

# Trends and Developments in Preemption in Life Sciences Litigation

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PREEMPTION IN LIFE SCIENCES

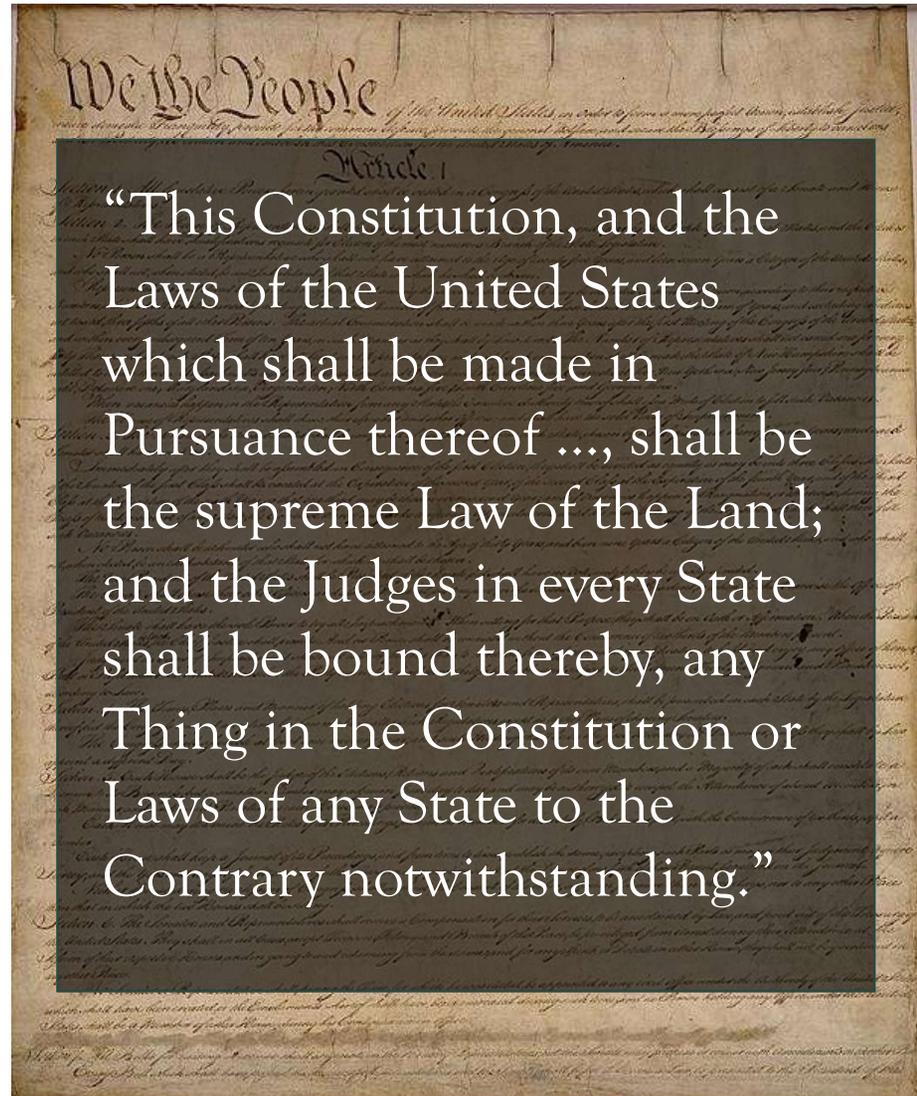
# Preemption Refresher

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Derives From  
Supremacy  
Clause

