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Product Liability Preemption: Analyzing the Supreme Court's New Decisions

Strategies for Asserting Preemption in an Uncertain Landscape

TUESDAY, AUGUST 16, 2011

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

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Product Liability Preemption: Analyzing Recent Decisions by U.S. Supreme Court

August 16, 2011

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Overview of Preemption Defense

Supremacy Clause

> Federal law "shall be the supreme Law of the Land . . . Any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."
>
> U.S. Const., Art. VI, cl 2

Overview of Preemption Defense

Manufacturer's compliance with federal law (e.g. federal safety standard or regulation) bars state tort claim that product is defective for not incorporating different design or warnings.

Overview of Preemption Defense

Preemption Analysis

- Congressional intent to preempt (or "clear and manifest purpose")
  - Express
  - Implied

Overview of Preemption Defense

Preemption Analysis

- Express Preemption Clause (e.g., when federal agency establishes standard, no State shall have authority to establish non-identical standard)
  - Savings Clause, (e.g., compliance with federal law does not exempt liability under common law)
- Implied Preemption
  - "Occupation of the Field" preemption
  - "Conflict" preemption
    - prevents or frustrates (or serves as "unacceptable obstacle" to) accomplishment of federal objective or
    - makes it impossible to comply with both state and federal law ("a demanding defense")
- Weight to be accorded to federal government's position

Bruesewitz v. Wyeth LLC, 562 U. S. ___, 131 S. Ct. 1068; 179 L. Ed. 2d 1 (2011)

Issue:

Whether National Childhood Vaccine Injury Act of 1986 ("NCVIA" or "Vaccine Act") bars state-law design-defect claims against vaccine manufacturers

Bruesewitz v. Wyeth LLC, 562 U. S. ___, 131 S. Ct. 1068; 179 L. Ed. 2d 1 (2011)

Facts:

- DTP vaccine made by Lederle Labs
- First approved by FDA in 1948
- At 6 months, Hannah Bruesewitz was administered DTP vaccine per CDC recommended schedule
- Within 24 hours, experienced seizures
- Diagnosis of “residual seizure disorder” and “developmental delay"

Bruesewitz v. Wyeth LLC, 562 U. S. ___, 131 S. Ct. 1068; 179 L. Ed. 2d 1 (2011)

Procedural History

- Plaintiffs filed Vaccine Injury Petition under Vaccine Act alleging "on-Table" injury
- Special master denied claims
- Parents elected to file suit in PA state court
  - Defective design
  - Strict liability
  - Negligent design
- Manufacturer removed case to federal court (ED PA)

Bruesewitz v. Wyeth LLC, 562 U. S. ___, 131 S. Ct. 1068; 179 L. Ed. 2d 1 (2011)

Vaccine Act

- US Court of Federal Claims
- No-fault compensation
- Vaccine Injury Table
  - If listed, no showing of causation
  - If unlisted or non-conforming presentation of side effects, must prove causation

Bruesewitz v. Wyeth LLC, 562 U. S. ___, 131 S. Ct. 1068; 179 L. Ed. 2d 1 (2011)

Vaccine Act

- *Quid Pro Quo* – Tort liability protection for vaccine manufacturers
  - Conditional immunity for failure to warn claims
  - Conditional immunity for punitive damages
  - Express elimination of liability for unavoidable adverse side effects

Bruesewitz v. Wyeth LLC, 562 U. S. ___, 131 S. Ct. 1068; 179 L. Ed. 2d 1 (2011)

Liability Limitation Clause in Vaccine Act

> "No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directives and warnings."
>
> 42 U.S.C. §300aa-22(b)(1)

Bruesewitz v. Wyeth LLC, 562 U. S. ___, 131 S. Ct. 1068; 179 L. Ed. 2d 1 (2011)

Holding:

Vaccine Act preempts design defect claims against vaccine manufacturers.

Bruesewitz v. Wyeth LLC, 562 U. S. ___, 131 S. Ct. 1068; 179 L. Ed. 2d 1 (2011)

Majority (Scalia, J.)

- Textual analysis
- Structural aspects of Vaccine Act and FDA regulatory scheme
- Consideration of legislative history *unnecessary*

Bruesewitz v. Wyeth LLC, 562 U. S. ___, 131 S. Ct. 1068; 179 L. Ed. 2d 1 (2011)

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Bruesewitz v. Wyeth LLC, 562 U. S. ___, 131 S. Ct. 1068; 179 L. Ed. 2d 1 (2011)

Majority - Textual analysis

- "Even though" clause clarifies "unavoidable"
  - For side effect to be considered "unavoidable," manufacturer must have properly prepared vaccine and provided proper directives and warnings
  - If liability for failure to use different design, "unavoidable would do no work."

