UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NATIONAL ASSOCIATION OF CONVENIENCE STORES, *et al.*,

Plaintiffs,

v.

NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE, *et al.*,

Defendants.

17 Civ. 5324 (VM)

STATEMENT OF INTEREST OF THE UNITED STATES OF AMERICA

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PRELIMINARY STATEMENT

The United States (the "Government") respectfully submits this Statement of Interest pursuant to 28 U.S.C. § 517,[1] to set forth its views regarding federal preemption of § 81.50 of the Health Code of the City of New York (the "City"), N.Y., Health Code tit. 24, § 81.50 ("Regulation 81.50"), which requires chain restaurants and similar retail food establishments to, among other things, display calorie information on menus and menu boards. Specifically, this Statement of Interest addresses whether the City's decision to begin enforcement of Regulation 81.50 on August 21, 2017—even though the U.S. Food and Drug Administration ("FDA") has set May 7, 2018, as the national compliance date for analogous federal requirements—is impermissible by operation of federal law. Plaintiffs, a group of trade associations representing restaurants and other businesses affected by the regulation, seek a preliminary injunction blocking the City's earlier compliance date on preemption grounds. The City has moved to dismiss the action.

The Government last provided its views on Regulation 81.50 as *amicus curiae* in *New York State Rest. Ass'n v. New York City Bd. of Health*, 556 F.3d 114 (2d Cir. 2009) ("*NYSRA*"), a case in which the Second Circuit found that an earlier iteration of Regulation 81.50 was not expressly preempted by the then-applicable provisions of the Federal Food, Drug, and Cosmetic Act (the "FDCA") as amended by the Nutrition Labeling and Education Act (the "NLEA"). *Id*. at 126-30. Although the Government supported this conclusion, its position was based on the statutory regime in existence at that time. *See id*. at 130-31.

[1] Pursuant to 28 U.S.C. § 517, "[t]he Solicitor General, or any officer of the Department of Justice, may be sent by the Attorney General to any State or district in the United States to attend to the interests of the United States in a suit pending in a court of the United States, or in a court of a State, or to attend to any other interest of the United States."

After *NYSRA* was decided, however, Congress enacted the Patient Protection and Affordable Care Act (the "Act") in March 2010. Pub. L. No. 111-148, 124 Stat 119 (Mar. 23, 2010). The Act, among other things, amended the relevant provisions of the FDCA to: (1) mandate new federal menu labeling requirements for chain restaurants and similar retail food establishments, and (2) expressly prohibit any state or local government from enacting any related requirement "not identical to" these new requirements. *Id*. § 4205. Congress delegated authority to the FDA to promulgate rules that would set forth the new federal menu labeling requirements. *Id*. §§ 4205(b), (c).

The preemption provision of the Act explicitly evinces Congress's intent for "national uniformity" in the realm of chain-establishment menu labeling requirements. As explained in detail below, under its delegated authority, as well as in response to additional Congressional action on the issue in the Consolidated Appropriations Act of 2016, the FDA has established May 7, 2018, as the national compliance date for federal menu labeling requirements. Accordingly, the City's attempt to begin enforcement of Regulation 81.50 in August 2017, nine months before compliance is required under analogous federal rules, is expressly preempted.

BACKGROUND

A. Statutory and Regulatory Framework

1. The Historical Federal Statutory Scheme Governing Food Labeling

The FDCA, enacted in 1938, generally prohibits the misbranding of food. In 1990, Congress passed the NLEA, Pub. L. No. 101-535, 104 Stat. 2535 (1990), requiring nutrition labeling on most packaged foods and regulating certain claims concerning food. The NLEA added two new sections to the FDCA. *See* 21 U.S.C.§§ 343(q), (r). The first, 21 U.S.C. § 343(q), mandated specific, uniform disclosures that must be made on food labels, giving rise to the

familiar "Nutrition Facts" panel on packaged foods. The second provision, 21 U.S.C. § 343(r), gave the FDA broad authority to regulate when and how a food purveyor may make claims about the nutrient content or certain health benefits of its product. The NLEA originally expressly exempted food "served in restaurants" and "retail establishments" from mandatory nutrition labeling, however. *See* 21 U.S.C. §§ 343(q)(5)(A)(i), (ii) (2008).

