

LOSS CONTROL
WEBINAR SERIES



***PHARMACOVIGILANCE
IN A POST
WYETH v. LEVINE WORLD***

*Wednesday, March 24, 2010
2:30 p.m. – 3:30 p.m. EST*

Genese K. Dopson

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Wyeth v. Levine

- On March 4, 2009, the U.S. Supreme Court decided *Wyeth v. Levine* and found that approval of a drug label by the Food and Drug Administration (FDA) does not give rise to the defense of federal preemption to shield the brand drug manufacturer from failure to warn claims.
- *The possibility of the defense of federal preemption for a brand drug manufacturer is not available in failure to warn claims.*

One year later

- Written opinions from courts throughout the country hold the defense of federal preemption is not available for brand prescription drug manufacturers.
- The majority of courts throughout the country have issued opinions that hold the defense of preemption is no longer available to generic prescription drug manufacturers.
- The growing impact on the manufacturer's duties related to pharmacovigilance.

Pharmacovigilance

- The science and activities related to the detection, assessment, understanding, and prevention of adverse effects or other drug related problems.

Webinar content

- We will review *Wyeth v. Levine* and some of the significant federal enactments and court decisions to examine how *Wyeth* has impacted and will likely continue to impact brand and generic drug manufacturers.
- We will conclude by briefly touching on:
 - *Wyeth's* impact on the development of warnings and labels
 - Trends in products liability litigation related to pharmacovigilance
 - The relationship between pharmacovigilance and product liability litigation
 - Risk management recommendations
 - The need for “transparency” throughout a company’s operations

What is “Preemption”?

- **Preemption comes from the Supremacy Clause of the U.S. Constitution.**
 - *The Constitution and laws of the United States shall be: **the supreme law of the land.***
 - *This means that federal law supersedes state law.*
 - *Preemption is a powerful affirmative defense that can preclude state tort law (barring lawsuits) if it applies.*

When does “Preemption” apply?

- **Express preemption**
 - A federal law or federal regulation specifically provides that the federal enactment supersedes state law.
- **Implied field preemption**
 - Arises when a state law occupies a field reserved for federal regulation or where the federal regulation is so pervasive that it is reasonable to infer Congress left no room for the States to supplement the federal law.
- **Implied conflict preemption**
 - Arises when a state law conflicts with a federal law and it is impossible for a private party to comply with both state and federal requirements or when state law is an obstacle to the accomplishment and execution of the purpose and objectives of Congress.

Why all the focus on preemption?

- ***Reigel v. Medtronic (Feb. 2008)***

- The U.S. Supreme Court held that Congress expressly preempted state tort law claims against medical device manufacturers whose devices are approved by the FDA under the more rigorous statutory scheme of (21 U.S.C. §360k(a).)

- ***Hope for the pending case of Wyeth v. Levine***

- After *Reigel*, brand drug manufacturers and defense attorneys hoped the Supreme Court would extend preemption defense for brand prescription drugs for failure to warn claims because FDA approved the labeling.

Leading up to the decision in Wyeth v. Levine...

History of Federal Regulation

Preemption: The Court must determine the intent of Congress

- *Did Congress intend the federal law to occupy the field?*
 - * *If yes, preemption applies*
 - * *If not, is there a conflict between state law and federal law?*
 - * *If not, is the state law an obstacle to the purpose of Congress?*

Congress enacted:

The first significant public health law in 1906

- Federal Food and Drugs Act,
(ch. 3915, 34 Stat. 768.)
- The Act prohibited the manufacture or interstate shipment of adulterated or misbranded drugs and supplemented protections for consumers that were already provided by state regulation and state common law liability.

In the 1930's Congress enacted: the Federal Food Drug, and Cosmetic Act (FDCA)

- **FDCA**
(ch.675, 52 Stat. 1040, as amended, 21 U.S.C. § 301 et seq.)
 - Out of increased concern about unsafe drugs and fraudulent marketing.
 - The Act provided for premarket approval of new drugs and required every manufacturer of a new drug to submit a new drug application (NDA), inclusive of reports about investigations and specimens of proposed labeling to the Food and Drug Administration (FDA) for review.

