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Preemption and the Federal Food, Drug, and Cosmetic Act (FD&C Act)

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SUMMARY

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Preemption and the Federal Food, Drug, and Cosmetic Act (FD&C Act)

First enacted in 1938, the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, empowers the Food and Drug Administration (FDA) to regulate various products affecting public health, including food, drugs, medical devices, cosmetics, and tobacco products. By FDA's estimate, the products it oversees in 2025 were valued at $4.1 trillion and accounted for about 21 cents of every dollar spent by U.S. consumers. In general, the FD&C Act prohibits the distribution of a covered product in interstate commerce that is "adulterated" or "misbranded," and defines, for each product type, the circumstances and standards under which that product is "adulterated" or "misbranded." Additional statutory or regulatory provisions often further refine the specific federal requirements that apply to specific subsets or components of a product type. Some subsets of drugs, devices, and tobacco products, for instance, must be reviewed by FDA before they can be lawfully marketed, while food and cosmetic products (with the exception of certain ingredients) generally are not subject to premarket review.

States have historically regulated many products covered by the FD&C Act based on their general police power to provide for the public health and safety of their residents. State regulation of such products might include statutes specific to certain products, along with more general consumer protection and products liability laws. State consumer protection and products liability laws provide mechanisms by which consumers allegedly injured by a relevant product may challenge the product's promotion, manufacture, design, and/or warning, on the grounds that the defendant manufacturers should have taken a different course of action with respect to those activities—some of which may be regulated by the FD&C Act and its implementing regulations.

Under the U.S. Constitution's Supremacy Clause, federal law supersedes (preempts) conflicting state law and can do so *expressly*—through explicit preemption provisions specifying the scope of preempted state law—or *impliedly*—where a state law is displaced because it conflicts with federal law or because federal law so thoroughly occupies the regulatory field as to leave no room for state activity. Over the FD&C Act's nearly 90-year history, Congress has amended the law to include provisions that expressly preempt certain state laws that address areas specifically regulated by the FD&C Act, such as state laws imposing requirements on the safety and efficacy of medical devices, labeling requirements for food and cosmetic products, and requirements on certain standards for tobacco products. In other instances, Congress has not spoken specifically to preemption, as is the case for FD&C Act provisions governing prescription drugs.

Courts—including the Supreme Court—have frequently considered the preemptive scope of the FD&C Act on state statutes and causes of action—an inquiry the Court has sometimes described as focused on discerning the intent of Congress. In practice, courts often look to the text, structure, and contextual background of the relevant FD&C Act provisions to determine their preemptive scope. This report provides an overview of the courts' FD&C Act preemption jurisprudence, focusing on the following FDA-regulated products: food products, prescription drugs, medical devices, cosmetics, and tobacco products. Generally speaking, these cases illustrate that while the FD&C Act's enforcement scheme impliedly preempts a particular type of state fraud claim (i.e., one alleging that an applicant made misrepresentations to FDA during a premarket review process), context-specific analyses are usually required to assess whether other state laws or claims are preempted. In these analyses, courts typically undertake a case-specific, often granular, comparative analysis of what an applicable federal law requires or permits and whether and to what extent the relevant state requirements conflict with federal requirements. The courts' nuanced approach often results in the preservation of at least some state claims or requirements—a result that arguably reflects the courts' recognition of states' long-standing, concurrent role in the regulation of these products. State requirements are most likely to survive preemption where Congress is silent on the interaction of federal and state law, but courts have sometimes understood the FD&C Act's express preemption provisions as leaving room for certain state requirements. At the same time, courts may be more likely to construe relevant FD&C Act provisions to have broader preemptive effect on certain aspects of product regulation that are not historically regulated by states. These considerations may inform Congress's decision on whether to modify existing express preemption provisions, add additional express preemption provisions, and consider the appropriate degree of specificity of any such provisions.

Contents

Background on Federal Preemption 3
Preemption and the FD&C Act 6
    Preemption Based on the FD&C Act's Enforcement Scheme 7
    Preemption Based on FD&C Act's Product-Specific Provisions 9
        Food Products 11
        Prescription Drugs 19
        Medical Devices 26
        Cosmetics 33
        Tobacco Products 36
Observations and Considerations for Congress 43

Contacts

Author Information 45

Under the United States' federalist system, the federal government and states share regulatory authority over public health matters, with states traditionally exercising the bulk of the authority pursuant to their general police power.[1] This inherent power enables states, within constitutional limits, to enact laws "to provide for the public health, safety, and morals" of the states' inhabitants.[2] At the same time, the federal government shares certain concurrent authority in this area emanating from its enumerated powers in the Constitution.[3] The regulation of products implicating public health—including food, drugs, biologics, medical devices, cosmetics, and tobacco products—reflects this overlapping authority.

Since 1906, Congress has enacted laws regulating products affecting public health, relying on its authority under the Commerce Clause to regulate persons or things in or affecting interstate commerce.[4] The Pure Food and Drug Act of 1906 prohibited the sale of misbranded or adulterated food and drugs in interstate commerce.[5] In 1938, Congress replaced that law with the Federal Food, Drug, and Cosmetic Act (FD&C Act, or the Act).[6] As amended over the years, the FD&C Act provides the federal legal framework governing the regulation of food, drugs, cosmetics, medical devices, tobacco, and other products. By the Food and Drug Administration's (FDA's) own estimate, the products it oversees in 2025 were valued at $4.1 trillion and accounted for about 21 cents of every dollar spent by U.S. consumers.[7]

Under its general framework, the FD&C Act prohibits the distribution of a covered product in interstate commerce that is "adulterated" or "misbranded."[8] The Act then defines, for each product type, the circumstances and standards under which that product is "adulterated" or misbranded."[9] Some regulated products are required to be reviewed by FDA before they can be lawfully marketed while other products are not. The 1938 law, for example, transformed the regulation of new drugs from a regime that removed harmful drugs off the market after the fact, to a regime that mandates premarket approval of new drugs—that is, a regime under which manufacturers of new drugs must demonstrate the products' safety before they can be sold on the market.[10] Over time, that premarket approval regime expanded to include a determination of

[1] *See* Jacobson v. Massachusetts, 197 U.S. 11, 25, 39 (1905) (upholding a state law authorizing local public health officials to require vaccination against smallpox, observing that "[a]lthough this court has refrained [] from any attempt to define the limits of [states' police] power, . . . it has distinctly recognized the authority of a State to enact quarantine laws and 'health laws of every description'" (quoting Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1, 203 (1824)); *see also* Elizabeth Y. McCuskey, *Body of Preemption: Health Law Traditions and the Presumption Against Preemption*, 89 TEMPLE L. REV. 95, 113–20 (2016) (providing an overview of state and federal authorities in the regulation of health matters).

[2] Barnes v. Glen Theatre, Inc., 501 U.S. 560, 569 (1991).

[3] *See* CRS Report R45323, *Federalism-Based Limitations on Congressional Power: An Overview*, coordinated by Kevin J. Hickey, at 1 (2023).

[4] *See generally* LIBR. OF CONG., *Persons or Things in and Instrumentalities of Interstate Commerce*, CONSTITUTION ANNOTATED, https://constitution.congress.gov/browse/essay/artI-S8-C3-6-3/ALDE_00013420/ (last visited Mar. 30, 2026) (providing overview of the Supreme Court's Commerce Clause jurisprudence); LIBR. OF CONG., *Intrastate Activities Having a Substantial Relation to Interstate Commerce*, CONSTITUTION ANNOTATED, https://constitution.congress.gov/browse/essay/artI-S8-C3-6-4/ALDE_00013421/(last visited Mar. 30, 2026) (same).

[5] Ch. 3915, 34 Stat. 768 (1906).

[6] Ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 331–399i).

[7] OFF. OF THE COMM'R, U.S. FOOD & DRUG ADMIN., FDA AT A GLANCE (2026), https://www.fda.gov/media/154548/download [https://perma.cc/TY9H-JKGK].

[8] *See* 21 U.S.C. § 331.

[9] *See, e.g.*, *id.* §§ 342–343, 351–352, 361–362, 387b–387c.

[10] *See* ch. 675, § 505, 52 Stat. at 1052.

efficacy in addition to safety.[11] Congress also applied the premarket review framework—with different product-specific standards—to the regulation of other products, including certain medical devices[12] and tobacco products.[13] Other products, such as food and cosmetic products, are generally (with the exception of certain ingredients)[14] not subject to premarket review but are subject to other federal requirements.[15]

Meanwhile, states maintain a role in the regulation of these products, often through a diverse set of laws that reflect the piecemeal approach to regulation that began in the 1800s.[16] For instance, while a majority of states have adopted the Uniform State Food, Drug, and Cosmetic Act based on the 1938 FD&C Act, significant variations remain among the food and drug laws of the different states because not all states have adopted all parts of the Uniform Act or incorporated all amendments to the federal FD&C Act.[17]

In addition to state statutes that specifically address products regulated by the FD&C Act, states have also enacted general consumer protection statutes that prohibit, to varying degrees, deceptive or unfair business practices.[18] These state consumer protection laws provide a mechanism for consumers allegedly harmed by a relevant product to seek redress for such harm if it stems from a prohibited practice.[19]

Finally, state tort law—developed through judicial decisions—applies to FD&C Act-regulated products.[20] State tort law, and in particular, products liability law, provides an avenue for individuals harmed by a product to assert claims challenging the manufacture, design, or warning of the product.[21]

The interaction between these sometimes overlapping federal and state laws implicates the preemption doctrine. Under the Constitution's Supremacy Clause,[22] federal law supersedes (preempts) conflicting state laws.[23] The Supreme Court has identified two general types of

[11] *See* Drug Amendments of 1962, Pub. L. No. 87-781, § 102, 76 Stat. 780, 781 (codified as amended at 21 U.S.C. §§ 321, 355).

[12] *See* Medical Device Amendments of 1976, Pub. L. No. 94-295, § 2, sec. 513(a)(1)(C), 90 Stat. 539, 541 (codified as amended at 21 U.S.C. § 360e).

[13] *See* Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. No. 111-31, § 101(b)(3), sec. 910, 123 Stat. 1176, 1807 (codified as amended at 21 U.S.C. § 387j).

[14] *See, e.g.*, 21 U.S.C. §§ 348, 379e.

[15] *See, e.g., id.* §§ 341, 342–343, 361–362, 364a–364e.

[16] *See* Peter Barton Hutt, et al., FOOD & DRUG LAW 424–25 (5th ed. 2022).

[17] *See id.* at 425–26.

[18] All 50 states have enacted general consumer protection statutes—sometimes referred to as Unfair and Deceptive Acts and Practices (UDAP) laws—that prohibit deceptive and/or unfair business practices. The specific scope of prohibited conduct and the entities subject to the prohibition vary among states. *See* NAT'L CONSUMER L. CTR., CONSUMER PROTECTION IN THE STATES: A 50-STATE EVALUATION OF UNFAIR AND DECEPTIVE PRACTICES LAWS 1–3 (2018), https://www.nclc.org/wp-content/uploads/2022/09/UDAP_rpt.pdf [https://perma.cc/2FW6-9D8Q].

[19] *See id.*

[20] State tort law originates in common law and provides a mechanism, through case-by-case litigation, for a person injured by the wrongful or injurious actions of another to recover damages. Products liability is a subset of tort law that permits a plaintiff injured by a defective product to recover damages from the manufacturer of that product. For more background information on state tort law, see CRS In Focus IF11291, *Introduction to Tort Law*, by Andreas Kuersten (2023).

[21] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (A.L.I. 1998).

[22] U.S. CONST., art. VI, Cl. 2.

[23] *See* Murphy v. Nat'l Collegiate Athletic Ass'n, 584 U.S. 453, 471 (2018); Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 108 (1992).

preemption: express and implied preemption. Federal law expressly preempts state laws when a federal statute or regulation contains explicit preemptive language.[24] Even when Congress is silent on a federal statute's preemptive effect, a state requirement can be impliedly preempted where it conflicts with federal law or where federal law so thoroughly occupies the regulatory field as to leave no room for state regulation.[25]

The FD&C Act implicates both express and implied preemption. Over the years, Congress has amended the Act to expressly preempt certain regulated products or topics, but sometimes there is uncertainty regarding these provisions' scope.[26] In other instances, Congress has not spoken directly to the preemptive effect of the FD&C Act's regulation of a particular matter, leaving it to courts, in disputed cases, to determine when or whether a state requirement is impliedly preempted.[27] Both express and implied preemption questions can arise when states regulate products or issues addressed directly by the FD&C Act, or when state law provides a cause of action (e.g., through products liability or consumer protection laws) for injuries allegedly caused by an FDA-regulated product.[28]

This report provides an overview of the courts' FD&C Act preemption jurisprudence, focusing on certain FDA-regulated products. It begins with an overview of the preemption doctrine, and then examines the doctrine as applied to the FD&C Act's general enforcement scheme as well as to the Act's product-specific regulatory schemes for the following categories of FDA-regulated products: (1) food products; (2) prescription drugs; (3) medical devices; (4) cosmetics; and (5) tobacco products.[29] For each product type, the discussion first highlights the relevant FD&C Act provisions, including any express preemption provisions, and then analyzes how courts have interpreted those provisions to determine their preemptive scope. The report concludes with selected observations and considerations for Congress.

Background on Federal Preemption

The U.S. Constitution's Supremacy Clause provides that "the Laws of the United States . . . shall be the supreme Law of the Land" notwithstanding "the Constitution or Laws of any State to the Contrary."[30] As interpreted by the Supreme Court, this Clause forms the basis of the federal preemption doctrine, under which federal law supersedes state laws if state laws "interfere with, or are contrary to federal law."[31] In describing the inquiry into whether—and to what extent—a federal law preempts state law, the Court has at times said that discerning congressional intent is

[24] *Murphy*, 584 U.S. at 478.

[25] *Id*. at 478-80.

[26] *See, e.g.*, *infra* "Case Law on the Preemptive Scope of FD&C Act Section 521 on State Tort Law Claims."

[27] *See infra* "Case Law on the Preemptive Scope of Selected Prescription Drug Provisions."

[28] *See, e.g.*, *infra* "Case Law on the Preemptive Scope of FD&C Act Section 521 on State Tort Law Claims."

[29] Other products subject to FDA regulation include other subcategories of food and drug products—such as dietary supplements (which are a subset of "food" under the FD&C Act), over-the-counter drugs, and animal drugs—as well as biological products. *See* 21 U.S.C. §§ 343(s), 355h, 360b; 42 U.S.C. § 262. Biological products, or biologics, are a diverse category of products (including vaccines and blood products) used to diagnose, prevent, and treat diseases and conditions; they are made from living organisms and are generally large, complex molecules. *See* 42 U.S.C. § 264(i)(1); *see also* CRS Report R44620, *Biologics and Biosimilars: Background and Key Issues*, by Hassan Z. Sheikh (2019). Unlike other FDA-regulated products, biological products are subject to the Public Health Service Act (PHSA) rather than the FD&C Act, but the relevant PHSA provisions incorporate by reference many FD&C Act provisions that apply to prescription drugs. *See, e.g.*, 42 U.S.C. §§ 262(a)(2)(B); 262(a)(2)(D); 262(h); 262(j). A discussion of the preemption jurisprudence pertaining to these other products is beyond the scope of this report.

[30] U.S. CONST. art. VI, cl. 2.

[31] Hillsborough Cnty. v. Automated Med. Labs, 471 U.S. 707, 712 (1985).

the "ultimate touchstone" in the analysis.[32] In practice, the Court has, to varying degrees, considered the text, structure, purpose, and contextual background of a federal statute when considering its preemptive effect.[33]

Federal law can preempt state law either *expressly* or *impliedly*. Express preemption occurs when a state law is displaced by explicit preemptive language—often called an express preemption provision—contained in a federal statute or regulation.[34] In those instances, determining the scope of the preemption clause is largely a matter of statutory construction.[35] The Supreme Court has instructed that Congress's intent with respect to express preemption is discerned "primarily" from a statute's text, but the Court has also often looked to the larger context and purpose of the particular statutory scheme, particularly in the context of discerning the preemptive scope of the FD&C Act.[36]

Even where a federal law's express preemption provision does not preempt a state law or where a federal law lacks an express preemption provision altogether, the federal law can still impliedly preempt state law when Congress's preemptive intent is implicit in the relevant federal law's structure and purpose.[37] The Supreme Court has identified two types of implied preemption: field preemption and conflict preemption.[38] Field preemption occurs when Congress has evidenced a desire to occupy the entire field of regulation, such that there is "no room for the states to supplement it."[39] Given states' traditional role in regulating the products subject to the FD&C

[32] Wyeth v. Levine, 555 U.S. 555, 565 (2009) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996)). *See also* Hughes v. Talen Energy Mktg., LLC, 578 U.S. 150, 162–63 (2016) (stating the same).

[33] *See, e.g.*, Wyeth v. Levine, 555 U.S. 555, 565-66 (2009) (considering the history of federal regulation of drugs and drug labeling when deciding whether a state measure was impliedly preempted by federal law); Va. Uranium, Inc. v. Warren, 587 U.S. 761, 767 (2019) (Gorsuch, J., lead opinion) (describing the Court's preemption analysis as "guided by the traditional tools of statutory interpretation"); *id.* at 785–87,791–93 (Kagan, J., concurring in judgment) (stating that "'the purpose of Congress is the ultimate touchstone' in determining whether federal law preempts state law," and focusing on the relevant text of the Atomic Energy Act and the law's purposes to determine its preemptive scope (quoting *Hughes*, 578 U.S. at 162–63)); Kansas v. Garcia, 589 U.S. 191, 208 (2020) (stating that the respondents' argument concerning implied preemption, "like all preemption arguments, must be grounded 'in the text and structure of the statute at issue'" (quoting CSX Transp., Inc. v. Easterwood, 507 U.S. 658, 664 (1993)); *id.* at 215 (Kagan, J., concurring in part) (analyzing whether a state law was impliedly preempted by a federal law by considering the federal law's "text, together with its structure, context, and purpose").

[34] *See, e.g.*, Riegel v. Medtronic, 552 U.S. 312, 330 (2008) (analyzing the scope of Medical Device Amendments' express preemption provision, which preempts state requirements that are "'different from, or in addition to' the requirements imposed by federal law" (quoting 21 U.S.C. § 360k(a)(1)). For more information about federal preemption, see CRS Report R45825, *Federal Preemption: A Legal Primer*, by Bryan L. Adkins, Alexander H. Pepper, and Jay B. Sykes (2023).

[35] *See* Cent. Maine Power Co. v. Maine Comm'n on Governmental Ethics & Election Pracs., 144 F.4th 9, 31 (1st Cir. 2025) (regarding a question about whether the Federal Election Campaign Act expressly preempted a state law prohibiting political campaign spending by certain "foreign government-influenced entity, observing that "issues of federal preemption are questions of statutory interpretation"); Adkins, Pepper & Sykes, *supra* note 34, at 3–4. *See generally* CRS Report R45153, *Statutory Interpretation: Theories, Tools, and Trends*, by Valerie C. Brannon (2023).

