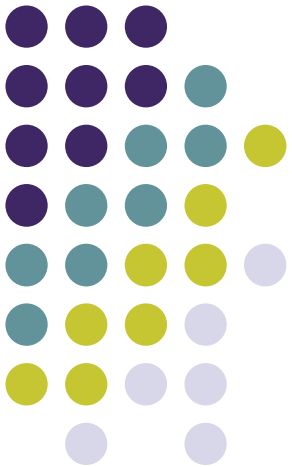
PREEMPTION

The Legal Doctrine And Its Effect on the Pharmaceutical Industry



William R. Golden, Jr.
Kelley Drye & Warren LLP

Preemption Basics

- The supremacy clause forms the foundation of federal preemption:
  - "When Congress so intends, the laws of the United States are 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.
  - Therefore, Congress has the power to prevent states from enacting laws that conflict with federal laws or regulations.

Preemption Basics

- **Express Preemption**
  - Explicit statutory command that state law be displaced
  - Courts focus on the plain wording and structure of the statute
- **Implied Preemption**
  - Congress has "occupied the field"
  - Conflict between state and federal law
  - Enforcement of the state law might frustrate federal purposes
  - Courts must look beyond plain wording and focus on Congressional intent and the circumstances of the particular case

Preemption Basics

- Preemption doctrine is often raised in litigation as a defense to state law claims
- If a court determines that the preemption doctrine applies, any claims based on the preempted state law must be dismissed
- Preemption doctrine applies to the common law as well as state statutes and regulations

Preemption of Claims Involving Drugs/Devices

- Principal Statutes:
  - Medical Device Amendments Act of 1976 ("MDA")
    - Express preemption
  - Food, Drug & Cosmetic Act ("FD&C Act")
    - Implied preemption

Medical Device Amendments ("MDA") Overview

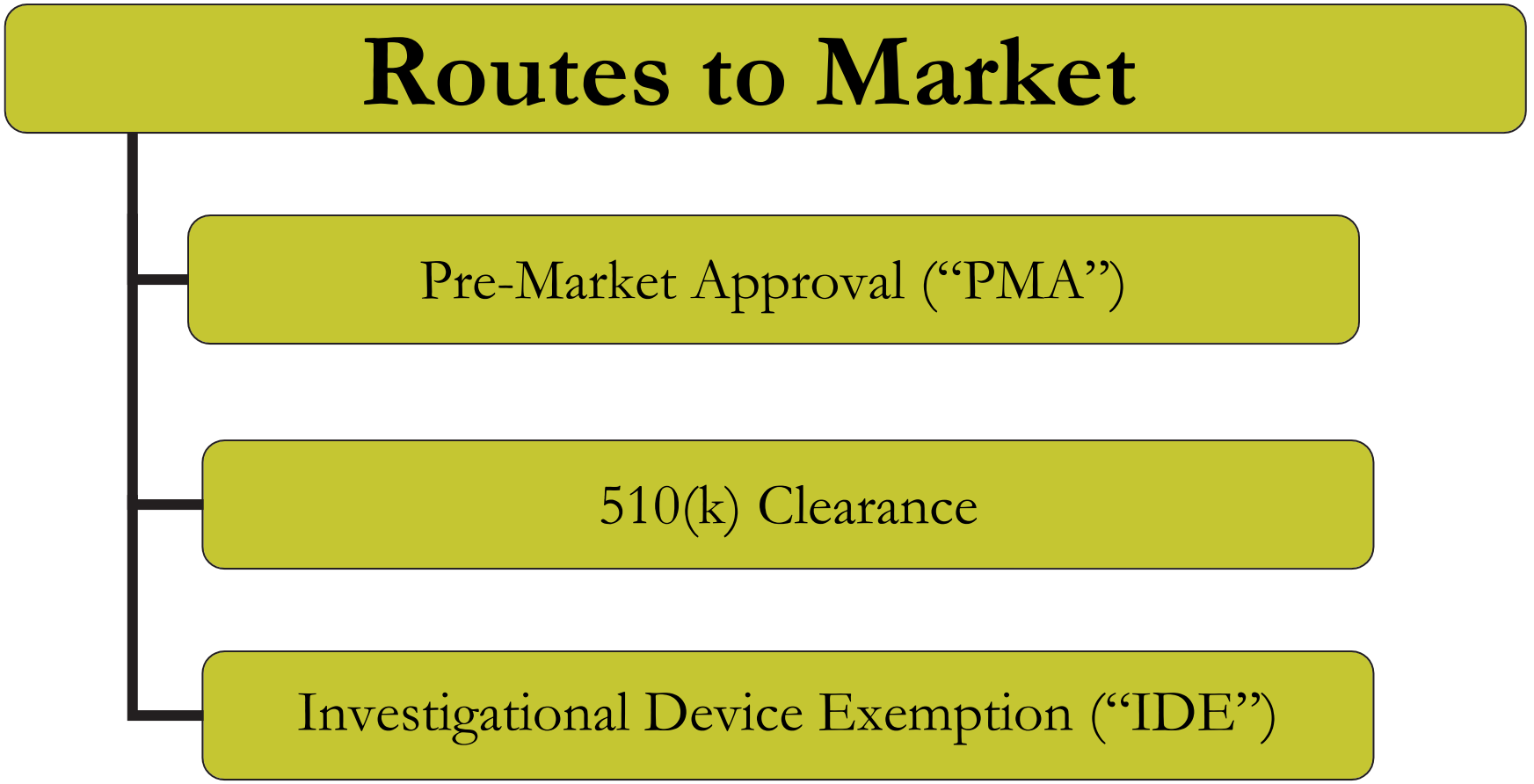
- The MDA charged the FDA with ensuring that medical devices are safe and effective before they are placed in the market

