UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NATIONAL ASSOCIATION OF CONVENIENCE STORES, NEW YORK ASSOCIATION OF CONVENIENCE STORES, FOOD MARKETING INSTITUTE, and RESTAURANT LAW CENTER, Plaintiffs, *—against—* NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE, NEW YORK CITY BOARD OF HEALTH, DR. MARY TRAVIS BASSETT, in her official capacity as Commissioner of the New York City Department of Health and Mental Hygiene, NEW YORK CITY DEPARTMENT OF CONSUMER AFFAIRS, and LORELEI SALAS, in her official capacity as Commissioner of the New York City Department of Consumer Affairs, Defendants.	17 Civ. 5324

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION FOR A PRELIMINARY INJUNCTION

STEPTOE & JOHNSON LLP
1114 Avenue of the Americas
New York, New York 10036
(212) 506-3900

Counsel for Plaintiffs

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INTRODUCTION

This motion seeks to immediately enjoin, on federal preemption grounds, enforcement of a New York City regulation, referred to as Regulation 81.50, requiring that calorie and related nutritional information be posted on menus boards and menus in restaurants, convenience stores, supermarkets and similar businesses.

New York City has announced that it will begin fining food service establishments on August 21, 2017 for failing to comply with Regulation 81.50. However, federal law prohibits any state or locality from imposing any food labeling regulation "that is not identical to" corresponding labeling requirements established by Congress and the U.S. Food and Drug Administration ("FDA"). 21 U.S.C. § 343-1(a)(4). Regulation 81.50 is not identical to the corresponding FDA regulations because Regulation 81.50 is effective immediately, with fines beginning next month, while the FDA has made a considered decision not to require compliance with federal regulations until May 2018. For businesses subject to the federal regulation (*i.e.*, chains with more than 20 stores operating under the same name), the net effect of New York City's premature implementation date is that *the entirety* of Regulation 81.50 is "not identical to" the federal standard and is therefore preempted.

In order to prevent irreparable harm, Plaintiffs (trade associations that represent convenience stores, supermarkets and other food establishments) request a preliminary injunction restraining the defendants (the relevant New York City agencies and officials) from implementing Regulation 81.50 at any time prior to the date that federal law requires compliance. Given the impending threat of enforcement, Plaintiffs respectfully request that the Court enter an injunction before August 21, 2017.

Plaintiffs are very likely to succeed on the merits of this case based on the broad, categorical statutory preemption language. In fact, courts have found FDA compliance dates to

be preemptive, even in the absence of the explicit preemption language in the governing statute here. *See, e.g., Hawkins v. Kellogg Co.*, 224 F. Supp. 3d 1002 (S.D. Cal. 2016); *Hawkins v. AdvancePierre Foods, Inc.*, No. 15-cv-2309-JAH (BLM), 2016 WL 6611099 (S.D. Cal. Nov. 8, 2016); *Backus v. ConAgra Foods, Inc.*, No. C 16-00454 WHA, 2016 WL 3844331 (N.D. Cal. July 15, 2016); *Backus v. Nestlé USA, Inc.*, 167 F. Supp. 3d 1068 (N.D. Cal. 2016) (FDA compliance dates preempted suits based on state common law that would, in effect, require compliance sooner).

Applying the federal preemption statute will preserve the uniformity that Congress sought to ensure. New York City stands alone among all state and local governments in pushing ahead with immediate and unlawful enforcement of its menu labeling standards prior to the federal compliance date. Indeed, California has announced that it would not — and could not — implement its otherwise identical menu labeling requirements until the federal standards go into effect. (Ex. 1.)[1] In announcing its delayed implementation date, California's Department of Health concluded that it was "unable to enforce menu labeling requirements until the [FDA] finalizes the rule." Helena B. Evich, *California Will Wait for FDA on Menu Labeling*, Politico.com (May 25, 2017) (copy attached as Ex. 2.)

Absent a preliminary injunction, food retailers (including Plaintiffs' members) will suffer irreparable harm. They will be forced to comply with onerous, local regulations that unlawfully impose substantial, unrecoverable costs. In addition, the FDA has delayed its rules until May 2018 so that it can address major uncertainties and other implementation problems, and, absent an injunction, the burden of all those problems will fall to covered businesses in New York City.

[1] Citations in the form "Ex. __" refer to the exhibits to the accompanying declaration of Charles Michael.

There is every reason to expect that the federal menu labeling requirements will change significantly by the time they become operative nationwide. Yet New York's premature implementation will force businesses to comply *nationally* with regulatory standards now that the FDA determined were yet in a workable form. Affected businesses have no other remedy for the substantial losses they will suffer as a result of the City's unlawful regulations.

The Court should therefore grant the motion and issue the requested injunction.

FACTS

A. The Parties

Plaintiffs are a group of trade associations representing grocers, convenience stores, and other businesses directly affected by New York City's premature implementation of its menu labeling requirements. Plaintiff associations are made up of individual businesses and chains, including businesses located in New York City and subject to both the New York City and federal menu labeling requirements because they are part of a group of 20 or more stores (with at least one location in New York City) selling prepared food items under a common business name. The associational plaintiffs sue the City Defendants on behalf of their affected members.

