST #8: *Bowerman v. Takeda Pharmaceuticals USA*, 492 S.W.3d 839 (Arkansas 2014)

- “Illegal exaction”
- Prescribing FDA-approved drug is not unlawful
- Reimbursing for prescribed drugs is not arbitrary

WORST #8: *Messick v. Novartis Pharmaceutical Corp.*, 747 F.3d 1193 (9th Cir. 2014)

- Reverses summary judgment, finds expert causation opinion should not have been excluded
- Unreliable expert opinion
  - Could not say that bisphosphonate caused the plaintiff's ONJ
  - "the current level of evidence does not fully support a cause-and-effect relationship"
  - "might never be proven"
- Ninth Circuit: Admissible based on "association" because of "inherent uncertainty"

BEST #9: *Martin v. Medtronic, Inc.,* 2014 WL 363 52921 (D. Ariz. July 23, 2014) and 2014 WL 6633540 (D. Ariz. Nov. 24, 2015)

- Rejects parallel claim
- Rejects claims of failure to report adverse events
- Rejects claim based on off-label promotion

WORST #9: *In re Actos (Pioglitazone) Products Liability Litigation*, 2014 WL 2872299 (W.D. La. June 23, 2014)

- Sanctions for spoliation of electronic data before the litigation ever began
- Litigation holds from as many as eight years earlier not complied with
- Dangers of overbroad and overlong litigation holds
- Sanctions allowed MDL plaintiffs to argue adverse inference to jury
- Never again – new Fed. R. Civ. P. 37(a) – no sanctions unless intent to deprive opponent in “the litigation”

BEST #10: *Shannon v. Fusco*, 89 A.3d 1156 (Md. 2014)

- Perennial plaintiff claim – doctors must tell patients about fact of FDA "non-approval" of any off-label use
- Allegedly part of informed consent obligation
- Rejected by almost every court, but still alleged
- Reversing intermediate court allowing theory, Maryland joins consensus
- FDA approval, provides no information about the treatment itself – therefore irrelevant to informed consent

WORST #10: *Hornbeck v. Medtronic, Inc.*, 2014 WL 2510817 (N.D. Ill. June 2, 2014)

- Wrong on preemption
- Wrong on Illinois negligence per se
- Wrong on component analysis

Thank you!

Questions?

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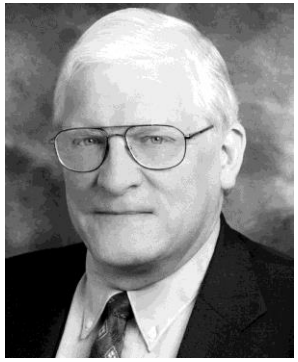
Contact Information



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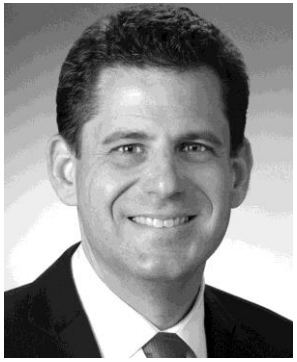

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