

UNITED STATES COURT OF APPEALS  
FOR THE SECOND CIRCUIT

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August Term, 2012

(Argued: November 6, 2012    Decided: February 26, 2013  
Corrected: February 26, 2013)

Docket No. 11-5167-cv

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U.S. SMOKELESS TOBACCO MANUFACTURING COMPANY LLC, U.S. SMOKELESS TOBACCO  
BRANDS INC.,

*Plaintiffs-Appellants,*

— v. —

CITY OF NEW YORK,

*Defendant-Appellee.*

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B e f o r e:

RAGGI, NEWMAN, LYNCH, *Circuit Judges.*

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Plaintiffs U.S. Smokeless Tobacco Manufacturing Company LLC and U.S. Smokeless Tobacco Brands Inc. sought an injunction in the Southern District of New York (Colleen McMahon, *Judge*) against enforcement of a New York City ordinance governing the sale of flavored tobacco products, which they argue is preempted by the Family Smoking Prevention and Tobacco Control Act. Plaintiffs appeal an award of

summary judgment in favor of the City. We affirm because the ordinance is not preempted.

AFFIRMED.

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KENNETH J. PARSIGIAN (Abigail K. Hemani, *on the brief*), Goodwin Procter LLP, Boston, Massachusetts, *for Plaintiffs-Appellants*.

MICHAEL JORDAN PASTOR, Assistant Corporate Counsel (Michelle Goldberg-Cahn, Sherrill Kurland, Larry A. Sonnenshein, Sharyn Michele Rootenberg, *on the brief*), *for Michael A. Cardozo, Corporation Counsel, New York, New York, for Defendant-Appellee*.

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GERARD E. LYNCH, *Circuit Judge*:

Plaintiffs U.S. Smokeless Tobacco Manufacturing Company LLC and U.S. Smokeless Tobacco Brands Inc. (collectively, “plaintiffs”) manufacture and distribute smokeless tobacco products, including flavored smokeless tobacco. On December 28, 2009, they filed suit in the United States District Court for the Southern District of New York (Colleen McMahon, *Judge*), challenging the validity of a New York City ordinance governing the sale of flavored tobacco products. Plaintiffs alleged that the ordinance, New York City Administrative Code § 17-715, is preempted by the Family Smoking Prevention and Tobacco Control Act (“FSPTCA” or “Act”), Pub. L. No. 111-31, 123 Stat. 1776 (2009), codified at 21 U.S.C. § 387 et seq., and sought an injunction against its enforcement. They now appeal an award of summary judgment entered on November 15,

2011, in favor of defendant, the City of New York (“the City”). Because we conclude that the ordinance is not preempted by the FSPTCA, we affirm the judgment of the district court.

## **BACKGROUND**

### **I. The Family Smoking Prevention and Tobacco Control Act**

Congress enacted the FSPTCA in 2009 to grant the Food and Drug Administration (“FDA”) authority to regulate tobacco products under the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* *See* 21 U.S.C. § 387a(a). Under the Act, the FDA’s authority extends to the regulation of “all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the [FDA] by regulation deems to be subject to [the Act].” *Id.* § 387a(b).

Of particular relevance to the present action is § 907 of the FSPTCA. Entitled “Tobacco Product Standards,” it sets out a “special rule for cigarettes,” which provides that “a cigarette or any of its component parts . . . shall not contain, as a constituent . . . or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice.” *Id.* § 387g(a)(1)(A). Section 907 further grants the FDA authority to revise the special rule for cigarettes, *id.* § 387g(a)(2), and to adopt additional product standards if “appropriate for the protection of the public health,” *id.* § 387g(a)(3)(A). Specifically, the FDA is authorized to establish standards “respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of . . . tobacco product[s],” *id.* § 387g(a)(4)(B)(i), and to adopt provisions restricting their sale

and distribution, id. § 387g(a)(4)(B)(v). The FDA may not, however, “ban[] all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products,” or “requir[e] the reduction of nicotine yields of a tobacco product to zero.” Id. § 387g(d)(3).