The National Association of Convenience Stores ("NACS"), headquartered in Alexandria, Virginia, is an international trade association that represents both the convenience and fuel retailing industries, with more than 2,200 retail and 1,800 supplier company members. (Beckwith Decl. ¶¶ 2-3.) The U.S. convenience store industry has more than 154,000 stores across the United States and had nearly $550 billion in sales in 2016. (*Id.* ¶ 5.) About 63 percent of the stores in the industry are owned by single-store operators (though many are still covered by the federal and New York City regulations that are the subject of this case because they are franchisees or contract with a refining company to use its brand name). (*Id.*) At the same time, many NACS members are national food service establishments that also would be affected by

the menu labeling regulations at issue in this case. *Id*. NACS members have locations that operate within New York City under brands such as Speedway and 7-Eleven, as well as convenience stores operating as BP, Mobil, and Sunoco gas stations. (*Id*. ¶ 4.)

Plaintiff New York Association of Convenience Stores ("NYACS") represents some 130 companies operating over 1,500 convenience stores in New York that sell food, beverages, motor fuel, and various other products. (Calvin Decl. ¶ 3.) NYACS was founded, in part, to provide collective advocacy for its members. (*Id.* ¶ 2.) Its membership includes convenience stores directly affected both by the New York City and federal regulation. (*Id.* ¶ 6.)

The U.S. members of Plaintiff Food Marketing Institute ("FMI") operate nearly 40,000 retail food stores and 25,000 pharmacies, employing more than 3.5 million workers in the United States and representing a combined annual sales volume of almost $770 billion. (Sarasin Decl. ¶ 2.) FMI membership covers the spectrum of diverse venues where food is sold, including single owner grocery stores, large multi-store supermarket chains and mixed retail stores. (*Id*.) FMI represents members affected by New York City's premature implementation of its menu labeling regulation, including grocery and pharmacy chains such as Fairway Market and those ShopRite™ stores that are members of the Wakefern Food Corp. cooperative. (*Id.* ¶ 3.)

The Restaurant Law Center ("RLC") is a public policy organization affiliated with the National Restaurant Association ("NRA"), the largest foodservice trade association in the world. (Amador Decl. ¶ 1.) The NRA was created in 1919 and launched the RLC, its affiliate, in 2015 to provide courts with the industry's perspective on legal issues significantly impacting the restaurant industry. (*Id.* ¶ 2.) NRA members have locations that operate within New York City, and would be subject to New York City Regulation 81.50, the menu labeling regulation, which covers food service establishments with 20 or more locations operating under a common

nationwide name. (*Id.* ¶ 5.) NRA represents about two thousand food service establishments covered by New York City Regulation 81.50, including corporate owned food service establishments as well as franchisees because of national aggregation with other franchisees and franchisor owned establishments. (*Id.* ¶ 6.)

Defendants sued here are the New York City offices and Commissioners responsible for enforcement of New York's menu labeling regulations, including the New York City Department of Health and Mental Hygiene (the "Department of Health"), the New York City Board of Health (the "Board of Health"), the Commissioner of the Department of Health (sued only in that official capacity), and the Department of Consumer Affairs and its Commissioner (also sued in her official capacity). *See* New York City Health Code § 81.50(f) ("Regulation 81.50"); N.Y.C. Charter §§ 553, 556, 558.

B. Preemption Under The Nutrition Labeling and Education Act

Understanding the current regulatory regime for food labeling requires a brief review of what has come before.

1. The Nutritional Labeling and Education Act

In 1990, Congress passed the Nutrition Labeling and Education Act, which mandated certain labeling on packaged food ("NLEA"). Pub. L. No. 101-535, 104 Stat. 2353 (1990). The statute established uniform federal requirements for nutritional labels on packaged food, as well as for certain health-related claims made about food products (such as "low sodium" or "high oat bran"). *See id.*; *see* H.R. Rep. No. 101-538 at 19 (1990), *as reprinted in* 1990 U.S.C.C.A.N. 3336, 3349 (giving examples of health claims).

NLEA contained two pertinent preemption provisions.

First, the statute barred state and local governments from adopting "any requirement for nutrition labeling of food that is not identical" to the federal requirements. Pub. L. No. 101-535,

§ 6, 104 Stat. 2353, 2363 (1990) (then codified at 21 U.S.C. §§ 343-1(a) (1990)). Because NLEA did not, at this time, establish nutritional labeling requirements for food prepared on site, the statute's preemption provision exempted (and thus permitted) local regulation of food "served in restaurants or other establishments" for "immediate human consumption" and food prepared in a "retail establishment" that is "ready for human consumption." *Id*. §§ 2, 6 (then codified at 21 U.S.C. §§ 343 (q)(5)(A)(i), (ii), 343-1(a) (1990)).