FDCA (continued)

- The Act also prohibited a manufacturer from distributing the new drug until the FDA approved the new drug application.
- The FDA could also reject an application if it determined the drug unsafe for use as labeled, *although if the agency failed to act, the application became effective 60 days after the filing.* (FDCA, §505(c), 52 Stat. 1052.)

Congress: **amended the FDCA in 1962**

- Required the manufacturer to demonstrate that its drug was safe and effective.
(§§ 102(d) 104(b), 76 Stat. 781, 784.)
- Prior to this, FDA had the burden to prove a drug was not safe. The amendment shifted the burden.
- The drug manufacturer is required to show proof that its drug is:

“safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling” and produce “substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling.

- The FDA approves product labeling as part of the NDA submission process.
(21 U.S.C. § 355; 21 C.F.R. § 314.105(b).)

Congress: Amended the FDCA in 1962

- The Supreme Court explained:
 - While Congress enlarged the FDA's powers to "protect the public health" and "assure the safety, effectiveness, and reliability of drugs," ***it also took care to preserve state law.***
 - In fact, the 1962 amendments added a saving clause specifying that a provision of state law would only be invalidated upon a "direct and positive conflict" with the FDCA.
 - Significantly, suits under state common law have continued to be filed unabated despite FDA regulation.
 - ***Even more significant, when Congress enacted an express preemption provision for medical devices in 1976 it declined to enact such a provision for prescription drugs.*** (§521, 90 Stat. 574; codified at 21 U.S.C. §360k(a).)

Wyeth v. Levine decision

1984 (ANDA)

The abbreviated new drug application

- Under the provisions of the Drug Price Competition and Patent Restoration Act of 1984, PL 98-417, more commonly known as the ***“Hatch-Waxman Act”***.
 - A generic manufacturer is not required to prove that its product is safe and effective, only that the product is ***“bioequivalent”*** to the brand name, or ***“listed”*** product.
 - Generally speaking, a drug is considered “bioequivalent” if the rate and extent of absorption of the generic product is not significantly different from that of the brand product.
(21 U.S.C. § 355 (j)(8)(B).)
 - The conditions of use and warning for the generic versions of the product must be identical to those for the brand-name product.
(21 U.S.C. § 355 (j)(2)(A).)

2007

Congress amends the FDCA

- In 2007, (121 Stat. 823)
- For the first time FDA is granted statutory authority:
 - To require a manufacturer to change its drug label based on safety information that becomes available after a drug's initial approval. (§ 901(a).)
 - A manufacturer is required to revise labeling to include additional warning information as soon as there is reasonable evidence of an association of a serious hazard. (21 C.F.R. § 201.80(e).)

March 4, 2009

Wyeth v. Levine decision

- *The 2007 Amendment did not contain a provision that required FDA to preapprove all changes to drug labels.*
 - Instead, the Amendment adopted a rule of construction to make it clear that manufacturers remain responsible for updating their labels. (121 Stat. 925-926.)
 - The manufacturer may change a products labeling after providing the FDA with notice of the change and the manufacturer can then effect the labeling change prior to actual FDA approval under the provisions of (21 C.F.R. §314.70(c)), which is referred to as the ***“change being effected” (CBE) provision.***
 - The CBE may be utilized only to ***“add or strengthen a contraindication, warning, precaution, or adverse reaction”***
or
 - To ***“add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product”.***
21 C.F.R. §§ 314.70(c)(6)(iii), (C).

Prior to Wyeth v. Levine

- Generic drug manufacturers vehemently argued the requirement:
 - that the labeling of the generic drug be identical to the brand label created grounds for preemption...
 - *because* the generic drug manufacturer could not comply with federal law requiring generic labeling to be identical to the brand labeling and...
 - also be subjected to state law claims that its labeling was inadequate.

Post Wyeth v. Levine

- The majority of decisions around the country hold:
 - that drug manufacturers,
including generic manufacturers:
 - are charged with crafting an adequate label
and
 - with ensuring that prescription drug warnings remain adequate as long as the drug is on the market.