Before imposing “restrictions on the sale and distribution of a tobacco product,” the FDA must determine “that such regulation would be appropriate for the protection of the public health.” Id. § 387f(d)(1). In deciding whether a regulation is appropriate, the FDA must consider “the risks and benefits to the population as a whole, including users and nonusers of the tobacco product.” Id. Specifically, the FDA must take into account “the increased or decreased likelihood that existing users of tobacco products will stop using such products,” as well as “the increased or decreased likelihood that those who do not use tobacco products will start using such products.” Id. § 387f(d)(1)(A), (B). Finally, the FDA may not “prohibit the sale of any tobacco product in face-to-face transactions by a specific category of retail outlets; or . . . establish a minimum age of sale of tobacco products to any person older than 18 years of age.” Id. § 387f(d)(3)(A).

Also central to this appeal is the Act’s preemption provision, set out in § 916. The section is composed of three parts. First, a preservation clause states, in relevant part:

Except as provided in [the preemption clause], nothing in this subchapter . . . shall be construed to limit the authority of . . . a State or political subdivision of a State . . . to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this subchapter, including a law, rule, regulation, or other measure

relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age . . . .

Id. § 387p(a)(1). A preemption clause then establishes an exception to this broad preservation of states’ authority, providing:

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 this subchapter relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

Id. § 387p(a)(2)(A). Finally, a saving clause carves out an exception to the exception, stipulating 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.” Id. § 387p(a)(2)(B).

## **II. The New York City Ordinance**

New York City Administrative Code § 17-715 prohibits the sale in New York City of “any flavored tobacco product except in a tobacco bar.” A flavored tobacco product is any item, not including cigarettes, that contains both tobacco and “a constituent that imparts a characterizing flavor.” Id. § 17-713(e). A characterizing flavor is “a distinguishable taste or aroma, other than the taste or aroma of tobacco, menthol, mint or wintergreen, imparted either prior to or during consumption of a tobacco product or component part thereof.” Id. § 17-713(b). A tobacco product is not deemed to have a

characterizing flavor “solely because of the use of additives or flavorings or the provision of ingredient information,” *id.*, but any “public statement or claim made or disseminated by the manufacturer of a tobacco product . . . that such tobacco product has or produces a characterizing flavor shall constitute presumptive evidence that the tobacco product is a flavored tobacco product,” *id.* § 17-713(e).

Although the City’s ordinance applies to all flavored non-cigarette tobacco products, there is no indication in the record that flavored cigars or non-cigarette products other than smokeless tobacco constitute a commercially significant product category, and in any event plaintiffs do not seek to challenge the ordinance insofar as it relates to products other than the flavored smokeless tobacco products they manufacture and distribute. Smokeless tobacco products are, as the term suggests, tobacco products used by means other than smoking. They include chewing tobacco, dip, and snuff, and, according to plaintiffs, they are typically consumed by adults, primarily in the South.

Plaintiffs represent, and the City does not contest, that there are only eight tobacco bars in New York City, all of which are in Manhattan and none of which sells flavored smokeless tobacco. Accordingly, we assume for purposes of this decision that such products are unavailable for purchase anywhere in the city.

## **DISCUSSION**

### **I. Legal Standards**

“We review *de novo* a district court’s application of preemption principles.” N.Y.

SMSA Ltd. P'ship v. Town of Clarkstown, 612 F.3d 97, 103 (2d Cir. 2010). “To determine whether a state or local law is preempted by federal law, we look to Congress’s intent.” 23-34 94th St. Grocery Corp. v. N.Y. City Bd. of Health, 685 F.3d 174, 180 (2d Cir. 2012). Where the federal statute contains an express preemption provision, we begin with the wording of that provision, CSX Transp. Inc. v. Easterwood, 507 U.S. 658, 664 (1993), but we must also consider the statute as a whole to determine whether the local ordinance actually conflicts with the overall federal regulatory scheme, Altria Grp., Inc. v. Good, 555 U.S. 70, 76-77 (2008). Where, as here, Congress has specifically addressed the preemption issue, our task is primarily one of interpreting what Congress has said on the subject. See Ass’n of Int’l. Auto. Mfrs., Inc. v. Abrams, 84 F.3d 602, 607 (2d Cir. 1996) (“Where an express clause is a reliable indicium of congressional intent, preemption is restricted to the terms of that provision.”).