The purpose of the NLEA's preemption provision was to ensure that "covered food would have a uniform nutrition label" dictated by federal law and that it would not be subjected to varying obligations on a state-by-state basis. *See* H.R. Rep. No. 101-538 at 7, 1990 U.S.C.C.A.N. at 3337. In adopting this provision, Congress recognized that the federal standards might preempt local laws mandating more information to consumers, but decided that "the net benefits from national uniformity in these aspects of the food label outweigh the loss in consumer protection that may occur as a result." *See* Final Rule Regarding State Petitions, 58 Fed. Reg. 2,462 at 2,462 (Jan. 6, 1993) (FDA adoption of preemption rules) (codified at 21 C.F.R. Part 100); *see also* 136 Cong. Rec. 35,095 (1990) (statement of Rep. Madigan) (the "fairest way to expect the food industry to support a nutrition labeling bill" was to preempt "burdensome State laws that interfered with their ability to do business in all 50 States").

Second, to address the need for uniformity regarding health-related claims about food, NLEA barred states and localities from adopting any "requirement respecting any claim" that "characterizes the level of any nutrient" or "the relationship of any nutrient . . . to a disease or a health-related condition" that is "not identical" to the federal requirements. Pub. L. No. 101-535, §§ 3, 6, 104 Stat. at 2357, 2363 (then codified at 21 U.S.C. §§ 343(r)(1), 343-1(a) (1990)).

Unlike the preemption provision for food labeling, this provision had no exception for restaurants or other similar food service establishments. The FDA's implementing regulations confirmed that restaurants would be subject to the statute's requirements. *See* 21 C.F.R. § 101.13(q)(5) ("A nutrient content claim used on food that is served in restaurants . . . shall comply with the requirements of this section."). Thus, for example, a restaurant could not describe its food as "low sodium" unless the food met federal standards for that description. And any non-identical local regulation of such claims would be preempted.

Congress contemplated that the FDA would issue regulations "to implement" the broad requirements of NLEA through more specific regulations. Pub. L. No. 101-535, § 2(b), 104 Stat. at 2356. Pursuant to this authority, the FDA interpreted the phrase "not identical to" in both preemption provisions broadly to refer to local food labeling requirements that "[a]re not imposed by or contained in the applicable [federal] provision (including any implementing regulation)" or that "[d]iffer from those specifically imposed by or contained in the applicable [federal] provision (including any implementing regulation)." 21 C.F.R. § 100.1(c)(4).

2. New York Mandates Menu Labeling

In December 2006, the Board of Health adopted the first version of Regulation 81.50, which at the time required restaurants and other food service establishments that made available calorie information to their customers by any means (via, for example, their internet sites or in printed brochures) to also include that information on menu boards and menus, so it would be "available at the time of ordering." (Ex. 3 at 1.)

In September 2007, a federal judge in this District (Judge Holwell) ruled that Regulation 81.50 was preempted by NLEA. *New York State Restaurant Ass'n v. New York City Bd. of Health*, 509 F. Supp. 2d 351 (S.D.N.Y. 2007). The court found that, because Regulation 81.50 applied only to establishments that *voluntarily* chose to disclose calorie information, it fell

outside the preemption provision governing state and local "*requirement[s]*" for food labeling (which allowed for local regulation) and was instead governed by the general preemption provision for health-related claims (which did not). *Id.* at 356-63. The court observed, however, that New York City would be "free to enact mandatory disclosure requirements" that would not be preempted. *Id*. at 363.

Acting on the court's suggestion, in January 2008, the Board of Health re-enacted Regulation 81.50, making menu labeling mandatory for "any establishment in the City of New York that is one of a group of 15 or more food service establishments doing business nationally under the same name and offering for sale substantially the same menu items." (Ex. 4 at 12.) This updated regulation was challenged on First Amendment and other grounds, but was ultimately upheld as lawful. *See N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health*, 556 F.3d 114 (2d Cir. 2009).

3. The Patient Protection and Affordable Care Act

In 2010, President Obama signed into law the Patient Protection and Affordable Care Act ("ACA"). Pub. L. No. 111-148, 124 Stat 119 (2010). The ACA mandated, for the first time in federal law, that certain retail food establishments (*i.e.*, those with 20 locations operating under the same name and with standard menu items) include a "nutrient content disclosure" statement next to menu items that would include information about the calories and related nutrients in each menu item, among other requirements. 21 U.S.C. § 343(q)(5)(H)(i), (ii). The ACA provided that the FDA would by regulation "specify the format and manner of the nutrient content disclosure requirements." *Id.* § 343(q)(5)(H)(x)(II)(bb). The ACA did not specify when the menu labeling provisions would be effective, but instead left it to the FDA to "promulgate proposed regulations to carry out" the statute. *Id.* § 343(q)(5)(H)(x)(I).

Because the ACA imposed new menu labeling requirements on restaurants and similar retail food establishments, the statute also made a corresponding change to the scope of food labeling preemption under NLEA. Specifically, the ACA replaced NLEA's general exception for local regulation of restaurants with an exception saving from preemption only local regulation of restaurants and other retail food establishments not covered by the ACA — *i.e.*, those with fewer than 20 locations operating under the same name. Pub. L. No. 111-148, § 4205, 124 Stat at 576. The provision (as amended) now reads:

> [N]o 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 . . . any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) of this title [*i.e.*, the ACA's retail food establishment requirements], 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 . . .

