



## *Wyeth v. Levine*

Federal preemption for Drug Torts on the Horizon?

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# Current State of Preemption Policy

## FDA Approval of Drug

- Required to Market a new drug (21 USC 355)
- Labeling must not be misleading (misbranded) (21 USC 331(b), 321(n) and 352 (a))
- FDA Approval Required to Change the Labeling (21 CFR 314.70) with certain exceptions



# Current State of Preemption Policy

## **CBE (Change being Effected)**

- 21 CFR 314.70 (b) (6)(i)(c)
- Drug manufacturer may “add or strengthen a warning” without prior FDA approval.
- Labeling “must be revised to include a warning about a clinically significant hazard as soon as there evidence of a causal relationship” – but a “causal relationship need not have been definitively established”



# Current State of Preemption Policy

## 2006 Preemption *Policy*

- Preamble, Requirements on Content and Format of Labeling, *71 Fed. Reg. 3922, 3933-36*
- “whether labeling revisions are needed is, in the end, squarely and solely FDA’s” decision.
- Liability claims based on failure to warn should be preempted including those in which “the substance” of the warning had been proposed to FDA and “statement had not been required by FDA.”



# Current State of Preemption Policy

## Deference to the FDA

- Policy statement not a rule – What level of deference under *Chevron*?
- FDA has proposed rule. 73 Fed. Reg. 2848 (Jan. 24, 2008).
  - Rule would have higher level of *Chevron* deference
- Liability claims based on failure to warn should be preempted including those in which “the substance” of the warning had been proposed to FDA and “statement had not been required by FDA.”



## Key Prior Opinions

### ***Buckman Co.. v. Plaintiff's Legal Comm.***

- 531 U.S. 341 (2001)
- Fraudulent misrepresentations regarding approval of bone screws
- Fraud on the agency claims preempt state law claims
- “Thus, although *Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim.”



## Key Prior Opinions

### ***Warner Lambert v. Kent***

- 128 S.Ct. 1168 (2008)
- Second Circuit decision distinguished Buckman
- Found drug manufacturers can be liable in tort for misrepresentations in submissions to FDA about risk-related matters.
- Supreme Ct. 4-4 decision (Roberts not participating), let Second Circuit decision stand.



## *Wyeth v. Levine*

### **The Case**

- Patient's forearm had to be amputated after “push-IV” of anti-migraine/nausea medication mistakenly made into artery.
- Label indicated “Extreme care” must be made if procedure performed. “Hanging IV bag” much preferred.
- Wyeth submitted and FDA rejected additional language regarding IV-push administration – Wyeth to “retain current language”
- Plaintiff's expert testified that push-IV procedure unreasonably dangerous.



## *Wyeth v. Levine*

### **Decision Below:**

- Vt. Supreme Court upheld jury verdict and relied on CBE rule in holding there was no preemption/conflict with FDA rules.
  - Court rejected FDA’s conclusion that approval of label preempted common law failure to warn claims
  - Found no clear conflict between state tort law and federal law, because Section 314.70(c) of the FDCA allows the manufacturer to make unilateral changes to the label to make the product “safer”
  - “Savings” provision in 1962 amendments to FDCA limited conflicts preemption to instances where compliance with the both the state and federal law is a “physical impossibility”



## *Wyeth v. Levine*

### **Question Presented**

- Whether the prescription drug labeling judgments imposed on manufacturers by the Food and Drug Administration ("FDA") pursuant to FDA's comprehensive safety and efficacy authority under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use.



# *Wyeth v. Levine*

## **Procedural History**

- Mar 12 2007            Petition for a writ of certiorari filed.
- Apr 20 2007            Amicus Brief of PhRMA
- Apr 20 2007            Amicus Brief of Prod. Liability Advisory Council
- Apr 20 2007            Brief of respondent Levine in opposition filed.
- Apr 30 2007            Reply of petitioner Wyeth filed.
- May 21 2007            Solicitor General invited to file Amicus .
- Dec 21 2007            Amicus Brief of United States filed.
- Jan 2 2008             Supplemental brief of Diana Levine filed.
- Jan 2 2008             Supplemental brief of petitioner Wyeth filed.
- May 26, 2008            Joint appendix and petitioner's brief on the merits
- August 1, 2008         Respondent's brief on the merits is due



## *Wyeth v. Levine*

### **Wyeth Petition for Cert:**

- Clear conflict. Wyeth would have to change an already approved label to comply w/ Vermont failure to warn.

### **U.S position**

- Impliedly preempted by the FDCA, because they challenge labeling that FDA approved, after being informed of the relevant health risks and benefits of requiring additional or different warnings.”
- Argued against expansive interpretation of 21 CFR 314.70(c).



# *Wyeth v. Levine*

## Issues

- Approved Indications v. Off-label
  - Scope and Nature of FDA authority
- Pre-approval warnings v. Post-approval warnings/emerging risks.
  - More limited authority to require post-approval modifications
    - Recent amendments to FDCA expand that authority
  - Negotiated changes and timing (Vioxx – 14 months for label change)
- Is this all process dependent?
  - Will the new post-approval AE monitoring process have an effect on the outcome?



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