Food and Drug Act

Breaking Down Statutory Text

This chart details which preemption sections of various omnibus and sectoral statutes deal with federal preemption.

Codified Section	Type of Preemption	Are the circuit courts in general agreement on what this means?
21 USCS § 391	Severability Clause	Yes – most of the decisions are focused on determining if state law claims and federal law are impossible to reconcile

Methodology

The statutory text overwhelmingly contains express preemption and various savings clauses. Express preemption is directly related to statutory text, and it is the only form of preemption with this quality. The remaining types of preemption – field, impossibility, and obstacle – are forms of *implied* preemption. As the name suggests, these preemption categories are implicit in every statute and consequently do not rely on statutory text. (However, sometimes a statute will explicitly address an implied preemption principle, such as 42 U.S.C. § 2000h-4.) Instead, implied preemption principles appear exclusively in case law. Case law that relies on a theory of implied preemption are appropriately notated.

Since courts have not addressed every issue, there may be areas that are marked as "Not litigated."

Legend:

Express Preemption
Field Preemption
Impossibility Preemption
Obstacle Preemption
Floor Preemption

Anti-Preemption Provision
Compliance Savings Clause
Remedies Savings Clause
Sunset Provision
Ceiling Preemption

Statutory Text

21 U.S.C. §391

If any provision of this Act [21 USCS §§ 301 et seq.] is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the Act [21 USCS §§ 301 et seq.] and the applicability thereof to other persons and circumstances shall not be affected thereby.

Summary

The Supreme Court has had multiple occasions to address the preemption of state law claims. Despite multiple decisions, there are still some areas of the case law that remain unclear.

In *Levine*, the Court held state law claims would be preempted if the manufacturer proved there was "*clear evidence* the FDA would have rejected the proposed change in the drug's label." However, the Court didn't articulate a test for determining when a factual record constituted "clear evidence."

Mensing and *Bartlett* address impossibility preemption. In both cases, the Supreme Court held the state law claims were preempted.

Since the most recent Supreme Court case, *Merck Sharp & Dohme Corp. v. Albrecht* (2019), there have not been any more Court of Appeals cases addressing the topic.

Ultimately, it appears that the Court of Appeals ask the same question: would it be possible for a defendant to comply with the state law claims and the federal law, without having to pull the product from the market? When it is possible, the common-law claims are allowed to proceed. When it is impossible to do both, such as when the state-law claim requires additional or different warnings, then the state law claims are preempted.

Case Law

Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001)

Facts: Plaintiffs were injured when orthopedic bone screws were used in their spines. Petitioner is a consulting company, employed by the screw's manufacturer, who allegedly made fraudulent statements to the FDA during the federal regulatory process. Plaintiffs allege the representations were a "but for" cause of injury.
Holding: The claims are implicitly preempted.

Wyeth v. Levine, 555 U.S. 555 (2009)

Facts: Wyeth manufactured a drug, Phenergan, with risks of catastrophic consequences. The warning label was deemed sufficient by the FDA. Levine developed gangrene and had her right forearm amputated after Phenergan entered her artery. Levine brought an action for common law negligence and strict liability against Wyeth. Wyeth argued that the suit was preempted by federal law.
Holding: The suit is not preempted. It is not impossible for Wyeth to comply with both the state- and federal-law obligations, nor is the suit an obstacle to the accomplishment of Congress' purpose.

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

Facts: Metoclopramide was approved by the FDA in 1980. Later evidence showed long-term use of metoclopramide can cause tardive dyskinesia. The warning label was updated twice: once in 1985, and again in 2009 to the FDA's strongest statement of caution. Plaintiff took generic metoclopramide in the early 2000's.
Rule: Federal law requires generic drugs to use "the same safety and efficacy labeling as their brand-name counterparts."

Holding: State law and federal law had different requirements; this is a case of impossibility preemption. The state-law tort claims are preempted.

Mutual Pharmaceutical Co. v. Bartlett, 570 U.S. 472 (2013)

Facts: Bartlett sought recovery under a design-defect claim against the manufacturer of a generic nonsteroidal anti-inflammatory drug. Federal law prohibited Mutual Pharmaceutical from unilaterally changing its label. The New Hampshire cause of action effectively required a different label with stronger warning, thereby imposed a duty *not* to comply with federal law.

Procedural History: The Court of Appeals held that Mutual Pharmaceutical should have pulled the drug, which would have complied with the federal and state law requirements. However, the Supreme Court rejects this rationale, holding that an actor should not be required to cease conduct to avoid liability. This rationale, if accepted, would defeat the point of impossibility preempted.

Holding: The design-defect claim is preempted.

Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668 (2019)

Facts: Merck manufactured a drug, Fosamax, that decreases the risk of osteoporotic fractures, while potentially causing stress fractures instead. In applying *Wyeth*, the Court of Appeals held "for a defendant to establish a preemption defense under *Wyeth*, the factfinder must conclude that it is highly probably that the FDA would not have approved a change to the drug's label." Similarly, the Court of Appeals held that "whether the FDA would have rejected a proposed label change is a question of fact."