21 U.S.C. § 343-1(a)(4).

4. FDA's Implementation of Federal Menu Labeling Requirements

In December 2014, the FDA issued a final rule to implement the menu labeling requirements. *See* Food Labeling Final Rule, 79 Fed. Reg. 71,156 (Dec. 1, 2014) (copy attached as Ex. 5). The final rule requires covered food service businesses to post on menus and menu boards the number of calories of every standard menu item adjacent to the item's name or price and to do so in the same or similar font size and with the same or similar color and contrasting background as the item or price. 21 C.F.R. § 101.11(b)(2)(i)(A). Covered businesses must also specify separately the calories from different "flavors or varieties" (such as a grilled cheese sandwich offered with cheddar or Swiss) and for each separate topping. *Id.* § 101.11(b)(2)(i)(A)(4).

Menus and menu boards are also required to include a statement about daily calorie intake recommendations, *id*. § 101.11(b)(2)(i)(B). Covered business must also post calorie information for self-service foods and food on display, *id.* § 101.11(b)(2)(iii), and make available to customers information about the amount of fat (saturated and trans fat), cholesterol, sodium, carbohydrates, fiber, sugar and protein of standard menu items, *id*. § 101.11(b)(2)(ii). The rule requires covered establishments to have a "reasonable basis for its nutrient declarations," and provides detailed instructions for determining nutrient content, using sources such as nutrient databases, cookbooks, laboratory analysis, or other reasonable means. *Id*. § 101.11(c).

Recognizing the complexity of the rule for certain covered entities, and in light of extensive comments on the compliance burdens, the FDA set the effective date of the rule as December 1, 2015. *See* 79 Fed. Reg. at 71,241 (copy attached as Ex. 5.) The agency further stated that "[w]e expect covered establishments to come into compliance with the requirements of this rule by December 1, 2015, i.e., the same date as the effective date of this rule." *Id.*

5. FDA's Postponement of Implementation and New York City's Response

The new federal requirements imposed substantial new obligations and costs on the covered businesses, including grocery stores, convenience stores, and others. The final rule is approximately 7,000 words long, and the FDA estimated that it would affect approximately 300,000 businesses (around 2,000 chains) and cost those businesses $388.43 million in upfront expenses, and $55 million in annual recurring costs. (Ex. 6 at 7.)

The federal regulations present special challenges for food establishments that permit customers a range of ingredient options. Restaurants, convenience stores, and other affected business owners have, not surprisingly, raised significant concerns about the cost and difficulties of complying with the onerous obligations of the FDA's final rule. In July 2015, the FDA, in

response to concerns that restaurants and similar retail food establishments lacked "adequate time to fully implement the requirements of the rule," extended the compliance date by one year, to December 1, 2016. Extension of Compliance Date, 80 Fed. Reg. 39,675, 39,676 (July 10, 2015) (copy attached as Ex. 7). The agency found that "allowing adequate time for covered establishments to fully implement the final rule's requirements . . . helps accomplish the primary objective of the final rule and is in the public interest." *Id.* The FDA did not change the effective date of the federal regulation; it remained December 1, 2015. *Id.* at 39,675.

In September 2015, New York City's Department of Health repealed and reenacted Regulation 81.50 to make its requirements "identical to the federal requirements." *See* Regulation 81.50 at 2 (copy attached as Ex. 8). The City's amended menu labeling requirements applied explicitly to both restaurants and "similar retail food establishments," which, for the first time, swept within the regulation's scope convenience stores, groceries or supermarkets that served restaurant-type food. *See* Regulation 81.50(a)(9). The City thus adopted both the federal calorie and related nutrient content disclosure requirements as its own. "In order to allow covered establishments to benefit from the additional time allowed by the FDA for compliance," the Department set Regulation 81.50's effective date as December 1, 2016, the same as the FDA's compliance deadline. (Ex. 8 at 2.) The Department noted that "[r]estaurant-like establishments, which are not yet required to provide calorie information, will benefit from the FDA's guidance and this additional time as they plan to come into compliance." (*Id.*)

6. Congress's Further Delay of the Compliance Date

As the federal compliance deadline drew nearer, concerns regarding the burdens of compliance and the lack of clarity from the agency prompted Congress to extend the deadline yet again. In December 2015, Congress passed and President Obama signed into law the Consolidated Appropriations Act, which prohibited federal funds from being used to implement

the menu labeling requirements until one year following the publication of certain additional guidance from the FDA. Pub. L. 114-113, § 747, 129 Stat. 2242, 2282 (2015) (copy attached as Ex. 9). The FDA published that guidance in May 2016, and stated that the rule would be enforced starting May 5, 2017. Guidance for Industry, 81 Fed. Reg. 27,067, 27,068 (May 5, 2016) (copy attached as Ex. 10). Because it did not formally change the compliance date at that time, the FDA subsequently published a rule that confirmed and clarified that the compliance date was also May 5, 2017. *See* Extension of Compliance Date, 81 Fed. Reg. 96,364, 96,365 (Dec. 30, 2016) (copy attached as Ex. 11).