Preemption analysis is guided by the presumption that a federal statute does not displace the local law “unless Congress has made such an intention clear and manifest.” Bates v. Dow Agrosiences LLC, 544 U.S. 431, 449 (2005) (internal quotation marks omitted). This assumption is particularly strong where, as here, a state or locality seeks to exercise its police powers to protect the health and safety of its citizens. Medtronic, Inc. v. Lohr, 518 U.S. 470, 475, 485 (1996); see N.Y. State Restaurant Ass’n v. N.Y. City Bd. of Health, 556 F.3d 114, 123 (2d Cir. 2009) (“The presumption against preemption is heightened ‘where federal law is said to bar state action in fields of traditional state regulation.’”), quoting N.Y. State Conference of Blue Cross & Blue Shield Plans v.

Travelers Ins. Co., 514 U.S. 645, 655 (1995). Accordingly, if there is any ambiguity as to whether the local and federal laws can coexist, we must uphold the ordinance. See Bates, 544 U.S. at 449; N.Y. State Restaurant Ass’n, 556 F.3d at 123.

## **II. Application**

The FSPTCA’s stated purposes include, on the one hand, reducing the use of, dependence on, and social costs associated with tobacco products and, on the other, allowing the continued sale of such products to adults “in conjunction with measures to ensure that they are not sold or accessible to underage purchasers.” FSPTCA § 3(7), codified at 21 U.S.C. § 387 note. These potentially conflicting purposes reflect Congress’s desire to reduce the serious health risks associated with tobacco use, see H.R. Rep. No. 111-58, pt. 1 at 2-4 (2009) (summarizing extensive human and financial costs of tobacco use), coupled with its recognition that there is no national consensus to abolish tobacco products altogether, particularly in light of the millions of adults who are addicted to them, see id. at 38 (noting that “prohibition of a product that is used regularly by a large number of heavily addicted adult users” would pose difficult questions of public health). Congress therefore prohibited the FDA from banning entire categories of products such as cigarettes or smokeless tobacco. 21 U.S.C. § 387g(d)(3). But it also recognized that the purposes of the Act would not be served by allowing unrestrained production of and access to all tobacco products. It therefore banned the use of flavoring additives in cigarettes and authorized the FDA to prohibit the use of other ingredients in tobacco products if it deems them particularly harmful to the public health. Id. § 387g(a).

Plaintiffs infer from Congress’s compromise with respect to federal policy that local governments “may not make it impossible or impracticable for adults to purchase tobacco products whose contents comply with the federal standards.” (Appellants’ Br. 37.) Significantly, however, no provision explicitly embodying such a restriction on state authority can be found in the text of the statute. While § 907(d)(3) prohibits the FDA from banning entire categories of tobacco products throughout the country, 21 U.S.C. § 387g(d)(3), the FSPTCA nowhere extends that prohibition to state and local governments.<sup>1</sup> To the contrary, the preservation clause of § 916 expressly *preserves* localities’ traditional power to adopt any “measure relating to or prohibiting the sale” of tobacco products. 21 U.S.C. § 387p(a)(1). That authority is limited only to the extent that a state or local regulation contravenes one of the specific prohibitions of the preemption clause. *Id.* The only prohibition relevant here forbids local governments to impose “any requirement . . . relating to tobacco product standards.” *Id.* § 387p(a)(2)(A). Even then, pursuant to the saving clause, local laws that would otherwise fall within the preemption clause are exempted if they constitute “requirements relating to the sale . . . of . . . tobacco products.” *Id.* § 387p(a)(2)(B). In other words, § 916 distinguishes between

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<sup>1</sup> Earlier versions of § 907 would have expressly reserved to the federal government authority to ban the sale of entire categories of tobacco products. *E.g.*, H.R. 2180, 107th Cong. § 907(b)(3) (2001); H.R. 4433, 108th Cong. § 907(b)(3) (2004); S. 2461, 108th Cong. § 907(b)(3) (2004); H.R. 1376, 109th Cong. § 907(b)(3) (2005); S. 666, 109th Cong. § 907(b)(3) (2005). These draft versions of the provision that ultimately became § 907(d)(3) were eventually rewritten to deny such power only to the FDA, and as enacted into law, this provision of the FSPTCA does not forbid such bans by state and local governments. *See* 21 U.S.C. § 387g(d)(3).

manufacturing and the retail sale of finished products; it 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.