[36] *See, e.g.*, Medtronic, Inc. v. Lohr, 518 U.S. 470, 486 (1996) (explaining that relevant to the analysis of an express preemption provision is the "'structure and purpose of the statute as a whole,' as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law" (citation omitted) (quoting Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992)).

[37] The Supreme Court has stated on several occasions that "the existence of a separate pre-emption provision does not bar the ordinary working of conflict pre-emption principles." Hillman v. Maretta, 569 U.S. 483, 498 (2013) (internal quotations omitted); *see also* Arizona v. United States, 567 U.S. 387, 406 (2012) (similar).

[38] *See* Adkins, Pepper & Sykes, *supra* note 34, at 17.

[39] City of Charleston v. A Fisherman's Best, Inc., 310 F.3d 155, 169 (4th Cir. 2002).

Act, courts have often declined to apply field preemption in areas covered by the Act.[40] However, in certain discrete contexts—such as drug importation—some courts have concluded that the relevant FD&C Act provisions evidenced an intent by Congress to occupy the regulatory field.[41]

The other type of implied preemption is the doctrine of conflict preemption, for which the Supreme Court has recognized two subcategories: impossibility preemption and obstacle preemption.[42] Impossibility preemption can occur when it is "impossible for a private party to comply with both state and federal requirements."[43] In addition to considering the relevant statutory text, context, and history, courts analyzing impossibility preemption tend to focus on a comparative analysis of the specific implementation of the federal law versus relevant state law.[44] The Supreme Court has seldom invoked impossibility preemption[45] and has described it as a "demanding defense" when used to defeat the effect of a state law.[46] At the same time, the Court has twice relied on the doctrine to hold that federal labeling requirements for generic drugs preempt state law claims that would require generic drug manufacturers to provide different or additional warnings in the drugs' labeling.[47]

Obstacle preemption can occur if the implementation of state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[48] The Supreme Court has said that "[w]hat is a sufficient obstacle [for purposes of obstacle preemption] is a matter of judgment to be informed by examining the federal statute as a whole and identifying its purpose and intended effects."[49] While obstacle preemption has played an important role in the Court's preemption jurisprudence since the mid-20th century, and has been invoked by the Court in the FD&C Act context to preempt certain state-law claims,[50] some Justices have called the doctrine into question. In particular, they criticize the doctrine for "invalidat[ing] state laws based on perceived conflicts with broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are not embodied within the text of federal law."[51]

[40] *See, e.g.*, Lefaivre v. KV Pharm. Co., 636 F.3d 935, 941 (8th Cir. 2010) (concluding that the federal scheme of drug regulation "is *not* 'so pervasive in scope that it occupies the field.'" (quoting *In re* Aurora Dairy Corp. Organic Milk Mktg. & Sales Pracs. Litig., 621 F.3d 781, 792 (8th Cir. 2010))).

[41] *See infra* notes 246-251 and accompanying text.

[42] *See* Adkins, Pepper & Sykes, *supra* note 34, at 23; Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 480 (2013); Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992).

[43] *Bartlett*, 570 U.S. at 480.

[44] *See infra* notes 229–235 and accompanying text.

[45] *See* Adkins, Pepper & Sykes, *supra* note 34, at 24 (noting that the Court's case law on impossibility preemption "is not as well developed as other areas of its preemption jurisprudence").

[46] Wyeth v. Levine, 555 U.S. 555, 573 (2009).

[47] *See id.*

[48] *Gade*, 505 U.S. at 98; *see also* Lamps Plus, Inc. v. Varela, 587 U.S. 176, 183 (2019) (similar).

[49] Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 373 (2000).

[50] *See infra* "Preemption Based on the FD&C Act's Enforcement Scheme."

[51] *Levine*, 555 U.S. at 583 (Thomas, J., concurring in the judgment); *see also* Kansas v. Garcia, 589 U.S. 191, 213 (2020) (Thomas, J., concurring) (similar); Va. Uranium, Inc. v. Warren, 587 U.S. 761, 778 (2019) (Gorsuch, J., lead opinion) ("[I]n piling inference upon inference about hidden legislative wishes we risk displacing the legislative compromises actually reflected in the statutory text . . . . [, and i]n disregarding these legislative compromises, we may only wind up displacing perfectly legitimate state laws on the strength of 'purposes' that only we can see, that may seem perfectly logical to us, but that lack the democratic provenance the Constitution demands before a federal law may be declared supreme.").

An area of potential uncertainty is whether and under what circumstances should a canon of statutory construction known as "presumption against preemption" apply.[52] This canon, rooted in principles of federalism and respect for state sovereignty, generally instructs that courts should not construe a federal law to preempt a state law implicating the state's historic police powers "unless that was the clear and manifest purpose of Congress."[53] In preemption cases, the Supreme Court has at times applied this canon and described it as one of the "cornerstones" of its preemption jurisprudence.[54] Other times, however, the Court has resolved preemption questions without referencing the canon.[55] The Court's FD&C Act preemption cases reflect this inconsistency.[56] As discussed further below, the Court has, for instance, relied on the canon to hold that the FD&C Act did not preempt a state-law claim alleging that a brand-name prescription drug manufacturer failed to provide adequate warning of a drug's risks.[57] At the same time, the Court, without referencing the presumption, has also held that the FD&C Act preempted state-law claims alleging similar failure-to-warn claims against a generic manufacturer.[58] Lower courts have also disagreed over whether the presumption applies when a case involves the interpretation of an express preemption clause.[59]

Preemption and the FD&C Act

Over the FD&C Act's nearly 90-year history, Congress has significantly expanded the scope of products subject to the law. The original 1938 FD&C Act regulated drugs, food, medical devices, and cosmetics,[60] but over time, Congress amended the law to add or refine the products—such as

[52] A canon of construction is a type of statutory interpretation tool sometimes used by courts to resolve ambiguities in statutory text. For more information about statutory interpretation and canons of construction, see CRS Report R45153, *Statutory Interpretation: Theories, Tools, and Trends*, by Valerie C. Brannon (2023), at 27–39.

[53] Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947); *see also, e.g.*, *Levine*, 555 U.S. at 565 ("[I]n all pre-emption cases, and particularly in those in which Congress has legislated . . . in a field which the States have traditionally occupied, . . . we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.") (citations and internal quotation marks omitted).

[54] *See* Wyeth v. Levine, 555 U.S. 555, 565 (2009).

[55] *See, e.g.*, Riegel v. Medtronic, 552 U.S. 312, 334 (2008) (Ginsburg, J., dissenting) (arguing that "Federal laws containing a preemption clause do not automatically escape the presumption against preemption," which the majority did not address in its analysis).

[56] *Compare, e.g.*, *Levine*, 555 U.S. at 565 (stating that the Court's preemption analysis "must be guided by two cornerstones," one of which is that the Court must "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress" (internal quotations omitted)), *with Riegel*, 552 U.S. at 321–25 (analyzing the preemption question without referencing presumption against preemption).

[57] *See infra* notes 222–227 and accompanying text.

[58] *See infra* notes 221–233 and accompanying text.

[59] *Compare, e.g.*, Dialysis Newco, Inc. v. Cmty. Health Sys. Grp. Health Plan, 938 F.3d 246, 259 (5th Cir. 2019) (stating that that under the Supreme Court's decision in *Puerto Rico v. Franklin California Tax-Free Trust*, 579 U.S. 115, 125 (2016)), a court should not apply any presumption against preemption if the relevant federal statute contains an express preemption clause); Watson v. Air Methods Corp., 870 F.3d 812, 817 (8th Cir. 2017); EagleMed LLC v. Cox, 868 F.3d 893, 903 (10th Cir. 2017); Atay v. Cnty. of Maui, 842 F.3d 688, 699 (9th Cir. 2016), *with* Lupian v. Joseph Cory Holdings LLC, 905 F.3d 127, 131 n.5 (3d Cir. 2018) ("[W]e have determined that, because [*Franklin California*] . . . did not address claims involving areas historically regulated by states, we would continue to apply the presumption against preemption to express preemption claims.").

[60] Ch. 675, 52 Stat. 1040 (1938).

food additives, dietary supplements, and tobacco products—subject to FDA regulation.[61] Despite its expansion, the FD&C Act's general structure and framework from 1938 remains.

At its heart, the FD&C Act prohibits the distribution of a covered product in interstate commerce that is "adulterated" or "misbranded."[62] The Act then defines, for each product type, the circumstances and standards under which that product is "adulterated" or "misbranded."[63] The law provides FDA with a range of administrative tools to enforce the Act, including warning letters, import alerts, recalls, debarments, and civil money penalties.[64] The scope of some of these administrative tools differs between product types.[65] For all product types, however, a violation of the FD&C Act can subject a person to civil or criminal enforcement actions before a federal court.[66] With limited exceptions for certain actions that may be brought by a state, the FD&C Act generally requires "all such proceedings for the enforcement, or to restrain violations of [the FD&C Act]" to be "by and in the name of the United States," precluding a private plaintiff from suing to enforce an FD&C Act requirement.[67] Courts have considered both the preemptive effect of the FD&C Act's general enforcement scheme, as well as the preemptive effect of FD&C Act's product-specific provisions.

Preemption Based on the FD&C Act's Enforcement Scheme

The FD&C Act's general enforcement scheme, the Supreme Court has held, impliedly preempts certain state-law claims based on the theory that a regulated entity made misrepresentations to FDA during a premarket review process to obtain FDA approval. In *Buckman v. Plaintiff's Legal Committee*, plaintiffs with injuries resulting from the use of orthopedic bone screws sued a consulting company that had assisted the screw manufacturer in obtaining FDA clearance to market the devices.[68] The plaintiffs, asserting state tort law claims, alleged that the manufacturer committed fraud on the FDA by giving the agency misleading information in order to obtain this clearance.[69] The plaintiffs argued that had the proper information been provided to the agency, FDA would not have cleared the devices and the plaintiffs would not have been injured.[70]

Relying on implied preemption principles—and more specifically, obstacle preemption principles—the Court held that the plaintiffs' state-law "fraud-on-the-FDA" claims were

[61] *See, e.g.*, Food Additives Amendment of 1958, Pub L. No. 85-929, 72 Stat. 1784 (codified as amended at 21 U.S.C. §§ 321, 342, 346); Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (codified as amended in scattered provisions of 21 U.S.C. Ch. 9); Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. No. 111-31, 123 Stat. 1776 (codified as amended at scattered statutes of 21 U.S.C. Ch. 9). Since 1972, FDA has also regulated biological products. *See* Suzanne White Junod, *Biologics Centennial: 100 Years of Biologics Regulation*, UPDATE, FOOD & DRUG L. INST., Nov.–Dec. 2002, at 40, *reprinted by* FDA, https://www.fda.gov/files/Biologics-Centennial--100-Years-of-Biologics-Regulation.pdf [https://perma.cc/C3EK-6DC9]. While biological products are subject to regulation under Public Health Service Act (PHSA) section 351, see *supra* note 29, PHSA section 351(j) specifically applies FD&C Act requirements to biological products. 42 U.S.C. § 262(j).

[62] *See* 21 U.S.C. § 331.

[63] *See id.* §§ 342, 343, 351, 352, 361, 362, 387b, 387c.

[64] *See* CRS Report R43609, *Enforcement of the Food, Drug, and Cosmetic Act: Select Legal Issues*, by Jennifer A. Staman (2018), at 10–20.

[65] *See, e.g.*, *id.* at 11–12 (explaining that FDA's mandatory recall authority does not apply to drug products).

[66] *See* 21 U.S.C. §§ 331–333, 337(a).

[67] *Id.* § 337(a).

[68] 531 U.S. 341, 343 (2001).

[69] *Id.*

[70] *Id.* at 344.

preempted because they conflicted with the federal scheme for enforcing the FD&C Act.[71] In the Court's view, given that the FD&C Act "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions,"[72] state-law fraud-on-the-FDA claims "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives."[73] The Court observed that where a regulated product is subject to a comprehensive premarket review scheme like the medical device at issue, "complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants."[74] In the Court's view, such burdens were "not contemplated by Congress" when it enacted the FD&C Act and the Act's amendments governing medical devices.[75]

While *Buckman* specifically involved a medical device subject to a premarket review process known as the section 510(k) clearance process,[76] the Court's reasoning—premised on the FD&C Act's enforcement scheme that applies across product types—suggests that state-law "fraud-on-the-FDA" claims related to other products subject to FDA premarket review could be similarly impliedly preempted under *Buckman*.[77] Subsequent case law, however, shows that this analysis can depend on the specific structure and operation of applicable state laws. Several states, for example, have enacted state statutes that generally insulate drug manufacturers from certain tort claims so long as FDA approved the product at issue.[78] These state laws, however, also contain an exception that preserves tort liability if the manufacturer withheld or misrepresented information that would have altered FDA's approval decision.[79] In other words, under these state statutes, a plaintiff must provide evidence of fraud-on-the-FDA not as part of asserting such a claim, but as a prerequisite to asserting an underlying products liability claim.[80] Several lower courts have considered whether state tort claims asserted under this type of statutory exception were impliedly preempted under *Buckman*, and they have reached different conclusions. At least two appellate courts concluded that because the applicable state law "ultimately requires the plaintiff to prove that the drug manufacturer defrauded the FDA, it conflicted with the FDA's duties and was preempted" under *Buckman*.[81] Another appellate court, however, concluded that under the relevant state law, the plaintiffs "[were] not pressing 'fraud-on-the-FDA' claims" subject to preemption under *Buckman*, but rather, they were "asserting claims that sound in traditional state

[71] *Id.* at 348.

[72] *Id.* at 349 n.4.

[73] *Id.* at 350.

[74] *Id.*

[75] *Id.*

[76] For information about section 510(k) clearance, see *infra* "Overview of Selected FD&C Act Provisions on Medical Devices."

[77] To the extent some Justices have cast doubt over obstacle preemption in general, as discussed above, such doubt raises a potential question as to *Buckman*'s validity, should the Supreme Court revisit its obstacle preemption jurisprudence. However, even if the Supreme Court reconsiders its obstacle preemption jurisprudence, any narrowing or elimination of the obstacle preemption doctrine may not end the preemption analysis in a given case. Other relevant FD&C Act provisions may have preemptive effect under other preemption principles. In *Buckman*, for instance, a lower court concluded that the state claims were also preempted by the express preemption provision that applies to medical devices. *See* 531 U.S. 341 at 347.

[78] *See, e.g.*, Desiano v. Warner-Lambert & Co., 467 F.3d 85, 87 (2d Cir. 2006) (analyzing Mich. Comp. Laws § 600.2946(5)); Lofton v. McNeal Consumer & Specialty Pharms., 672 F.3d 372, 374 (5th Cir. 2012) (analyzing TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(a)(1)).

[79] *See, e.g.*, *Desiano*, 467 F.3d at 87; *Lofton*, 672 F.3d at 374.

[80] *See Lofton*, 672 F.3d at 377.

[81] *Lofton*, 672 F.3d at 377; *see also* Garcia v. Wyeth-Ayerst Labs., 385 F.3d 961, 965–66 (6th Cir. 2004) (similar).

tort law."[82] Because the plaintiffs' claims, in the court's view, were "premised on traditional duties between a product manufacturer and . . . consumers" and were not "derive[d] from, or . . . based on, a newly-concocted duty between a manufacturer and a federal agency," such claims were not preempted under *Buckman*.[83]

More broadly, lower courts have also considered whether state-law claims based on state laws that incorporate or mirror FD&C Act requirements are impliedly preempted under *Buckman*. The courts that have considered this question have generally concluded that such claims were not preempted.[84] In *Davidson v. Sprout Foods, Inc.*, consumers of certain baby food products sued the product maker, alleging that the relevant product labels violated California's Sherman Law, which incorporates by reference all federal food labeling requirements.[85] The defendant argued, and the district court agreed, that the plaintiffs' state claims were preempted under *Buckman* because "Sherman Law depends upon and adopts the [FD&C Act] and regulations as state law," and thus the claims amounted to an impermissible attempt to privately enforce the FD&C Act.[86] Reversing the district court, the U.S. Court of Appeals for the Ninth Circuit (Ninth Circuit) held that the plaintiffs' claims based on the Sherman Law were not impliedly preempted because the FD&C Act "did not . . . purport to limit enforcement of . . . parallel state laws in any way."[87] The Ninth Circuit observed that unlike *Buckman*, in which the plaintiffs' state-law claims were premised solely on violations of FD&C Act duties, the *Davidson* plaintiffs' claims were based on violations of state-law duties, which happened to impose identical standards as federal law.[88] The U.S. Court of Appeals for the Fifth Circuit (Fifth Circuit) applied similar reasoning in *Zyla Life Sciences, L.L.C. v. Wells Pharma of Houston, L.L.C.*[89] The Fifth Circuit held that a drug manufacturer's claims against a competing compounding pharmacy based on state unfair competition law that incorporated federal standards were not impliedly preempted.[90]

Preemption Based on FD&C Act's Product-Specific Provisions

While the core structure and general enforcement scheme of the FD&C Act has remained the same since 1938, the law's product-specific provisions and standards have evolved over time and vary based on a particular product type's nature and risk profile. Over the years, Congress—in addition to amending the product-specific standards and provisions—has also added express preemption provisions in certain parts of the FD&C Act. The Act had no express preemption

[82] *Desiano*, 467 F.3d at 94–95.

[83] *Id.*

[84] *See, e.g.*, Davidson v. Sprout Foods, Inc., 106 F.4th 842, 844–45 (9th Cir. 2024); Zyla Life Sci., L.L.C. v. Wells Pharma of Houston, L.L.C., 134 F.4th 326 (5th Cir. 2024); Allergan, Inc. v. Athena Cosmetics, Inc., 738 F.3d 1350, 1355 (Fed. Cir. 2013). *But see* Nexus Pharms., Inc. v. Cent. Admixture Pharm. Servs., Inc., 48 F.4th 1040, 1050–51 (9th Cir. 2022).

[85] *Davidson*, 106 F.4th at 844–45.

[86] *See id.* at 847 (internal quotations omitted).

[87] *Id.* at 848.

[88] *Id.* at 848–49.

[89] 134 F. 4th 326, 331 (5th Cir. 2025).