The FDA's additional guidance did not resolve the ongoing industry concerns. In April 2017, NACS and the National Grocers Association ("NGA") filed a citizen's petition asking the FDA to pause and reconsider its final rule. (Ex. 12.) The petition requested the stay and reevaluation of the final rule because of the confusion it had created and because of the significant costs of compliance on non-restaurant retailers. (*Id.*) NACS and the NGA pointed out that the FDA staff could not provide clarification on basic questions, such as the distinction between a menu (which would require calorie data) and an advertisement or marketing piece (which would not) or how to "provide calorie counts for fried chicken, given that chickens (and their various parts) come in different sizes." (*Id.* at 5, 6.) Citing the "impossibility of compliance for many businesses," NACS and the NGA requested a further delay of implementation of the final rule. (*Id.* at 6.)

7. FDA's Further Postponement of Implementation

On May 4, 2017, the FDA announced a further postponement of the compliance date to May 7, 2018. Extension of Compliance Date, 82 Fed. Reg. 20,825, 20,827 (May 4, 2017) (copy attached as Ex. 13). The postponement was based on "continued, fundamental questions and concerns with the final rule," including that "[r]etailers with many different and diverse business

models have raised concerns about how the rule lacks flexibility to permit them to provide meaningful nutrition information to consumers given their type of business and different operations." *Id*. The FDA noted that there remained many "complex" and unanswered questions about, for example, "calorie disclosure signage for self-service foods, including buffets and grab-and-go foods" and about how to distinguish menus from advertisements. *Id*. Accordingly, additional time was necessary to "consider what opportunities there may be to address these fundamental and complex questions and reduce the cost and enhance the flexibility of these requirements." *Id*. The FDA concluded that "it would not make sense" to require covered establishments "to come into compliance with the rule (for which compliance is not yet required), as well as incur additional ongoing costs to maintain or update compliance, when these requirements may change as a result of our reconsideration of the rule." *Id.*

The FDA subsequently responded to the petition for reconsideration filed by NACS and the NGA, stating that it had not yet reached a decision on the merits of the petition, but noting that NACS and NGA could provide comments during the delay period. (Ex. 14.)

8. New York Moves Ahead With Its Menu Labeling Requirements

On May 18, 2017, New York City Mayor Bill de Blasio announced that the City would begin enforcing Regulation 81.50, notwithstanding the FDA's year-long postponement of the parallel federal rules. (Exs. 15, 16.) The City's regulation thus put into effect immediately menu labeling requirements applicable to food service chains (including convenience stores) with 15 or more locations nationwide. The Department of Health stated that it would "start enforcement by educating chain food service establishments" immediately, and that it will begin issuing citations and fines for noncompliance on August 21, 2017. (Ex. 15.)

C. Procedural History

On July 14, 2017, Plaintiffs filed this lawsuit, seeking injunctive and declaratory relief against enforcement of Regulation 81.50, on the ground that it is expressly preempted by 21 U.S.C. § 343-1(a)(4), insofar as Defendants have announced an intention to enforce it prior to the May 7, 2018 compliance date established by the FDA.

ARGUMENT

I. STANDARD FOR A PRELIMINARY INJUNCTION

"A plaintiff seeking a preliminary injunction must establish that [it] is likely to succeed on the merits, that [it] is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [its] favor, and that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc*., 555 U.S. 7, 20 (2008); *see also Friends of the E. Hampton Airport, Inc. v. Town of E. Hampton*, 841 F.3d 133, 143 (2d Cir. 2016) (preemption case).

II. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS BECAUSE REGULATION 81.50 IS NOT "IDENTICAL" TO FEDERAL LAW ON THE CRITICAL ISSUE OF ITS COMPLIANCE DATE

Plaintiffs are virtually certain to succeed on the merits of their claims because federal law expressly preempts New York City's effort to require compliance with its menu labeling regulation well before the federal regulations require compliance with their menu labeling requirements. In addition, New York City's premature implementation frustrates Congress's desire for national uniformity of menu labeling standards for covered establishments.

The U.S. Constitution declares that U.S. law is the "the supreme Law of the Land," the "Laws of any state to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2. "Put simply, federal law preempts contrary state law." *Hughes v. Talen Energy Mktg., LLC*, 136 S. Ct. 1288, 1297 (2016). Preemption can be "express" when "Congress' command is explicitly stated in the statute's language," or "implied" from the "structure and purpose" of federal law. *Shaw v. Delta*

Air Lines, Inc., 463 U.S. 85, 95 (1983) (quotations omitted). Preemption is implied if, among other things, state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992) (quotations omitted). Carrying out the "purpose of Congress is the ultimate touchstone in every pre-emption case." *Hughes*, 136 S. Ct. at 1297 (quotation omitted).