Bruesewitz v. Wyeth LLC, 562 U. S. ___, 131 S. Ct. 1068; 179 L. Ed. 2d 1 (2011)

Majority - Textual analysis

- Omission of design-defect liability was deliberate choice, not inadvertence.

Bruesewitz v. Wyeth LLC, 562 U. S. ___, 131 S. Ct. 1068; 179 L. Ed. 2d 1 (2011)

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42 U.S.C. §300aa-22(b)(1)

Bruesewitz v. Wyeth LLC, 562 U. S. ___, 131 S. Ct. 1068; 179 L. Ed. 2d 1 (2011)

Majority - Textual analysis

- "If clause" is not a nullity, as dissent contends
  - some side effects are avoidable, some are unavoidable
- "If clause" means

  manufacturer must establish the condition(s) that the vaccine was properly labeled and manufactured

Bruesewitz v. Wyeth LLC, 562 U. S. ___, 131 S. Ct. 1068; 179 L. Ed. 2d 1 (2011)

Majority - Textual analysis

- Rejects "unavoidable" as term of art
- Comment k "Unavoidable unsafe products"

≠

"Side effects that were unavoidable"

Bruesewitz v. Wyeth LLC, 562 U. S. ___, 131 S. Ct. 1068; 179 L. Ed. 2d 1 (2011)

Majority – Structural Analysis

- Structure of Vaccine Act & FDA vaccine regulatory scheme
  - Persuasive regulation of manufacturing process and labeling
  - Silence on criteria to evaluate vaccine and competing designs.
  - Suggests a reason for omission of design defects was no basis of liability for design defects
- Vaccine Act provides other means to achieve two beneficial effects of design-defect torts (i.e., improved designs and compensation for unavoidable side effects)

Bruesewitz v. Wyeth LLC, 562 U. S. ___, 131 S. Ct. 1068; 179 L. Ed. 2d 1 (2011)

Majority – Structural Analysis

- Silence regarding design–defect liability was not inadvertent.
- Instead, "reflects a sensible choice to leave complex epidemiological judgments about vaccine designs to the FDA and National Vaccine Program rather than juries."

Bruesewitz v. Wyeth LLC, 562 U. S. ___, 131 S. Ct. 1068; 179 L. Ed. 2d 1 (2011)

Majority – Legislative History

- "Since [majority interpretation] is the only interpretation supported by the text and structure [of the Vaccine Act], even those of us who believe legislative history is a legitimate tool of statutory interpretation have no need to resort to it."
- Dissent's contention that legislative history contradicts preemption "is mistaken."

Bruesewitz v. Wyeth LLC, 562 U. S. ___, 131 S. Ct. 1068; 179 L. Ed. 2d 1 (2011)

Concurring Opinion (Breyer, J.)

- Textual question is close
- Therefore, would consider
  - legislative history
  - statutory purpose
  - FDA view (supported by expert medical opinion).
- Other sources reinforce Majority's conclusion

Bruesewitz v. Wyeth LLC, 562 U. S. ___, 131 S. Ct. 1068; 179 L. Ed. 2d 1 (2011)

Concurring Opinion (Breyer, J.)

Federal government (amicus brief) urges preemption

- Accorded "significant weight"
- Supported by leading public health organizations

Bruesewitz v. Wyeth LLC, 562 U. S. ___, 131 S. Ct. 1068; 179 L. Ed. 2d 1 (2011)

Dissenting opinion (Sotomayor, J.)

- Baseline rule:

  "State law shall apply to a civil action brought for damages for a vaccine-related injury or death." 42 U.S.C. §300aa-22

- Exception:

  Unavoidability as liability exemption

Bruesewitz v. Wyeth LLC, 562 U. S. ___, 131 S. Ct. 1068; 179 L. Ed. 2d 1 (2011)

Dissenting opinion (Sotomayor, J.)

- Text
- Structure
- Legislative history
- Supports no broad preemption of all design-defect claims

Bruesewitz v. Wyeth LLC, 562 U. S. ___, 131 S. Ct. 1068; 179 L. Ed. 2d 1 (2011)

Dissenting opinion (Sotomayor, J.)

