

Forget Tort Reform We want Immunity!!

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I. Introduction

Large corporations and business interests are tired of the “death by a thousand cuts” approach to so-called tort reform efforts. The Tort reform “cuts” were in many forms such as arbitration; who recalls the Scintilla rule?; caps on damages; Daubert or expert challenges; some folks even claim business biased judges sit on appellate courts throughout the country. That is simply not enough. The most recent attempt at national tort reform is better described as tort destruction. The current administration’s attempts to preempt state law by inserting pro-preemption language in federal agency rules has been characterized as back-door tort “reform.” The effort has surfaced in places as diverse as:

- The FDA’s prescription drug labeling regulations
- The Consumer Product Safety Commission’s mattress flammability standard
- The National Highway Traffic Safety Administration’s roof crush standard
- The Department of Transportation’s regulations governing fuel economy

Recent News: October 15, 2008 Wall Street Journal article reported that Bush administration officials, in their last weeks in office, are pushing to rewrite a wide array of federal rules with changes or additions that could block product safety lawsuits by consumers and States. The administration has written language aimed at preempting product litigation into 50 rules governing everything from motorcycle brakes to pain medicine. In 2008 alone, lawsuit protection language has been added to 10 new regulations, including one issued October 8 at the Department of Transportation that limits the number of seatbelts car makers can be required to install and prohibits suits by injured passengers who did not get to wear one. None of these has gone through the publication and public hearing process. Congress has not passed legislation to this effect. This is a one man effort.

Preemption is meant to be used in rare circumstances—to ensure that legal rights are protected. Now preemption is being used to take away rights, which is a perversion of its purpose.

For consumers, workers, the injured and other victims, preemption may be a brick wall like no other. When your client has been injured by a defective car, truck, medical device, boat, tobacco product, pesticide, or pharmaceutical drug, or has been victimized by a bank or other lending institution, the defendant will probably assert that federal law preempts your client's state law damages claim.

II. Definition of Preemption

The Supremacy Clause – “This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land . . . any thing in the Constitution or Laws of any State to the Contrary notwithstanding.” Art. VI, cl. 2.

Preemption Defined – a constitutionally mandated principle which demands that federal law trumps state law when the two conflict or in the rare instances when a federal law is so comprehensive that there's no role left for state law to fill.

A. *Express Preemption* – Express preemption exists if a federal statute explicitly states that it preempts state law (and if Congress, in passing the statute, was exercising authority granted to it under the U.S. Constitution).

1. The federal Employee Retirement Income Security Act of 1974 (ERISA) preempts all state laws “insofar as they may now or hereafter relate to any employee benefit plan,” except that state “laws . . . which regulate insurance, banking, or securities” are saved from preemption. 29 U.S.C. 1144(a) and (b)(2)(A).
2. The Interstate Commerce Commission Termination Act preempts state laws concerning price, routes, or services of motor carriers, except that “the safety regulatory authority of a state” with respect to motor vehicles is saved from preemption.

B. *Implied Preemption* – also known as field preemption, arises when Congress has legislated comprehensively, thus occupying an entire field of regulation and leaving no room for the States to supplement federal law.

1. Nuclear Safety. Pacific Gas & Electric Co. v. State Energy Resources Conservation & Dev. Comm'n, 461 U.S. 190, 212-13 (1983).
2. Collective Bargaining. Metropolitan Life Ins. Co. v. Massachusetts, 471 U.S. 724, 750-51 (1985).
3. Alien Registration. Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

4. Airline Safety and Travel. City of Burbank v. Lockheed Air Terminal, Inc., 411 U.S. 624, 638-39 (1973).

Respondent air terminal asked for an injunction against the enforcement of an ordinance adopted by petitioner city, which made it unlawful for a so-called pure jet aircraft to take off from the city's airport between 11 p.m. of one day and 7 a.m. the next day, and also made it unlawful for the operator of that airport to allow any such aircraft to take off from that airport during such periods. The district court found the ordinance to be unconstitutional on both [Supremacy Clause](#) and [Commerce Clause](#) grounds. The appellate court affirmed the district court on the grounds of the [Supremacy Clause](#). On appeal, the city argued that though the federal government had the right to regulate airspace, that the city should be able to impose regulations for its own airport. The court held that the Federal Aviation Act of 1958, as amended by the Noise Control Act of 1972, controlled the preemption issue and mandated federal preemption over the ordinance because the Federal Aviation Administration, in conjunction with the Environmental Protection Agency, had full control over aircraft noise, which therefore preempted state and local control. The ordinance therefore could not stand.