In enacting the NLEA, Congress added two express preemption provisions to the FDCA, 21 U.S.C. §§ 343-1(a)(4) and (a)(5), which addressed the scope of preemption for mandatory nutrition labeling requirements under § 343(q). Section 343-1(a)(4) expressly preempted any state or municipal "requirement for nutrition labeling of food that is not identical to the requirement of [§ 343(q)], except a requirement for nutrition labeling of food which is exempt under [certain provisions of § 343(q)]." 21 U.S.C. § 343-1(a)(4). Because food served in restaurants and retail establishments was explicitly exempt from the requirements of section 343(q), state or municipal authority to impose nutrition labeling requirements on restaurants was undisturbed by the NLEA.

2. Recent Amendments to Federal Food Labeling Requirements

In March 2010, the Act amended section 343(q) of the FDCA to require that chain restaurants and similar retail food establishments disclose calorie information. *See* 21 U.S.C. § 343(q)(5)(H). The Act also specifically required the FDA to "promulgate proposed regulations to carry out" the provisions of this new mandate. *Id*. § 343(q)(5)(H)(x).

The Act, in a section entitled "National Uniformity," also amended the relevant preemption provisions of section 343-1 of the FDCA. Pub. L. No. 111-148, 124 Stat 119, § 4205(c). The Act struck the language from section 343-1(a)(4) that excepted from preemption any requirements for labeling of food that were exempt under section 343(q), and inserted

language that makes clear that the preemption provision now applies to nutrition labeling for food that is sold in restaurants and similar retail food establishments with 20 or more locations. *Id.* Specifically, the relevant provision of section 343-1 now reads:

> [N]o State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect . . . any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q), except that this paragraph does not apply to food that is offered for sale in a restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items unless such restaurant or similar retail food establishment complies with the voluntary provision of nutrition information requirements under section 343(q)(5)(H)(ix) of this title . . . .

21 U.S.C. § 343-1(a)(4).

Further emphasizing the preemptive nature of the new requirements, Congress included a rule of construction stating that nothing in the Act's amendments should be construed "to preempt any provision of State or local law," with the conspicuous and explicit exception of any state or local provision that "establishes or continues into effect nutrient content disclosures of the type required" under § 343(q)(5)(H). Pub. L. No. 111-148, 124 Stat 119, §4205(d). The FDA did promulgate regulations, however, enabling states or localities to seek an exemption for any requirement that would be blocked under the terms of section 343-1(a) as "not identical to" federal requirements. 21 C.F.R. § 100.1(c)(4). The applicable provision specifies that the language "'[n]ot identical to' does not refer to the specific words in the requirement but instead means that the State [or local] requirement directly or indirectly imposes obligations or contains provisions concerning the . . . labeling of food" that is not imposed by, or differs from requirements imposed by, section 343. *Id.*

3. The Compliance Schedule for Implementation of Federal Regulations Governing Menu Labeling

The federal rule regarding menu labeling was promulgated by the FDA on December 1, 2014, 79 Fed. Reg. 71156 (Dec. 1, 2014). The FDA established December 1, 2015, as the effective date of the new regulations. *Id*. In July 2015, however, the FDA, in light of requests "to extend the compliance date of the final rule based on concerns that covered establishments do not have adequate time to fully implement the requirements of the rule," extended the date by which businesses would have to comply by one year, to December 1, 2016. 80 Fed. Reg. 39675, at 39676 (July 10, 2015). The effective date of the rule, however, was kept at December 1, 2015. *Id*. at 39675.