- "If clause" reference to side effects that were unavoidable must refer to something other than manufacturing and labeling defects.
  - Only remaining and recognized defect – side effect caused by vaccine design

Bruesewitz v. Wyeth LLC, 562 U. S. ___, 131 S. Ct. 1068; 179 L. Ed. 2d 1 (2011)

Dissenting opinion (Sotomayor, J.)

- Congressional intent that vaccine manufacturer demonstrate that particular side effects of a vaccine's design were "unavoidable" and vaccine is otherwise free from manufacturing and labeling defects
- Presumption against preemption unless clear and manifest purpose of Congress (footnote 15)
- Decision to bar all design defect claims "is one that Congress must make, not this Court"

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Product Liability Preemption: Analyzing Recent Decisions by U.S. Supreme Court

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Why Preemption is Important

- First, preemption is potent. When applicable, the defense eliminates the entire failure-to-warn piece of the plaintiff's case, which typically includes the strict liability, negligence, warranty, and consumer protection act claims that are based on alleged inadequacies in the drug's package insert.

- Second, preemption is broad. Preemption applies to any claim challenging the adequacy of the generic drug's labeling, assuming compliance with the Hatch Waxman Amendments.

- Third, preemption is a legal question. Most defenses in product liability cases are tied to a particular plaintiff's facts: What did the treating physician say? What dose did the plaintiff ingest? When did the plaintiff take the drug?

Preemption Preamble

- On January 18, 2006, the FDA issued its rulemaking for labeling requirements that set forth the Agency's position on preemption of state court warning claims for FDA-approved drugs. "Preemption Preamble"
  - --Source of Confusion
  - --Created Inconsistent Rulings in Federal and State Jurisdictions

First Real Test: *Wyeth v. Levine,* 555 U.S. 555 (2009)

- It would have been impossible for Wyeth to comply with the state law duty to modify Phenergan's label without violating federal law

- Plaintiff's claim created an unacceptable obstacle to the execution of Congress' full purposes and objectives because it substitutes a lay jury's decision about drug labeling for the expert judgment of the FDA

REJECTED: *Wyeth v. Levine,* 555 U.S. 555 (2009)

- Court found that Wyeth could, in fact, have changed/strengthened its warning pursuant to the FDA's Changes Being Effected ("CBE") regulations which permit a manufacturer to change its "label to 'add or strengthen a contraindication, warning, precaution, or adverse reaction'" without waiting for agency approval."

  --CBE permits label changes when a company acquires new information and where new analyses or data justify a change

- "Powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness."

NARROW DECISION

- The Supreme Court decided *Levine* relatively narrowly. Other preemption doctrines—express preemption and field preemption remained unaffected.
- Court did not address applicability to generic manufacturers

Why Are Generic Manufacturers Different?

- Generic drugs are approved pursuant to an Abbreviated New Drug Application "ANDA"
- Generic manufacturers need not conduct clinical trials
- Must Show bioequivalence to reference listed drug "RLD"
- Generic drug labeling cannot deviate from the labeling of RLD
- Generic labeling must remain consistent with RLD
- Generic manufacturers could not use the CBE process

PLIVA, INC. v. Mensing, 564 U.S.___ (2011)

PLAINTIFFS' ALLEGATIONS

- Plaintiffs claimed they developed severe neurological problems (tardive dyskinsea) as a result of taking metoclopramide, a generic version of Wyeth's drug Reglan
- Plaintiffs filed claims against PLIVA, INC. (generic manufacturer) alleging, *inter alia*, that PLIVA failed to warn of the risks of developing tardive dyskinsea as a result of ingesting metroclopramide
- Plaintiffs alleged that PLIVA, INC. failed to request a labeling change through the CBE process
- Plaintiffs alleged that PLIVA, INC. failed to report safety information directly to the medical community

PLIVA, INC. v. Mensing, 564 U.S.___ (2011)

PLIVA, INC'S RESPONSE

- Plaintiffs Claims were preempted for two reasons:

1. It was impossible to add warnings required by Plaintiffs' claims because it would violate federal law which prohibits generic manufacturers from unilaterally adding or subtracting language from the label of the RLD

2. Plaintiffs' claims created an impermissible conflict with, and posed an obstacle to, congressional objectives applicable to generic drug manufacturers under the FDCA.

PLIVA, INC. v. Mensing, 564 U.S.___ (2011)

LOWER COURTS REJECTED PLIVA'S ARGUMENTS

- Eighth Circuit (Mensing)
- Fifth Circuit (DeMahy)

Both courts concluded generic manufacturers failed to show it was impossible to add warnings regarding the risks of developing tardive dyskinesia and comply with federal law because generic manufacturers could have (1) proposed a label change for both brand-name and generic drugs through the prior approval process; or, alternatively, (2) requested that the FDA send out a warning letter to health care professionals.