C. Conflict Preemption – exists in two forms:

1. Direct Conflict – also known as impossibility preemption; occurs when it is impossible for a private party to comply with both state and federal requirements.
2. Indirect Conflict – also known as obstacle preemption; exists where state law stands as an obstacle to the accomplishment and execution of the full purpose and objectives of Congress.

III. Supreme Court Preemption Decisions

***Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992)** – this case involved warnings on cigarette labels. The Supreme Court held that state **claims based on failure to warn were preempted** by the Public Health Cigarette Smoking Act of 1969. The Court determined that the broad language of the preemption provision in the 1969 Act expressly preempted state law claims based on failure to warn. Claims based on express warranty, intentional fraud and misrepresentation, or conspiracy were not preempted.

***Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996)** – this case involved a pacemaker wire. The U. S. Supreme Court held that state claims regarding the negligent design of the pacemaker wire were not expressly preempted because the review process was not a review of the safety and efficacy of the device, and therefore, did not impose any “requirements” that would preempt state law.

Sprietsma v. Mercury Marine, 537 U.S. 51 (2002) – this case involved propeller guards. The U. S. Supreme Court held that the Federal Boat Safety Act of 1971 did not expressly or impliedly preempt the plaintiff’s state law claims. The preemption clause of the 1971 Act only applied to state statutes and regulations, and the savings clause of the Act specifically preserved liability under state common law.

Bates v. Dow Agrosciences, L.L.C., 544 U.S. 431 (2005) – this case involved a pesticide. The U. S. Supreme Court held that Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) did not expressly or impliedly preempt the plaintiffs’ state-law damages claims as the claims could not impose requirements in addition to or different from FIFRA’s.

Riegel v. Medtronic, 128 S. Ct. 999 (2008) – The U. S. Supreme Court addressed the issue of whether 21 U.S.C. 360k(a) preempts state law tort claims against medical device manufacturers that have received pre-market approval (PMA) under the Medical Device Amendments Act (MDA). The Court held that the MDA’s preemption clause bars common law claims challenging the safety or effectiveness of a medical device marketed in a form that received PMA from the FDA. That case evaluated heart devices, which are Class III medical devices approved through a PMA process. Thus, although Congress included express preemption for certain devices the Riegel decision does not preempt all device cases.

For example, our firm is currently handling a somewhat new litigation involving pain pumps used to manage post operative pain. Though preemption will be asserted we believe this defense will fail. Pain pumps are Class II medical devices and have been in use since the 1980’s. Unlike Class III devices, pain pumps did not undergo the FDA PMA approval process. Pain pumps are “substantially equivalent” to devices that are already approved under a PMA process thus the manufacturers did not need to submit substantial safety and efficacy data on their products to the FDA prior to putting them on the market. In other words, the pain pump manufacturers marketed and promoted their products without extensive FDA oversight and approval. Device cases will continue to be evaluated on a case by case basis and are not all preempted as a result of Riegel.

IV. An Alabama Preemption Decision

Barnhill v. TEVA Pharmaceuticals, USA, Inc. (S.D. Ala. 2007) (Butler, J.) – a 12 year old child from Atmore developed Stevens-Johnson-Syndrome after taking an antibiotic manufactured by the defendant. She filed numerous state law claims against the manufacturer.

- A. Defendant’s argument** – all of plaintiff’s claims are due to be dismissed because the manufacture and sale of the drug is regulated by federal law and FDA regulations. Consequently, the doctrine of federal preemption precludes liability under state law especially considering the fact that this is a generic version of the drug.