In December 2015, however, Congress passed the Consolidated Appropriations Act of 2016. That statute directed that no funds could "be used to implement, administer, or enforce" the FDA's menu-labeling rule until the later of December 1, 2016, or one year after the date on which the Government issues a "Level 1 guidance with respect to nutrition labeling of standard menu items in restaurants and similar retail food establishments." Pub. L. No. 114-113, 129 Stat 2242 (Dec. 18, 2015), § 747. The Level 1 guidance was published by the FDA on May 5, 2016. *See* 81 Fed. Reg. 27,067 (May 5, 2016). In accordance with Congress's direction, the FDA subsequently set the compliance date for the rule as May 5, 2017, one year from the date of the publication of the guidance. 81 Fed. Reg. 96,364 (Dec. 30, 2016).

In May 2017, the FDA issued an interim final rule extending the compliance date again by one year, to May 7, 2018. 82 Fed. Reg. 20,825 (May 4, 2017). In doing so, the agency cited "the diverse and complex set of stakeholders affected by the rule and continued, numerous, and fundamental questions they raise regarding the final rule and its implementation." *Id*. at 20,827.

In particular, the FDA noted the need to assess "critical implementation issues" around unresolved matters: these included how to address "calorie disclosure signage for self-service foods, including buffets and grab-and-go foods," and how to distinguish "a menu, which requires the posting of calorie information, from advertisements and other marketing pieces, which do not require calorie information." *Id*.

B. New York City Announces Intent to Enforce Regulation 81.50

Regulation 81.50 requires covered businesses to post reasonably-calculated calorie-count information on menus and menu boards: caloric values must be placed next to each item of food offered for sale in a sufficiently conspicuous position, size, and color, for each separate size, flavor, and variety available for purchase. N.Y., Health Code tit. 24, § 81.50(c). Any restaurant or "similar retail food establishment that is part of a chain with 15 or more locations nationally" is a covered business. *Id*. § 81.50(a)(2).[2] The current version of Regulation 81.50 was enacted by the City's Board of Health on September 9, 2015, "to be identical to regulations" set at the federal level. *Id*. at Notes. Indeed, the substantive provisions of Regulation 81.50 track the requirements for calorie information on menus and menu boards as found in the analogous FDA rule. *See* 21 C.F.R. § 101.11(b)(2).

When it enacted the current form of Regulation 81.50 in September 2015, the City not only adopted the substantive requirements of the federal rule, but also set the same compliance date for the local regulation as the FDA originally had adopted for the federal regulations, December 1, 2016. N.Y., Health Code tit. 24, § 81.50(h). The City explained that covered

[2] While the federal menu labeling requirements apply to chains of 20 or more locations, 21 U.S.C. § 343(q)(5)(H), the difference is immaterial for present purposes, *see* 79 Fed. Reg. at 71249 (permitting states and localities to enact labeling requirements that apply to establishments that are not part of a chain with 20 or more locations), and it is not invoked by Plaintiffs as a separate basis for preemption.

establishments would "benefit from the FDA's guidance" during this "additional time as they plan to come into compliance." *See* City Dep't of Health and Mental Hygiene Not. of Adoption ("City Notice") [Dkt. No. 14-8].

In May 2017, despite the further extension set by the FDA, the City announced that it would begin enforcing compliance with Regulation 81.50 as of August 21, 2017, by beginning to issue notices of violation to non-compliant establishments. *See* "De Blasio Administration Announces New Calories Labeling Rules," dated May 23, 2017 ("City Press Release") [Dkt. No. 14-15].

C. Procedural History

In response to the City's stated intention to enforce compliance with Regulation 81.50, Plaintiffs filed suit on July 14, 2017, *see* Compl. [Dkt. No. 1], seeking to enjoin the City's planned enforcement of Regulation 81.50 as invalid under principles of federal preemption. *See* Mem. of Law in Support of Preliminary Injunction [Dkt. No. 9]. The City filed a motion to dismiss the complaint, alleging that Plaintiffs had failed to state a claim for relief. *See* City's Mot. Dismiss [Dkt. No. 39].