A. Congress Has Expressly Preempted New York's Premature Enforcement of Menu Labeling Requirements

This is plainly a case of express preemption. The controlling preemption statute provides that state and local governments cannot, either directly or indirectly, impose "any requirement for nutrition labeling of food ***that is not identical*** to the requirement of" 21 U.S.C. § 343(q), the statutory provision governing menu labeling. 21 U.S.C. § 343-1(a)(4) (emphasis added). For these purposes, a state or local rule or regulation is "not identical to" 21 U.S.C. § 343(q) if the state or local rule imposes any requirements that "[a]re not imposed by or contained in" or that "[d]iffer from" 21 U.S.C. § 343(q) or "any implementing regulation." 21 C.F.R. § 100.1(c)(4).

Here, New York City's Regulation 81.50 is "not identical to" one of the "implementing regulation[s]," *id.*, of 21 U.S.C. § 343(q) — namely, the FDA's regulation mandating compliance as of May 7, 2018. 82 Fed. Reg. at 20,827. Contrary to the May 7, 2018 compliance date under federal law, New York City's Regulation 81.50 is effective immediately. Defendants have announced they will start enforcing the requirements and issuing fines under Regulation 81.50 on August 21, 2017, a full nine months earlier than the compliance date under federal law.

The effect of New York's premature compliance date is to require national retail food establishments with a presence in New York City to comply with menu labeling and other requirements *on a nationwide basis* now, notwithstanding the FDA's considered decision to defer implementation until May 2018. Regulation 81.50 requires establishments with standard

menu and other prepared food items to determine calorie counts and make other nutrient content determinations; thus, covered establishments located both in New York City and elsewhere must make those determinations for any standard menu items. A food establishment with stores in all 50 states that happens to operate a single store in New York City, for example, must make the nutrient determinations required by the FDA's regulation today (*e.g.*, total calories, total calories from fat, saturated fat, etc., *see* 21 C.F.R. § 101.11(b)(2)(ii)) for all of its standard menu items — regardless of whether the FDA ever actually implements those requirements after May 7, 2018. New York City's premature implementation controls conduct well beyond its borders, supplanting the FDA's determination to permit further time to implement its requirements.

Regulation 81.50 contains requirements that "[d]iffer from" and that "[a]re not imposed by" federal law, 21 C.F.R. § 100.1(c)(4). New York City's implementation of its regulation prior to the compliance date under federal law is expressly preempted.

B. New York's Premature Enforcement Would Also Frustrate Uniform Federal Standards and Is Preempted Under Implied Preemption Standards as Well

Premature implementation of New York City's Regulation 81.50 is also impliedly preempted because it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Gade*, 505 U.S. at 98. Federal labeling requirements are designed to ensure that national food businesses are subject to "uniform" regulation across the country. *See* H.R. Rep. No. 101-538 at 7, *as reprinted in* 1990 U.S.C.C.A.N. at 3337. This uniform labeling system "benefits both manufacturers and consumers of food products." *Nemphos v. Nestle Waters North Am., Inc.*, 775 F.3d 616, 620 (4th Cir. 2015). "Manufacturers can produce and market foods consistently and cost effectively across the United States," while "[c]onsumers gain a reliable and comprehensible means of ascertaining the nutritional content of the foods they buy, wherever they may live or travel in this country." *Id.*

The concern for uniformity is especially acute in this case because the FDA has announced that it is considering rule changes to address various "complex" and unanswered questions raised by the current regulations. 82 Fed. Reg. at 20,825. If New York City is allowed to issue fines in the meantime, businesses will have to take steps to conform to the New York City rules right away (or face fines beginning August 2017) and then may have to shift to a different set of federal rules nine months later (in May 2018). In other words, New York City is seeking to implement a regulation that may never have to be complied with at the national level.

But whatever changes may occur in the FDA's regulations, national chains will have differing governing standards for their menus and signs in the intervening time before the federal rules are in effect. The result is that there will be one standard for New York City, and another for the rest of the country. The burdens of complying with inconsistent regulations would be magnified if other state and local jurisdictions followed New York's lead and adopted and enforced their own menu labeling standards prior to FDA's compliance date. Especially for national chains with locations outside of New York, this defeats the very purpose of the federal menu labeling standard — to avoid exactly this type of patchwork of inconsistent regulation.

C. Courts Have Held Similar State and Local Premature Enforcement to be Preempted

In similar contexts, the Supreme Court — and lower federal courts applying similar federal food statutes — have barred efforts to use state law to mandate compliance with regulatory objectives ahead of a federal agency's compliance date. Courts have done so even absent explicit preemption provisions in the relevant federal statutes — *i.e.*, on the grounds that inconsistent state enforcement dates are *impliedly* preempted.