[90] *Id.* (stating that "[t]he question presented on appeal is whether the state laws somehow conflict with the [FD&C Act] by incorporating it" and concluding that "[t]hey do not"). *But see Nexus Pharms*., 48 F.4th at 1050–51 (holding that a drug manufacturer's state unfair competition claim against a competing compounding pharmacy was impliedly preempted because the claim turned on whether the compounded drugs distributed by the defendant qualified for an exception from FDA approval—a determination regarding whether a violation of the FD&C Act had occurred). The defendant in *Zyla Life* has filed a petition for certiorari with the Supreme Court seeking review of the Fifth Circuit's decision. Petition for a Writ of Certiorari, Wells Pharma of Houston, L.L.C. v. Zyla Life Sci., L.L.C., No. 25-257 (U.S. Sep. 2, 2025).

provisions until 1976, when Congress enacted the Medical Device Amendments (MDA).[91] The MDA includes a provision that preempts state laws imposing additional or different requirements related to the safety and efficacy of medical devices.[92] Since 1976, Congress has added several preemption provisions that apply to specific product categories or topics, including with respect to food labeling,[93] cosmetics labeling and packaging,[94] and certain tobacco product standards.[95]

Courts, including the Supreme Court, have weighed in on the preemptive scope of these product-specific FD&C Act provisions on many occasions. Many of these cases focus on the extent to which the FD&C Act preempts state tort or consumer protection law claims.[96] Because the products regulated by the FD&C Act are generally consumer products, injuries allegedly caused by such products implicate both state tort law—specifically, state products liability law[97]—and state laws protecting consumers from unfair or deceptive practices.[98] In suits that alleged products liability claims, the plaintiffs often asserted that the manufacturer had defectively manufactured or designed the product at issue, or failed to provide adequate warning of certain risks.[99] Had the manufacturers differently manufactured or designed the product, or provided certain different or additional warnings, the plaintiffs typically alleged, they would have avoided the injuries.[100] With respect to consumer protection claims, the plaintiffs often alleged that the manufacturers deceptively or unfairly marketed the relevant products in a manner that harmed the plaintiffs.[101] In addition to these tort and consumer protection claims, some courts have also considered whether and to what extent the FD&C Act preempted certain state statutes enacted to address certain products or topics also regulated by the Act.

The sections below provide an overview of the preemptive scope of the FD&C Act's product-specific provisions for food products, prescription drugs, medical devices, cosmetics, and tobacco products. For each product type, the discussion begins with an overview of selected FD&C Act provisions and continues with an analysis of relevant case law regarding the provisions' preemptive scope.

[91] *See* Pub. L. No. 94-295, sec. 521, 90 Stat. 539, 574 (codified as amended at 21 U.S.C. § 360k) (1976).

[92] *Id.*

[93] Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, § 6, sec. 403A, 104 Stat. 2353, 2362 (codified as amended at 21 U.S.C. § 343-1).

[94] Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 412(d), sec. 752, 111 Stat. 2296, 2376 (codified as amended at 21 U.S.C. § 379s).

[95] Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. No. 111-31, § 101(b), sec. 916, 123 Stat. 1776, 1820 (codified as amended at 21 U.S.C. § 387p).

[96] *See, e.g.*, *infra* "Case Law on the Preemptive Scope of Selected Prescription Drug Provisions"; "Case Law on the Preemptive Scope of FD&C Act Section 916."

[97] *See supra* note 20.

[98] *See* NAT'L CONSUMER L. CTR., *supra* note 18, at 1–3.

[99] *See, e.g.*, *infra* "Case Law on the Preemptive Scope of Selected Prescription Drug Provisions."

[100] *See infra* "Case Law on the Preemptive Scope of Selected Prescription Drug Provisions."

[101] *See, e.g.*, *infra* "Case Law on the Preemptive Scope of FD&C Act Section 916."

Food Products[102]

Overview of Selected FD&C Act Provisions on Food Products

The original 1938 FD&C Act prohibited the introduction of misbranded or adulterated food in interstate commerce.[103] Under the law, such food products were misbranded if, for instance, their labeling included false and misleading statements; such products were adulterated, for instance, if their content did not comply with established mandatory food standards called *standards of identity*.[104] Over the years, Congress amended the FD&C Act's food provisions on many occasions to impose additional requirements.[105] For example, while most food products do not need to undergo premarket review before they can be lawfully marketed, Congress, under the Food Additives Amendment of 1958[106] and the Color Additive Amendments of 1960,[107] created a system of premarket review of certain food ingredients. In 1990, Congress also enacted the Nutrition Labeling and Education Act (NLEA), which amended the FD&C Act to establish uniform labeling requirements for food sold in interstate commerce.[108]

Under current law, food products must comply with various labeling requirements. For instance, a food label must bear,[109] if applicable, the name of the food specified in the relevant standard of identity, which defines the mandatory or optional ingredients and characteristics of a food.[110] If there is no relevant standard of identity, the food label must bear the common or usual name of the food.[111] A food is deemed misbranded under the Act if the food's label represents the product as a food for which a standard of identity has been issued, and the product does not conform to the definition.[112]

Labels of food in package form must also bear nutrition information, including the serving size, the number of servings per container, and the amounts of nutrients in each serving size.[113] This information must appear on an "information panel," or the part of the label immediately to the right of the package's principal display that is most likely to be shown to consumers in retail

[102] Except in limited circumstances, *food* as defined by the FD&C Act includes dietary supplements. *See* 21 U.S.C. § 321(ff). Because an analysis of the courts' preemption jurisprudence relating to dietary supplements is beyond the scope of this report, this report uses the terms *food products* or *food* to refer to non-dietary-supplement food products.

[103] Ch. 675, 52 Stat. 1040 (1938). FDA and the U.S. Department of Agriculture (USDA) share responsibility for food regulation. USDA regulates certain meat, poultry, and egg products, and FDA regulates all other foods. *See Formal Agreement Between USDA and FDA Relative to Cooperation and Coordination*, FDA, https://www.fda.gov/food/international-interagency-coordination/formal-agreement-between-usda-and-fda-relative-cooperation-and-coordination [https://perma.cc/3LEA-73DU] (last visited Mar. 19, 2026). USDA's regulation of food is beyond the scope of this report.

[104] The Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1040 (1938) (codified at 21 U.S.C. §§ 321, et. seq.); *see also* HUTT ET AL., *supra* note 16, at 469.

[105] *See*, *e.g.* Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (1958).

[106] *Id*.

[107] Pub. L. No. 86-618, 74 Stat. 397 (1960).

[108] Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353.

[109] 21 U.S.C. § 343(g).

[110] *Id.* § 341; 21 C.F.R. §§ 131.3–169.182 (2025) (standard of identity regulations). The FD&C Act directs FDA to promulgate standards of identity whenever "such action will promote honesty and fair dealing in the interest of consumers." 21 U.S.C. § 341.

[111] *Id.* § 343(i).

[112] *Id.* § 343(g).

[113] *See* 21 U.S.C. § 343(q)

sale.[114] In addition, FDA regulations set out requirements for nutrient content claims that may be included on food packages.[115] A nutrient content claim characterizes the level of a nutrient in a product.[116] If a manufacturer chooses to include a nutrient content claim on a product's label,[117] the claim must meet the applicable regulatory requirements.[118] For example, FDA regulations define many terms, including "more," "fortified," "enriched," "high potency," "light ," "free," and "low" and specify the conditions under which manufacturers may use these terms on their labels.[119]

In addition to labeling requirements, FDA must approve the use of certain food ingredients called *food additives* as safe before they can be used in products.[120] Food containing any food additive that has not been approved as safe is deemed to be adulterated and may be subject to FDA enforcement.[121] The FD&C Act defines food additive as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food" if the substance is not generally recognized as safe (GRAS).[122] A substance is GRAS—and therefore not a food additive subject to premarket review—if "experts qualified by scientific training and experience to evaluate its safety" generally recognize the intended use of the substance to be safe.[123] According to this statutory definition, qualified experts must base their view of a general recognition of safety on either (1) scientific procedures or (2) common use of a substance in food prior to January 1, 1958.[124] FDA has promulgated regulations recognizing certain ingredients as GRAS, which is sometimes called the GRAS list.[125] This list, however, is not comprehensive because it "is impracticable to list all substances that are [GRAS]."[126]

[114] 21 C.F.R. §§ 101.2(b), 101.2(d), 101.1 (2025).

[115] *Id.* § 101.72. The FD&C Act also imposes requirements on health claims, which are claims that link the consumption of a nutrient to a disease or health-related condition. 21 U.S.C. § 343(r)(1)(B). For example, a label for a product that is high in calcium (such as milk) may state that consuming the product may reduce the risk of osteoporosis. 21 C.F.R. § 101.72 (2025). The FD&C Act allows a manufacturer to include a health claim on a food's label only when FDA has promulgated a regulation approving the health claim, based on a determination that there is "significant scientific agreement" among qualified experts that the claim is supported. 21 U.S.C. § 343(r). To date, FDA has promulgated regulations approving 12 health claims. *See* 21 C.F.R §§ 101.72–101.83 (2025). FDA has also opted to exercise enforcement discretion to allow the use of certain so called "qualified health claims" that do not meet the statutory criteria with the use of an appropriate disclaimer. *See Guidance for Industry: FDA's Implementation of Qualified Health Claims*: *May 2006*, FDA (Sep. 20, 2018), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-fdas-implementation-qualified-health-claims [https://perma.cc/Z6TZ-N523].

[116] 21 U.S.C. § 343(r)(1)(A).

[117] 21 C.F.R. § 101.13(b) (2025).

[118] *Id.* §§ 101.54–101.69.

[119] *See id*. §§ 101.54–101.62.

[120] 21 U.S.C. §§ 342(a), 348(a)–(g).

[121] *Id.* § 342(a).

[122] *Id.* § 321(s).

[123] *Id*.

[124] *Id*.

[125] *See* 21 C.F.R. pt. 182 (2025).

[126] *Id.* § 182.1(a) ("It is impracticable to list all substances that are generally recognized as safe for their intended use. However, by way of illustration, the Commissioner regards such common food ingredients as salt, pepper, vinegar, baking powder, and monosodium glutamate as safe for their intended use.").

Selected FD&C Act Provisions on Preemption Related to Food Products

Recognizing the role that states and localities traditionally play in food regulation, Congress has directly addressed the interplay between the FD&C Act and state and local law through several express preemption and "no preemption" provisions. For example, section 416 of the FD&C Act directs FDA to promulgate regulations that generally require those engaged in the transportation of food to use sanitary transportation practices prescribed by the agency.[127] Subsection (e) of section 416 generally preempts state or local requirements "concern[ing] the transportation of food" if complying with both federal and state/local requirements is impossible or if complying with state/local requirements presents an obstacle to carrying out the federal requirements.[128] On the other hand, other FD&C Act provisions, under the heading of "No preemption," expressly preserve any non-federal requirements.[129] FD&C Act section 418(i)(6), for example, expressly preserves any "non-Federal law regarding the safe production of food."[130] Similarly, section 419(f)(5) preserves any "non-Federal law regarding the safe production, harvesting, holding, transportation, and sale of fresh fruits and vegetables."[131]

With respect to food labels, the FD&C Act, as amended by the NLEA, also includes an express preemption provision, entitled "National Uniform Nutrition labeling," that forbids states and localities from establishing any requirement that is "not identical to" specified federal requirements related to food labeling.[132] This labeling preemption provision (FD&C Act section 403A) states the following:

> (a) Except [in certain circumstances], no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—
>
> > (1) any requirement for a food which is the subject of a standard of identity established under section [401] of this title that is not identical to such standard of identity or that is not identical to the requirement of section [403(g)] of this title, except [in certain circumstances],
> >
> > (2) any requirement for the labeling of food of the type required by section [403(c), 403(e), 403(i)(2), 403(w), or 403(x)] of this title that is not identical to the requirement of such section, except [in certain circumstances],
> >
> > (3) any requirement for the labeling of food of the type required by section [403(b), 403(d), 403(f), 403(h), 403(i)(1), or 403(k)] of this title that is not identical to the requirement of such section, except [in certain circumstances],
> >
> > (4) any requirement for nutrition labeling of food that is not identical to the requirement of section [403(q)] of this title, except [in certain circumstances], or
> >
> > (5) any requirement respecting any claim of the type described in section [403(r)(1)] of this title made in the label or labeling of food that is not identical to the requirement of section [403(r)] of this title, except [in certain circumstances].[133]

[127] 21 U.S.C. § 350e(b).

[128] *Id.* § 350e(e)(1).

[129] *See id.* §§ 350g(l)(6), 350h(f)(5).

[130] *Id.* § 350g(l)(6).

[131] *Id.* § 350h(f)(5). Both of the "no preemption" provisions in sections 418(l)(6) and 419(f)(5) state that compliance with applicable federal law does "not relieve any person from liability" under relevant state law. 21 U.S.C. §§ 350g(l)(6), 350h(f)(5).

[132] *Id.* § 343-1(a).

[133] *Id.* § 343-1.

This preemption provision cross-references numerous requirements or prohibitions of the FD&C Act's misbranded food section under section 403.[134] The cross-referenced provisions include, for instance, labeling requirements related to a food's standard of identity, nutritional information, and nutrient content claims, limiting states' ability to establish requirements that are "not identical" to these federal requirements.[135]

The NLEA also contains a savings clause that limits FD&C Act section 403A's preemptive effect and expressly preserves certain types of state laws or remedies.[136] The clause provides that "[the NLEA] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under FD&C Act section 403A."[137] It further states that section 403A "shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food."[138] The provision also clarifies that section 403A "shall not be construed to affect" the preemptive scope of any other provision of the FD&C Act.[139]

Case Law on the Preemptive Scope of Selected FD&C Act Provisions on Food Products

To date, courts that have considered the preemptive effect of the FD&C Act provisions governing food products have primarily considered whether and to what extent FD&C Act section 403A expressly preempts consumers' state-law claims regarding a food label. These consumer claims generally involve state consumer protection or tort claims alleging that a food label is misleading or does not adequately warn of the risks associated with a food product.[140] In addition, at least one court has considered the preemptive effect of FDA's GRAS determination on a state statute prohibiting that substance.[141]

Case Law on the Preemptive Scope of FD&C Act Section 403A on Food Labeling

Although the U.S. Supreme Court has not addressed the scope of FD&C Act section 403A, lower courts have opined on the extent to which consumer state-law claims are preempted by the clause. Generally, lower courts have held that state-law claims that were interpreted to impose additional or different labeling requirements from what applicable FDA regulations require were preempted because such state claims sought to impose labeling that was "not identical" to federal requirements under FD&C Act section 403A.[142]

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[134] *See id.*

[135] *See id.* § 343.

[136] 21 U.S.C. § 343-1 notes. The savings clause is not codified, but rather included in the statutory notes. *Id.* When a public law is added to a statutory note, it has the same legal effect as a public law that is added to the code. *See* Aldana v. Del Monte Fresh Produce, N.A., Inc., 416 F.3d 1242, 1251 (11th Cir. 2005) (per curiam) ("That the [Torture Victim Protection Act of 1991 (TVPA)], which was published in the Statutes at Large, appears in the United States Code as a historical and statutory note to the Alien Tort Act does not make the TVPA any less the law of the land.").

[137] 21 U.S.C. § 343-1 notes.

[138] *Id.*

[139] *Id.*

[140] *See e.g.* Nemphos v. Nestle Waters N.A., Inc., 775 F.3d 616, 618 (4th Cir. 2015) (considering state tort law claims that Nestle failed to warn consumers of the risk of dental fluorosis and claims that Nestle violated the Maryland Consumer Protection Act, which prohibits unfair and deceptive trade practices acts, by engaging in misleading marketing).

[141] Marrache v. Bacardi, U.S.A, 17 F.4th 1084, 1089 (11th Cir. 2021).

[142] *See Nemphos*, 775 F.3d at 625 ("The warning requirement Nemphos seeks is simply not identical to the FDA's (continued...)

For example, in *Pardini v. Unilever United States*, the Ninth Circuit considered the plaintiffs' allegations that the "I Can't Believe It's Not Butter! Spray" product's label misrepresented its fat and calorie content.[143] The plaintiffs alleged that the front of the product's label, which claimed that it has 0 calories and 0 grams of fat, was misleading because the 12-ounce bottle of the product contains 1160 calories and 124 grams of fat.[144] The defendant argued that the plaintiffs' claim that the label was misleading was preempted because the label's claims complied with FDA regulations that specifically governed "zero fat" claims and that the plaintiffs were seeking to impose different labeling requirements.[145] The court agreed with the defendant. In particular, the court observed that under applicable FDA regulations, for products categorized as a "spray type," their amount of fat and calories must be expressed in terms of a prescribed serving size of 0.25 grams.[146] When the amount of fat and calories in a designated serving size was below a certain threshold (5 calories and 0.5 grams of fat), the regulations also required the product to reflect that the product has zero calories or fat per serving on the label's information panel.[147] The court concluded that because the defendant properly categorized the product as a "spray type," its nutrition labeling complied with the relevant requirements, which allowed for the defendant to round the amount of calories and fat down to zero.[148] Accordingly, the court held that the plaintiffs' claim—which would have required the defendant to label the product differently from what FDA regulations required—was expressly preempted.[149]

Courts have also held that state-law claims seeking to impose additional disclosures beyond what FDA regulations require would impose a requirement that is "not identical to" the FD&C Act requirements and are therefore preempted.[150] For example, in *Turek v. General Mills*, the manufacturer of a "chewy bar" included claims on the front of its label that the product contained "35% of your daily fiber" and called it "Fiber Plus."[151] The plaintiff alleged that the product contained "non-natural fiber" which provided fewer of the benefits of consuming fiber, may cause stomach problems in some people, and may be harmful to women who were pregnant or breastfeeding.[152] The plaintiff argued that the product's label was misleading because it did not disclose that the product used an inferior form of fiber that was not "natural" and may be harmful to some.[153] The U.S. Court of Appeals for the Seventh Circuit (Seventh Circuit) held that the labeling claims challenged by the plaintiff were compliant with all applicable FDA regulations

existing standard of identity. As such, her failure-to-warn claim is preempted."); Young v. Johnson & Johnson, 525 F. App'x 179, 185 (3d Cir. 2013) ("Because Young's state law action seeks to impose standards that are not identical to those set forth in the regulations, it is expressly preempted by the NLEA as it relates to those claims").

[143] Pardini v. Unilever United States, Inc., 65 F.4th 1081, 1083 (9th Cir. 2023).

[144] *Id*.

[145] *Id*. at 1084.

[146] *Id*. at 1089–90 (citing 21 C.F.R. § 101.12(b) ("The [reference amounts in the chart] shall be used as the basis for determining serving sizes for specific products")).

[147] *Id*. at 1085 (citing 21 C.F.R. §§ 101.9(c)(1), 101.9 (c)(2), 101.60(b)(1)(i), 101.62(b)(1)(i)).

[148] *Id*. at 1091.

[149] *Id*.

[150] Turek v. Gen. Mills, Inc., 662 F.3d 423, 427 (7th Cir. 2011) ("The disclaimers that the plaintiff wants added to the labeling of the defendants' inulin-containing chewy bars are not identical to the labeling requirements imposed on such products by federal law, and so they are barred."); *Nemphos*, 775 F.3d at 625 ("[The plaintiff] seeks a required warning that is additional to and certainly 'not identical to' the federal standard. The FDA's standard of identity . . . does not demand a warning about dental fluorosis." (quoting 21 C.F.R. § 100.1(c)(4)).

[151] *Turek*, 662 F.3d at 425.

[152] *Id*. at 426.