Because Plaintiffs' action implicates the FDA's interests in the functioning of its regulations and questions of interpretation of federal law, the Government now files the Statement of Interest to present its views to the Court.

ARGUMENT

Federal law expressly preempts the City's effort to begin enforcing Regulation 81.50 in August 2017, nine months ahead of compliance date set by the FDA. Section 343(q) of the Act mandated new national menu-labeling requirements and delegated to the FDA the authority to "promulgate proposed regulations to carry out this clause." 21 U.S.C. § 343(q)(5)(H)(x). To

ensure a uniform federal scheme, the Act also contained an express preemption provision that bars any state or locality from establishing or enforcing any "requirement" that is "not identical to" the statutory and regulatory requirements imposed under section 343(q). 21 U.S.C. § 343-1(a)(4); Pub. L. No. 111-148, 124 Stat 119, § 4205. Exercising its authority under section 343(q), FDA determined via a duly promulgated regulation that restaurants would not have to comply with the new federal requirements until May 2018. Although FDA has properly decided as part of its implementation of the Act's requirements to postpone compliance until May 2018, for reasons described below, the City has unilaterally chosen to begin enforcement. The City's premature compliance date is a "requirement" that is "not identical to" the requirements imposed by the FDA, and is therefore squarely preempted.

The Act unequivocally demonstrated Congress's intent that menu labeling requirements be established with national uniformity, specifically through regulatory requirements to be set by the FDA. To fulfill that purpose, the FDA has been tasked with determining when and in what circumstances uniform menu-labeling rules will be enforced across the nation. The City may not choose to take its own path in the face of this clear expression of Congressional purpose.

A. The City's Separate Compliance Date For Menu Labeling Requirements Is Expressly Preempted

1. The Express Preemption Provision Created an Exclusively Federal Statutory and Regulatory Regime For Covered Establishments

Foundational to federalism is the principle that, while "both the National and State Governments have elements of sovereignty the other is bound to respect," where the two come into conflict, "Congress has the power to preempt state law." *Arizona v. United States*, 567 U.S. 387, 398-99 (2012) (citations omitted); U.S. Const. art. VI, cl. 2 (Supremacy Clause). One manner in which Congress exercises that authority is by "withdraw[ing] specified powers from

the States by enacting a statute containing an express preemption provision." *Wurtz v. Rawlings Co., LLC*, 761 F.3d 232, 238 (2d Cir. 2014) (citing *Arizona*, 567 U.S. at 399); *see also Chamber of Commerce of United States of America v. Whiting*, 563 U.S. 582, 592 (2011). It is true that "the historic police powers of the States" should not be "cavalierly" assumed "to be superseded by the Federal Act," *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (internal quotation marks omitted), particularly in regulatory realms in which states and localities have historically provided oversight, *see Florida Lime & Avocado Growers v. Paul*, 373 U.S. 132, 144 (1963) (describing states' interest in "fraud and deception in the sale of food"). But where there exists an "express command" to preempt, even in a realm typically occupied by state and local regulation, state and local governments must give way to the "clear and manifest purpose of Congress." *Medtronic*, 518 U.S. at 485 (citations omitted).

For "the purpose of Congress is the ultimate touchstone of pre-emption analysis," *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (internal quotation marks omitted), and "any understanding of the scope of a pre-emption statute must rest primarily on 'a fair understanding of [that] congressional purpose,'" *Medtronic*, 518 U.S. at 485 (citing *Cipollone*, 505 U.S. at 530 n.27). In enacting the Act and amending the FDCA and NLEA, Congress made its objectives crystal clear with respect to the regulation of calorie counts on menus. Section 343(q), as amended by the Act, includes the general mandate that covered establishments must post calorie counts on menus and menu boards. 21 U.S.C. § 343(q)(5)(H)(ii). Section 343(q) also provides that the FDA "shall promulgate proposed regulations to carry out this clause." *Id.* § 343(q)(5)(H)(x). Congress then adopted an express preemption provision with respect to these federal requirements, establishing that no locality may establish any new, or continue any existing, requirement, either directly or indirectly, that is "not identical to the requirement of

