HUNTON& WILLIAMS

New Directions in Federal Preemption

FDA Regulatory Symposium

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September 30, 2009

Preemption

The Physician Labeling Rule (PLR) Preamble

- In January of 2006, FDA set forth its position on preemption in the preamble of the PLR.
- Under the PLR, FDA approval of a drug's labeling was intended to preempt state failure-to-warn claims based on:
  - (1) failing to put in Highlights section or otherwise emphasize information that already appears elsewhere in the labeling;
  - (2) failing to include in an advertisement information that appears in the labeling, in cases where the sponsor's brief summary complies with FDA Guidance.

Preemption

PLR Preamble (cont'd)

- (3) failing to include contraindications or warnings that are not supported by evidence that meets the standards set forth in the PLR, e.g., requiring that contraindications reflect "known hazards and not theoretical possibilities";
- (4) failing to include a statement in labeling or in advertising, the substance of which had been proposed to and rejected by FDA;
- (5) failing to include in labeling or in advertising a statement, the substance of which FDA has prohibited in labeling or advertising;
- (6) making statements that FDA approved for inclusion in the drug's label.

Preemption

Supreme Court on PLR Preamble

In *Wyeth v. Levine*, the Supreme Court held that:

- The FDA did not "offer[] States or other interested parties notice or opportunity for comment" about "a sweeping position on the FDCA's pre-emptive effect" and therefore the preamble is "inherently suspect in light of this procedural failure."
- The preamble is "at odds with what evidence we have of Congress' purposes."
- The preamble "reverses the FDA's own longstanding position without providing a reasoned explanation. . .of how state law has interfered with the FDA's regulation of drug labeling during decades of coexistence."

2009 WL 529172, at *13

Preemption

Supreme Court on PLR Preamble (cont'd)

In *Wyeth v. Levine*, the Supreme Court held that:

- "Not once prior to [plaintiff's] injury did the FDA suggest that state tort law stood as an obstacle to its statutory mission."
- "[T]he 'complex and extensive' regulatory history and background relevant to this case, undercut the FDA's recent pronouncements of pre-emption."
- "[T]he Government's explanation of federal drug regulation departs markedly from the FDA's understanding at all times relevant to this case."

2009 WL 529172, at *13

Preemption

Supreme Court on PLR Preamble (cont'd)

- The Court further stated:

> State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times.

2009 WL 529172, at *12

- FDA does not have the resources to police drug labeling.

Preemption

State Tort Suits will Undermine the Public Health

- The FDA is the expert public health agency charged by Congress with ensuring that drugs are safe and effective and that FDA-approved labeling adequately informs users of the risks and benefits of the product.
  - The public health is best served by the FDA, and not lay juries and judges, deciding what information should appear on a product's label.
  - Labeling decisions involve a complicated weighing of risks and benefits in a large population.
    - While a particular warning may have helped a particular plaintiff, that same warning may be detrimental to other users.

Preemption

State Tort Suits will Undermine the Public Health (cont'd)

- Overwarning, just like underwarning, can have a negative effect on patient safety and public health.
  - Exaggeration of risk could discourage appropriate use of a beneficial drug.
  - The addition of speculative risks may limit physician appreciation of potentially far more significant contraindications and warnings.

Preemption

State Tort Suits will not Help FDA Make Labeling Decisions

- The Court in *Levine* never stated what warning Wyeth should have added to the product's label through a CBE supplement.
  - Not at all clear how the State-law failure-to-warn case helped improve the label.
  - On September 16th FDA Required a Boxed Warning that merely repeats existing warnings.
    - IV push may still be used.

Preemption

State Tort Suits will Increase the Number of Questionable CBE Supplements

- Scope of the "Changes Being Effected" (CBE) provision in 21 CFR § 314.70(c).
  - CBE provision allows manufacturers to amend labeling to add or strengthen warnings prior to FDA review of the labeling changes.
  - Manufacturers must give 30 days notice to FDA. The FDA will review and may reject or modify the warnings.
- In light of the Court's decision in *Levine*, courts will likely reject preemption defenses in State-law failure-to-warn cases unless the FDA has considered and rejected the warning at issue.
  - Expect manufacturers to increase the number of CBE supplements, thereby stretching FDA's limited resources even further.

Preemption

The Physician Labeling Rule (PLR) Preamble Post *Levine*

- Under *Levine*, FDA approval of a drug's labeling will no longer preempt state failure-to-warn claims in all six (6) of the areas discussed by the PLR Preamble:
  - (1) failing to put in Highlights section or otherwise emphasize information that already appears elsewhere in the labeling;
  - (2) failing to include in an advertisement information that appears in the labeling, in cases where the sponsor's brief summary complies with FDA Guidance.

Preemption

PLR Preamble (cont'd)

- (3) failing to include contraindications or warnings that are not supported by evidence that meets the standards set forth in the PLR, e.g., requiring that contraindications reflect "known hazards and not theoretical possibilities";
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Thank you.

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