[153] *Id*.

related to dietary fiber.[154] Because the disclaimers the plaintiff sought to add to the label "[were] not identical to the labeling requirements imposed on such products by federal law," they were expressly preempted.[155]

In contrast, courts have generally held that two kinds of state-law claims are not preempted by FD&C Act section 403A: (1) state claims that allege as false or misleading certain labeling claims that a defendant is not specifically required or permitted to include by FDA regulations;[156] and (2) state claims that seek to impose requirements interpreted to be identical to what federal law requires.[157]

Courts have generally held that claims focused on additional labeling claims not specifically required or permitted by FDA regulations that a defendant *chose* to include were not preempted by FD&C Act section 403A.[158] For example, in *Hawkins v. Kroger Company*, the Ninth Circuit held that a plaintiff's claim—that a bread crumb product's front label stating that the product had "0g Trans Fat per serving" was misleading because the product did have small amounts of trans fat—was not preempted.[159] The court observed that while FDA regulations required the amount of trans fat per serving to be stated on the information panel on the side of the label and required such amount to be expressed as zero "[i]f the serving contains less than 0.5 gram," these requirements did not apply to nutrient content claims—which can only be made if they were not "false or misleading in any respect"—on the front of the label.[160] The court further observed that FDA had "explicitly decided not to authorize a 'No Trans Fat' nutrient content claim in light of a lack of scientific information."[161] Accordingly, the court held that because FDA regulations did not "authorize the contested statement," the state-law claims were not preempted.[162]

Similarly, in *Bell v. Publix Super Markets*, the Seventh Circuit held that certain consumers' state-law claims—that a product's label stating it was "100% Grated Parmesan Cheese" was misleading because the product contained cellulose powder and potassium sorbate to prevent the grated cheese from caking and getting moldy—were not preempted by federal law.[163] Under federal law, grated cheese is subject to an FDA standard of identity that allows products labeled as "grated cheese" to include cellulose powder and potassium sorbate,[164] and the defendant argued that because it had complied with the standard, the plaintiffs' claims were preempted

[154] *Id.* at 426–27.

[155] *Id*. at 427.

[156] *See, e.g.*, Bell v. Publix Super Markets Inc., 982 F.3d 468, 474 (7th Cir. 2020).

[157] *See* Lilly v. ConAgra, 743 F.3d 662, 665 (2014).

[158] *Bell*, 982 F.3d at 474; *see also*, Chacanaca v. Quaker Oats Co., 752 F. Supp. 2d 1111, 1123 (N.D. Cal. 2010) (determining deceptive labeling claims regarding pictures on the front of the label, which are not regulated by the FD&C Act, and the phrase "wholesome," for which FDA has not issued a regulation, are not preempted).

[159] Hawkins v. Kroger Co., 906 F.3d 763, 767, 773 (9th Cir. 2018).

[160] *Id*. at 770 (internal quotations omitted). *See also id.* ("'Information that is required or permitted by § 101.9 . . . and that appears as part of the nutrition label, is not a nutrient content claim . . . . If such information is declared elsewhere on the label . . . it is a nutrient content claim and is subject to the requirements for [such] claims.'" (alteration in original) (quoting 21 C.F.R. § 101.13(c))). Unlike in *Pardini*, in which a challenged nutrient content claim on the front label was explicitly permitted by applicable FDA regulation, *see* 21 C.F.R. § 101.62(b), the challenged nutrient content claim in *Hawkins* was not subject to applicable FDA regulation. *See Hawkins*, 906 F.3d at 771.

[161] *Id*. at 771.

[162] *Id*. at 772.

[163] *Bell*, 982 F.3d at 474.

[164] *See* 21 U.S.C. § 343(g) ("A food shall be deemed to be misbranded . . . If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations . . . unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard . . ."); 21 C.F.R. § 133.146 (standard of identity for grated cheeses).

because they sought to impose different standard-of-identity requirements.[165] The Seventh Circuit rejected this argument, reasoning that because the standard-of-identity regulation does not address whether products may be labeled with an additional modifier such as "100%," a state-law claim seeking to prevent its use in certain circumstances did not establish a new requirement different from the standard of identity.[166] Because the plaintiffs were seeking to "stop defendants from voluntarily adding deceptive language to the federally permitted label,"[167] the court concluded that the state-law claims based on defendant's use of the "100%" modifier were not preempted.[168]

A second category of state-law claims that courts have held are not preempted by FD&C Act section 403A are those that seek to impose requirements interpreted to be identical to those set out in FDA regulations.[169] For example, in *Lilly v. ConAgra Foods*, the Ninth Circuit concluded that a plaintiff's claim under state law—that defendant's sunflower seed label misrepresented the amount of sodium content of the sunflowers—was not preempted by federal law.[170] The plaintiff alleged that the sunflower seed label declared the amount of salt in the sunflower seed but did not include the amount of salt that was in the coating on the sunflower shell.[171] The defendant argued that under federal law, manufacturers need not include the amount of sodium on inedible components like the shell, and therefore the plaintiff's claim imposed requirements that differed from federal requirements and thus was preempted.[172] Siding with the plaintiff, the court observed that applicable FDA regulations required declaration of the amounts of nutrient and food component content to be "based on only the edible portion of food, and not bone, seed, shell, or other inedible components."[173] The court reasoned that, even though the sunflower seed shell is not meant to be consumed, the coating on the shell is edible and therefore must be included in the sodium declaration on the food's label.[174] The court concluded that because the "plaintiff's state-law claims, if successful, would impose no greater burden than those imposed by federal law, her state-law claims [were] not preempted."[175]

Case Law on the Preemptive Scope of FDA's GRAS Regulation

While the majority of courts that have considered the preemptive effect of the FD&C Act's food provisions have focused on section 403A, at least one court has considered the implied preemptive effect of the FD&C Act's food additive and GRAS regulations on state statutes that restrict the use of certain substances in food.[176] Concerns over the safety of certain food

[165] *See Bell*, 982 F.3d at 483–84.

[166] *Id*. at 484.

[167] *Id*. The court noted that the NLEA preemption clause does not include the FD&C Act's general prohibition of "false or misleading" labeling, and therefore the preemption clause "does not expressly preempt state-law prohibitions on deceptive statements that sellers add voluntarily to their labels or advertising." *Id*. (quoting 21 U.S.C. § 343(a)).

[168] *Id*. at 485. The court also briefly addressed the argument that the FD&C Act impliedly preempted the plaintiff's claims, concluding that impossibility preemption did not apply because it was possible to comply with applicable state and federal requirements. *Id*. at 486.

[169] *See* Lilly v. ConAgra, 743 F.3d 662, 665 (2014).

[170] *Id*.

[171] *Id*. at 664.

[172] *Id*. at 665.

[173] *Id*. (quoting 21 C.F.R. §§ 101.9(b), 101.12(a)(6)).

[174] *Id*.

[175] *Id*. at 663.

[176] *See* Marrache v. Bacardi, U.S.A, 17 F.4th 1084, 1089 (11th Cir. 2021).

ingredients have led several states to enact legislation that would prohibit the use of certain food substances.[177]

In *Marrache v. Bacardi*, the U.S. Circuit Court for the Eleventh Circuit (Eleventh Circuit) considered a Florida law that banned adding certain substances to liquor and held that the state law was not preempted.[178] The Florida law at issue banned the use of, among other things, grains of paradise, a botanical that was used in one of the defendant manufacturer's gin products.[179] Grains of paradise, however, is included on the non-exhaustive list of GRAS substances promulgated by FDA and expressly identified by the agency as "generally recognized as safe."[180] A consumer sued the defendant manufacturer, asserting that the defendant violated state consumer protection laws by selling products containing an ingredient banned under state law.[181] In response, the defendant argued, among other things, that the plaintiff's claims were preempted because the underlying state law conflicted with applicable federal regulations because it prohibited the use of a food substance FDA had specifically found to be GRAS.[182]

The court rejected the defendant's argument, concluding that the state law was not preempted because it was not impossible for the defendant to comply with both state and federal law, nor did the Florida law frustrate the purposes of the Food Additives Amendment.[183] The court first concluded that compliance with both laws was possible because while FDA had determined grains of paradise to be GRAS, permitting them to be included in food or alcohol, neither the FD&C Act nor its implementing regulations required foods with grains of paradise to be sold in all states.[184] Thus, the court reasoned, the defendant may comply with both federal and state law "by selling [its product] without grains of paradise in Florida while selling [its product] with grains of paradise in other states."[185] The court next concluded that the Florida law did not frustrate Congress's purpose in enacting the Food Additives Amendment.[186] Congress's purpose in enacting the Food Additives Amendment—"as derived from the statutory text—was to prohibit unsafe food additives from being included in food and alcohol to protect the health and safety of the public."[187] The court reasoned that the statute does not indicate that Congress intended to require states to allow the sale of GRAS substances.[188]

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[177] *See, e.g.*, CAL. HEALTH & SAFETY CODE § 109025(a) (West 2026) (prohibiting the sale of a food product for human consumption that contains brominated vegetable oil, potassium bromate, or propylparaben); TEX. EDUC. CODE ANN. § 33.901(b) (West 2026) (banning certain food additives including brominated vegetable oil in school lunches).

[178] *Marrache*, 17 F.4th at 1092–97. At least one other court has considered a challenge of another state law restricting the use of certain substances in food. In *International Ass'n of Color Manufacturers v. Singh*, the district court considered a West Virginia law banning "'any added substance or ingredients which are poisonous or injurious to the health'" including several color additives. No. 2:25-cv-00588, 2025 WL 3721864, at *2 (S.D.W. Va. Dec. 23, 2025) (quoting W. VA. CODE § 16-7-2(b)(7)). The court preliminarily enjoined the state from enforcing the law after determining that the plaintiff was likely to succeed on the merits of its claim that the phrase "poisonous or injurious to the health" is "unconstitutionally vague" and "leaves the door open for arbitrary enforcement." *See id.* at *10–11. The plaintiff in *Singh* did not argue that the West Virginia ban was preempted by the FD&C Act. *See id.* at *3–12.

[179] FLA. STAT. § 501.212.

[180] *Id.* § 182.10.

[181] *Marrache*, 17 F. 4th at 1089–90.

[182] *Id.* at 1091.

[183] *Id.* at 1095–97.

[184] *Id*. at 1095.

[185] *Id*.

[186] *Id*. at 1096–97.

[187] *Id*. at 1097.

[188] *Id*.

Prescription Drugs

Overview of Selected FD&C Act Provisions on Prescription Drugs

Since the original FD&C Act was enacted in 1938, there has been a federal system of premarket review of new drugs in the United States.[189] The initial system, however, was more akin to a notification system. The process required a manufacturer to submit a new drug application, including evidence of the drug's safety, to FDA for review but generally allowed the application to take effect after 60 days unless FDA could show that the drug was not safe for use as labeled.[190] In 1962, Congress enacted the Kefauver-Harris Drug Amendments (Drug Amendments) in response to incidences of birth defects caused by thalidomide in other countries, revamping the drug preapproval process.[191] The Drug Amendments not only require FDA to affirmatively approve a new drug application before a drug could be marketed, shifting the burden to prove safety from FDA to the manufacturer, but also require that a manufacturer demonstrate that a new drug is both safe *and* effective for its intended use.[192]

Under current law, to market a new drug, a manufacturer must file with FDA a New Drug Application (NDA), which must include, among other things, "full reports" of investigations into the drug's safety and effectiveness; a list of the drug's components; and "specimens of the labeling proposed to be used for such drug."[193] The FD&C Act directs FDA to deny an NDA if it finds, for example, the reports of testing show that the drug is unsafe or ineffective or if the "proposed labeling" does not make the drug "safe for use under the conditions prescribed, recommended, or suggested."[194] Where "necessary to ensure that the benefits of the drug outweigh the risks," FDA may also approve a drug subject to a risk evaluation and mitigation strategy, or REMS.[195] A REMS is a drug safety plan that mitigates the risks of a drug using strategies beyond FDA-approved labeling.[196] Such strategies may include dissemination of additional patient information, development of a communication plan with health care providers, and restrictions on distribution (e.g., by requiring dispensing entities to obtain special certifications).[197]

Once FDA has approved an NDA, the agency places the drug at issue on a public list of approved drugs.[198] The drugs on this list are known as *listed drugs*.[199] The law requires post-market surveillance of the drug by FDA, and requires the agency to withdraw approval of a new drug if it finds that the drug is unsafe, or that there is a lack of substantial evidence that the drug is effective.[200] The manufacturer must also comply with certain post-approval requirements,

[189] *See* ch. 675, 52 Stat. 1040 (1938).

[190] *See* Wyeth v. Levine, 555 U.S. 555, 566–67 (2009).

[191] Pub. L. No. 87-781, 76 Stat. 780 (1962); *see also Part III: Drugs and Foods Under the 1938 Act and Its Amendments*, FDA (Feb. 1, 2018), https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-iii-drugs-and-foods-under-1938-act-and-its-amendments [https://perma.cc/UQK8-NUDL] (providing an overview of the history of the amendments of FD&C Act's prescription drug provisions).

[192] *See Levine*, 555 U.S. at 566–67.

[193] 21 U.S.C. § 355(b)(1).

[194] *Id.*

[195] *Id.* § 355-1.

[196] *See id.* § 355-1(e) & (f).

[197] *See id.*

[198] *Id.* § 355(j)(7).

[199] *Id.* § 355(j)(2)(A)(i).

[200] *Id.* § 355(e)

including reporting "adverse events" to FDA and periodically submitting any new information that may affect the FDA's previous conclusions about the safety, effectiveness, or labeling of the drug.[201] While the manufacturer generally cannot make changes to the drug, including "[c]hanges in labeling," without obtaining FDA approval for the change,[202] FDA's "Changes Being Effected" regulations permit a manufacturer to add or strengthen a warning without prior approval by FDA.[203]

If a manufacturer wants to market a generic version of an already-approved brand-name drug, the manufacturer can file an abbreviated new drug application (ANDA) to show that the generic drug is therapeutically equivalent to a brand-name drug (i.e., a listed drug).[204] An ANDA generally must include "information to show that the new drug is bioequivalent to the listed drug,"[205] and "information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug."[206] The generic applicant is not required to conduct its own safety and effectiveness testing, but is permitted to rely upon the safety and effectiveness evidence presented in the NDA for the listed drug.[207] The FDA may withdraw approval of an ANDA for a generic drug if it finds that the labeling for the generic drug "is no longer consistent with that for the listed drug."[208] The current NDA holder of a brand-name drug may change a drug's labeling, but a generic drug manufacturer cannot and generally must ensure that its labeling remains the same as the labeling for the listed drug.[209]

Drugs manufactured in foreign countries that are imported into the United States for commercial distribution must comply with the same FD&C Act requirements as domestically manufactured drugs, including premarket approval.[210] Foreign-made drugs that have not undergone premarket approval, even if made with the same active ingredient as an FDA-approved drug, are generally considered unapproved new drugs that cannot be introduced into the U.S. market.[211] FD&C Act section 801(d)(1)(B) explicitly prohibits the importation of unapproved prescription drugs for commercial use, with two exceptions: (1) when authorized by the Secretary of Health and Human Services (HHS) pursuant to a drug shortage, and (2) pursuant to an FDA-authorized drug importation program under FD&C Act section 804.[212]

[201] *Id.* § 355(k).

[202] *See* 21 C.F.R. § 314.70(b)(1)-(2) (2025).

[203] *Id.* § 314.70(c)(6)(iii). The labeling change must be submitted to FDA in a supplemental NDA, which FDA may disapprove. If the agency disapproves the supplemental NDA, "it may order the manufacturer to cease distribution" of the relevant drug product. *Id.* § 314.70(c)(7).

[204] 21 U.S.C. § 355(j).

[205] *Id.* § 355(j)(2)(A)(iv).

[206] *Id.* § 355(j)(2)(A)(v).

[207] *See* SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharm., Inc., 211 F.3d 21, 26 (2d Cir. 2000).

[208] 21 C.F.R. § 314.150(b)(10) (2025).

[209] *Id.* §§ 314.94(a)(8), 314.127(a)(7). Certain limited differences in the labeling of the generic and the reference listed drug may be permitted. For instance, a generic drug manufacturer may propose labeling that omits the portions of the reference listed drug's labeling that are covered by an applicable patent or exclusivity. *See id.* For more information about this labeling difference—resulting in what is commonly known as a "skinny label" for the generic version—see CRS In Focus IF12700, *"Skinny Labels" for Generic Drugs Under Hatch-Waxman*, by Kevin J. Hickey (2026).

[210] *See* 21 U.S.C. §§ 331, 351, 355(a).

[211] *See id.*

[212] *Id.*§ 381(d)(1).

Added to the FD&C Act in the early 2000s,[213] section 804 authorizes FDA to promulgate regulations to establish a drug importation program under which pharmacists and wholesalers could import certain unapproved prescription drugs from Canada into the United States.[214] In order for the program to become effective, the HHS Secretary must certify that the program would pose no additional risk to the public's health and safety and would offer "significant reduction in the cost" to U.S. consumers.[215] The HHS Secretary made the requisite certification for the first time in 2020, and issued a final rule implementing the importation program.[216] Under the program, states and Indian Tribes may submit proposals to FDA to, on a time-limited basis,[217] import Canada-approved versions of certain FDA-approved prescription drugs.[218] Section 804(j) grants FDA the authority to waive the importation requirements for certain cases of importation for personal use that are consistent with FDA guidance.[219]

Case Law on the Preemptive Scope of Selected Prescription Drug Provisions

The FD&C Act's prescription drug provisions do not contain an express preemption provision.[220] Because prescription drugs are often the subject of state products liability lawsuits, courts are frequently confronted with questions regarding whether and to what extent the FD&C Act's elaborate premarket approval scheme for drugs impliedly preempts state-law claims that allege that a drug manufacturer inadequately warned of the risks of, or defectively designed, a drug. In addition to the premarket approval scheme, some courts have also considered how other aspects of the FD&C Act's prescription drug regulation—such as the Act's importation and REMS restrictions—impliedly preempt related state laws.

Case Law on the Preemptive Scope of Prescription Drug's Premarket Approval Scheme

With respect to the FD&C Act's preemption of state tort law claims, the Supreme Court has weighed in on these questions on multiple occasions, describing the preemption issues presented as "difficult . . . questions" that have "repeatedly vexed the Court."[221] In several cases, the Supreme Court considered the circumstances under which the FD&C Act preempts state claims alleging that a drug manufacturer failed to provide adequate warnings about the risks of a drug.

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[213] The provision was first added by the Medicine Equity and Drug Safety Act, Pub. L. No. 106-387, § 745, 114 Stat. 1549, 1549A–36 (2000) and amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1121(a), sec. 804, 117 Stat. 2066, 2464.

[214] 21 U.S.C. § 384(b). Under applicable implementing regulations, a prescription drug is eligible for importation if it is approved by Health Canada (the relevant Canadian regulatory agency) and an FDA-approved version of the drug is currently marketed in the United States. 21 C.F.R. § 251.2 (2025).

[215] *Id.* § 384(*l*)(1).

[216] *See Importation of Prescription Drugs*, 85 Fed. Reg. 62094, 62095 (Oct. 1, 2020) (codified at 21 C.F.R. pts. 1, 251).

[217] 21 C.F.R. § 251.6 (2025) (stating that authorization for an authorized importation program typically terminates automatically after two years, or a shorter period if a shorter period is authorized).

[218] *See id.* §§ 251.1(a), 251.2 (definitions of "eligible prescription drug" and "Section 804 Importation Program Sponsor ('SIP Sponsor')").

[219] 21 U.S.C. § 384(j).