In *Geier v. American Honda Motor Co.*, the Court addressed a 1984 Department of Transportation regulation mandating that automobile manufacturers install airbags or other

passive restraint devices. 529 U.S. 861 (2000). The DOT standard did not require immediate compliance with its passive-restraint requirements. Instead, it "deliberately sought a gradual phase-in of passive restraints." *Id.* at 879 (emphasis removed). DOT required the manufacturers to initially equip only 10% of their new car fleet with passive restraints, and then increased the percentage in three annual stages, up to 100% of the new car fleet after September 1, 1989. *Id.*

An injured plaintiff brought a tort suit in the District of Columbia on the theory that his 1987 Honda Accord, manufactured before the requirement of full compliance, was negligently designed because it lacked airbags. *Id.* at 881. The Supreme Court held that the injured plaintiff's state tort claims were preempted. It did so even though such tort actions were explicitly saved from the *express* preemption provision in the governing statute. *Id.* at 869-71. The *Geier* Court reasoned that such a claim "would have required all manufacturers to have installed airbags in respect to the entire District-of-Columbia-related portion of their 1987 new car fleet, even though [the DOT standard] at that time required only that 10% of a manufacturer's nationwide fleet be equipped with any passive restraint device at all." *Id.* at 881. The plaintiff's claims thus would have stood as an obstacle to the "the gradual passive restraint phase-in that the federal regulation deliberately imposed." *Id.* at 881.

Applied here, *Geier* would require this Court to find that New York's implementation of its menu labeling requirements is preempted, even if the statute did not have its robust express preemption provision. As in *Geier*, Congress and the FDA have made considered determinations to permit further time to implement uniform federal menu labeling requirements. Permitting one jurisdiction to jump the line and impose its own standards conflicts with the federal determination and requires this Court to find the local implementation preempted.

Consistent with *Geier*, a series of decisions in California federal district courts have held preempted efforts to apply state requirements prior to FDA-established compliance dates for federal standards. *See Hawkins v. Kellogg Co.*, 224 F. Supp. 3d 1002 (S.D. Cal. 2016); *Hawkins v. AdvancePierre Foods, Inc.*, No. 15-cv-2309-JAH (BLM), 2016 WL 6611099 (S.D. Cal. Nov. 8, 2016); *Backus v. ConAgra Foods, Inc.*, No. C 16-00454 WHA, 2016 WL 3844331 (N.D. Cal. July 15, 2016); *Backus v. Nestlé USA, Inc.*, 167 F. Supp. 3d 1068 (N.D. Cal. 2016).

In *Hawkins v. Kellogg Company*, for instance, a plaintiff filed a class action under California law against a cookie manufacturer on the theory that the cookies included partially hydrogenated oil ("PHO"), which was allegedly unsafe for human consumption. 224 F. Supp. 3d at 1006. The FDA had determined that PHO was no longer considered "Generally Recognized as Safe" under federal law, but established "June 18, 2018, as a compliance date by which time food producers must have removed PHO from their food." *Id*. at 1008. Even in the absence of an express preemption provision, the *Hawkins* court concluded that the federal regulatory scheme preempted state common law causes of action seeking to bring about that same result sooner. *Id*. at 1013. The court explained that allowing the suit to go forward would "seriously disrupt the market by causing food manufacturers to immediately throw out all existing products containing PHO without affording manufacturers time to reformulate the products, find alternative ingredients to PHO, and manufacture the revamped products." *Id*. at 1015. In other words, the suit would bring about the "consequences that the FDA explicitly sought to avoid" in deferring the compliance date of the regulation. *Id*.

Similarly, the court in *Backus v. Nestlé USA, Inc*., facing facts virtually identical to *Hawkins*, concluded that claims challenging the use of PHO in "Coffee-mate" products were preempted, because the claims would impede the "fulfillment of the FDA's objectives, as

embodied in its regulatory scheme setting a three-year compliance period." 167 F. Supp. 3d at 1074; *see also AdvancePierre Foods, Inc*., 2016 WL 6611099 (reaching same conclusion in case challenging PHOs in microwavable sandwiches); *ConAgra Foods*, 2016 WL 3844331, *3-4 (same in case involving margarine).

Following the reasoning of these cases, the immediate enforcement of Regulation 81.50 would greatly disrupt the FDA's carefully considered compliance date of May 2018 by requiring immediate compliance with the federal standard in New York City. On that basis alone, Regulation 81.50 would be barred under implied preemption. Immediate local compliance will frustrate the federal uniformity objective, and will further frustrate FDA's purpose in extending the compliance date — to consider further modifications to the federal standard to minimize the regulatory burdens associated with the regulation.

While these cases compel the conclusion that Regulation 81.50's immediate implementation is implicitly preempted, the case for preemption here is even stronger because Congress explicitly barred any state regulation that is "not identical to" the corresponding federal requirements. 21 U.S.C. § 343-1(a)(4). As the Fourth Circuit recently noted, this broadly-worded statute "preempts 'any' applicable state requirement, not just some of them." *Nemphos*, 775 F.3d at 621. It leaves no doubt that the "purpose of Congress" — the "ultimate touchstone" of preemption, *Hughes*, 136 S. Ct. at 1297 — was to block *any* inconsistent local law, including inconsistency as to the compliance date. New York's efforts to enforce Regulation 81.50 before the federal compliance date of May 7, 2018 are therefore preempted. Accordingly, Plaintiffs are highly likely to prevail on the merits of this case.