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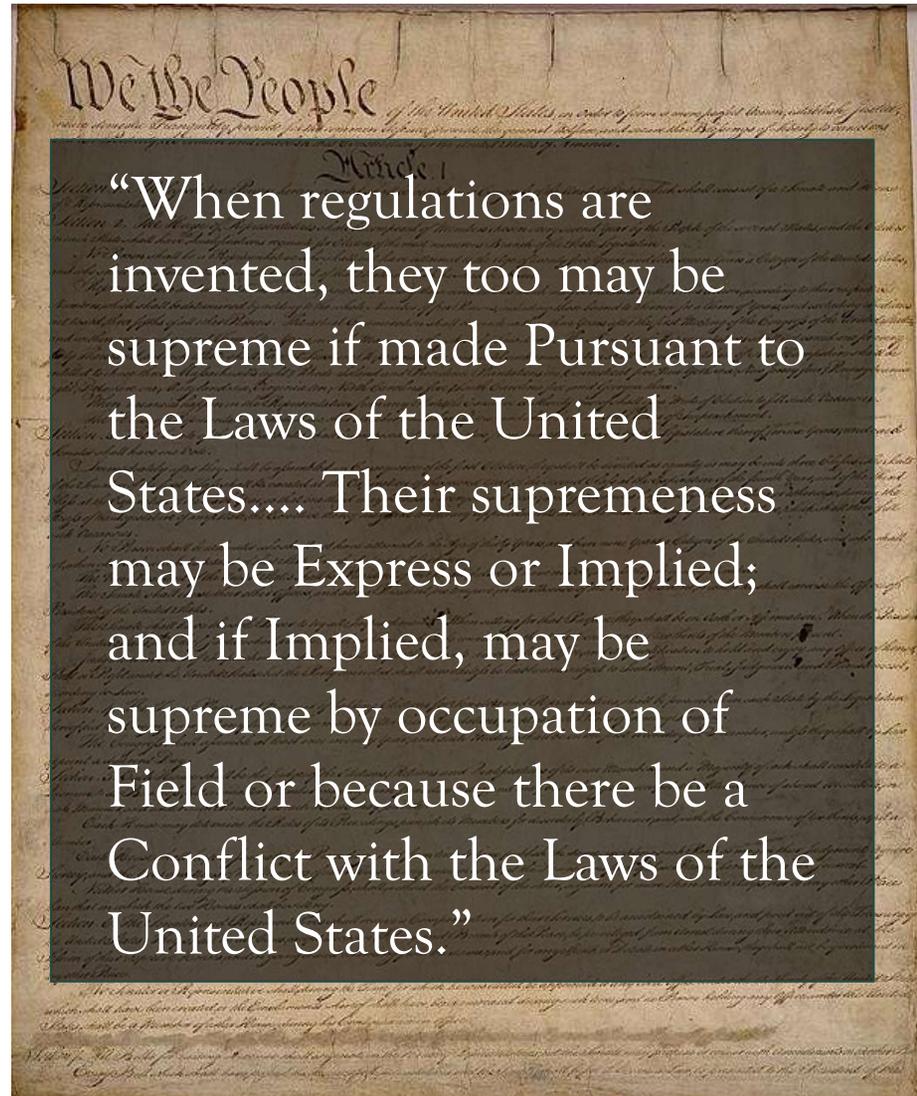


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# Preemption Refresher

Derives From  
Supremacy  
Clause

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# Preemption Refresher

## Express Preemption

- Congress may explicitly state its intention to preempt inconsistent state laws.
- “[N]o State ... may establish or continue in effect ... any requirement which is different from, or in addition to, any requirement applicable under this Act....” 21 U.S.C. § 360k(a).

# Medical Device Express Preemption

- “Informed by” FDA regulations, the Supreme Court held in *Medtronic v. Lohr* (1998) that only “specific requirements applicable to a particular device” matter to preemption.
- It later held that (1) premarket approval establishes a federal “requirement” for a Class III device, and (2) state common-law actions may impose “requirements” and so may be preempted. *Riegel v. Medtronic* (2008).
- Class I and II devices not subject to PMA may or may not be subject to qualifying federal “requirements.”

# Preemption Refresher

## Implied Preemption

- Even if Congress does not expressly say it intends to preempt state law, courts may sometimes infer that intent from what it did say.
- Three types of implied preemption:
  1. Field
  2. Obstacle
  3. Impossibility

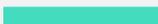
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# Preemption Refresher

## Implied “Field” Preemption

- Rarely applicable.
- Only if the scope and breadth of federal regulation is so pervasive it’s reasonable to infer Congress intended to “occupy the field,” leaving no room for state involvement.

***Arizona v. United States,***  
**567 U.S. 387 (2012)**



**Implied “Field”  
Preemption  
Example**

- The Immigration and Nationality Act, which requires foreign nationals to carry an alien registration document, preempted an Arizona statute that made violations criminal under state law.
- Where there is field preemption, “States may not enter, in any respect, an area the Federal Government has reserved for itself.”

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# Preemption Refresher

Implied  
“Obstacle”  
Preemption

- The particular state law in question is an obstacle to the federal government’s execution of Congressional purposes and objectives.

***Geier v. Am. Honda Motor Co.,  
529 U.S. 861 (2000)***

- State-law tort claim for designing a car without airbags was preempted by NHTSA's FMVSS 208.
- Objective of FMVSS 208 was to encourage manufacturers to gradually develop a mix of passive restraint devices. Threat of tort liability would effectively have required airbags, posing an obstacle to the federal objective.