U.S. Supreme Court Decision
in
Wyeth v. Levine

Wyeth v. Levine

129 S.Ct. 1187 (March 4, 2009)

- Plaintiff was supposed to receive an intravenous injection of Phenergan, which is a brand drug manufactured by Wyeth.
- However, the drug entered Levine's artery and she developed gangrene resulting in the amputation of a forearm.
- She sued in Vermont state court alleging Wyeth had failed to provide an adequate warning about the significant risks associated with administering Phenergan by intravenous injection.
- The Vermont jury found Levine's injury would not have occurred if Phenergan's label had an adequate warning and awarded in favor of the plaintiff.
- The trial court ***refused to overturn the jury's verdict based on Wyeth's claim that plaintiff's failure to warn claims were preempted by federal law because the labeling had been approved by the FDA.***

Wyeth v. Levine

In U.S. Supreme Court, Wyeth argued:

- That the state law claims were preempted because it was impossible for Wyeth to comply with both the state law duties underlying those claims and its federal labeling duties. *The preemption argument was rejected.*
- The Supreme Court noted that, although a manufacturer generally may change a drug label only after the FDA approves a supplemental application, *the agency's "changes being effected" (CBE) regulation permits certain preapproval labeling changes that add or strengthen a warning to improve drug safety.*
- Pursuant to the CBE regulation, Wyeth could have unilaterally added a stronger warning about intravenous administration and there was no evidence that FDA would have rejected such a labeling change.

Wyeth v. Levine

The U.S. Supreme Court noted:

- That Wyeth's cramped reading of the CBE regulation and its broad assertion that unilaterally changing the Phenergan label would have violated federal law governing unauthorized distribution and misbranding of drugs are based on:

the fundamental misunderstanding that the FDA, rather than the manufacturer bears primary responsibility for drug labeling.

- It is a central premise of the Food, Drug, and Cosmetic Act (FDCA) and the federal regulations

that the manufacturer bears responsibility for the content of its label at all times.

Impact of:
Wyeth v. Levine

A Brand Prescription Drug Manufacturer Owes No Duty to Plaintiff Consuming a Generic Product

Case specific examples: 

Moretti v. Wyeth

U.S.D.C. (Nevada) (March 20, 2009)

- Plaintiff was diagnosed with a neurological disorder called tardive dyskinesia after she consumed generic metoclopramide.
- She sued Wyeth, the brand manufacturer of Reglan (metoclopramide), alleging fraud and misrepresentation.
- Wyeth's summary judgment was granted.
 - The Nevada court granted Wyeth's motion for summary judgment and held that a brand manufacturer has no duty to warn about the risks associated with their competitor's drugs.

Morris v Wyeth, Inc, et al.
U.S.D.C. (W.D.Louisiana) (November 23, 2009)

- Held that:

The brand prescription drug manufacturer

may not be held liable under the law of Louisiana

for the warning provided by a generic manufacturer.

Schrock v Wyeth et al.

601 F. Supp. 2d 1262, 1267 (W.D. Okla. 2009)

- Plaintiffs sued Wyeth and generic manufacturers for failure to warn after she developed tardive dyskinesia following her consumption of generic metoclopramide.
- In granting Wyeth's motion for summary judgment, the court noted that:
 - *twenty-four courts in fourteen different states have rejected the assertion that a brand prescription drug manufacturer has a duty to warn about a product it did not manufacture.*

The majority of courts that have issued opinions find:

- The preemption defense:
is not available to Generic Drug Manufacturers.
- Generic Drug Manufacturers:
have a duty to warn.

A couple of case specific examples: 

Schrock v Wyeth et al.

601 F. Supp. 2d 1262, 1267 (W.D. Okla. 2009)

- Plaintiffs sued Wyeth and generic manufacturer for failure to warn after she developed tardive dyskinesia following her consumption of generic metoclopramide. Plaintiff never consumed the Wyeth's product.
- The generic defendant filed a motion to dismiss asserting federal law (ANDA) required its labeling to be the same as the brand drug and that it could not comply with both state and federal law and asserting state law must be preempted.
- The court cited *Wyeth v. Levine* in denying the generic drug manufacturers' motion to dismiss based on the argument of federal preemption.

Stacel v. Teva Pharmaceuticals, USA ***620 F.Supp.2d 899 (N.D. ILL. 2009)***

- Plaintiff sued the generic manufacturer claiming her drug-induced lupus was caused by minocycline. She claimed negligent failure to warn, fraud and misrepresentation.
- Teva moved to dismiss based on preemption under the FDCA (ANDA), arguing its labeling must be the same as the label of the brand prescription drug manufacturer and that CBE “Change being effected” provisions of 21 C.F.R. § 314.70 do not apply to manufacturers of generic drugs.
- The court disagreed and denied Teva’s request for preemption and the motion to dismiss finding key parts of the Supreme Court’s decision in *Wyeth v. Levine* applicable to generic manufacturers...