Plaintiffs argue that the City’s ordinance, on its face a sales regulation, is in fact a product standards regulation designed to “evade express federal preemption . . . by artful crafting that elevates form over substance.” (Appellants’ Br. 28-29.) Certainly, any purported sales ban that in fact “functions as a command” to tobacco manufacturers “to structure their operations” in accordance with locally prescribed standards would not escape preemption simply because the City “fram[ed] it as a ban on the sale of [tobacco] produced in whatever way [it] disapproved.” Nat’l Meat Ass’n v. Harris, 132 S. Ct. 965, 972-73 (2012); see Engine Mfrs. Ass’n v. S. Coast Air Quality Mgmt. Dist., 541 U.S. 246, 254 (2004) (“[A] standard is a standard even when not enforced through manufacturer-directed regulation . . .”). But it does not follow that every sales ban – many of which would likely have some effect on manufacturers’ production decisions – should be regarded as a backdoor “requirement . . . relating to tobacco product standards” that is preempted by the FSPTCA, 21 U.S.C. § 387p(a)(2)(A). Such a broad reading of the preemption clause, which collapses the distinction between sales and product regulations, would render superfluous § 916’s three-part structure, and in particular would vitiate the preservation clause’s instruction that the Act not be “construed to limit the authority of . . . a State or political subdivision of a State . . . to enact . . . and enforce any

. . . measure . . . prohibiting the sale . . . of tobacco products,” 21 U.S.C. § 387p(a)(1). Because “[s]tatutes should be construed, if possible, to give effect to every clause and word,” Cal. Pub. Emps.’ Ret. Sys. v. WorldCom, Inc., 368 F.3d 86, 106 (2d Cir. 2004), and in light of our presumption that Congress has not limited the exercise of local police powers, we adopt a narrower reading of the preemption clause that also gives effect to the preservation clause.

To constitute a product standard subject to preemption, a local sales regulation must be “something more than an incentive or motivator,” Nat’l Meat Ass’n, 132 S. Ct. at 973 (internal quotation marks and brackets omitted); it must require manufacturers to alter “the construction, components, ingredients, additives, constituents . . . and properties” of their products, 21 U.S.C. § 387g(a)(4)(B). See Bates, 544 U.S. at 443 (federal law preempting state “requirements” for labeling of pesticide products did not preempt state product liability suits that “might ‘induce’ a pesticide manufacturer to change its label”); cf. Nat’l Meat Ass’n, 132 S. Ct. at 974 (noting a “significant” difference between “[a] ban on butchering horses for human consumption” and a statute that “reaches into the slaughterhouse’s facilities and affects its daily activities”). A local sales regulation that does not clearly infringe on the FDA’s authority to determine what chemicals and processes may be used in making tobacco products does not fall within this description and is therefore not preempted.

The line between regulating the sale of a finished product and establishing product standards will not always be easy to draw. Any finished product can be described in

terms of its components or method of manufacture. “Flavored tobacco products” are no exception, and can arguably be described either as a category of finished product or as products that are manufactured with ingredients that impart a flavor. We find the first description more plausible. Whether a product is governed by Administrative Code § 17-715 depends on its characteristics as an end product, and not on whether it was manufactured in a particular way or with particular ingredients. Unlike the FSPTCA’s “special rule for cigarettes,” which prohibits manufacturers from producing cigarettes that contain “an artificial or natural flavor” as a constituent or additive, 21 U.S.C. § 387g(a)(1)(A), the city ordinance explicitly does not turn on “the use of additives or flavorings,” but rather on whether the product itself imparts “a distinguishable taste or aroma,” N.Y. City Admin. Code § 17-713(b). In other words, the 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. No matter the level of generality used to define “flavored tobacco products,” the ordinance is not easily read to direct manufacturers as to which ingredients they may or may not include in their products. We are therefore not persuaded that the City is infringing on the role reserved for the federal government, and in particular the scientifically expert FDA, of assessing the relative risks of specific ingredients or methods of production.<sup>2</sup>

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<sup>2</sup> The City’s regulation is therefore easily distinguishable from the California statute invalidated as a manufacturing standard in National Meat Association. That law expressly prohibited the sale of meat that was not produced in accordance with specific rules to be applied at the slaughterhouse with respect to the kinds of animals that were, according to the state, fit for butchering – rules that were in conflict with more forgiving federal standards.