Both Courts also rejected defendants' argument that plaintiffs' claims created an impermissible conflict with, and posed an obstacle to, congressional objectives applicable to generic drug manufacturers under the FDCA.

PLIVA, INC. v. Mensing, 564 U.S.___ (2011)

- Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA) require generic manufacturers to utilize identical warning labels as their brand-name counterparts, it would be "impossible" for generic manufacturers to comply with both state and federal laws; therefore, state law must accordingly give way to federal law.

PLIVA, INC. v. Mensing, 564 U.S.___ (2011)

SUPREME COURT'S POSITION 5-4 (Thomas, J.)

- Rejected plaintiffs' argument that generic manufacturers could have unilaterally revised their product label under the CBE process.
- Deferred to FDA's interpretations regarding the CBE provisions, concluded that the CBE process was not available to generic drug manufacturers.
- Rejected plaintiffs' argument that generic manufacturers could have issued "Dear Doctor' letters to provide additional warnings to health care providers.
- Rejected any argument that the generic drug manufacturers could and therefore should have proposed stronger warning labels to FDA if they believed additional warnings were necessary

PLIVA, INC. v. Mensing, 564 U.S.___ (2011)

"Whether a private party can act sufficiently independently under federal law to do what state law requires may sometimes be difficult to determine. But this is not such a case. Before the [generic manufacturers] could satisfy state law, the FDA – a federal agency – had to undertake special effort permitting them to do so. To decide these cases, it is enough to hold that when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for preemption purposes."

PLIVA, INC. v. Mensing, 564 U.S.___ (2011)

DISSENT (SOTOMAYOR, J.)

- Require generic manufacturers to *prove* that FDA would not have accepted a label change request
- Presumption against Preemption
- Patient taking generic drug may be left without remedy

PLIVA, INC. v. Mensing, 564 U.S.___ (2011)

POSSIBLE EFFECTS?

- *Conte v. Wyeth*, 168 Cal.App.4th 89 (Cal.App. Dist.1 2008)
- *Kellogg v. Wyeth*, 612 F. Supp. 2d 437 (D. Vt. April 10, 2009)

Pre-emption Under the FMVSS

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Williamson v. Mazda Motor of America, Inc.

- Decision issued February 23, 2011, by US Supreme Court;
- Held: FMVSS §208 does not pre-empt state tort suits related to a manufacturer's decision not to install a lap and shoulder belt, instead of a lap only belt, in a rear center seat;
- Supreme Court found no express or conflict pre-emption.

Contrast: *Geier v. American Honda Motor Co., Inc.*

- May 22, 2000, US Supreme Court decision involving earlier version of FMVSS §208;
- In *Geier* the Court found that FMVSS §208 pre-empted state tort claims related to passive restraint systems.
- While there was no express pre-emption, state tort claims were pre-empted because they "stood as an obstacle to the accomplishment of a significant federal regulatory objective."

Geier
Three Questions for Pre-emption Analysis

1. Does the Act's express pre-emption provision pre-empt the state tort claim?

2. Does the saving clause bar or limit the operation of ordinary conflict pre-emption principles?

3. Does the state tort action conflict with the federal regulation?

Geier and *Williamson:* Striking Similarities

- Both cases involve FMVSS §208
- Both cases involve different generations of the same regulation
- Similar claims about vehicle safety restraining devices
- In both cases the Supreme Court found no express pre-emption and that the savings clauses did not preclude the operation of conflict pre-emption.

DuaneMorris

Geier and *Williamson:* Different Outcomes

- In *Geier* state law tort claims were pre-empted by FMVSS §208's requirement for passive restraint system
- In *Williamson* state law tort claims for seat belt system were not pre-empted by FMVSS §208
- Supreme Court's explanation: In *Geier* the state tort action was an obstacle to accomplishing a "significant federal regulatory objective," but not so in *Williamson*.

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Rectifying *Geier* and *Williamson*

- In *Geier* the manufacturers had a choice of passive restraint systems, and the choice was allowed to promote safety*;*
- In *Williamson* the choice in lap and shoulder vs. lap only seat belt systems was based upon the regulatory belief that requiring lap and shoulder belts in all interior seats would not be cost effective.
- Cost benefit analysis left to manufacturers.

PANEL COMMENTS

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