B. The Court's determination that the plaintiff's claims are not preempted

1. There is a general presumption against preemption of state tort law claims
 - a. Congress does not cavalierly preempt state-law causes of action
 - b. Because matters of public health and safety traditionally fall within the domain of the states, it must be presumed that Congress did not intend to supersede the states' powers to regulate – “**States rights**”
 - c. Historically, common law liability has formed the bedrock of state regulation, and common law tort claims have been described as “a critical component of the States' traditional ability to protect the health and safety of their citizens
 - d. The presumption against preemption in these areas also applies to regulations issued by a federal agency
 - e. To prevail on its preemption argument, the defendant must demonstrate a conflict between state tort law and federal labeling requirements “that is strong enough to overcome the presumption that state and local regulation of health and safety matters can constitutionally coexist with federal regulation”
2. The FDA's labeling requirements do not conflict with State failure to warn claims
 - a. The FDA regulations quite clearly permit manufacturers to make unilateral changes in labeling to add new warnings or strengthen existing ones, EVEN GENERIC DRUGS:

“The FDA regulations quite clearly permit manufacturers to make unilateral changes in labeling to add new warnings or strengthen existing ones. 21 C.F.R. § 314.70(c)(6)(iii). Consequently, as numerous courts have held, it is possible to comply with the FDA's labeling requirements *and* provide additional warnings that might be necessitated by state law. But Teva USA argues that our case is different because it involves a generic drug, and the FDA *may* revoke approval if the generic label no longer conforms to the label of the listed drug.

Teva USA points to 21 C.F.R. § 314.150(b)(10) which permits the FDA to withdraw approval of an ANDA if its labeling is no longer consistent with the labeling for the listed drug. However, the purpose of this regulation was not to prevent a generic manufacturer from improving or

strengthening its warnings. It was, instead, to ensure that the FDA could require a generic manufacturer “to modify its labeling to match labeling changes in the reference listed drug.” 57 Fed. Reg. 17970. In other words, if the manufacturer of the listed drug changes its labeling, the FDA can require the generic manufacturer to do so as well. This is the only harmonious interpretation of the two regulations. Otherwise, the FDA permits a generic manufacturer to strengthen or modify its labeling, on one hand, only to suspend its approval because the new label does not conform to the label for the listed drug.” Citing Judge Butler’s Order

- b. It is possible to comply with the FDA’s labeling requirements and provide additional warnings that might be necessitated by state law

3. The FDA’s current position on labeling and preemption is not binding and should not be given deference

- a. The FDA’s preamble to the 2006 implementing regulations, which states that the FDA believes that under existing preemption principles, FDA approval of labeling under the FDCA preempts conflicting or contrary state law, is a nonbinding advisory opinion

Note: The process of implementing new rules at FDA began several years ago. The rules have to be made public and hearings are held for public comment. The Preamble was inserted a couple of years AFTER the hearings by the administration with no public comment or hearing being made on the preamble.

- b. The best reason for rejecting the Preamble is that whatever deference would be owed to an agency’s view in contexts where a presumption against federal preemption does apply, an agency cannot supply on Congress’s behalf, the clear legislative statement of intent required to overcome the presumption against preemption
- c. An agency’s advisory opinion is entitled to deference only to the extent it has the power to persuade
- d. The FDA’s position is not persuasive
 - 1. It represents an about-face from the agency’s position until 2001, that the FDA labeling rules were not intended to preempt state law

2. It leads to a result contrary to the purpose of the FDCA – if an FDA-approved label establishes both a floor and a ceiling for a manufacturer’s duty to warn, then the manufacturer has no incentive ever to disclose risk information it may subsequently discover
3. It would nullify its own regulations which place an affirmative duty upon drug manufacturers to revise a drug’s label to include a warning “as soon as there is reasonable evidence of an association of serious hazard with a drug”

V. The Upcoming Supreme Court Preemption Decision

Wyeth v. Levine (2008) – On April 7, 2000, Diana Levine went to a clinic near Marshfield, Vermont to treat a migraine headache. She received an intramuscular injection of Demerol (for her headache), along with Phenergan (for nausea, which is associated with a migraine headache and is a common side effect of Demerol). After Ms. Levine's migraine recurred later that day, she returned to the clinic, where she received a second Demerol-Phenergan combination. In accordance with the instructions in Phenergan's package insert, the physician's assistant administered this dose of Phenergan through an IV-push injection into Ms. Levine's right arm.