section 343(q).” 21 U.S.C. § 343-1(a)(4); Pub. L. No. 111-148, 124 Stat 119, § 4205; *see also Wyeth v. Levine*, 555 U.S. 555, 567 (2009) (describing statute with similar language as an “express pre-emption provision”). Accordingly, it is clear “from the language of the pre-emption statute and the ‘statutory framework’ surrounding it,” *Medtronic*, 518 U.S. at 486 (citation omitted), that Congress intended states and local governments to be bound by the Act’s mandate, as interpreted and carried out by the FDA.

That Congress delegated to an administrative agency the responsibility for ultimately effectuating the detailed terms of the menu labeling requirements is of no moment. To understand congressional intent in the context of express preemption, courts must look to the “‘structure and purpose of the statute as a whole,’ as revealed not only in the text, but through . . . the way in which Congress intended the statute and its *surrounding regulatory scheme* to affect business, consumers, and the law.” *Id*. (quoting *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 98 (1992) (emphasis added)). As explained, Congress explicitly intended for the terms of national menu labeling to be set by rules promulgated by the FDA. There is no doubt that a “federal agency acting within the scope of its congressionally-delegated authority may pre-empt state regulation and hence render unenforceable state or local laws that are otherwise not inconsistent with federal law.” *See New York v. F.C.C.*, 486 U.S. 57, 63–64 (1988) (citation omitted). As a result, the City is expressly precluded from adopting conflicting menu labeling requirements for restaurants and similar retail food establishments covered under the statutory and regulatory scheme set up by Congress in the Act.

2. The City’s Compliance Date Is “Not Identical To” The Federal Date and Is Precluded

Despite the unambiguity of Congress’ intent to create a national regime of menu labeling requirements, the City proposes to set its own unilateral compliance date that is in conflict with

the FDA's considered decision about the appropriate deadline. The City is expressly preempted from doing so. Congress directed in no uncertain terms that no state or locality may create or continue to enforce any existing "requirement . . . that is not identical to the requirement of section 343(q)." 21 U.S.C. § 343-1(a)(4). The City's contention that Congress "did not disturb" any existing state and local menu-labeling requirements with the Act's passage is therefore incorrect. Mem. of Law in Support of Mot. Dismiss ("City Br.") [Dkt. No. 42] at 13. The City's further assertion, that "nothing in either the Congressional or the administrative record suggests that" the City is "preempted from enforcing [its] own requirements concerning menu labeling . . . prior to the compliance date" set by the FDA, is also erroneous. *Id*. at 14.

State and local governments are prohibited from imposing any obligation "not identical to" a federal requirement established under the menu labeling authority added to the FDCA by the ACT. 21 U.S.C. § 343-1(a)(4). The FDA's implementing regulations make clear that the term "not identical to" applies not only to the "specific words" of section 343(q), but also to any requirement that either "directly or indirectly imposes obligations or contains provisions concerning the . . . labeling of food" that "are not imposed by" or "differ from those specifically imposed by" section 343(q). 21 C.F.R. § 100.1(c)(4). Requiring covered establishments to comply with menu labeling requirements nine months earlier than federal law requires certainly imposes, quite directly, an obligation not found in section 343(q) and in its implementing regulations.

Those regulations, as set by the FDA at the instruction of Congress, include a compliance date for national requirements of May 2018. Notwithstanding this fact, the City argues that because the federal requirements are already in effect as a legal matter, it should have a free hand to begin enforcement along its own compliance schedule, in the face of what it calls the FDA's

"enforcement delay" and "passive failure to regulate." City Br. at 14. This contention misapprehends the regulatory purposes of the compliance date, the role that it plays in the governing statutory scheme, and the FDA's ongoing efforts at finalizing national requirements in advance of the compliance date.