**Implied  
Obstacle  
Preemption  
Example**

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## No “Obstacle” Preemption Example

### ***Williamson v. Mazda Motor of Am., Inc.*, 562 U.S. 323 (2011)**

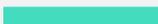
- State tort claim based on failure to install seat belts with shoulder straps was not preempted by federal law saying seat belts were optional.
- The purpose of that law was not to gradually develop mix of devices (as in *Geier*), but to allow auto manufacturers to do their own cost/benefit analysis on whether to include such seat-belt devices.

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# Preemption Refresher

Implied  
“Impossibility”  
Preemption

- If compliance with both federal and state requirements would be impossible, it can be inferred that Congress intended to preempt any such conflicting state requirements.



# No Implied Impossibility Preemption Example

## *Wyeth v. Levine,* 555 U.S. 555 (2011)

- Wyeth argued state-law labeling claim preempted because it could not change its label without FDA approval. Court rejected argument, saying Wyeth could have used the “changes being effected” procedure.

***PLIVA, Inc. v. Mensing,***  
**564 U.S. 604 (2011)**

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**Implied  
Impossibility  
Preemption**  
Example

- Different result in case against generic-drug manufacturers, given FDA interpretation that generic makers could not use the CBE procedure. It would therefore be impossible for them to comply with federal and state requirements.

***In re Fosamax Litigation  
(3d Cir. Sept. 20, 2024)***

**No Implied  
Impossibility  
Preemption**

**Example**

- FDA's rejection of a proposed warning did not preempt failure-to-warn claims.
- That FDA rejected a proposed warning for multiple reasons, one non-substantive, did not prove the proposed warning would have been rejected substantively under the "changes being effected" pathway.
- Because of the ambiguity and because one of FDA's reasons was not substantive, the "presumption against preemption" required rejecting the defense.

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# Preemption Refresher

## Implied Preemption

- Field and conflict preemption more often require determining Congressional intent from statutes that are ambiguous or silent about preemption.
- Impossibility preemption, by contrast, generally does not require an analysis of Congressional intent, only whether it is possible to comply with federal and state standards.

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# ***Goodbye Chevron:***

***Loper Bright Enterp. v. Raimondo***

# *Loper v. Raimondo*

- Under *Chevron*, courts were sometimes required to defer to an agency's interpretation of a statute under certain circumstances.
- *Chevron* two-step analysis:
  - **One:** Has Congress “directly spoken to the precise question”?
  - **Two:** If not (the statute is silent or ambiguous), a court must defer to the agency's own interpretation of the statute as long as it's “reasonable.”

# *Loper v. Raimondo*

- Held that what it called “the *Chevron* project” was “fundamentally misguided” and “unworkable.” 603 U.S. 369 (2024).
- Courts should defer to agency findings of fact, but not statutory interpretations. They must use “independent judgment” to decide whether an agency acted within its statutory authority.
- *But* they may pay “[c]areful attention” to those interpretations to “help inform” this, and a particular statute might clearly delegate authority. But no deference merely because law is ambiguous.

# *Loper v. Raimondo*

Not generally retroactive: “[W]e do not call into question prior cases that relied on the *Chevron* framework. The holdings of those cases that specific Agency actions are lawful . . . are still subject to statutory *stare decisis*[.]”

- Unless “other circumstances” (other than *Loper* itself) also warrant departing from *stare decisis*.



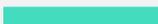
## Question

How does *Loper* affect  
preemption defenses?



# Express Preemption Unaffected

- *Loper* shouldn't affect express preemption because there is no need to discern Congressional intent.
- “FIFRA expressly authorizes the EPA to prescribe regulations. We therefore conclude that *Loper* does not undermine the validity of the EPA regulations in this case.” *Schaffner v. Monsanto* (3d Cir. 2024).



# Implied Impossibility Preemption Unaffected

- *Loper* should have little effect because the analysis is limited to ability to comply with both federal and state requirements.
- “In such cases, the Court has performed its own conflict determination, relying on the substance of State and federal law and not on Agency proclamations of preemption.” *Wyeth*, 555 U.S. at 576.

# Field and Conflict Preemption?

- These analyses more often involve agency regulations that purport to preempt state law without explicit authorization from Congress.
- Supreme Court has repeatedly held that “a pre-emptive regulation’s force does not depend on express congressional authorization.” *See, e.g., Cohen v. Apple Inc.*, 46 F.4<sup>th</sup> 1012 (9<sup>th</sup> Cir. 2022) (citing cases).

# *Loper* and Implied Preemption

- The question now is whether these cases committed the same sin as *Chevron*, giving too much deference to agencies.
- In filings across the country, parties are contesting the application of implied preemption in light of *Loper*.
- The lion's share of these cases are still pending (or courts have found ways to avoid deciding this difficult issue).