During the IV-push injection, the Phenergan penetrated one of Ms. Levine's arteries. In the ensuing weeks, the tissue in her right forearm died and she experienced extreme pain. Her fingers slowly turned black as they lost all blood circulation.

Doctors initially amputated Ms. Levine's hand. After several days, during which the gangrene spread down her forearm and Ms. Levine continued to experience excruciating pain, she underwent a second operation to amputate what was left of her forearm below her elbow. After her amputations, Ms. Levine has continued to experience physical and “phantom pain” in her right arm and tendonitis from over-using her left arm, while enduring emotional trauma and depression.

In Vermont Superior Court, Ms. Levine asserted state-law negligence and products-liability claims premised on Wyeth's failure to provide proper warnings and instructions regarding the foreseeable risks of IV-push injection of Phenergan. The amended complaint alleged that Phenergan was defective because, among other things, the company failed to instruct clinicians to administer the drug intravenously using the IV-drip technique.

In its verdict, the jury specifically rejected Wyeth's contention that unforeseeable negligence of the physician's assistant, rather than Wyeth's failure to warn, caused Ms. Levine's injury. The jury awarded damages to compensate Ms. Levine's economic and non-economic losses - including past and future medical expenses and the loss of her ability to earn a living.

The trial court denied Wyeth's post-judgment motion asserting preemption. The court recognized that Wyeth could comply with both Vermont law and federal law, because FDA's CBE regulation permitted Wyeth to change its labeling to prohibit IV-push administration or strengthen the warnings about IV push without prior FDA approval.

The Vermont Supreme Court affirmed, concluding that Wyeth had shown no “actual[] conflict[]” between the trial court's judgment and federal law.

The drug company appealed to the United States Supreme Court. The Court granted certiorari to answer the following question.

A. *The question presented . . .*

Whether Food and Drug Administration (“FDA”) approval of a prescription drug's labeling preempts state-law failure-to-warn claims in the absence of any express preemption provision in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., or any evidence that FDA considered the risks and benefits of the specific method of administering the drug that caused the injuries upon which the state-law claim is premised.

B. *The plaintiff's position . . .*

- I. Congress’s long acceptance of state-law failure-to-warn claims against drug manufacturers decisively undermines Wyeth’s implied preemption argument
 - A. In The FDCA And Its Amendments, **Congress Expressed No Intent To Preempt State-Law Failure-To-Warn Claims Against Drug Manufacturers**
 - B. The Statutory History Supports A Presumption Against Preemption
- II. It is not impossible for Wyeth to comply with federal law and the state-court judgment
 - A. The FDCA Did Not Compel The Specific Warning Found Inadequate In This Case And Permits Drug Manufacturers To Strengthen Warnings
 - B. FDA Regulations Encourage And Permit Changes In Labeling To Increase Safety. Wyeth’s argument that FDA regulations do not allow it to change it’s label unilaterally is not a fair reading of the text of that provision as the overwhelming majority of appellate courts have concluded.
 - C. Wyeth Can Comply With The Vermont Judgment Without Changing Its Label

- III. The Vermont judgment poses no obstacle to the federal regime
 - A. Vermont Law Complements The Federal Regime
 - B. Wyeth's Obstacle-Preemption Arguments Have No Merit
 - C. FDA's Inconsistent Position Is Entitled To No Weight

C. *The defendant drug company's position . . .*

- I. Respondent's Claims Are Preempted Because It Is Impossible For Wyeth To Comply With Both The State-Law Duties Those Claims Impose And Its Federal Labeling Duties
 - A. The FDCA And Vermont Law Imposed Irreconcilable Requirements On Wyeth
 - B. The Vermont Court Misinterpreted The CBE Regulation
- II. Requiring Wyeth To Comply With A State-Law Duty To Foreclose IV Push Administration Would Obstruct The Purposes And Objectives Of The Act And Its Implementation By FDA
 - A. Congress Mandated FDA To Make Particularized, Labeling-Specific Decisions That Balance Competing Considerations To Advance The Public Health.