In any event, even if the ordinance were construed as establishing a product standard that falls within § 916’s preemption provision, it would not be preempted, because it also falls within that section’s saving clause. The saving clause excepts from preemption local laws that establish “requirements relating to the sale . . . of . . . tobacco products.” 21 U.S.C. § 387p(a)(2)(B). As a regulation limiting the businesses at which flavored tobacco may be sold, the city ordinance establishes a “requirement[] relating to the sale . . . of . . . tobacco products” within the plain meaning of the saving clause.

Plaintiffs contend that the ordinance is not rescued by the saving clause because it effects an outright ban on the sale of flavored tobacco products, and the saving clause cannot be read to include sales bans. Plaintiffs point to the difference in language between the preservation clause, which refers to “measure[s] relating to *or prohibiting* the sale” of tobacco products, *id.* § 387p(a)(1) (emphasis added), and the saving clause, which refers only to “requirements relating to the sale” of tobacco products, *id.* § 387p(a)(2)(B). We need not determine whether this reading of the saving clause is correct. While the sales restriction imposed by the City’s ordinance is severe, it does not constitute a complete ban, as it permits the limited sale of flavored tobacco products within New York City.

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See *Nat’l Meat Ass’n*, 132 S. Ct. at 970. To be sold in the state, meat would have to be processed in a particular way. The ordinance at issue here does not concern itself with the mode of manufacturing, or with the ingredients that may be included in tobacco products. Rather, it prohibits the sale of a recognized category of tobacco products, characterized by their flavor and marketed as a distinct product. Plaintiffs’ effort to characterize the ordinance as a manufacturing standard is tantamount to describing a ban on cigarettes as a manufacturing standard mandating that cigars be manufactured in minimum sizes and with tobacco-leaf rather than paper wrappings.

We are mindful that the limitations imposed by the ordinance as described by appellants are very strict; in another context, their proximity to a ban might concern us. However, given Congress's explicit decision to preserve for the states a robust role in regulating, and even banning, sales of tobacco products, we adopt a broad reading of the saving clause and a limited view of the kinds of restrictions that would constitute a ban and require us to address the permissibility of outright prohibitions under the saving clause. This interpretation of § 916 both follows from its plain language and comports with the FSPTCA's overall objectives. Cf. Geier v. Am. Honda Motor Co., 529 U.S. 861, 872 (2000) (declining to interpret a saving provision to allow state law to directly conflict with the statute's purposes and so "permit[ the federal law] to defeat its own objectives"). The City's restriction on the sale of flavored tobacco products advances the FSPTCA's objective of reducing the use and harmfulness of tobacco products, especially among young people, see FSPTCA § 3(2), 21 U.S.C. § 387 note, without trenching on Congress's competing goal of keeping tobacco products generally available to addicted adults. It regulates a niche product, not a broad category of products such as cigarettes or smokeless tobacco, and it allows that product to be sold within New York City, although to a limited extent.<sup>3</sup>

Accordingly, we conclude that Administrative Code § 17-715 is a regulation of

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<sup>3</sup>Accepting *arguendo* plaintiffs' representation that flavored smokeless tobacco is not available in any of the tobacco bars licensed to sell it does not undermine our conclusion that the ordinance does not effect a ban. A decision by owners of tobacco bars not to sell the product is a commercial choice that does not result from the ordinance itself. In addition, there is no evidence in the record or representation by either party that other products covered by the ordinance but not manufactured or distributed by plaintiffs, such as flavored cigars or pipe tobacco, are not sold in tobacco bars.

sale and not a veiled attempt to regulate the manufacture of tobacco products. The ordinance represents an exercise of local police power that Congress specifically allowed in enacting the FSPTCA, and thus it is not preempted.

### **CONCLUSION**

The district court correctly found plaintiffs' claim of preemption without merit and awarded summary judgment in favor of the City. We therefore **AFFIRM** the district court's judgment.