As their names suggest, the effective date is when applicable administrative rules are officially published and come into legal effect, *cf. Sweet v. Sheahan*, 235 F.3d 80, 88 (2d Cir. 2000) (describing the creation of enforceable obligations upon effective date of regulations promulgated under statute), while the compliance date is the separate deadline by which affected parties must complete preparations to conform with the provisions before facing enforcement penalties, *see Nat. Res. Def. Council v. EPA*, 489 F.3d 1364, 1373-74 (D.C. Cir. 2007).[3] The setting of a compliance date by a federal agency is no mere ministerial detail. Rather, the compliance date is a key tool that may be utilized by agencies tasked by Congress to build regulatory frameworks imposing new obligations on industries and affected parties. In enacting

[3] The City asserts that some provisions of section 343(q) became effective immediately upon enactment of the Act, independent of FDA rulemaking. *See* City Br. at 13. Whether the requirements in question were in effect as of the Act's passage in 2010 or upon the effective date of the enabling regulations in 2015 is ultimately irrelevant to the present analysis: whether the City is preempted from beginning enforcement of Regulation 81.50 as of today, when there is no dispute as to the status of the federal regime.

The City also suggests that it "has been enforcing" the menu labeling requirements at issue since at least March 2010. *Id*. What the City means by this assertion is unclear, which appears to be undermined by the City's own publicized declaration in May 2017 that it would begin enforcement as of August 2017. *See* City Press Release. It is also undermined by the fact that, by its own admission, the City has previously held off on enforcing compliance and deferred to the federal compliance date. *See* N.Y., Health Code tit. 24, § 81.50(h) (deferring City compliance date to match then-planned federal date); City Notice (explaining that deferring City compliance date so that covered establishments "will benefit from the FDA's guidance and this additional time as they plan to come into compliance"). The City may have been enforcing past versions of Regulation 81.50, which was then impacted by the enactment of the Act and the new federal requirements, *see* City Br. at 8 & n.2, but such previous enforcement is irrelevant to the issue of preemption of the present Regulation 81.50.

the Clean Air Act, for instance, Congress empowered the Environmental Protection Agency ("EPA") not only to establish exclusive national emission standards, but also to set schedules for compliance with them in the period following their effective dates. *See* 42 U.S.C. § 7412(i)(3)(A); *see also Jackson v. Gen. Motors Corp.*, 770 F. Supp. 2d 570, 573 (S.D.N.Y. 2011) (describing the "sweeping preemption provision" of the Clean Air Act), *aff'd sub nom. Butnick v. Gen. Motors Corp.*, 472 F. App'x 80 (2d Cir. 2012). Part and parcel of an agency's regulatory authority is the ability to respond to practical problems in interpreting statutory standards as well as "additional compliance strategies" that come to light in the interim period between effective and compliance dates. *See Nat. Res. Def. Council v. EPA*, 749 F.3d 1055, 1057-58 (D.C. Cir. 2014) ("When the EPA sets an emissions standard, it also determines a schedule for compliance with that standard."). Thus, an agency's ability to determine the timing of the compliance date, as opposed to the effective date, is an important element of a regulatory regime. *See id*. at 1061 (upholding agency's resetting of compliance date). Since the FDA has set a compliance date in the future for the menu labeling requirements in question, has solicited public comments, and is considering those comments to ensure a smooth implementation, there is no legally enforceable obligation yet to comply with them. *C.f. Backus v. Biscomerica Corp.*, 2017 WL 1133406, at *3 (N.D. Cal. Mar. 27, 2017) (noting importance of compliance date as set by Congress and FDA under separate provision of the FDCA and Appropriations Act, to allow FDA to consider "additional 'scientific evidence'").