Note: You might expect the Preamble argument working here. However, in the Riegel decision last term, Justice Scalia seemed to warn the FDA and drug companies not to rely on the Preamble argument. They have not as the Amicus filed by the United States can address this for the Wyeth.

- B. The Vermont Judgment Conflicts With Congress's Public-Health Objectives
 - C. The 1962 Amendments To The FDCA Do Not Limit The Application Of This Court's Settled Conflict Preemption Principles
- D. *Amicus briefs supporting the plaintiff***

1. *Former FDA Commissioners Dr. Donald Kennedy and Dr. David A. Kessler*

- I. State Failure-To-Warn Litigation Does Not Conflict with The FDA's Authority Over Drug Labeling

- II. The FDA's Post-Approval Monitoring System Cannot, On Its Own, Safeguard Public Health
- III. Congress's Refusal to Preempt Failure-To-Warn Cases Counsels Against Finding Implied Preemption.

2. The National Coalition Against Censorship

Wyeth had the right, under the First Amendment, to provide more robust warnings and could, therefore, comply with state law requirements that it do so

- A. The First Amendment protects the right of drug companies to make truthful statements about their products
 - 1. More robust warnings than those contained in the FDA label constitute pure, not commercial, speech and are subject to the most extensive First Amendment protection
 - 2. Even If It Were Deemed Commercial Speech, Wyeth Has A First Amendment Right To Issue Truthful Warnings
 - a. Issuing Warnings Is Neither Unlawful Nor Inherently Misleading
 - b. While the FDA May Have A “Substantial Interest” In Protecting The Health and Safety of Citizens, It Cannot Restrict Truthful Information Out of Fear That it May be Misused
 - c. The Purported Restrictions on Speech Do Not Advance the Government's Substantial Interest in Protecting the Health and Safety of Consumers
 - d. A Restriction On Warnings Is More Extensive than Necessary
 - 3. As the industry itself vociferously argues, the First Amendment permits drug manufacturers to provide truthful information about their products in addition to the FDA-approved drug label
- B. To avoid constitutional doubts, the statute and regulation should be interpreted to allow drug companies to issue additional warnings
- C. Because Wyeth had a First Amendment right to issue more robust warnings about its product than those contained in the FDA-approved label, it could comply with state law requiring those more robust warnings

Note: Drug companies are lobbying to try to get rid of the provisions in the law that allow them to change their own drug labels!!

3. *Constitutional and Administrative Law Scholars*

- I. The Presumption Against Preemption Applies in This Case
 - A. The Rake Presumption Is a Critical Component of This Court's Federalism Jurisprudence
 - B. The Longstanding *Rice* Presumption is Consistent with the Supremacy Clause
 - C. The *Rice* Presumption Applies to Cases of Implied Conflict Preemption
- II. FDA Approval of a Drug Does Not Preempt Supplementary State Regulation
 - A. Congress Has Conspicuously Declined to Preempt State Claims Concerning Drugs
 - B. State Tort Litigation Provides a Valuable and Necessary Supplement to FDA Review
 - C. The FDA's "Preemption Preamble" Warrants Little or No Deference

4. *The National Conference of State Legislatures*

- I. The FDA's Failure to Give The States Proper Notice and an Opportunity to Comment deprives the preamble of any force or entitlement to deference
- II. The FDA Acted Well Outside the Scope of the Authority Delegated to it by Congress and its New Presentation Position is *Ultra Vires*
- III. The Preamble's Reversal of the FDA's Longstanding Position Against Preemption Undermines the Argument for Deference

5. *Members of Congress*

- I. The History of the FDCA Confirms That It Does Not Preempt Failure-to-Warn Claims.
- II. Congress Confirmed Its Understanding In a Series of Amendments To The FDCA
- III. The FDA's Longstanding Position Was Consistent With Congress' Understanding
- IV. This Court Should Not Upset Congress' Settled Expectations