- Established a Classification Scheme
  - Devices ranked by potential health risk to public

Medical Device Classifications

- Class I
  - pose little or no risk of illness or injury
  - subject to only minimal regulation
  - elastic bandages; sterile examination gloves
- Class II
  - potentially more harmful than Class I devices
  - manufacturers must comply with “special controls”
  - wheelchairs; surgical drapes
- Class III
  - present a potential unreasonable risk of illness or injury
  - strictly regulated
  - bone screws; pacemakers

Class III Medical Devices



Routes to Market

- **PMA**
  - rigorous process, repeated modifications to submissions
  - "reasonable assurance" that device is safe and effective
  - analogous to new drug approval process
- **510(k)**
  - limited form of review
  - "substantially equivalent" to product already on the market
  - "grandfathered" devices
- **IDE**
  - innovative technology exception
  - for use in human trials

Preemption Under the MDA

Congress did not want innovations in device technology "stifled by unnecessary restrictions."

H.R. Rep. No. 94-853 at 12 (1976).

Express Preemption Under the MDA

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –

(1) which is different from, or in addition to, any requirement applicable under this [Act] to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this [Act].

21 U.S.C. § 360k(a).

Scope of Preemption Under MDA: *Medtronic, Inc. v. Lohr*

518 U.S. 470 (1996)

- Facts:
  - Pacemaker had received 510(k) clearance as "grandfathered" device
  - Pacemaker failed requiring immediate surgery
  - Lohr brought common law tort claim against manufacturer
- Issue:
  - Does the MDA preempt Lohr's state common law tort claims?

Lohr

- Answer:
  - No preemption
- Decision:
  - 5 – 4 divisive ruling
  - 3 opinions
  - No clear majority

Lohr – No Conflict/No Preemption

- Justice Stevens' Opinion
  - 510(k) clearance focused on equivalence, not safety
  - 360k preempts only "*specific, conflicting state statutes* and regulations rather than the general duties enforced by common-law actions." 518 U.S. at 489.
  - "rare indeed" for a common-law suit to lead to a specific requirement. 518 U.S. at 502-503.