In that vein, contrary to the notion that it has somehow failed to regulate, the FDA has established a set of regulatory requirements for national menu-labeling and has established a compliance date based upon ongoing interaction with affected stakeholders, in order to resolve "critical implementation issues" before finalization of the requirements. These include, for

instance, issues regarding how to provide calorie information for self-service foods and foods with natural calorie variations, and distinguishing menus, for which such information is required, from similar marketing displays like advertisements, for which it is not. 82 Fed. Reg. 20,825, at 20,827. Congress too, no less, recognized the importance of the FDA completing this process of finalizing workable uniform requirements before officially commencing enforcement: in the Appropriations Act of 2016, it explicitly directed that no funds could "be used to implement, administer, or enforce" the Act's menu-labeling requirements until at least one year after the FDA issued a Level 1 guidance explaining the requirements to affected parties. Pub. L. No. 114-113, 129 Stat 2242 (Dec. 18, 2015), § 747. It does not follow in face of the above, as the City argues, *see* City Br. at 13-14, that Congress—having emphasized the need for national uniformity in menu labeling, expressly prohibited inconsistent state and local requirements to that end, and then directed the FDA to delay compliance with the new federal requirements until further guidance could be issued—meant to tolerate, or even encourage, a locality's enforcement of its own requirements in the meantime.[4]

Even if the City's characterization of the FDA's posture as a delay were correct, which it is not, the City cannot rely upon a supposed void created by the agency to justify its position. As the Supreme Court has made clear, localities may not use the purported "failure of . . . federal officials affirmatively to exercise their full authority" as an excuse to "use their police power to enact a regulation" in a regulatory realm that is otherwise expressly preempted. *Ray v. Atl.*

[4] The City's citation to the Federal Register to suggest otherwise is unavailing. While the FDA did recognize in its rulemaking in December 2014 that some establishments are already subject to state and local labeling requirements, rather than indicating that the agency therefore would tolerate non-uniform enforcement, the FDA actually emphasized this fact as a further rationale for the need for compliance with federal requirements. *See* 79 Fed. Reg. 71,156, at 71,239.

Richfield Co., 435 U.S. 151, 178 (1978). Where "no such regulation is appropriate or approved pursuant to the policy of the statute" in question, the locality cannot assert supposed federal acquiescence or inattention to act unilaterally, especially when "Congress intended to centralize all authority over the regulated area in one decisionmaker: the Federal Government." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 286 (1995) (citing *Ray*).[5] As discussed above, Congress clearly intended to centralize authority over menu labeling requirements on a national basis in the Federal Government, specifically in the FDA, which has been mandated not only to take the lead in setting those national requirements, but to take the time to properly finalize them before enforcement.[6]

Acknowledging that the federal requirements have come into effect, the City asserts that it is not bound by the terms of one of those requirements, the date of compliance. Because the

[5] Notably, if the City believed it appropriate as a matter of policy to move ahead with enforcement of its menu labeling requirements ahead of the FDA, the existing regulatory framework provided them with a means to seek that option in cooperation with the FDA in lieu of unilateral action. State and local governments wishing to implement requirements otherwise blocked by the express preemption provision of the Act and section 343-1(a) can apply for a waiver providing an exception to preemption. *See* 21 C.F.R. § 100.1(c)(4).