V. Preemption Would Disrupt The Congressional Drug Safety Scheme

6. *American Association for Justice*

- I. Federal Regulation of Prescription Drugs and State Tort Liability for Inadequate Warnings Have Coexisted Compatibly For a Century
 - A. A Common Law Cause of Action for Failure to Warn of the Risks Posed by Drugs is Long-Standing and Widely Recognized
 - B. Congress and, Until Recently, the FDA Regarded State Tort Liability and Federal Regulation As Complementary
 1. Congress Has Shown No Intention To Preempt Common Law Tort Claims Concerning Prescription Drugs
 2. The FDA, Prior to this Decade, Regarded State Tort Liability and Federal Regulation As Complementary
 - C. State Tort Liability Supports Federal Regulation in Advancing Congress's Goal of Safe and Effective Pharmaceuticals
- II. State Tort Law Has Always Taken Compliance with Federal Regulatory Standards Into Account In Determining Liability
 - A. Under the Traditional Common Law Rule, Compliance with Federal Regulations is Evidence of Non-Negligence, But Not Dispositive
 - B. Virtually Every State, and the Congress, Have Declined to Treat Regulatory Compliance as Conclusive of Non-Negligence
 - C. An FDA Compliance Defense Would Pose Many Problems
- III. Because State Tort Law Takes Appropriate Account of Compliance with FDA Labeling Requirements, There Can Be No “Direct and Positive Conflict” Between State and Federal Law That Would Justify Preemption

7. *The New England Journal of Medicine*

- I. The FDA lacks sufficient information and resources to serve as the sole monitor of pharmaceutical risks
- II. The FDA's limitations as the sole monitor of pharmaceutical risks are illustrated by drugs that had to be withdrawn for safety reasons

- A. Fenfluramine/Dexfenfluramine (Pondimin/Redux)
 - B. Propulsid
 - C. Rezulin
 - D. Baycol
 - E. Rofecoxib (Vioxx)
 - F. Bextra
 - G. Aprotinin (Trasylol)
- III. Petitioner's policy arguments in favor of preemption lack any empirical basis
- A. The Risk of "Over-warning" is More Theoretical Rather Than Real
 - B. Petitioner's/*Amici's* Economic Arguments for Preemption Are Little More Than a General Indictment of the Entire Product Liability System
- IV. Under this country's regulatory framework, effective monitoring of drug risks requires a robust tort system

E. Amicus briefs supporting the defendant

***1. Washington Legal Foundation and American College of
Emergency Physicians***

- I. FDCA requires FDA to specifically regulate drug labeling based on a balancing of federal objectives
- II. Recent scientific and medical studies confirm the adverse public health consequences of overwarning
 - A. SSRI Drug Warnings Lead to Increased Incidence of Suicide
 - B. Warnings Against Fish Consumption in Pregnancy Lead to Lower Child IQ Scores
 - C. Warnings Against Third Generation Oral Contraceptives Lead to Increased Rates of Abortion
 - D. Warnings Against Vaccines Lead to Outbreaks of Measles
- III. The Court has consistently preempted state tort law claims that would impose requirements that differ from the balanced judgment of the federal government
 - A. The Federal Government's Regulatory Oversight of the Product Must Reach the Specific Conduct at Issue

- B. The Federal Government's Exercise of Its Regulatory Authority Must Reflect a Balancing of Different Federal Objectives

2. The Generic Pharmaceutical Association

Federal Drug Labeling Laws Preempt State-Law Tort Claims That Seek To Hold Drug Manufacturers Liable For Using FDA-Approved Labeling

3. The Chamber of Commerce of the United States

- I. The Doctrine Of Implied Conflict Preemption Flows Directly From The Supremacy Clause, Serves A Vital Role In Our Constitutional Scheme, And Was Entrusted To Judicial Enforcement By The Framers
 - A. The Origins Of The Supremacy Clause
 - B. This Court's Longstanding Interpretation Of The Supremacy Clause As The Source Of Obstacle And Impossibility Preemption
 - C. This Court's Unwillingness To Create A Hierarchy Of Types Of Conflict Preemption And The Vital, Independent Functions Of Impossibility And Obstacle Preemption
 - D. This Court's Well-Established Method Of Adjudicating Conflict Preemption Issues
- II. This Court Should Reverse The Flawed Decision Below And Clarify The Doctrine Of Implied Conflict Preemption
 - A. The Lower Court's Reliance On The Presumption Against Preemption Was Mistaken
 - B. The Lower Court's Reading Of Section 202 Was Wrong And Nonsensical
 - C. The FDA's Views About The Detrimental Effects Of Recent Product Liability Litigation On Its Regulatory Regime Are Persuasive And Should Be Given Significant Weight