Lohr – Preempt Different Requirements

- Justice O'Connor's Dissenting Opinion
  - Preemption is appropriate to the extent that state common law imposes *additional requirements* on manufacturers
  - State common law tort suits impose "requirements" on manufacturers

Lohr – FDA's Views Important

- Justice Breyer's Concurrence
  - state common law tort suits impose requirements specific to medical devices
  - look to FDA's intentions – FDA could have specifically regulated or provided guidance
  - no specific pacemaker regulations, no preemption

Preemption Landscape Post-*Lohr*

Post-*Lohr*: PMA Device Cases

- Does FDA's approval of PMA (Class III) devices preempt state common law tort claims?
  - The overwhelming majority of Post-*Lohr* decisions have held that PMA approval results in preemption
    - PMA approval process is rigorous and device specific

Post-*Lohr*: PMA Device Cases

- Supreme Court case on federal motor vehicle safety standards clarifies *Lohr*:
  - *Geier v. American Honda*, 529 U.S. 861 (2000)
    - "requirements" include state common law tort claims
    - State law claims would impose requirements that are "in addition to or different from" FDA requirements

Post-*Lohr.* Developments in PMA Device Cases

- *Cupek v. Medtronic, Inc., 405 F.3d 421 (6th Cir. 2005)*
  - Plaintiffs sued a pacemaker manufacturer on a failure to warn tort theory
  - The court held that federal law preempted these claims because they would require the manufacturer to comply with state requirements *different from or at least in addition to* the PMA requirements

- *McMullen v. Medtronic, Inc., 421 F.3d 482 (7th Cir. 2005)*
  - Plaintiff brought suit claiming that manufacturer of an implanted dental device on a post sale duty to warn theory
  - The court noted that FDA regulations permitted but did not require a manufacturer to temporarily amend a warning pending FDA approval of the proposed changes. Plaintiff's claim was preempted because the federal standard is *permissive* –state law claim cannot convert it to a *mandatory* requirement

FDA and Express Preemption

- What is the FDA's position on Express Preemption?
  - PMA process imposes device-specific requirements that trigger preemption
  - State product liability claims impose requirements that are different from or in addition to FDA requirements
    - *Amicus Curiae* Letter Brief for the United States, *Horn v. Thoratec Corp., 376 F.3d 163 (3d Cir. 2004).*

Riegel v. Medtronic, Inc.,
___ U.S. ___ (2008)

- Decided February 20, 2008
- Establishes that MDA expressly preempted state law claims aimed at PMA devices.
- Did not address preemption of non-PMA devices

Riegel – Facts

- During a coronary angioplasty procedure, the balloon catheter burst, causing Riegel to undergo emergency coronary artery bypass graft surgery.
- Riegel sued Medtronic claiming that the catheter (Class III device) had been designed, labeled and manufactured in a way that violated New York common law.
- The lower court dismissed strict liability, implied warranty, and negligent design, testing, inspection and distribution claims based on preemption. Claims for breach of express warranty and negligent manufacturing based on failure to follow federal standards were upheld.

Riegel

- **Justice Scalia's 7 member majority opinion**
  - First question: whether device specific requirements imposed by FDA under MDA?
    - Answer: yes
  - Second question: whether tort claims based on state common law constituted "requirements" and thus preempted?
    - Answer: yes

Riegel

- Third question: what about state "requirements" that are not "different from or in addition to" federal requirements?
  - Answer: not preempted
    - Riegel's claims for negligent manufacturing and breach of express warranty paralleled the federal requirements.

Riegel

- **Justice Ginsburg's dissent**
  - MDA was intended to broaden protection for consumers, not narrow them by giving immunity to the industry.

What *Reigel* Did Not Address

- Open questions:
  - Fraud on the FDA not affected by *Reigel*
    - *Buckman v. Plaintiffs' Legal Committee* – Implied preemption case. Supreme Court held that claims of fraud on the FDA could not stand
    - *But see Warner-Lambert v. Kent* – Supreme Court deadlocked on whether claims were viable under Michigan law which precluded all product liability claims except those premised on fraud on the FDA
  - IDE devices
    - Not addressed in *Reigel*, but based on pre-*Reigel* decisions, courts likely to find state claims preempted

FDA and Implied Preemption

- "Fraud-on-the FDA" claims preempted due to inherent conflict with FDA decisions
- FDA-approved labeling and advertising immunized by preemption doctrine

Scope of Preemption Under FD&C Act: *Wyeth v. Levine*

- Facts:
  - Phenergan is a prescription drug for nausea
  - FDA approved Phenergan as safe and effective when administered intramuscularly or by IV injection. FDA required warning that "INTRA-ARTERIAL INJECTION [CAN] RESULT IN GANGRENE…" and the statement that "Under no circumstances should Phenergan Injection be given by intra-arterial injection…"
  - Hospital administered intravenously by IV push a dose of Phenergan that was twice the labeled dosage
  - Levine developed gangrene and lost her forearm

Wyeth – Conflicting State Requirement?