Holding: The Court of Appeals should have treated preemption as a question of law. Preemption is a decision for a judge, not a jury.

Drager v. PLIVA USA, Inc., 741 F.3d 470 (4th Cir. 2014)

Facts: Shirly Gross, represented by Drager, suffered permanent injuries after being prescribed metoclopramide. Drager sued under state-law theories of negligence, breach of warranty, fraud and misrepresentation, strict liability, and failure to warn. After *Mensing*, PLIVA filed a motion for summary judgement, asserting impossibility preemption.

Holding: The claims are preempted.

Cupek v. Medtronic, Inc., 405 F.3d 421 (6th Cir. 2005)

Facts: Defendant's pacemaker leads were implanted in the spouses of Plaintiffs. Plaintiffs alleged multiple state-law claims, including failure to warn and failure to recall.

Holding: Any state-law claim that Defendant failed to warn or recall would constitute state requirements "different from" or "in additional to" federal requirements, which are preempted.

Mason v. SmithKline Beecham Corp. (*Mason II*), 596 F.3d 387 (7th Cir. 2010)

Facts: Tricia Mason committed suicide after starting Paxil, an antidepressant. Her parents sued the manufacturer for negligence.

Rule: In *Levine*, the Court set the standard for preemption: there would be preemption if the manufacturer proved there was "*clear evidence* the FDA would have rejected the proposed change in the drug's label."

Application: There is no clear standard for what constitutes "clear evidence." Instead, the Seventh Circuit compares the administrative history of Paxil to the administrative history of Phenergan (the drug from *Levine*). Here, the manufacturer did not meet its burden.
Holding: Plaintiff's claims are not preempted.

Wagner v. Teva Pharms. USA, Inc., 840 F.3d 355 (7th Cir. 2016)

Facts: Wagner developed breast cancer after taking prescription brand-name and generic hormone therapy drugs. Wagner asserts various state law tort claims.
Rule: This holding relies on *PLIVA, Inc.* and *Bartlett*. Federal law preempts tort claims "when the generic drug manufacturer could not have abided by this duty without: (1) changing the drug's formula; (2) changing the drug's label; or (3) withdrawing the generic drug from the market altogether."
Holdings: The Wisconsin state-law claims are preempted.

Ebner v. Fresh, Inc., 838 F.3d 958 (9th Cir. 2016)

Facts: Ebner brought a suit against Fresh for deceiving consumers about the quantity of lip balm in its "Sugar" product line, in both its labeling and its design/packaging. Ebner's claim is brought under California's Sherman Food, Drug, and Cosmetic Law ("Sherman Law").
Application: Plaintiff's state law claim, under California's Sherman Law, enforces a standard that is identical to federal duty under the FDCA. Because the Sherman Law does not require something "different from or in addition to" the federal law, it is not impossible to comply with both.
Holdings: The claims are not preempted. However, both fail on the merits.

Guarino v. Wyeth, LLC, 719 F.3d 1245 (11th Cir. 2013)

Facts: Guarino took metoclopramide for four months and thereafter developed tardive dyskinesia. Two years after she took the medication, the FDA changed its approach, diving the drug its strongest cautioning against taking the medication beyond twelve weeks. Guarino sued under many theories of liability, relating to failure to communicate to medical providers of the risks of long-term use.
Application: The court applied *Mensing*'s analysis.
Holding: Whether a claim is presented as failure-to-warn or failure-to-communicate does not alter the analysis; the claim is preempted.

Allergan Inc. v. Athena Cosmetics, Inc., 738 F.3d 1350 (Fed. Cir. 2013)

Facts: Athena Cosmetic's products, in the RevitaLash line, contain prostaglandin derivative, an FDA-approved prescription drug. Allergan sued Athena for violating California's unfair competition law, for marketing, selling, and distributing a new drug without approval from the FDA or California State Department of Health Services.
Holding: There is not obstacle preemption. There is not impossibility preemption.

Further Readings

Victor E. Schwartz and Christopher E. Appel, *Where's the Beef?: A Guide to Judges on Preemption of State Tort Litigation Involving Branded Drugs*, 89 U. CIN. L. REV. 597 (2021)

Elizabeth Marley, *Note: Healing a Fractured Preemption Doctrine: The Impact* of Merck Sharp & Dohme Corp. v. Albrecht *on Impossibility Preemption Defenses*, 89 FORDHAM L. REV. 265 (2020)

Eric Lindenfeld, *Clear Evidence Clarified*. 75 FOOD DRUG L.J. 346 (2020)

Marcia Boumil, *FDA Approval of Drugs and Devices: Preemption of State Laws for "Parallel" Tort Claims*, 18 J. HEALTH CARE L. & POL'Y 1 (2015)

Amanda Frost, *Judicial Review of FDA Preemption Determinations*. 54 FOOD & DRUG L.J. 367 (1999)