Stacel v. Teva Pharmaceuticals, USA

620 F.Supp.2d 899 (N.D. ILL. 2009) (continued)

Citing to *Wyeth v. Levine*, the *Stacel* court noted:

“First, the [Supreme] Court noted that when Congress amended the FDCA in 1982 to expand the FDA’s powers to protect the public health and to assure the safety, effectiveness, and reliability of drugs, Congress expressly found that state-law claims should not be preempted except for incidents of ‘direct and positive conflict’ with the FDCA. Subsequent amendments continued to affirm this position. **‘[T]hrough many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulations that the manufacturer bears responsibility for the content of its label at all times.’** **Manufacturers are ‘charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market.’** [21 C.F.R. § 201.80(e) requires manufacturers to revise labels to include additional warning information ‘as soon as there is reasonable evidence of an association of a serious hazard with a drug.] Although the FDA could subsequently reject the amended label, the [Supreme] Court was unpersuaded by the argument that manufacturers ran the risk of being accused of having ‘misbranded’ their products by utilizing the CBE process. ... The [Supreme] Court also observed that the manufacturer’s argument would leave injured parties with no remedy, for injured parties have no cause of action under the FDCA. Although Congress has the authority to eliminate certain remedies if it chooses to do so, the [Supreme] Court assumed Congress ‘determined that widely available state rights of action provide appropriate relief for injured consumers.’ Congress was aware of state tort remedies and chose not to foreclose them.”

Pharmacovigilance Has Arrived

Forst v. Smithkline Beecham Corp.

602 F. Supp.2nd 960 (2009)

- Gary and Bonita Forst sued GlaxoSmithKline (GSK), the brand manufacturer of Paxil CR, alleging after Gary attempted suicide two weeks after he began using the drug:
 - Negligence
 - ***Negligent pharmacovigilance***
 - Strict liability for failure to warn related to the adequacy of its warnings
- Plaintiffs asserted the labeling did not have any specific warnings regarding an increased risk of suicidality caused by Paxil itself.

Forst v. Smithkline Beecham Corp.

602 F. Supp.2nd 960 (2009)

- GSK filed a motion for summary judgment arguing it owed no duty to warn about possible adverse effects as no causal link had been established between Paxil and increased suicidality in patients over age 24.
- GSK's motion was denied in its entirety after Plaintiffs submitted evidence that Dr. Russell Katz of the FDA stated that Paxil's clinical trial data showed "causality" and plaintiffs pointed to GSK's own 2006 analysis of its previous clinical trial data that demonstrated a patient on Paxil was six times more likely to attempt suicide as one on a placebo.
 - ***The court opined that GSK was not insulated from plaintiff's failure to warn claims because the FDA did not require enhanced warnings.***

Forst v. Smithkline Beecham Corp.

-- continued

- In response to GSK's assertion that its product carried FDA approved labeling and additional warnings would have violated federal law...
 - **The court specified that drug manufacturers have an affirmative duty to add new warnings to drug labels as soon as there is *reasonable evidence of an association of a serious hazard* with the drug and that a causal relationship need not have been proved.**
(21 C.F.R. § 201.80.)
- *Thus GSK had a duty to update its labeling to warn against the enhanced risk.*

**Trends In
Product Liability Litigation
Related to
*Pharmacovigilance***

Pharmacovigilance

- Relates to:
 - The collection, monitoring, researching, assessing and evaluating information
 - From healthcare providers and patients
 - About adverse effects of medications
 - With a view toward identifying new information about hazards associated with medicines and preventing harm to patients.
 - Pharmacovigilance is concerned with:
 - instances of *adverse drug reaction (ADR)*.
 - An **ADR** is officially described as:
 - “A response to a drug which is noxious and unintended, and which occurs at doses normally used for the prophylaxis, diagnosis or therapy of disease or for the modification of physiological function.”

How does Pharmacovigilance pertain to product liability litigation?