- State Claim:
  - Inadequate warnings and instructions on labeling rendered "Phenergan not reasonably safe for intravenous administration because the foreseeable risks of harm…are sufficiently great in relation to its foreseeable therapeutic benefits [that doctors would not prescribe the drug intravenously]
  - Levine's lawyer argued to the jury: "Thank God we don't rely on the FDA to…make the safety decision. You will make that decision."
  - The trial court agreed, instructing: "[I]t's for you to decide the nature and scope of the warning required."

Wyeth – Conflicting State Requirement?

- Trial Verdict:
  - $7.4 million awarded to Levine in damages
- Appeal to Vermont Supreme Court:
  - Majority. No preemption unless Wyeth could show FDA would have rejected precise labeling change sought by Levine's attorney
  - Dissent. Preemption doctrine should have been applied. Risk assessments should be made by FDA "in furtherance of the federal objective of advancing the public health by balancing the risks and benefits of new drugs and facilitating their optimal use."

Wyeth – Issue for the Supreme Court

- Does FDA's approval of labeling indications and warnings under its comprehensive safety and effectiveness regulatory scheme preempt state product liability claims that would require the drug maker to change that labeling to make drugs, in a jury's view, reasonably safe for use?
- Factors to be considered:
  - Deference due to FDA's opinion
  - Impact of FDA regulation allowing warnings to be strengthened based on new evidence pending FDA approval of proposed changes under 21 C.F.R. §314.70.

Wyeth – Arguments for Preemption

- FDA's "intent" to preempt entitled to deference
- Evidence pertinent to strengthening warning is solely evidence of a "new risk", not evidence already considered by FDA
- Product liability claims by imposing more stringent labeling requirements than the FDA have a chilling effect on the research and development of new drugs.

Wyeth – Arguments Against Preemption

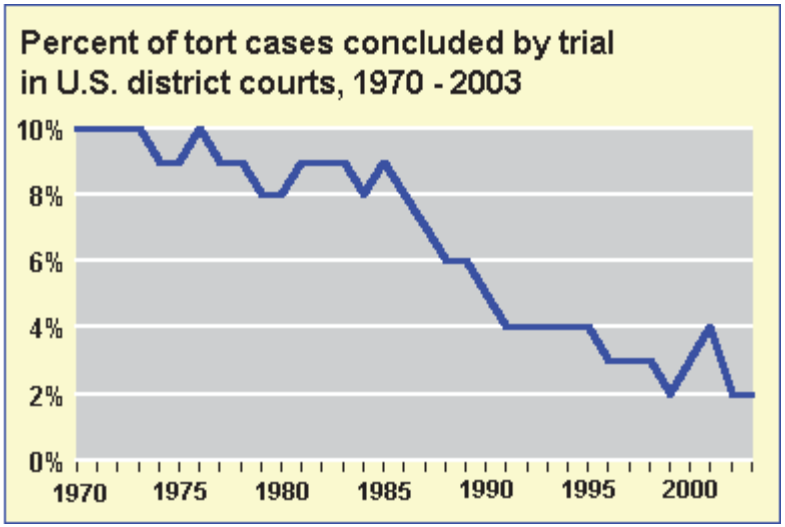
- FDA labeling requirements simply establish a minimum floor for warnings
- Drug makers have the right to strengthen warnings after FDA's initial approval of a new drug
- Conflict preemption only occurs when complying with both federal and state requirements is impossible.

Wyeth – Prediction

Looking Ahead

- Congressional Action
  - U.S. House Committee on Oversight and Government Reform hearings.
  - U.S. Senate
  - States
- FDA
  - On May 29, 2008 proposed rule on labeling indicates Agency position on preemption unchanged

Potential Impact – Tort Landscape



Federal Courts

Tort trial cases terminated in
U.S. district courts, 2002 – 2003

Total number tort cases concluded:	98,786
Jury and bench tort trials	1,647
Tort trials with plaintiff winners	704
Tort trials with monetary awards	590
Median damage awards	$201,000