[220] The Drug Amendments of 1962 included a provision stating that "[n]othing in the amendments made by this Act . . . shall be construed as invalidating any provision of State law . . . unless there is a direct and positive conflict between such amendments and such provision of State law." Pub. L. No. 87-781, § 202, 76 Stat. 780, 793. In *Wyeth v. Levine*, the Supreme Court described this provision as a "saving clause" and observed that "when Congress enacted an express pre-emption for medical devices in 1976, it declined to enact such a provision for prescription drugs." 555 U.S. 555, 567 (2009) (citations omitted)).

[221] Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 492 (2013).

In *Wyeth v. Levine*, the Court held that certain state claims that sought to strengthen the warnings of a *brand-name* prescription drug were not preempted as long as there was no "clear evidence" that FDA would deny approval of the warnings sought.[222] Because the brand manufacturer was allowed under FDA regulations to add warnings without obtaining FDA approval, the Court reasoned, it may have been possible for the manufacturer to comply with both federal law and a state-law duty to strengthen warnings, so long there was not any "clear evidence that the FDA would not have approved" the change to the drug's label.[223] Complying with a state-law duty to strengthen warnings also would not have obstructed the "purposes and objectives of federal drug labeling regulation."[224] Congress, the Court observed, chose not to "provide a federal remedy for consumers harmed by unsafe or ineffective drugs in the 1938 statute or in any subsequent amendment."[225] This choice, the Court reasoned, supported the application of the presumption against preemption and reflected Congress's "determin[ation] that widely available state rights of action provided appropriate relief for injured consumers" and perhaps the "recogni[tion] [that] state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings."[226] More recently, in *Merck Sharp & Dohme Corp. v. Albrecht*, the Court clarified that "clear evidence" that FDA would have denied approval of warnings sought "is evidence that shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning."[227]

In *PLIVA v. Mensing*[228] and *Mutual Pharmaceutical v. Bartlett*,[229] the Supreme Court held that similar state claims seeking to strengthen the warnings of *generic* prescription drugs *were* preempted. Unlike brand manufacturers who were permitted to add warnings, the Court observed that relevant FDA regulations prohibited the defendant generic manufacturers from "independently changing" a generic drug's label, which must be the same as the reference listed drug.[230] Accordingly, the Court concluded—without referencing the presumption against preemption—that it was impossible for the generic manufacturers to both comply with a state tort duty "to change the label" while simultaneously adhering to their "federal-law duty to keep the label the same."[231] This conflict, the Court held, was not diminished by the fact that the generic manufacturer could ask FDA for assistance in changing the corresponding brand-name label.[232] In *Bartlett*, the Court further rejected the argument that a generic manufacturer could avoid the conflict by choosing to "stop selling" its product, reasoning that "if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be 'all but meaningless.'"[233]

[222] Wyeth v. Levine, 555 U.S. 555, 573–75 (2009).

[223] *See id.* at 568–571.

[224] *Id.* at 573.

[225] *Id.* at 574.

[226] *Id.* at 574–75.

[227] 587 U.S. 299, 303 (2019).

[228] 564 U.S. 604 (2011).

[229] 570 U.S. 472 (2013).

[230] *Mensing*, 564 U.S. at 617; *see also Bartlett*, 570 U.S. at 484–86 (concluding that the plaintiffs' design defect claim amounted to a claim seeking to strengthen the warnings for the generic drug at issue, and stating that under *Mensing*, "federal law prevents generic drug manufacturers from changing their labels").

[231] *Mensing*, 564 U.S. at 618; *see also Bartlett*, 570 U.S. at 484–86.

[232] *Mensing*, 564 U.S. at 619.

[233] *Bartlett*, 570 U.S. at 488 (quoting *Mensing*, 564 U.S. at 621).

Applying *Levine*, *Mensing*, and *Bartlett*, lower courts have also considered whether and to what extent the FD&C Act's premarket approval scheme for prescription drugs preempts state claims alleging that a drug had been defectively designed. In general, courts that have considered design defect claims with respect to generic drugs have held that such claims were preempted under *Mensing* and *Bartlett*.[234] These courts reasoned that because a generic drug must be "identical in active ingredients, safety, and efficacy" as its reference listed drug, the federal duty of "sameness" made it impossible for a generic manufacturer to simultaneously comply with a state-law duty to change a drug's design.[235]

Whether design-defect claims against brand manufacturers are preempted is less settled. Lower courts have generally agreed that a state-law claim was preempted if it sought to impose a duty on a brand manufacturer to adopt, post-FDA approval, an alternative design for a drug.[236] Such a state-law duty, in the courts' view, "clearly" conflicted with federal law since FDA regulations prohibited a manufacturer from making any major changes to the "'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'"[237] Courts, however, have disagreed over whether the FD&C Act preempted state claims alleging that relevant state law imposed a duty on a brand manufacturer to adopt a safer alternative design *before* seeking FDA approval.[238] Under this theory, the plaintiffs argued, the state claim was not preempted because "there is no federal law that would have prohibited [the brand manufacturers] from designing a different drug in the first instance."[239]

In *Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, the U.S. Court of Appeals for the Sixth Circuit held that a claim based on a brand manufacturer's pre-approval duty to adopt alternative design was preempted because the claim was premised on a state-law duty that was too speculative, requiring a court to assume that the alternative design would have been approved by FDA.[240] Absent a basis for such an assumption, the court concluded that it was "unable to conceive of any coherent pre-approval duty that [the manufacturers] would have owed to [the plaintiff] when it was developing [the drug]," leaving the post-approval duty as the only viable duty, but one that is preempted by FDA regulations restricting major design changes.[241]

Since *Yates*, some district courts in other circuits confronting similar claims have disagreed. These courts observe that under *Yates*, an injured plaintiff "can *never* bring a defective design claim against a [brand] drug manufacturer."[242] This result, in these courts' view, is inconsistent with *Levine*, which recognized that Congress "determined that widely available state rights of action provided appropriate relief for injured consumers"[243] and indicated that "FDA is not the be-all-end-all in drug regulations."[244] Congress, in these courts' view, did not intend to shield

[234] *See, e.g.*, Hernandez v. Aurobindo Pharma USA, Inc., 582 F. Supp. 3d 1192, 1208–09 (M.D. Fla. 2022); In re Pamidronate Prods. Liab. Litig., 842 F. Supp. 2d 479, 484 (E.D.N.Y. 2012) (listing cases).

[235] *See In re Pamidronate*, 842 F. Supp. 2d at 484.

[236] *See, e.g.*, Guidry v. Janssen Pharms, Inc., 206 F. Supp. 3d 1187, 1206 (E.D. La. 2016).

[237] *See id.* (quoting *Bartlett*, 570 U.S. at 477).

[238] Yates v. Ortho-McNeil-Janssen Pharms, Inc., 808 F.3d 281, 299 (6th Cir. 2015).

[239] *Id.*

[240] *Id.* at 300.

[241] *See id.*

[242] *See, e g.*, *Guidry*, 206 F. Supp. 3d at 1206; *In re* Tepezza Mktg., Sales Pracs. & Prods. Liab. Litig., No. 23 C 3568, 2023 WL 7281665, at *2 (N.D. Ill. Nov. 3, 2023) (citing cases).

[243] *Guidry*, 206 F. Supp. 3d at 1207 (internal quotations omitted) (citing *Levine*, 55 U.S. at 574).

[244] *Id.*

brand manufacturers from liability "if their drug causes harm due to a defect in design simply because the FDA said the drug was safe."[245]

Case Law on the Preemptive Scope of Other FD&C Act Prescription Drug Requirements

Other than state tort law claims, a few courts have also considered whether and to what extent the FD&C Act's prescription drug requirements preempt state requirements imposed by state legislatures or agencies.

In *Ouellette v. Mills*, a district court considered a challenge filed by Maine pharmacists against provisions of a Maine statute that waived certain pharmacy licensure requirements and authorized state residents to receive mail-order prescription drugs for personal use from licensed retail pharmacies located in Canada, the United Kingdom, Australia, or New Zealand.[246] Ruling in favor of the pharmacists, the court held that the Maine statute was preempted because it was "contrary to clear Congressional intent to occupy the field of pharmaceutical importation."[247]

In applying field preemption principles, the *Ouellette* court concluded—based on legislative history of the state law stating that it was intended to provide residents access to cheaper prescriptions—that the relevant field of regulation was not the field of pharmacist licensure, but the field of "importation of foreign pharmaceuticals."[248] Congress, the court observed, had created a complex regulatory scheme covering the importation of pharmaceuticals into the United States under the FD&C Act and has legislated explicitly with respect to the importation of drugs from Canada under FD&C Act section 804.[249] In the court's view, these actions evidenced an intent by Congress for the FD&C Act to "occup[y] the field of importation of pharmaceuticals from foreign countries."[250] By singling out certain countries from which prescription drugs may be imported, the court concluded, the state law "compromises the tightly regulated structure set up by the [FD&C Act] and the federal government's ability to 'speak with one voice' when it regulates foreign commerce."[251]

In addition to importation, several courts have also considered whether state laws that restrict access to certain FDA-approved drugs are preempted. In *Zogenix, Inc. v. Patrick*, a district court examined a Massachusetts emergency order, issued during the opioid crisis, that generally barred the prescribing and dispensing of a then-newly-FDA-approved opioid medication based on concerns about diversion, overdose, and abuse.[252] Applying obstacle preemption principles, the district court issued a preliminary injunction against the implementation of the order, holding that the order was preempted by the FD&C Act.[253] In the court's view, Massachusetts's ban on the drug was an "obstruction" that undermined FDA's authority to make "drugs available to promote and protect the public health."[254] When the state later imposed certain prescribing and dispensing restrictions on the opioid medication short of a ban, the district court conducted a fact-specific analysis to consider the impact of the restrictions and whether they amounted to a de facto ban on

[245] *Id.*

[246] 91 F. Supp. 3d 1, 4 (D. Me. 2015).

[247] *Id.* at 12.

[248] *Id.* at 9.

[249] *Id.* at 10.

[250] *Id.* at 10.

[251] *Id.* at 10–11. (quoting Japan Line, Ltd. v. Los Angeles County, 441 U.S. 434, 499 (1979)).

[252] No. 14-11689, 2014 WL 1454696, at *1 (D. Mass. Apr. 15, 2014).

[253] *Id.* at *2.

[254] *Id.*

the medication.[255] The court preliminarily enjoined certain prescribing restrictions because they "would severely frustrate [the medication's] availability," but declined to enjoin other dispensing restrictions because the record did not sufficiently show that the restrictions would cause pharmacies not to carry the drug.[256]

Several courts have also considered whether the FD&C Act preempts state restrictions on medication abortion. Following the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, which overruled *Roe v. Wade* and held that the U.S. Constitution does not confer a right to an abortion,[257] numerous states enacted laws aimed at restricting access to abortion, including medication abortion.[258] Mifepristone, a drug used in medication abortion, was approved by FDA and subject to a REMS that imposes certain controls over the drug's distribution.[259] The most recent REMS, updated in 2023, requires health care professionals who prescribe the drug to be certified; meet specified qualifications (e.g., the ability to assess the duration of a pregnancy accurately); and ensure that patients receive and sign a patient agreement form relating to mifepristone use.[260] This version eliminated a prior REMS control that required an in-person office visit to health care providers in specified health care settings,[261] allowing patients to obtain the drug through the mail from certified prescribers or pharmacies.[262]

Lower courts in at least two cases have considered challenges that certain state laws limiting access to medication abortion are preempted by FDA's regulatory controls for mifepristone. In *Bryant v. Stein*, the court considered a physician's challenge against North Carolina's medication abortion regulations, which included numerous requirements, including an in-person 72-hour advance consultation to review the consent form; use of an ultrasound; blood-type testing; prescription by physicians only; in-person prescribing, dispensing, and administering; and scheduling of an in-person follow-up appointment.[263] After closely examining the evolution of FDA's REMS requirements for mifepristone and the nature of the state requirements, the court concluded that some of the state requirements—such as physician-only prescription; in-person prescribing, dispensing, and administering; and an in-person follow-up appointment—"impose[d] safety restrictions on the distribution of [mifepristone]" that FDA had "expressly considered and rejected."[264] Accordingly, those state requirements, in the court's view, "stand as an obstacle to the congressional objective of providing a comprehensive regulatory system for the use and distribution of higher-risk drugs under the direction and supervision of the FDA."[265] However, the court held that other state requirements—such as the in-person advance consultation, ultrasound,

[255] *Zogenix*, No. 14-11689, 2014 WL 3339610, at *4 (D. Mass. July 8, 2014), *vacated in part*, No. 14-11689, 2014 WL 4273251 (D. Mass. Aug. 28, 2014).

[256] *Id.* at *5. The district court later lifted the preliminary injunction on the prescribing restrictions after the state modified the restrictions to be consistent with the relevant FDA-approved label. *See Zogenix*, 2014 WL 4273251, at *3.

[257] Dobbs v. Jackson Women's Health org., 597 U.S. 215, 231 (2022).

[258] *See The Availability and Use of Medication Abortion*, KFF (Mar. 10, 2025), https://www.kff.org/womens-health-policy/fact-sheet/the-availability-and-use-of-medication-abortion/ [https://perma.cc/8PL4-P3C2].

[259] *See* FDA, RISK EVALUATION AND MITIGATION STRATEGY (REMS): SINGLE SHARED SYSTEM FOR MIFEPRISTONE 200 MG (2023) [hereinafter 2023 MIFEPRISTONE REMS], https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_REMS_Full.pdf [https://perma.cc/YJ4C-V9GH].

[260] *See id.*

[261] *See* FDA, RISK EVALUATION AND MITIGATION STRATEGY (REMS) (2016), https://www.fda.gov/media/164649/download [https://perma.cc/3LZA-X4JK].

[262] *See* 2023 MIFEPRISTONE REMS, *supra* note 259.

[263] 732 F. Supp. 3d 485, 502, 505 (M.D.N.C. 2024).

[264] *Id.* at 490, 505–09.

[265] *Id.* at 505–09.

and blood-type testing requirements—were not preempted because they concerned regulation of "general patient health and safety, informed consent to the termination of pregnancy, and regulation of the medical profession," which pertained to issues that were "beyond regulating the safe use of mifepristone."[266]

In *GenBioPro v. Sorsaia*, a manufacturer of generic mifepristone challenged certain West Virginia laws that generally prohibit abortion (including access to mifepristone) except under limited circumstances and bar health care providers from prescribing medication abortion drugs via telemedicine.[267] Affirming the district court, the U.S. Court of Appeals for the Fourth Circuit (Fourth Circuit), after first determining that the presumption against preemption applied, held that West Virginia's abortion ban as applied to mifepristone use was not preempted by FDA actions that authorized and regulated the sale of the drug.[268] In authorizing FDA "to establish minimum safety rules for administering drugs like mifepristone where they may be legally prescribed," the Fourth Circuit reasoned, the FD&C Act's REMS provision "did not create a right to utilize any particular high-risk drug."[269] Because the REMS provision did not reflect an intent "to guarantee nationwide access to mifepristone," it was not impossible for the manufacturer to comply with both FDA regulations and the state ban, nor [did] the state ban pose an obstacle to the REMS provision's goal of ensuring drug access.[270] The appellate court, however, also noted that the district court's conclusion with respect to the state's separate telemedicine restriction was not at issue in the appeal.[271] With respect to the state telemedicine restrictions on mifepristone, the district court held that the restriction was "unambiguously preempted by the 2023 REMS," which "reflects a determination by the FDA that when mifepristone is prescribed, it may be prescribed via telemedicine."[272] The state telemedicine restrictions, the courts reasoned, made it impossible for a licensed medical professional prescribing mifepristone to comply "with both the access determination made by the FDA and the access determination made by West Virginia as to telehealth."[273]

Medical Devices

Overview of Selected FD&C Act Provisions on Medical Devices

In addition to drugs, the original 1938 FD&C Act also subjected medical devices to FDA regulation. Unlike for new drugs, however, the 1938 law did not authorize FDA to conduct premarket review of new medical devices.[274] Instead, FDA's authority over medical devices was primarily limited to seizing or obtaining an injunction against medical devices that were misbranded or adulterated, after the devices were already on the market.[275] FDA began to focus its regulatory efforts on medical devices around the 1960s, after developments in the relevant industries—including electronics, plastics, and design engineering—led to the invention of

[266] *Id.* at 502–03.

[267] No. 3:23-0058, 2023 WL 5490179, at *1–2 (S.D.W.Va. Aug. 24, 2023), *aff'd sub nom.*, GenBioPro, Inc. v. Raynes, 144 F.4th 258 (4th Cir. 2025).

[268] *Raynes*, 144 F.4th at 273, 275–77.

[269] Id. at 276.

[270] *Id.* at 275–76.

[271] *Id.* at 268 n.1.

[272] *Sorsaia*, 2023 WL 5490179 at *10.

[273] *Id.* at *11.

[274] *See* ch. 675, §§ 501–505, 52 Stat. 1040, 1049–53 (1938).

[275] *See id.*

sophisticated devices—such as heart pacemakers, defibrillators, and surgical implants—used to address critical medical conditions.[276] After several high-profile reports of safety concerns in the early 1970s related to various devices, including the Dalkon Shield, several cardiac pacemakers, and certain intraocular lenses,[277] Congress enacted the Medical Device Amendments of 1976 (MDA).[278]

The MDA amended the FD&C Act to establish a regulatory regime that oversees medical devices based on the risk posed to the consumer. Specifically, the MDA, as amended, established three classes of devices based on the degree of regulatory control needed to provide assurance of a device's safety and effectiveness. Class I medical devices, considered low risk, are subject to general controls that include manufacturer registration and listing of manufactured devices.[279] Class II devices, considered moderate risk, are subject to general controls as well as certain "special controls" deemed necessary by FDA to reduce or mitigate risk.[280] Special controls may include, for instance, special labeling requirements, mandatory performance, and post-market surveillance.[281] Class III devices are considered the highest risk, because the devices are used to support or sustain human life, are important in preventing impairment of human health, or present a potential, unreasonable risk of illness or injury.[282] Class III devices, with certain exceptions, are subject to general controls and premarket approval (PMA) by FDA before they can be lawfully marketed.[283]

The PMA process is the most stringent approval pathway that FDA can require.[284] Under this process, an applicant must submit a PMA application that includes, among other things, information regarding proposed labeling, foreign and U.S. marketing history, summary of clinical and nonclinical studies, conclusions drawn from such studies, and information regarding the components, ingredients, and operating principles of the device.[285] After a device has received premarket approval, the manufacturer generally cannot make, without FDA approval, changes to the device—including changes in labeling, indication, performance, or design specifications—that would affect the device's safety or effectiveness.[286]

The most commonly used premarket approval pathway for medical devices, however, is the premarket notification pathway, commonly referred to as the *510(k) clearance*.[287] Under this pathway, through which most Class II devices are made available,[288] a device manufacturer must submit a 510(k) notification at least 90 days prior to marketing the device.[289] The submission

[276] HUTT ET AL., *supra* note 16, at 1597.

[277] *Id.* at 1597–98.

[278] Pub. L. No. 94-295, 90 Stat. 539 (1976).

[279] 21 U.S.C. § 360c(a)(1)(A).

[280] *Id*. § 360c(a)(1)(B).