Pharmacovigilance in litigation

- Plaintiff attorneys continue to ask the following questions:
 - “What did the company know?”
 - “When did the company know?”
 - “How long did it take for the company to take remedial action?”
- Why do plaintiff attorneys ask these questions?
 - Simple, they are looking for any delay to take action.
 - Delayed action is the recipe for big plaintiff verdicts.
 - *Wyeth v. Levine* and its progeny make it clear
 - that brand and generic drug companies bear primary responsibility for drug labeling at all times,
 - that there is a mechanism in place to provide notice to the FDA and initiate labeling changes prior to obtaining FDA approval.
- **Lesson:** *There may be no valid excuse for failing to act.*

Cost of Litigation: eDiscovery

- Drug companies must exercise pharmacovigilance from the inception throughout the life of the drug.
- We should expect Plaintiff attorneys to seek documentation about standard operating procedures related to:
 - receipt of information about adverse events,
 - adverse event investigation,
 - reporting and analysis,
 - the adequacy of adverse event investigation, reporting and analysis,
 - as well as action taken by the drug company.



Forst v. GlaxoSmithKline

negligent pharmacovigilance

- Plaintiff actually included a cause of action for ***negligent pharmacovigilance*** in addition to inadequate warnings.
- The plaintiff attempted suicide on March 17, 2004, as a result of taking Paxil, an antidepressant that made him even more depressed.
- **The plaintiffs sought and obtained discovery about similar adverse events as far back as 1989.**
- The plaintiff defeated GSK's summary judgment motion by demonstrating that GSK's own 2006 analysis of its previous clinical trial data demonstrated a patient on Paxil was six times as likely to attempt suicide as one on a placebo.
- Negative evidence related to a manufacturer's diligence in its pharmacovigilance can be ***powerful evidence*** in favor of a plaintiff's claim for compensatory and punitive damages.

Risk Management Recommendations

Adverse reaction/event collection and single case processing

- Maintenance of validated database for:
 - centralized collection,
 - permanent retention,
 - retrieval of postmarketing spontaneous reports.
- Real time medical review of all post-marketing adverse reaction reports
- Follow-up of appropriate cases
- Preparation and electronic submission of case reports to regulatory authorities

Post-marketing signal detection

- Periodic review of line listings for suspected adverse reactions.
- Signal detection methodology appropriate to the drug and number of adverse incidents.
- Surveillance of post-marketing risks based on assessment and evaluation of collected adverse reaction data.
- Routine review of the worldwide scientific literature based on safety literature searches performed on weekly basis.

Aggregate reports

- Preparation of reports for health authorities, including Periodic Safety Update Reports and equivalent safety summaries.
- Ad hoc safety reports or interim reports on specific topics as requested by FDA, regulatory authorities or as dictated by signal detection activities.

Continuous oversight of safety

- Continuous monitoring and management of the safety profile and benefit risk balance of marketed products.
- Activities as a result of pharmacovigilance issues including labeling updates, assessment of need for risk minimization measures and communication with FDA and other regulatory authorities as appropriate.

The need for
“transparency”
throughout a company’s
operations

Pharmacovigilance

There is no hiding the ball.

In litigation:

- the rules for discovery are broad and courts are liberal in allowing plaintiffs access to information.

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UPCOMING WEBINAR

Pharmacovigilance - March 24, 2010 2:30 PM EDT



Genese K. Dopson, JD, is a Partner in the San Francisco office of Wilson Elser Moskowitz Edelman & Dicker LLP. She is a former Oncology Head Nurse and her practice focuses on the defense of pharmaceutical and medical device manufacturers, as well as personal injury and employment discrimination matters. In this webinar, Ms. Dopson recaps the *Wyeth v. Levine* decision and recent state court decisions and discusses how *Wyeth* has impacted—and likely will continue to impact—generic drug manufacturers.

FDA Outlook for 2010

- Webinar, Slides
- Podcast (15 minutes)

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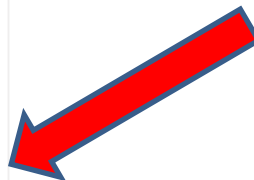
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PHARMACOVIGILANCE

Of the issues that have long faced the drug industry, drug safety is at the top of the list. Pharmacovigilance is the term used for the **drug safety system oversight**. The FDA defines it as "all scientific data gathering activities related to the detection, assessment and understanding of adverse events." These resources contain information about pharmacovigilance and **related trends in products liability litigation**.

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