



Medmarc®

Litigation and Claims Trends for the Life Sciences Industry

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Generic Preemption

- Historical perspective
- *PLIVA, Inc. v. Mensing*, 564 U.S. ---, 131 S. Ct. 2567 (2011)
- The Fifth, Sixth, and Eighth Circuits.

Plaintiffs' Response

- New theories of liability against the generics:
 - Failure to communicate label change
 - Negligent marketing of the product
 - Timeliness of label change
 - Design defect

Plaintiffs' Response

- Strategy against the brands:
 - Negligent misrepresentation
 - Failure to communicate
 - Motions for reconsideration of pre-*Mensing* dismissals

Mensing's Progeny

- Favorable decisions
- Unfavorable decisions
- Philadelphia and New Jersey mass tort programs

The Future

- Decisions in Philadelphia and New Jersey
- Citizen petition
- Congressional action
- Chipping away at the decision on the basis of innovative state-law claims



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2011 Litigation Trends

- Class actions revamped
- Medical research called into question
- Reaching to stay in state court
- Brand drug manufacturers under attack
- Generics under closer scrutiny
- 2011 marks the second highest FDA clearance for new drugs

Life science products in the crosshairs

- Vaginal mesh products
- Pain pumps
- Insulin drugs and
- Insulin pumps

On the horizon

- In light of the record NDAs granted this year, increased pressure on brand manufacturers
- Rise in multi-plaintiff, multi-state litigation
- MDL drop-outs
- Forum shopping
- Devices as cyber-weapons
- Manufacturers turn the tables on plaintiff firms