[281] *Id*.

[282] *Id*. § 360c(a)(1)(C)(ii).

[283] *Id*. § 360e(c)(1).

[284] *See* U.S. FOOD & DRUG ADMIN., *Premarket Approval (PMA)* (May 16, 2019), https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-approval-pma [https://perma.cc/3QAP-YQGS] ("PMA is the most stringent type of device marketing application required by FDA.").

[285] *Id*.

[286] *Id*. § 360e(d)(5); 21 C.F.R. § 814.39 (2025).

[287] *See* CRS Report R47374, *FDA Regulation of Medical Devices*, by Amanda K. Sarata, at 8 (2023). The reference to "510(k)" refers to the FD&C Act section that imposes the premarket notification requirement.

[288] *See id*.

[289] 21 U.S.C. §§ 360(k), (n)(1).

must demonstrate that the device proposed to be marketed is *substantially equivalent* to a certain device already on the market (i.e., a predicate device).[290] A device is "substantially equivalent" to a predicate device if it has (1) the same intended use and the same technological characteristics as the predicate device, or (2) the same intended use, different technological characteristics, and information and data that demonstrate safety and effectiveness, and does not "raise different questions of safety and effectiveness than the predicate device."[291] So unlike a PMA application, which must include safety and efficacy data concerning the device at issue, a 510(k) submission is focused instead on information comparing the device at issue to a predicate device.[292]

FD&C Act Section 521: Preemption Provision Related to Medical Devices

When Congress enacted the MDA in 1976, at least 13 states had specific statutes or rules regulating medical devices.[293] To define the federal and state roles in regulating medical devices, the MDA added an express preemption provision at FD&C Act section 521.[294] Subsection (a) of the provision states the following:

> [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 chapter 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 chapter.[295]

Subsection (b) carves out an exception to the scope of preemption under subsection (a). Under subsection (b), FDA may, upon application by a state or its political subdivision, exempt state or local device requirements that are either (1) "more stringent" than federal ones; or (2) "required by compelling local conditions" and where "compliance with the requirement would not cause the device to be in violation of any applicable requirement" under the FD&C Act.[296] FDA's implementing regulations related to section 521 also provide that the provision does not extend to "[s]tate or local requirements of general applicability [whose] purpose . . . relates either to other products in addition to devices."[297]

Courts have evaluated the scope of MDA's express preemption provision on numerous occasions, primarily in the context of considering whether and to what extent the provision preempts state tort law claims alleging manufacturing, design, and/or warning defects related to certain medical devices. In the context of hearing aids, courts have also considered the extent to which the provision preempts state-enacted device requirements.

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[290] *See* 21 U.S.C. § 21 U.S.C. §§ 360c(f)(1)(A)(ii), 360e(b), (i); 21 C.F.R. § 807.92 (2025). A predicate device may be (1) a device that was legally marketed prior to May 28, 1976; (2) a device which has been reclassified from class III to class II or I; or (3) a device cleared through the 510(k) notification process. 21 C.F.R. § 807.92(a)(3) (2025).

[291] 21 U.S.C. § 360c(i)(1)(A).

[292] *See id.*

[293] HUTT ET AL., *supra* note 16, at 1597.

[294] 21 U.S.C. § 360k.

[295] *Id*. § 360k(a).

[296] *Id*. § 360k(b).

[297] 21 C.F.R. § 808.1. The regulation provides examples of these state requirements, including general electrical codes, the Uniform Commercial Code, and unfair trade practices in which the requirements are not limited to devices. *See id.*

Case Law on the Preemptive Scope of FD&C Act Section 521 on State Tort Law Claims

The Supreme Court has twice considered the scope of the MDA preemption provision (FD&C Act section 521) as applied to state tort law claims, in *Medtronic v. Lohr*[298] and *Riegel v. Medtronic*.[299] In these cases, the Supreme Court generally held that the extent to which section 521 preempts state claims depends in part on how that device received marketing approval from FDA. The Court's reasoning in these cases indicates that the preemptive scope of section 521 is broadest for devices approved through the PMA process, the most rigorous approval pathway, limiting the types of claims a plaintiff may assert based on alleged injuries resulting from the use of such devices.[300] The preemptive scope of section 521 for devices cleared through 510(k) notification, on the other hand, is narrower.[301]

In *Lohr*, the Supreme Court considered the preemptive scope of section 521 as applied to state claims alleging manufacturing, design, and labeling defects regarding a pacemaker that was cleared for marketing under the 510(k) notification process.[302] A majority of the Court agreed that section 521 did not preempt these particular state tort claims, but no majority of Justices agreed on the extent to which the provision preempts state-law tort actions in general.[303]

In *Lohr*, the plaintiffs sued a pacemaker manufacturer after a component of the device, implanted in one of the plaintiffs, allegedly failed and caused her to suffer a heart block requiring emergency surgery.[304] The plaintiffs asserted various tort claims alleging that the pacemaker was defectively designed and manufactured, and that the manufacturer failed to provide adequate warnings and labels regarding the risk of the device.[305] According to the Court, analyzing the preemptive scope of section 521 "require[s] a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations."[306]

The Court held that section 521 did not preempt the plaintiffs' defective design claims because the 510(k) clearance process does not impose federal design requirements related to the "safety" and "effectiveness" of the device.[307] Because the 510(k) process merely established that the pacemaker was "substantially equivalent" to a device already on the market, the Court reasoned, FDA "did not 'require' [defendant's] pacemaker to take any particular form for any particular reason," nor did the agency "formally review[]" the device "for safety or efficacy."[308] The Court similarly held that the plaintiffs' manufacturing and labeling/warning defect claims were not preempted.[309] In the Court's view, "the allegedly pre-empting federal requirement" at issue—certain labeling and "Good Manufacturing Practices" requirements set forth in FDA regulations

[298] 518 U.S. 470 (1996).

[299] 552 U.S. 312 (2008).

[300] *See Riegel*, 522 U.S. at 320–21.

[301] *See Lohr*, 518 U.S. at 493, 498–99.

[302] *Id.* at 492–501, 502

[303] *See id.* at 508 (Breyer J., concurring in judgment); *id.* at 512–13 (O'Connor, J., concurring in part, dissenting in part).

[304] *Id.* at 480–81.

[305] *See id.* at 481, 492.

[306] *Id.* at 500.

[307] *Id.* at 493.

[308] *Id.*

[309] *Id.* at 498–99.

that are generally applicable to devices and their manufacturers—were not sufficiently specific to the pacemaker to constitute federal requirements "applicable to the device" under section 521 to have preemptive force.[310]

While a majority of Justices in *Lohr* agreed that the plaintiffs' state-law tort claims were not preempted under section 521, a different majority of Justices also expressly indicated that "the MDA will sometimes preempt a state-law tort suit."[311] This open question regarding the circumstances under which state-law tort claims are preempted led to continued litigation in the lower courts.

In *Riegel v. Medtronic*, the Supreme Court resolved some aspects of the open questions when it held that certain state-law tort claims based on alleged injuries related to a medical device approved through the PMA process were preempted under section 521. In *Riegel*, the plaintiffs sued a catheter manufacturer after the catheter, used in a coronary angioplasty procedure for one of the plaintiffs, ruptured during the procedure and caused the patient to develop a heart block, requiring emergency coronary bypass surgery.[312] The plaintiffs alleged that the catheter was defectively designed, labeled, and manufactured in a manner that violated applicable state common law.[313] Siding with the defendant, the Court affirmed the dismissal of the plaintiffs' claims as preempted.[314]

In reaching this conclusion, the Court first concluded that the PMA process—unlike the 510(k) notification process and the generally applicable labeling and manufacturing requirements at issue in *Lohr*—imposes device-specific federal requirements.[315] Unlike the 510(k) notification process—which focuses on a device's substantial equivalence to an already marketed device and does not require a device to "take any particular form for any particular reason"—the PMA process, the Court observed, "*is* federal safety review."[316] Under the PMA process, an approved device must "be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness."[317] The Court then held that a state's "requirements" subject to preemption under section 521 "include[] its common-law duties."[318] In so concluding, the Court rejected the plaintiffs' argument that section 521 "exclud[es] common-law duties from the scope of pre-emption" and preempts only state regulatory law or state requirements specific to the device.[319] Accordingly, because the plaintiffs asserted that the catheter device "violated state tort law notwithstanding compliance with the relevant federal requirements"—such that the applicable common law duties imposed requirements beyond federal requirements—the Court held that their state claims were preempted.[320]

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[310] *Id.*

[311] *See id.* at 503 (Breyer, J., concurring in part and in the judgment); *see also* 518 U.S. at 512–13 (O'Connor, J., concurring in part, dissenting in part) (agreeing that plaintiffs' design defect claims were not preempted, but concluding that some or all of plaintiffs' manufacturing and labeling claims would be preempted if they "would compel [the defendant] to comply with requirements different from, or in addition to, those required by the FDA").

[312] Riegel v. Medtronic, Inc., 552 U.S. 312, 320 (2008).

[313] *Id.* at 320.

[314] *See id.* at 321, 330.

[315] *See id.* at 323.

[316] *Id.*

[317] *Id.*

[318] *Id.* at 324.

[319] *See id.* at 324–25, 327–28.

[320] *See id.* at 330.

At the same time, the Court acknowledged that section 521 does not preempt all state claims related to a device approved under the PMA process.[321] Specifically, the Court observed that even if state common-law duties impose relevant state safety and efficacy "requirements," they are preempted under section 521 "only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law."[322] In other words, state requirements that "parallel" federal requirements are not preempted.[323] In *Riegel*, however, the Court observed that because the plaintiffs did not argue that they had asserted parallel state claims, it declined to consider, in the first instance, whether the plaintiffs had raised parallel claims, and affirmed the dismissal of their claims.[324]

Following *Riegel*, lower courts have generally concluded that for devices approved through the PMA process, *Riegel*, combined with the Court's decision in *Buckman*,[325] leave a "'narrow gap' through which a state-law claim must fit to escape preemption by the [FD&C Act]."[326] In general, lower courts have held that state-law claims related to PMA-approved devices avoid preemption only if they rest on a state-law duty that parallels a federal-law duty.[327] As a practical matter, this means that many design or manufacturing defect claims—to the extent that they assert that a PMA-approved device should have been designed or manufactured differently from the specifications FDA had approved—are preempted.[328] Some parallel state claims, however, have been found to escape preemption. For example, several courts have concluded that certain state-law failure-to-warn claims were not preempted to the extent that they alleged that a defendant failed to report serious injuries and malfunctions of the device as required by both applicable FDA regulations *and* applicable state tort law duty to provide "adequate warnings or instructions."[329]

Case Law on the Preemptive Scope of FD&C Act Section 521 on State Device-Specific Requirements

In addition to cases that considered the preemptive scope of FD&C Act section 521 as applied to state tort claims, several lower courts have also considered section 521 as applied to device-specific requirements enacted by states, particularly with respect to hearing aids.[330]

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[321] *See id.*

[322] *Id.* (quoting 21 U.S.C. § 360k(a)(1)).

[323] *See id.* (stating that section 521 "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements" (quoting *Lohr*, 518 U.S. at 495)).

[324] *Id*.

[325] *See supra* "Preemption Based on the FD&C Act's Enforcement Scheme."

[326] Perez v. Nidek, 711 F.3d 1109, 1120 (9th Cir. 2013) (quoting In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010); *see also* Hughes v. Boston Sci. Corp., 631 F.3d 762, 768 (5th Cir. 2011) ("[W]e must ask whether the state law at issue creates a requirement that is related to the device's safety or effectiveness and is 'different from or in addition to' a federal requirement." (quoting 21 U.S.C. § 360k(a))).

[327] *See, e.g.*, Stengel v. Medtronic Inc., 704 F.3d 1224, 1233 (9th Cir. 2013).

[328] *See, e.g.*, *Hughes*, 631 F.3d at 768 ("It is clear that all of Hughes's state products liability claims that purport to impose liability on Boston Scientific despite Boston Scientific's compliance with the applicable FDA design and manufacturing specifications, as approved by the FDA during the PMA process, seek to impose different or additional state duties and are expressly preempted.").

[329] *See, e.g.*, *id*. at 769; *Stengel*, 704 F.3d at 1233.

[330] FDA regulations governing hearing aids changed significantly after the agency, pursuant to section 709 of the FDA Reauthorization Act of 2017, Pub. L. No. 115-52, 131 Stat. 1005, established an over-the-counter category of hearing (continued...)

At least one state, for example, had sought to invoke the preemption exemption process under section 521(b) for the state's hearing aid requirements. Specifically, in 1978, Massachusetts enacted a state law regulating the sale of hearings aids in that state.[331] The state requirements were more stringent than the then-applicable FDA hearing-aid regulations in two respects: (1) the state law required all consumers—with the exception of those with a religious waiver—to obtain a medical evaluation from a physician before purchasing a hearing aid, while FDA regulations generally permitted adults who had been provided with specified warnings to waive the medical evaluation requirement; and (2) the state law, unlike the FDA regulations, also required a "hearing test evaluation" by a physician or audiologist.[332] After FDA denied Massachusetts's application for exemption following a public hearing and receipt of comments, the state sued to challenge the denial.[333] The U.S. Court of Appeals for the First Circuit, in *Massachusetts v. Hayes*, upheld FDA's denial of exemption.[334] In doing so, the court rejected the state's argument that section 521(b) required FDA to grant an exemption "whenever state regulations are 'more stringent' and do not unduly burden interstate commerce."[335] In the court's view, FDA's "statutory authority to grant exemption from preemption is plainly discretionary."[336] The court further concluded that FDA's denial of exemption was not arbitrary and capricious, given the agency's review of evidence related to the predictive value of audiological testing and its conclusion that "audiological evaluation is not necessary to provide reasonable assurance of the safety or effectiveness of hearing aids."[337]

For state hearing aid requirements not subject to exemption from preemption, several courts have considered the extent to which they were preempted by section 521(a). Several courts have held, for instance, that state laws which required hearing aid purchasers to undergo presale "fitting and testing" services by specified licensed professionals were preempted by then-applicable federal regulations.[338] In the courts' view, because applicable federal regulations generally required purchasers to undergo an auditory evaluation *or* provide a signed waiver, an auditory examination was effectively optional; thus, a state law *requiring* presale fitting and testing imposed a safety and efficacy requirement "in addition to" federal requirements and was preempted.[339] In contrast,

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aids. The FDA hearing aid regulations referenced in the cases discussed in this section are no longer in effect, but the courts' analysis of those regulations relative to applicable state requirements illustrates how courts approach the preemption analysis involving state device-specific requirements.

[331] *See* Massachusetts v. Hayes, 691 F.2d 57, 59 (1st Cir. 1982) (discussing MASS. GEN. LAWS ch. 93, §§ 72–74).

[332] *Id.* at 59. As discussed in note 330 *supra*, the federal hearing aid regulations referenced in *Hayes* and other cases discussed in this section are no longer in effect.

[333] *Id*. at 59.

[334] *Id*.

[335] 691 F.2d at 61.

[336] *Id*. at 60.

[337] *Id.* at 63. (quoting Exemption from Preemption of State and Local Hearing ALD Requirements; Applications for Exemption, 45 Fed. Reg. 67326, 67329 (Oct. 10, 1980)).

[338] *See*, *e.g.*, Mo. Bd. of Exam'rs for Hearing Instrument Specialists v. Hearing Help Express, Inc., 447 F.3d 1033, 1036–37 (8th Cir. 2006) (holding that a Missouri statute that prohibited mail order sales of hearing aids "without prior fitting and testing by a hearing instrument specialist" was preempted by applicable federal regulations); METX, LLC v. Wal-Mart Stores Tex., LLC, 62 F. Supp. 3d 569, 582, 584 (E.D. Tex. 2014) (interpreting certain Texas licensure regulations to require a "fitter and dispenser" of hearing aids to "perform a pre-sale non-waivable 'audiological evaluation'" and holding that such a requirement imposed an additional safety and efficacy requirement applicable to hearing aids and was thus expressly preempted by federal law).

[339] *See*, *e.g.*, *Mo. Bd. of Exam'rs*, 447 F.3d at 1036–37; *METX, LLC*, 62 F. Supp. 3d at 582, 584. *But see* Smith v. Pingree, 651 F.2d 1021, 1023–24 (5th Cir. 1981) (holding that a Florida law requiring a hearing aid dispenser to conduct, in a certified testing room, a presale "hearing test to determine the degree and type of hearing deficiency" was (continued...)

another court held that a state's general licensure requirements for hearing aid dispensers, which were not tied to the state's separate pre-sale testing requirements, were not expressly preempted by section 521(a).[340]

Cosmetics

Overview of Selected FD&C Act Provisions on Cosmetics

The FD&C Act, since its initial enactment in 1938, prohibits the marketing of adulterated or misbranded cosmetics (i.e., cosmetics that are unsafe or mislabeled).[341] A cosmetic is deemed adulterated, for instance, if it contains any substances that are poisonous, putrid, or unsanitary, or otherwise contain a "substance which may render it injurious to users."[342] A cosmetic is deemed misbranded, for instance, if its "labeling is false or misleading in any particular."[343] In 1966, Congress enacted the Fair Packaging and Labeling Act (FPLA), which authorized FDA to issue regulations governing the labeling and packaging of many cosmetic products.[344] In 1970, Congress additionally enacted the Poison Prevention Packaging Act of 1970 (PPPA) to require special packaging to protect children from injury or illness from handling or ingesting household substances, including cosmetics.[345] Cosmetic products that do not comply with FPLA and PPPA requirements are deemed misbranded under the FD&C Act.[346] These authorities governing cosmetics, which generally do not need to undergo premarket review,[347] remained largely unchanged until Congress enacted the Modernization of Cosmetics Regulation Act of 2022 (MoCRA).[348] MoCRA expanded FDA's regulatory authority over cosmetics in several respects. While cosmetic products generally still are not subject to premarket review, MoCRA requires cosmetics manufacturers to report serious adverse events, register their facilities and list cosmetic products with FDA, and substantiate the safety of their products.[349] MoCRA also expanded the labeling requirements for cosmetics, including requiring product labels to identify each fragrance allergen contained in the product.[350]

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not preempted because then applicable federal regulation did not "preclude the state from initiating minimal requirements relating to the mechanics of fitting the hearing aid to the patient").

[340] Taylor v. Polhill, 964 F.3d 975, 982–84 (11th Cir. 2020).

[341] Ch. 675, 52 Stat. 1040 (1938).

[342] 21 U.S.C. § 361(a), (b), (c), (d).

[343] *Id.* § 362(a).

[344] Pub. L. No. 89-755, 80 Stat. 1296 (1966) (codified as amended at 15 U.S.C. §§ 1451–1461). The FPLA applies to the packaging and labeling of "consumer commodities," which include cosmetics "customarily produced or distributed for sale through retail sales agencies or instrumentalities for consumption by individuals, or use by individuals for purposes of personal care . . . and which [are] usually . . . consumed or expended in the course of such consumption or use." 15 U.S.C. § 1459(a).

[345] Pub. L. No. 91-601, 84 Stat. 1670 (1970). Regulations implementing the PPPA are promulgated by the Consumer Product Safety Commission. *See* 16 C.F.R. §§ 1700.1–1700.20 (2025).