4. PhRMA and BIO

- I. State-Law Tort Claims Challenging Prescription Drug Labeling Undermine FDA Decisionmaking And Pose A Threat To Public Health
 - A. FDA's Authority To Approve Drug Labeling Is Central To The Agency's Balancing Of Risks And Benefits

- B. The Volume Of State-Law Tort Litigation Challenging FDA-Approved Labeling Has Expanded Significantly
 - C. State-Law Tort Suits Encourage Labeling Statements That Are Not Based on Science, Discouraging Physicians and Patients from Using Beneficial Medicines
 - D. State-Law Tort Suits Can Deprive Doctors and Patients of Critical Medicines, By Inhibiting Drug Development or Driving Beneficial Drugs from the Market
- II. Respondent's State-Law Tort Claims Are Preempted Under Well-Established Preemption Principles
 - A. Respondent's State-Law Claims Are Preempted Because Adding The Instructions And Warnings At Issue Would Violate Federal Law
 - B. Respondent's State-Law Claims Are Preempted Because They Conflict With FDA's Balancing Of Risks And benefits
 - C. **Limiting Preemption to Cases In Which FDA Has Expressly Rejected Specific Labeling Language Will Cause FDA To Be Inundated With Labeling Applications**

5. DRI – The Voice of the Defense Bar

- I. Litigating prescription drug labeling issues FDA already has resolved interferes with FDA's federal mandate and leaves regulated entities in an impossible position
 - A. FDA, The Expert Federal Agency, Is Charged By Congress With Exclusively And Extensively Regulating Prescription Drugs And Their Risks
 - B. FDA's Determinations About Individual Prescription Drugs Make Conflicts With State Law Inevitable
- II. Judges and juries are not properly equipped to make the judgments Congress delegated to the expert agency
 - A. Courts Routinely Defer To Expert Regulators
 - B. Juries Are Poor Substitutes For FDA In This Context
 - C. Experience Shows That, Absent Preemption, Lay Fact-finders May Disrupt The Careful Balances Struck By FDA

- III. “Regulating” drug labeling through state law undermines the purposes of the FDCA and harms public health

6. *The United States*

The FDCA preempts tort claims that would impose liability for the use of labeling that the Food and Drug Administration approved after being informed of the relevant risk

- A. FDA's approval of a drug, including its labeling, reflects the agency's expert weighing of the health risks and benefits of the drug as labeled
- B. FDA's approval of a drug preempts claims challenging the FDA-approved design or labeling when FDA has been made aware of the relevant risk
- C. Federal law does not permit manufacturers to make unilateral changes to FDA-approved labeling based on previously available information
- D. Neither the 1962 nor the 2007 amendments to the FDCA displaced the operation of ordinary conflict-preemption principles

Basic premise of this argument is the FDA is the gold standard in regulation. However, in December 2006, FDA Commissioner Andrew von Eschenback, MD requested that the Science Board, which is the Advisory Board to the Commissioner, form a Subcommittee to assess whether science and technology at the FDA can support current and future regulatory needs. Not surprisingly, this Subcommittee reported back:

- The FDA cannot fulfill its mission because its scientific base has eroded and its scientific organizational structure is weak.
- The FDA cannot fulfill its mission because its scientific workforce does not have sufficient capacity and capability.
- The FDA cannot fulfill its mission because its information technology (IT) infrastructure is inadequate.