[6] None of the cases that the City cites to argue against express preemption is availing. Two cases concern a now-repealed section of the Federal Railroad Safety Act that expressly *permitted* state and local rules so long as there was "no federal rule, regulation, standard, or order covering the same subject matter." *S. Pac. Transp. Co. v. Pub. Utilities Comm'n of State of Cal.*, 647 F. Supp. 1220, 1224 (N.D. Cal. 1986), *aff'd*, 820 F.2d 1111 (9th Cir. 1987); *see also Missouri Pac. R. Co. v. R.R. Comm'n of Texas,* 833 F.2d 570, 573 (5th Cir. 1987). The Act, in direct contrast, expressly prohibits the local regulation at issue. Next, *Altria Grp., Inc. v. Good* dealt with the narrow issue of whether the preemption provision of the Medical Device Amendments Act preempted common-law fraud claims by private consumers. 555 U.S. 70, 87-88 (2008). The line quoted by the City is taken out of context from a portion of the analysis unrelated to express preemption, and, in any event, hardly stands for the notion that local governments are free to make their own interpretations of "agency nonenforcement" in a preempted area. *See id*. at 89-90. Finally, *TV Pix, Inc v. Taylor*, is a fifty-year old case dealing in part with field preemption of Nevada's regulation of antenna television companies, under a statutory scheme without any language comparable to the express preemption provisions at issue here. 304 F. Supp. 459, 464 (D. Nev. 1968), *aff'd*, 396 U.S. 556 (1970).

governing statutory and regulatory framework established by the Act expressly preempts the City from making such a unilateral determination, the City should not be allowed to begin enforcement of Regulation 81.50 in advance of the FDA's national compliance date.

B. *NYSRA*'s Holding That Regulation 81.50 Is Not Preempted Is No Longer Valid

To avoid any confusion, it bears mention that, although the Second Circuit addressed federal preemption of a prior version of Regulation 81.50 in *NYSRA* in 2009, that decision no longer governs the outcome of this case. In *NYSRA*, the Circuit considered whether the prior iteration of Regulation 81.50's requirement that calorie counts be posted was blocked by federal law. The Second Circuit held that it was not expressly preempted. 556 F.3d at 127-30. In reaching this conclusion, however, the Court relied on the FDCA's then-operative exemption clause, which expressly excepted from exemption state and local "nutrition labeling" requirements for restaurants and similar retail food establishments. *Id*. at 127 (citing 21 U.S.C. § 343-1(a) (2008)). The Government, whose analysis the Court adopted, *id*. at 130-31 (citing FDA's *amicus* brief), shared this view based on then-existing statutory scheme.

One year after *NYSRA* was decided, however, Congress amended that very clause to create the new section 343-1(a) under the Act. As noted at length, the newly-enacted language eliminates the exception from exemption for nutrition labeling for restaurants and similar retail food establishments. Pub. L. No. 111-148, 124 Stat 119, §4205(c). The law now imposes "national uniformity" of the Act's menu labeling requirements on all covered establishments. 21 U.S.C. 343-1(a). Accordingly, as *NYSRA* has been overtaken by legislative changes to the statutory scheme in question, that decision's analysis is no longer applicable.

C. The FDA's Compliance Date is Presumptively Valid and Its Legal Effect Is Not At Issue in This Action

Finally, the City contends that, even assuming that express preemption principles did apply to preclude its premature enforcement of Regulation 81.50, it should be free to move ahead because it doubts the validity of the FDA's 2017 interim final rule extending the compliance date to May 2018. City Br. at 16-19. The Court should reject this line of argument. The City's attack on the validity of the extension is, in the City's own terms, a legal challenge under the Administrative Procedure Act that is not properly before the Court. The Government is not a party to this action, nor is there an administrative record upon which the Court could review the validity of the compliance date. *See City of Duluth v. Fond Du Lac Band of Lake Superior Chippewa*, 702 F.3d 1147, 1153 (8th Cir. 2013) (explaining city government cannot challenge agency action by circumventing APA in suit where agency is not a party). A challenge to the validity of the rule was recently filed in June 2017, in a separate action that is ongoing. *See CSPI v. Price*, No. 17 Civ. 01085 (D.D.C.). For present purposes, the Court should accord the rule setting the May 2018 compliance date a "presumption of regularity." *United States Postal Serv. v. Gregory*, 534 U.S. 1, 10 (2001).

CONCLUSION

For the foregoing reasons, the Court should enjoin any attempt by the City of New York to set the compliance date of Regulation 81.50 earlier than the compliance date of analogous federal regulations.

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Respectfully submitted,

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