[346] *See* 15 U.S.C. § 1456(a); 21 U.S.C. § 362(f).

[347] The Color Additive Amendments of 1960 requires color additives included in certain FDA-regulated products, including cosmetics, to be subject to premarket approval. *See* Pub. L. No. 86-618, 74 Stat. 397 (1960); 21 U.S.C. § 379e.

[348] Pub. L. No. 117-328, §§ 3501–3508, 136 Stat. 4459, 5847 (2022) (codified as amended at 21 U.S.C. §§ 364–364j). Additionally, over the years, some legislation has amended the FD&C Act's provisions on cosmetics, but these changes did not significantly alter FDA's authority over cosmetics regulation. *See, e.g.*, Microbead-Free Waters Act of 2015, Pub. L. No. 114-114, 129 Stat. 3129 (2015) (codified as amended at 21 U.S.C. § 331 note).

[349] 21 U.S.C. § 364c.

[350] *Id.* § 364e(b).

FD&C Act Sections 752 and 614: Express Preemption Provisions Related to Cosmetics

With respect to cosmetics, the FD&C Act contains two express preemption clauses that reflect Congress's recognition of states' concurrent role in regulating these products. FD&C Act section 752, enacted in 1997, states the following:

> [N]o State . . . may establish or continue in effect any requirement for labeling or packaging of a cosmetic that is different from or in addition to, or that is otherwise not identical with, a requirement specifically applicable to a particular cosmetic or class of cosmetics under [the FD&C Act], the Poison Prevention Packaging Act of 1970 . . . , or the Fair Packaging and Labeling Act . . . .[351]

At the same time, section 752(d) specifically states that this preemption clause "shall [not] be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State."[352] Section 752(e) further states that the section does not "apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997."[353]

In 2022, MoCRA added a second preemption clause at FD&C Act section 614. The provision states, in relevant part, the following:

> No State . . . may establish or continue in effect any law, regulation, order, or other requirement for cosmetics that is different from or in addition to, or otherwise not identical with, any requirement applicable under [the FD&C Act] with respect to registration and product listing, good manufacturing practice, records, recalls, adverse event reporting, or safety substantiation.[354]

Section 614 also explicitly preserves state laws in several respects. To preserve state regulation of cosmetic ingredients, the provision clarifies that section 614 should not be "construed to prevent any State from prohibiting the use or limiting the amount of an ingredient in a cosmetic product," nor should section 614 be construed to prohibit a state from continuing in effect any state requirement that directed the reporting of a cosmetic ingredient to the state that was in effect at the time of MoCRA's enactment.[355] In addition, section 614 includes a savings clause stating that no MoCRA provision or any of its implementing regulations "shall be construed to modify, preempt, or displace any action for damages or the liability of any person under the law of any State, whether statutory or based in common law."[356]

Case Law on the Preemptive Scope of FD&C Act Section 752

To date, courts that have considered the preemptive scope of the FD&C Act's cosmetics provisions appear to have addressed only the preemptive scope of FD&C Act section 752.[357] In

[351] *Id.* § 379s(a).

[352] *Id.* § 379s(d).

[353] *Id.* § 379s(e). Available legislative history indicates that this subsection was intended to preserve state laws like California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). *See* 143 CONG. REC. 25797 (1997) ("Most importantly, this provision does nothing to affect California's Proposition 65, an innovative state initiative that has helped reduce Californians' exposure to toxic hazards."); CAL. HEALTH & SAFETY CODE §§ 25249.5–25249.14.

[354] 21 U.S.C. § 364j(a).

[355] *Id.* § 364j(b).

[356] *Id.* § 364j(c).

[357] As of the date of publication, no court appears to have addressed the preemptive scope of FD&C Act section 614.

these cases, the plaintiffs' claims generally involved state-law claims alleging that a cosmetic product's label was misleading or did not adequately warn of the risks associated with the product.[358]

When considering whether these claims were preempted, courts have generally held that state-law claims interpreted to impose labeling requirements identical to those required by the FD&C Act were not preempted by section 752.[359] For example, in *Astiana v. Hain Celestial Group*, the plaintiffs brought claims under California's unfair competition and false advertising laws and for common law fraud alleging that a cosmetic labeled "all natural" or "pure natural" duped consumers seeking natural products into buying products that were full of artificial and synthetic ingredients.[360] The court considered whether the state-law claims imposed a requirement that was "different from or in addition to, or that is otherwise not identical with" a cosmetics requirement in the FD&C Act.[361] The court concluded that they did not.[362] If the label stating the product was "all natural" and "pure natural" was misleading as the plaintiffs claimed, the court reasoned, it would also violate the FD&C Act, which prohibits cosmetic labeling that is "false or misleading in any particular."[363] The Ninth Circuit therefore held that the plaintiffs' claims were not preempted because they would impose requirements identical to those imposed by the FD&C Act.[364]

On the other hand, courts have concluded that certain state claims that sought to add additional disclaimers not required by applicable federal requirements were preempted.[365] In *Critcher v. L'Oreal USA, Inc.*, consumers who had purchased liquid cosmetic products alleged that they were unable to dispense a portion of the product from the containers.[366] They asserted state-law claims based on allegations that they were duped "into buying more of the cosmetics than they could use" and that the product labels should have disclosed that the products could not be fully dispensed from their containers.[367] The plaintiffs, however, conceded that the packaging complied with federal packaging requirements and that the labels accurately stated the amount of product contained in each package.[368] The U.S. Court of Appeals for the Second Circuit held that the plaintiffs' claims were preempted because the FD&C Act does not impose obligations to include

[358] *See* Astiana v. Hain Celestial Grp., Inc., 783 F.3d 753, 757 (9th Cir. 2015); *Ebner*, 838 F.3d at 965 (noting that the plaintiffs asserted claims under California's False Advertising Law, California Consumers Legal Remedies Act, California's Unfair Competition Law, and unjust enrichment).

[359] *See id.*; Ebner v. Fresh, Inc., 838 F.3d 958, 965 (9th Cir. 2016) ("Because the Sherman Law does not amount to something 'different from or in addition to' what federal law already requires, . . . preemption does not bar Plaintiff's claim." (citation omitted) (quoting 21 U.S.C. § 379s(a))). Lower courts have also grappled with how to interpret FD&C Act section 752's savings clause that explicitly preserves state products liability claims. In at least one case, the court held that the plaintiffs' non-products-liability claims (e.g., negligent misrepresentation and breach of warranty claims) were not preempted, to the extent they were based on the same allegations as plaintiffs' products liability claims. *See In re* Hair Relaxer Mktg., Sales Pracs. & Prods. Liab, Litig,, 702 F. Supp. 3d 692, 699–701 (N.D. Ill. 2023).

[360] *Astiana*, 783 F.3d at 756.

[361] *Id*. at 757 (quoting 21 U.S.C. § 379s(a)).

[362] *Id.* at 759.

[363] *Id.* at 757–58 (quoting 21 U.S.C. §§ 362(a), 379s).

[364] *Id*. at 759.

[365] Critcher v. L'Oreal USA, Inc., 959 F.3d 31, 33 (2d Cir. 2020).

[366] *Id*.

[367] *Id*.

[368] *Id*. at 37.

supplemental disclosures regarding the amount of accessible product, which would impose labeling requirements "in addition to" those mandated by the FD&C Act.[369]

Tobacco Products

Overview of Selected FD&C Act Provisions on Tobacco Products

The original 1938 FD&C Act did not expressly authorize FDA to regulate tobacco products. Before 1996, FDA generally took the position that it lacked jurisdiction under the FD&C Act to regulate tobacco products.[370] As evidence of tobacco manufacturers' knowledge regarding the health effects of their products mounted,[371] however, FDA promulgated a final rule in 1996 that would have imposed several restrictions on the sale, distribution, and advertisement of tobacco products.[372] FDA asserted that it had jurisdiction to regulate tobacco products based on its determination "that nicotine is a 'drug' and that cigarettes and smokeless tobacco are 'drug delivery devices[.]'"[373] A group of tobacco manufacturers, retailers, and advertisers sued to challenge the rule.[374] In 2000, the Supreme Court held in *FDA v. Brown & Williamson Tobacco Corp.* that "[c]onsidering the [FD&C Act] as a whole, it is clear that Congress intended to exclude tobacco products from the FDA's jurisdiction."[375] In the Court's view, under the FD&C Act's regulatory regime, "FDA may not . . . conclude that a drug or device cannot be used safely for any therapeutic purpose and yet, at the same time, allow that product to remain on the market,"[376] yet Congress had "foreclosed the removal of tobacco products from the market" in other tobacco-specific legislation.[377] Given that tobacco products "cannot be used safely for any therapeutic purpose [yet] they cannot be banned," the Court reasoned that these products "simply d[id] not fit" within the FD&C Act's regulatory scheme.[378]

In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act (TCA), which amended the FD&C Act to expressly authorize FDA to regulate tobacco products as a category separate from food, drug, devices, and cosmetics.[379] The TCA establishes the central federal regulatory regime for the manufacture, marketing, and distribution of tobacco products.[380] In establishing this regulatory regime, the TCA aims to balance competing interests in protecting

[369] *Id*.

[370] *See* FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 143–44 (2000) (observing that, between 1965 and 2000, Congress had "enacted six separate pieces of legislation . . . addressing the problem of tobacco use and human health," and had done so "against the backdrop of the FDA's consistent and repeated statements that it lacked authority under the [FD&C Act] to regulate tobacco absent claims of therapeutic benefit by the manufacturer").

[371] *See* HUTT ET AL., *supra* note 16, at 1821–22.

[372] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents, 60 Fed. Reg. 44396 (Aug. 28, 1996) (codified as amended at 21 C.F.R. pts. 801, 803, 804, 807, 820, 897 (2025)).

[373] *Brown & Williamson Tobacco Corp.*, 529 U.S. at 127 (quoting 60 Fed. Reg. 44396, 44397, 44402 (Aug. 28, 1996)).

[374] *Id.* at 120.

[375] *Id.* at 142.

[376] *Id.* at 142.

[377] *Id.* at 137.

[378] *Id.* at 143.

[379] Pub. L. No. 111-31, 123 Stat. 1776 (2009).

[380] *See, e.g.*, 21 U.S.C. §§ 387b, 387c, 387f, 387f-1, 387g, 387j.

the public's health against the harmful effects of smoking and youth tobacco use, while preserving access to lawfully marketed tobacco products for adult consumers.[381]

Among other requirements, the TCA requires all new tobacco products—i.e., those not commercially marketed in the United States prior to February 15, 2007—to receive prior authorization from FDA before being marketed to the public.[382] In particular, the TCA requires FDA to deny an application seeking authorization for a new tobacco product if the agency finds that "there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health."[383] In addition, the TCA, based on Congress's recognition that flavors can make tobacco products more appealing to youth and expose users to additional carcinogens or other toxic constituents,[384] also expressly prohibits the manufacture and sale of cigarettes or cigarette components with flavors other than tobacco or menthol.[385] The same provision, at FD&C Act section 907(b), further authorizes FDA to adopt, through notice-and-comment rulemaking, additional tobacco product standards if the agency finds that such a standard "is appropriate for the protection of the public health."[386] FDA may also promulgate restrictions on the sale and distribution of a tobacco product—including restrictions on the access to, and the advertising and promotion of, the tobacco product.[387] Additionally, the TCA imposes certain labeling requirements[388] on top of those already required under then-existing federal law.[389]

While the TCA explicitly applies to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, the statute also authorizes FDA to deem other tobacco products subject to the law.[390] In 2016, FDA invoked this authority and promulgated what is known as the Deeming Rule, which subjected certain electronic nicotine delivery system products—products commonly known as e-cigarettes or vapes—to the TCA's regulatory regime.[391] Under the rule, entities seeking to legally market their e-cigarettes that were on the market as of August 8, 2016, or any new e-cigarette products, were generally required to submit a premarket tobacco product application and receive marketing authorization from FDA.[392]

As of the date of this report, FDA has authorized 35 tobacco-flavored e-cigarettes and 6 menthol-flavored e-cigarettes for lawful marketing.[393] With respect to those products, the agency generally

[381] Pub. L. No. 111-31, § 3, 123 Stat. at 1781.

[382] 21 U.S.C. § 387j(a).

[383] *Id.*§ 387j(c)(2).

[384] *See* H.R. REP. NO. 111-58, pt. 1, at 4 (2009).

[385] 21 U.S.C. § 387g(a)(1)(A). The provision, however, also expressly preserves FDA's authority to establish tobacco product standards relating to menthol and other flavors. *See id.*

[386] *Id.* § 387g(a)(3)(A), (b), (d).

[387] *Id.* § 387f(d)(1).

[388] *See, e.g.*, *id.* § 387t(a), § 387g(a)(4)(C).

[389] The Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. No. 89-92, 79 Stat. 282 (1965) and the Comprehensive Smokeless Tobacco Health Education Act of 1986, Pub. L. No. 99-252, 100 Stat. 30 (1986), as amended, impose certain labeling requirements and advertising restrictions on cigarettes and smokeless tobacco, respectively.

[390] 21 U.S.C. § 387a(b).

[391] Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28974, 28976 (May 10, 2016).

[392] *Id.*

[393] *E-Cigarettes,"Vapes" and Other Electronic Nicotine Delivery Systems (ENDS) Authorized by the FDA*, FDA (Mar. 13, 2026), https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/e-cigarettes-vapes-and-other-electronic-nicotine-delivery-systems-ends-authorized-fda [https://perma.cc/Z829-PKGG].

concluded that they were "appropriate for the protection of public health" because they can benefit adult smokers by helping them switch to less harmful tobacco products.[394] FDA has not authorized any dessert-, candy-, or fruit-flavored (sweet-flavored) e-cigarettes for lawful marketing. According to FDA, the applications for such products to date "lacked sufficient evidence that the benefit to adult smokers who used the flavor products would overcome the public health concern posed by the well-documented and considerable appeal of the products to youth."[395]

FD&C Act Section 916: Provision Including Express Preemption Clause Related to Tobacco Products

The TCA also included a provision, at FD&C Act section 916, that addresses the interaction of federal and state/local laws. Prior to the TCA's enactment in 2009, federal laws regulating tobacco products were primarily focused on certain labeling requirements and advertising restrictions for certain tobacco products.[396] Accordingly, before 2009, states and localities played a key role in regulating the sale and use of tobacco products within their respective jurisdictions. For instance, states and localities, to varying degrees, mandated smoke-free indoor and outdoor spaces,[397] prohibited the sales of cigarettes in vending machines and near schools,[398] and imposed excise taxes on tobacco products.[399] Section 916, entitled "Preservation of State and local authority," addresses the interaction of the TCA and relevant state and local laws in three parts.[400]

The first part of section 916, at subsection (a)(1), is often referred to as the preservation clause.[401] It generally states that, subject to the preemption clause at subsection (a)(2)(A), nothing in the TCA and its implementing rules shall be construed to limit the authority of a federal agency, state, locality, or tribe to enact or promulgate "any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under [the TCA]."[402] Subsection (a) specifies that such additional requirements include those "relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and

[394] *See, e.g.*, Press Release, FDA, FDA Authorizes Marketing of Four Menthol-Flavored E-Cigarette Products After Extensive Scientific Review (June 21, 2024), https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-four-menthol-flavored-e-cigarette-products-after-extensive-scientific [https://perma.cc/D6DQ-VMKG]; *FDA Issues Marketing Decisions on NJOY Ace E-Cigarette Products*, FDA (Apr. 26, 2022), https://www.fda.gov/tobacco-products/ctp-newsroom/fda-issues-marketing-decisions-njoy-ace-e-cigarette-products [https://perma.cc/JT7M-L6UJ].

[395] Press Release, FDA, FDA Permits Marketing of E-Cigarette Products, Marking First Authorization of Its Kind by the Agency (Oct. 12, 2021), https://web.archive.org/web/20211221170154/https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-e-cigarette-products-marking-first-authorization-its-kind-agency.

[396] *See supra* note 389 and accompanying text.

[397] *See* AM. NONSMOKERS' RTS. FOUND., CHRONOLOGICAL TABLE OF U.S. POPULATION PROTECTED BY 100% SMOKEFREE STATE OR LOCAL LAWS (2026), https://no-smoke.org/wp-content/uploads/pdf/EffectivePopulationList.pdf [https://perma.cc/XLF6-7BK9].

[398] *See* R.J. Reynolds Tobacco Co. v. Cnty. of Los Angeles, 29 F.4th 542, 549 (9th Cir. 2022); *see also State Laws on Tobacco Control—United States, 1998*, CTRS. FOR DISEASE CONTROL & PREVENTION, MMWR (June 25, 1999), https://www.cdc.gov/mmwr/preview/mmwrhtml/ss4803a2.htm [https://perma.cc/CRT7-WDC2] (providing an overview of state laws on tobacco control as of 1998).

[399] *State Laws on Tobacco Control—United States, 1998*, *supra* note 398.

[400] 21 U.S.C. § 387p.

[401] *See, e.g.*, R.J. Reynolds Tobacco Co. v. City of Edina, 60 F.4th 1170 (8th Cir. 2023) ("To achieve national uniformity while still respecting States' police power, the [TCA] has three sections relating to preemption: the Preservation Clause, the Preemption Clause, and the Savings Clause.").

[402] 21 U.S.C. § 387p(a)(1).

promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products."[403]

The second part of section 916, at subsection (a)(1)(A), is a preemption clause.[404] It states that

> No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of [the TCA] relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.[405]

The third part of section 916, at subsection (a)(1)(B), is a savings clause that qualifies the preemption clause.[406] It states that the preemption clause "does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products."[407]

Section 916(b) clarifies that "no provision of [the TCA] relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State."[408]

Case Law on the Preemptive Scope of FD&C Act Section 916

As states and localities continue to play a role in the regulation of tobacco products, lower courts have considered the preemptive scope of FD&C Act section 916 on several occasions, primarily in the context of e-cigarette regulation. Even though no sweet-flavored e-cigarettes have received FDA authorization for lawful marketing to date, such products continue to be widely available.[409] To address the availability of unauthorized flavored e-cigarettes, some states and localities have, for instance, restricted or banned the sale of such products within their jurisdictions.[410] In addition, state and local governments, consumers, and/or competing e-cigarette manufacturers have also sued certain e-cigarette manufacturers and other defendants, alleging that the defendants, in violation of applicable state unfair or deceptive acts or other related laws, unlawfully marketed or distributed certain unauthorized or defectively designed e-cigarettes, or engaged in a false and deceptive marketing campaign related to certain e-cigarettes.[411] Several lower courts have considered the preemptive scope of section 916 as applied to local ordinances that restricted or banned the sale of all flavored e-cigarettes and to state consumer protection or tort law claims.

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[403] *Id.* § 387p(a)(1).

[404] *Id.* § 387p(a)(2)(A).

[405] *Id.*

[406] *Id.* § 387p(a)(2)(B).

[407] *Id.*

[408] *Id.* § 387p(b).