7. *Product Liability Advisory Council, Inc.*

- I. The presumption against preemption is inapplicable to conflict preemption analysis
 - A. This Court's recent decisions indicate that the presumption against preemption does not apply to conflict preemption analysis
 - B. Basic principles preclude application of the presumption against preemption in conflict preemption analysis
- II. The decision below thwarts important federal policy by erroneously denying

preemptive effect to the FDA's approval of petitioner's drug label

- A. State-law failure-to-warn liability conflicts with the FDA's goals of preventing overwarning and patchwork regulation
 - B. The decision below misconstrues the relevant FDA regulation
- III. The decision below conflicts with this Court's precedent
- A. The decision below conflicts with this Court's decisions concerning the deference due executive agencies
 - B. The decision below conflicts with this Court's decisions concerning the effect of savings clauses on implied preemption

VI. Is this the right case for Preemption?

Core issue: Did Congress, in passing the Federal Food, Drug and Cosmetic Act ("FDCA") or in amending it, mean to preempt injured persons from bringing lawsuits under state tort law against drug companies whose products injured them?

None of the arguments brought by Wyeth and Amicus filers cast any real doubt on the obvious answer: NO.

So where will the court go with this decision? As with any case facts will play an important role. When Phenergan was first approved for sale by the FDA in 1955, a determination was made that it was safe and effective. Levine claims that starting in 1967, Wyeth knew about additional risks that made Phenergan unsafe unless accompanied by certain warnings concerning IV push. Wyeth's response here is that the FDA made a judgment that the warnings Wyeth proposed rendered the product safe and appropriately retained as an option for Phenergan delivery. This is not obvious from the appellate record.

Both Wyeth and the FDA proposed and counter-proposed substantive changes concerning the warning that physicians should have about the risk of inter-arterial leakage, the FDA never proposed restricting the method of delivery due to this risk. In fact, the warning language adopted was in essence the language suggested by Wyeth to the FDA.

There is nothing in the record for the Court to consider to suggest that the FDA ever considered the possibility that the warning label for Phenergan should have warned against IV push except in case of an emergency. Can this "silence" by the FDA interpreted as an endorsement of the use of IV push in circumstances in circumstances other than an actual emergency? To draw this conclusion, the Court

will be entering into pure conjecture on two fronts: one in which FDA believed that Wyeth answered the risk/benefit on IV push when it failed to suggest a stronger warning and another in which the FDA did not form or express an opinion on the risk/benefit of the additional warning.

Under this record, the plaintiff has the stronger case on preemption. The question in preemption can be characterized in this way: Did the FDA actually make a thoughtful, exhaustive, and well informed decision about the warning and usage issue at the crux of this particular case and second, whether the state tort law would frustrate a federal policy decision for consumer health protection made in conjunction with that decision.

Two recent decision shed some light on this question. In Colacicco v. Apotex, Inc., the plaintiff's estate claimed that there should be additional warnings for suicide using SSRI anti-depressants. The 3rd Circuit held that the case was preempted because the FDA had "clearly and publicly" stated it's position that "there is no evidence that Paxil is associated with an increased risk of suicidal thinking in adults," and the FDA did not allow the company to change the label. By contrast, in McDarby v Merck a New Jersey appellate Court denied preemption as it was clear that the FDA had never decided the Vioxx did not increase the cardiovascular risk even though the FDA had not yet required a warning on Vioxx for these risks.

The Vioxx litigation has supplied a wealth of publicly available information including congressional testimony from Dr. David Graham and internal documents that indicate a shocking reality that the regulatory system does not work or at least it did not in Vioxx. The investigative arm of Congress, the GAO, made this determination in 2005 and in 2006 an internal investigative panel at the FDA made the same findings. The manufacturer always has more information and has a better understanding about their product than a regulatory agency. The "buck" should stop with the company, not the FDA.

Conclusion

Federal agencies, looking forward and reviewing information submitted by the manufacturer, decide whether it can market the product. Juries and judges, looking backward and reviewing all relevant information, decide whether the manufacturer must compensate a consumer allegedly injured by the product. Market forces determine if the manufacturer makes any others changes. Congress intended to give consumers more protection than market forces were providing, not less.

While there is a great deal to say regarding the differential expertise of the FDA, juries and the social costs of tort litigation under varying state-wide standards, it is the legislative, not the executive or judicial branches, that should speak on these issues. Watch out or Preemption can lead to "No Liberty, No justice but Immunity for ALL."