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# Recent Developments

# Plaintiffs' Arguments

- *Loper* changes everything!
- Implied preemption is unconstitutional!
- “Issue for Review: Did the District Court err in finding [implied] preemption without independently examining the entire statutory framework of the Food Drug and Cosmetic Act?”
  - Plaintiffs’ Opening Brief, *In re Oral Phenylephrine Mkt. & Sales Litig.*, Nos. 24-3296, 25-119 (2d Cir. Mar. 26, 2025) (argued Mar. 4, 2026).

# Defendants' Arguments

- *Loper* doesn't change that much!
- Again, *Loper* should be irrelevant to impossibility preemption, where the issue is whether the federal and state requirements are in fact inconsistent.
- *Chevron* didn't mandate deference, and *Loper* concedes that some weight may need to be given to agency interpretations (*Wyeth* said the same thing in 2009).



## ***Bennett v. Indivior Inc.***

*(In re Suboxone Buprenorphine/  
Naloxone Film Prods. Liab. Litig.)*  
2024 WL 5264278 (N.D. Ohio Dec.  
31, 2024)

- Rejected argument that implied preemption is unconstitutional in light of *Loper*.
- “[*Loper*] says little, if anything about preemption doctrine.”
- “[*Loper*] involves questions of deference to Agency interpretations of ambiguous statutes, and preemption involves determining the intent of Congress, not an Agency.”

# *Durnell v. Monsanto Co.*

- Plaintiff sued for “failure to warn,” alleging Roundup caused his cancer. Jury found for Plaintiff.
- Monsanto argued that Plaintiff’s failure-to-warn claim was both expressly and impliedly preempted, and appealed after the trial court denied its JNOV.



## ***Durnell v. Monsanto Co. (cont.)***

- **Monsanto's argument for express preemption:**
  - FIFRA prohibits states from imposing labeling requirements that are in addition to or different from the federal requirements.
  - But FIFRA also says “[a] pesticide is misbranded if ... the label does not contain a warning or caution statement which may be necessary and if complied with ... is adequate to protect health and the environment.”
- **REJECTED: Missouri Court of Appeals found the state's “strict liability failure to warn” cause of action is consistent with FIFRA in that it only requires a plaintiff to prove that a defendant “did not give adequate warning of the danger” of a product.**

## ***Durnell v. Monsanto Co. (cont.)***

- **Monsanto's argument for implied preemption:**
  - Pesticide warning labels must be approved by the EPA, so it would be impossible for Monsanto to comply with an inconsistent state-law requirement.
  - The regulatory history of glyphosate is “clear evidence” the EPA would not approve a cancer warning—including the agency's conclusion that glyphosate is “not likely to be carcinogenic to humans.”
- **REJECTED:** The Court of Appeals found “the possibility of impossibility is not enough.” The EPA's historical actions regarding Roundup did not constitute clear evidence of an irreconcilable conflict.

## ***Durnell (cert. granted)***

- Monsanto argues that express preemption applies:
  - State law makes a manufacturer strictly liable for harm caused by an “unreasonably dangerous product” without consideration of economic or social benefits. But under FIFRA, a manufacturer can only add warnings that are “necessary and...adequate to protect health and the environment,” and FDA must take into account the “economic, social and environmental costs and benefits of the use of the pesticide.”
- Monsanto argues that implied impossibility preemption applies:
  - “The court of appeals insisted that none of EPA’s actions carried the ‘force of law.’ But that misses the point, as clear evidence that the agency would have rejected any effort to revise the label can come from materials that do not independently have the force of law.”

## ***Durnell (cert. granted)***

- Durnell argues express preemption does not apply:
  - “EPA’s approval of pesticide labeling without a chronic-risk warning is not naturally characterized as a FIFRA ‘requirement’ that no such warning appear.” And for good reason: EPA’s registration decisions are ‘based in significant part on proposed labeling and scientific studies submitted by the manufacturer.’ Those submissions may be inaccurate, incomplete, or proven inadequate based on later research.”
- Durnell argues that implied preemption does not apply:
  - “There is no ‘clear evidence’ showing Durnell's failure-to-warn claim is preempted. EPA has promulgated no regulation requiring certain warnings on glyphosate-based product labels and barring others.”

# What could *Durnell* mean?

- **For express preemption:** What is a legal “requirement”?
- **For implied preemption:** Even if *Loper* requires that the administrative agencies are entitled to no deference in their statutory interpretation, what persuasive effect do their actions hold in establishing in a unique circumstance like *Durnell*?

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Questions?