[409] *See, e.g.*, CDC FOUND., MONITORING E-CIGARETTE TRENDS IN THE UNITED STATES: URGENT ACTION NEEDED TO PROTECT KIDS FROM FLAVORED E-CIGARETTES 17 (2024), https://tobaccomonitoring.org/wp-content/uploads/2024/11/2024MonitoringE-CigaretteTrendsUS-1.pdf. [https://perma.cc/YD9C-2PUY].

[410] *See, e.g.*, CAMPAIGN FOR TOBACCO-FREE KIDS, STATES & LOCALITIES THAT HAVE RESTRICTED THE SALE OF FLAVORED TOBACCO PRODUCTS (2025), https://assets.tobaccofreekids.org/factsheets/0398.pdf [https://perma.cc/ZF7Y-PSQ3].

[411] *See, e.g.*, NJOY, LLC v. Imiracle (HK) Ltd., 760 F. Supp.3d 1084, 1096–97 (S.D. Cal. 2024); In re JUUL Labs, Inc. Mktg., Sales Pracs. & Prods. Liab. Litig., 497 F. Supp. 553, 576–78 (N.D. Cal. 2020); Colgate v. JUUL Labs, Inc., 345 F. Supp. 3d 1178, 1184–85 (N.D. Cal. 2018).

Case Law on the Preemptive Scope of FD&C Act Section 916 As Applied to Local Ordinances Restricting Sale of Flavored E-Cigarettes

At least three appellate courts have considered whether FD&C Act section 916 preempts local ordinances that restrict or ban the sale of flavored e-cigarettes (i.e., sweet- or menthol-flavored e-cigarettes) within the relevant locality.[412] In each case, the relevant ordinance either limited the sale of such products to specially licensed establishments (i.e., tobacco bars) or banned their sale altogether.[413] In response, affected e-cigarette manufacturers filed suits to challenge the ordinances, arguing that the applicable sales restriction or ban was preempted by section 916 because the flavor restriction or ban constituted a "tobacco product standard[]" and imposed a requirement "different from, or in addition to" federal requirements.[414] In each case, the court held that section 916's preemption clause did not expressly preempt the relevant sales restriction or ban, and that even if the sales restriction or ban were subject to the preemption clause, they were saved from preemption under the savings clause.[415]

In these cases, the courts generally recognized section 916 to be composed of three parts. The first part, the preservation clause, generally "broadly preserves state, local, and tribal power to enact *any* regulation concerning tobacco products that is 'in addition to or more stringent' than those promulgated by the TCA."[416] The preemption clause, according to these courts, immediately follows the preservation clause to carve out certain exceptions or define its limits.[417] Relevant to the ordinances restricting or banning the sale of flavored e-cigarettes is the preemption clause's limit that "[n]o State or political subdivision of a State may establish . . . with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under [TCA] *relating to tobacco product standards*."[418] These courts held that the applicable sales restriction or ban did not constitute a product standard subject to preemption because those standards "pertain[] to the production or marketing stages up until the actual point of sale."[419] In the courts' view, "[a] local sales regulation"—which operates on a finished product and "does not clearly infringe on the FDA's authority to determine what chemicals and processes may be used in making tobacco product"—"is therefore not preempted."[420]

[412] R.J. Reynolds Tobacco Co. v. City of Edina, 60 F.4th 1170 (8th Cir. 2023) (per curiam); R.J. Reynolds Tobacco Co. v. Cnty. of L.A., 29 F.4th 542 (9th Cir. 2022); U.S. Smokeless Tobacco Mfr. Co. v. City of N.Y., 708 F.3d 428 (2d Cir. 2013).

[413] *See U.S. Smokeless Tobacco Mfr. Co.*, 708 F.3d at 431 (considering a New York City ordinance that bans the sale of flavored tobacco products except in a tobacco bar); *City of Edina*, 60 F.4th at 1173 (considering a city ordinance that banned the sale of all flavored tobacco products).

[414] *See U.S. Smokeless Tobacco Mfr. Co.*, 708 F.3d at 434; *City of Edina*, 60 F.4th at 1175; *Cnty. of L.A.*, 29 F. 4th at 553–54.

[415] *See U.S. Smokeless Tobacco Mfr. Co.*, 708 F.3d at 435; *City of Edina*, 60 F.4th at 1175–77; *Cnty. of L.A.*, 29 F. 4th at 558.

[416] *Cnty of L.A.*, 29 F.4th at 550 (quoting 21 U.S.C. § 387p(a)(1)); *see also U.S. Smokeless Tobacco Mfg. Co.*, 708 F.3d at 431 (noting that section 916's preemption clause "establishes an exception to [the preservation clause's] broad preservation of states' authority"); *City of Edina*, 60 F.4th at 1174 ("Essentially, the Preservation Clause tells us that there is no 'field preemption' for the TCA—states and cities are free to go above and beyond the requirements of the TCA to curb tobacco use.").

[417] *See U.S. Smokeless Tobacco Mfg. Co.*, 708 F.3d at 431; *Cnty. of L.A.*, 29 F.4th at 551; *City of Edina*, 60F.4th at 1174.

[418] 21 U.S.C. § 387p(a)(2)(A) (emphasis added).

[419] *Cnty. of L.A.*, 29 F.4th at 554; *see also U.S. Smokeless Tobacco Mfg. Co.*, 708 F.3d at 435 ("[T]he City does not care what goes into the tobacco or how the flavor is produced, but only whether final tobacco products are ultimately characterized by—or marketed as having—a flavor.").

[420] *U.S. Smokeless Tobacco Mfg. Co.*, 708 F.3d at 434; *see also Cnty. of L.A.*, 29 F.4th at 554 (similar).

The courts, however, also recognized that "[t]he line between regulating the sale of a finished product and establishing product standards will not always be easy to draw."[421] "'Flavored tobacco products,'" one court observed as an example, "can arguably be described either as a category of finished product or as products that are manufactured with ingredients that impart a flavor."[422] Accordingly, these courts further held that even if the ordinances were construed as establishing a tobacco product standard subject to preemption, they were "saved" from preemption by the savings clause, which "except[s] . . . from preemption . . . 'requirements relating to the sale . . . of[] tobacco products [to] individuals of any age.'"[423] The savings clause, according to the courts, reinforces what is first established in the preservation clause—"that the regulation and prohibition of tobacco product sales falls squarely within the purview of states, localities, and tribal entities."[424] In the courts' view, section 916's three-part structure "reserves regulation at the manufacturing stage exclusively to the federal government, but allows states and localities to continue to regulate sales and other consumer-related aspects of the industry in the absence of conflicting federal regulation."[425]

Case Law on the Preemptive Scope of FD&C Act Section 916 As Applied to State Tort and Consumer Protection Law Claims

Local governmental entities, as well as certain consumers and other private parties, have also filed suit against certain e-cigarette manufacturers, often alleging claims based on state consumer protection and/or tort laws. These suits have alleged, for instance, that the defendant e-cigarette manufactures, in violation of state consumer protection laws, marketed certain unauthorized e-cigarettes, or engaged in certain misleading or deceptive conduct—including through product designs that appealed to youth and statements on product labels and websites—with respect to certain e-cigarettes.[426] Some suits have also alleged that the defendant e-cigarette manufacturers failed to adequately warn of the products' risks in violation of state tort laws.[427] In response, the defendant e-cigarette manufacturers have argued that such claims were preempted by FD&C Act section 916.[428] With the exception of certain claims based on product labeling, lower courts that have considered the preemption question have generally held that section 916 did not preempt these state-law claims.[429]

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[421] *U.S. Smokeless Tobacco Mfg. Co.*, 708 F.3d at 434.

[422] *Id.* at 435.

[423] *Cnty. of L.A.*, 29 F.4th at 555 (alterations in original) (quoting 21 U.S.C. § 387p(a)(2)(B)). *See also U.S. Smokeless Tobacco Mfg. Co.*, 708 F.3d at 435 (similar).

[424] *Cnty. of L.A.*, 29 F.4th at 555. *See also City of Edina*, 60 F.4th at 1175–76.

[425] *U.S. Smokeless Tobacco Mfg. Co.*, 708 F.3d at 434. *See also Cnty. of L.A.*, 29 F.4th at 555 (stating that section 916's three-part structure "reveals a careful balance of power between federal authority and state, local, and tribal authority, whereby Congress has allowed the federal government to set the standards regarding how a product would be manufactured and marketed, but has left states, localities, and tribal entities the ability to restrict or opt out of that market altogether"); *City of Edina*, 60 F.4th at 1177 (holding that interpreting the ordinance to be "rescued by the Savings Clause" is a result compelled by the federalism canon because the ordinance implicated the states' traditional police powers to protect public health and safety, which has been invoked by state and local authorities to enact "public health measures directed at the dangers of tobacco use" since the early 1900s).

[426] *See, e.g.*, NJOY, LLC v. Imiracle (HK) Ltd., 760 F. Supp. 1084, 1107–10 (S.D. Cal. 2024); Colgate v. JUUL Labs, Inc., 345 F. Supp. 3d 1178, 1188 (N.D. Cal. 2018); In re JUUL Labs, Inc., Mktg, Sales Pracs. & Prods. Liab. Litig., 497 F. Supp. 3d 553, 575–78 (N.D. Cal. 2020).

[427] *See, e.g.*, *In re JUUL Labs, Inc.*, 497 F. Supp. 3d at 587–88.

[428] *Id*. at 583–84.

[429] *See, e.g.*, *In re JUUL Labs*, 497 F. Supp. 3d at 587–88; *NJOY*, 760 F. Supp. 3d at 1109; *Colgate*, 345 F. Supp. 3d at 1189–90.

In *In re: JUUL Labs, Inc.*, *Marketing, Sales Practices, and Products Liability Litigation*, for instance, a county government, several school districts, and certain consumers sued an e-cigarette manufacturer and its distributors and retailers, alleging that the defendants violated applicable state consumer protection and products liability laws.[430] In particular, the plaintiffs alleged that the manufacturer defendant designed its e-cigarettes to maximize addiction and to appeal to youth while further promoting the products, with the assistance of the distributor and retailer defendants, by targeting youths.[431] Among other claims, the plaintiffs alleged that (1) the manufacturer defectively designed their e-cigarettes in its choice of the products' nicotine yields, ingredients, and flavorings as well as their "sleek easily concealable design"; (2) the manufacturer defendant provided misleading or inadequate warnings on its product labels by failing to disclose the greater addictiveness of its products; and (3) the defendants engaged in false and misleading advertising of the manufacturer's e-cigarettes by promoting the products as "a fun and safe alternative to cigarettes that would help smokers quit."[432] In response to defendants' argument that these claims were expressly preempted by section 916, the court held that only the plaintiffs' labeling claims based on inadequate disclosures regarding nicotine addiction were preempted, given that FDA had specified the precise language and placement of the nicotine warning label.[433] The other claims, the court reasoned, were not expressly preempted because FDA had not yet promulgated "any actual design or product standards for [e-cigarettes]"[434] and section 916's exception clause under subsection (a)(2)(B) expressly "preserves state requirements regarding the 'exposure to, access to, the advertising and promotion of, or use of, tobacco products.'"[435]

Similarly, in *NJOY, LLC v. Imiracle (HK) Ltd.*, an e-cigarette manufacturer with products authorized by FDA sued its competitors and their retailers for violations of the applicable state consumer protection law.[436] The plaintiff alleged that the defendants unlawfully sold unauthorized flavored e-cigarettes and deceptively marketed those products—including through packaging, labels, and website representations—as lawful.[437] In response to defendants' argument that the plaintiff's claims were preempted, the court held that plaintiff's claims were preempted to the extent they were based on "deficiencies in the inclusion or omission of information on [the e-cigarettes'] labels."[438] In the court's view, such claims imposed "additional or different labeling requirements" than what FDA requires.[439] At the same time, the court held that the plaintiff's claims were not preempted to the extent they "relie[d] on conduct or practices unrelated to labeling," including claims related to misleading website representations and violations of the state's ban of flavored e-cigarettes.[440]

[430] 497 F. Supp. 3d at 575–78.

[431] *Id.*

[432] *Id.* at 577, 587, 590–91.

[433] *Id.* at 588 (citing 21 C.F.R. § 1143.3(a)(1)); *see also* Colgate v. JUUL Labs, Inc., 345 F. Supp. 3d 1178, 1188 (N.D. Cal. 2018) ("Considering the statutory and regulatory scheme in its entirety, I find that the FDA, through its authority under the TCA has prescribed the precise language and placement of warning labels on covered tobacco products such as ENDS under 21 C.F.R. §§ 1143.3(a)(1)(2).").

[434] *In re JUUL Labs., Inc.*, 497 F. Supp. 3d at 587.

[435] *Id.* at 590 (quoting 21 U.S.C. § 387p(a)(2)(B)).

[436] 760 F. Supp. 3d 1084, 1096, 1107–08 (S.D. Cal. 2024).

[437] *Id.*

[438] *Id.* at 1106.

[439] *Id.* at 1107.

[440] *Id.* at 1109.

Observations and Considerations for Congress

Both Congress's amendments of the FD&C Act over the years addressing preemption and the courts' jurisprudence on FD&C Act preemption reflect the recognition of states' long-standing role in concurrently regulating the products subject to the FD&C Act.

Congress has chosen to include express preemption provisions for some FD&C Act product-specific provisions but not others. Until the Medical Device Amendments of 1976 (MDA), the FD&C Act did not include provisions that expressly preempt state law.[441] The FD&C Act's prescription drug provisions—which set up the earliest regulatory framework for premarket review of a product in the original 1938 FD&C Act—still does not include an express preemption provision.[442] Where Congress has included express preemption provisions, their scope is generally tethered to the scope of the applicable federal regulation. For instance, when the MDA subjected certain medical devices to premarket review by FDA for safety and efficacy, the express preemption provision (FD&C Act section 521) preempts state laws that impose different or additional safety and effectiveness requirements.[443] For food and cosmetic products subject to federal labeling requirements, the applicable express preemption provisions preempt non-identical labeling requirements to promote national uniformity in labeling.[444] Depending on the relevant status of state regulation, Congress sometimes further calibrated the scope of preemption to specifically preserve certain application of state law. FD&C Act section 916, which addresses the interaction of federal and state law for tobacco products, for instance, sandwiched the express preemption provision between both a preservation clause and a savings clause that qualify the express preemption clause by preserving certain state requirements, including those relating to the sale and promotion, or use, of tobacco products by individuals of any age.[445]

The courts' FD&C Act preemption jurisprudence reflects a similar recognition of states' role in the regulation of these products. With the exception of a particular type of fraud claim that the Supreme Court has found to be impliedly preempted by the FD&C Act's general enforcement scheme,[446] courts considering FD&C Act preemption questions frequently undertake a case-specific, often granular, comparative analysis of what federal law requires or permits and whether and to what extent the relevant state requirements conflict with federal requirements.[447] The case law indicates that courts may be especially reluctant to find the existence of a conflict where Congress has not spoken directly with respect to preemption.[448] For instance, with respect to brand prescription drugs, the Supreme Court in *Wyeth v Levine*, relying in part on the presumption against preemption, rejected the argument that state-law claims seeking to strengthen a brand-name drug's risk warnings are generally preempted, even though such warnings are subject to FDA regulatory requirements.[449] Instead, the court held that such failure-to-warn claims may survive preemption as long as there was no "clear evidence that FDA would not have

[441] *See supra* notes 92–94 and accompanying text.

[442] *See supra* "Overview of Selected FD&C Act Provisions on Prescription Drugs."

[443] *See supra* "FD&C Act Section 521: Preemption Provision Related to Medical Devices."

[444] *See supra* "Selected FD&C Act Provisions on Preemption Related to Food"; "FD&C Act Sections 752 and 614: Express Preemption Provisions Related to Cosmetics."

[445] *See supra* "FD&C Act Section 916: Provision Including Express Preemption Clause Related to Tobacco Products."

[446] *See supra* "Preemption Based on the FD&C Act's Enforcement Scheme."

[447] *See, e.g., supra* "Case Law on the Preemptive Scope of Selected FD&C Act Provisions on Food"; "Case Law on the Preemptive Scope of Selected Prescription Drug Provisions"; "Case Law on the Preemptive Scope of FD&C Act Section 521 on State Tort Law Claims."

[448] *See supra* "Case Law on the Preemptive Scope of Selected Prescription Drug Provisions."

[449] *See supra* notes 222–226 and accompanying text.

approved."[450] In addition, although courts appear to generally agree that the premarket approval scheme preempts state-law claims seeking to impose an alternative design for drugs *post*-approval, some lower courts have held that not all design defect claims against brand-name drugs are necessarily preempted by the fact of FDA approval.[451] At the same time, in at least one discrete instance, a lower court interpreted the FD&C Act's prescription drug provisions to have broader preemptive scope with respect to drug importation—an aspect of drug regulation not historically subject to state regulation.[452]

Where Congress has included express preemption provisions in the FD&C Act, courts have typically interpreted the provisions' preemption of "additional," "different," or "non-identical" state requirements addressing particular areas subject to federal regulation to mean that state laws or claims seeking to impose requirements that parallel federal requirements are *not* preempted.[453] Here, too, courts often analyze the state requirements a plaintiff seeks to impose, the applicable federal requirements and their degree of regulation, and whether the state requirements may be construed to impose identical obligations as federal regulations.[454] As interpreted by courts to date, even the MDA's express preemption provision for medical devices—arguably the broadest preemption provision discussed in this report—has not been interpreted to preempt all state claims asserted against a medical device subject to the most stringent form of premarket review.[455] Where a case raises difficult preemption questions, courts have also explicitly looked to historical regulatory roles of the states on a topic to parse a carefully calibrated express preemption provision.[456] These nuanced analyses often lead to few bright-line results and the preservation of at least some state requirements at issue in a particular case.[457]

The case law on FD&C Act preemption suggests that courts may be likely to give effect to state requirements where possible, particularly given courts' recognition of states' long-standing role in the regulation of products subject to the FD&C Act. State requirements may be most likely to survive preemption where Congress is silent on the interaction of federal and state law. Existing express preemption provisions have also been interpreted to leave room for certain state requirements. At the same time, there is some indication that courts may be more likely to construe relevant FD&C Act provisions to have broader preemptive effect on certain aspects of product regulation that is not historically regulated by states. These considerations may inform Congress's decision on whether to modify existing express preemption provision, add additional express preemption provisions, and consider the appropriate degree of specificity of any such provisions.

[450] *See id.*

[451] *See supra* notes 237–245 and accompanying text.

[452] *See supra* notes 246–251.

[453] *See supra* "Case Law on the Preemptive Scope of Selected FD&C Act Provisions on Food"; "Case Law on the Preemptive Scope of FD&C Act Section 521 on State Tort Law Claims"; "Case Law on the Preemptive Scope of FD&C Act Section 752."

[454] *See id.*

[455] *See supra* "Case Law on the Preemptive Scope of FD&C Act Section 521 on State Tort Law Claims."

[456] *See supra* note 425 and accompanying text.

[457] *See supra* "Case Law on the Preemptive Scope of Selected FD&C Act Provisions on Food"; "Case Law on the Preemptive Scope of FD&C Act Section 521 on State Tort Law Claims"; "Case Law on the Preemptive Scope of FD&C Act Section 916."

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