III. PLAINTIFFS AND THEIR MEMBERS FACE IRREPARABLE HARM

Plaintiffs and their members face the risk of irreparable harm in at least two ways: (i) they face enormous and ultimately unrecoverable costs to comply with a regulatory regime now

that is likely to change by May 2018, and (ii) they face fines, business disruption and other harms from rules that are so unworkable that the FDA saw fit to delay their implementation.

A. Plaintiffs And Their Members Face Enormous Compliance Costs That Will Never Be Recoverable

Absent an injunction, Plaintiffs and their members will be forced to incur substantial costs — as the FDA has already recognized (Ex. 6 at 7) — to comply with Regulation 81.50, including nutritional analysis for existing food items, and for new food items as they are offered. Based on the experience of its members, Plaintiff FMI estimates this analysis to cost up to $1,000 per item, which will impose "staggering" costs on establishments that wish to offer a range of options, as in a salad bar or hot food bar. (Sarasin Decl. ¶ 15.) In addition, Plaintiffs' members will have to incur substantial costs for:

- updating menu boards and signs;
- training and recordkeeping;
- legal review to ensure full compliance;
- purchasing and programming new scales that can produce nutrition information for "grab-and-go" items; and
- printing the detailed "written nutritional information" that must be available "on the premises" for customers, *see* Regulation 81.50(e).

(*Id*. ¶ 9; *see also* Amador Decl. ¶¶ 24-26.)

These costs will be particularly burdensome for establishments that operate only one or a few outlets as franchisees of companies, such as individual 7-Eleven stores, or gas stations (*e.g*., Sunoco, BP and Mobil) operating with convenience stores. (Beckwith Decl. ¶ 19; Calvin Decl. ¶ 15.) Regulation 81.50 covers food service establishments with 15 or more locations "doing business under the same name and offering for sale substantially the same menu items," *see* Regulation 81.50(a)(2), and so will apply even if the ownership among the stores is completely

separate and diffuse. The result is that many true small businesses will have to build an elaborate compliance apparatus as if they were national chains.

These losses are irreparable because, even if the Court ultimately grants the declaratory relief sought in this lawsuit, the City's sovereign immunity will prevent any recovery after the fact. *Valdez v. City of New York*, 960 N.E.2d 356, 362 (N.Y. 2011). The Second Circuit has held that irreparable harm flows from exactly these circumstances. *United States v. New York*, 708 F.2d 92, 93 (2d Cir. 1983) (injury is irreparable "because a suit . . . to recover the damages sustained . . . would be barred by the Eleventh Amendment").

Following this reasoning, in *Metropolitan Taxicab Board of Trade v. City of New York*, No. 08 Civ. 7837(PAC), 2008 WL 4866021, at *7 (S.D.N.Y. Oct. 31, 2008), Judge Crotty found irreparable injury in a preemption challenge to fuel efficiency regulations of the New York City Taxicab & Limousine Commission because, if the regulations went into effect, cab drivers would "incur costs to comply with the regulations which they cannot recover in an action" against the City. *Id*. at *7. For the same reason, there is irreparable injury here.[2]

B. Attempting To Comply With Regulation 81.50 In Its Current, Unworkable Form Creates the Risk of Additional Irreparable Harm

Absent an injunction, regulated establishments will also be forced to navigate the significant and "complex" open questions that have led the FDA to delay implementation of its rules, 82 Fed. Reg. at 20,825, while the parallel New York City rules — with the same "complex" issues — are enforced in isolation. This will place the establishments at the risk of

[2] *See also Odebrecht Const., Inc. v. Sec'y, Fla. Dep't of Transp.*, 715 F.3d 1268, 1289 (11th Cir. 2013) ("[N]umerous courts have held that the inability to recover monetary damages because of sovereign immunity renders the harm suffered irreparable."); *John E. Andrus Mem'l, Inc. v. Daines*, 600 F. Supp. 2d 563, 572 n.6 (S.D.N.Y. 2009) (concluding that "irreparable harm may be presumed" because "Defendant is a state official entitled to sovereign immunity").

stiff fines (and the attendant reputational harm) or having to change their business models or food offerings to steer clear of potential violations. Worse, businesses with multistate operations will effectively have to deal with these problems on a national scale.

The Plaintiffs' accompanying declarations from offer multiple examples of these types of problems (*see* Beckwith Decl., Calvin Decl., Sarasin Decl., Amador Decl.):

- Supermarket chains that offer "build-your-own" foods (such as salad bars, soup bars, or hot bar areas) will be required to discern and disclose the calorie counts of huge volumes of food types and combinations, or else abandon those offerings. (Sarasin Decl. ¶ 15.)

- Calorie information for self-service food must be posted "either on a sign adjacent to and clearly associated with the corresponding food, or on a sign attached to a sneeze guard above the food item," *see* Regulation 81.50(b)(5), and so a grocery store that switches out the various serving salad or hot bar bins throughout the day (such as for breakfast, lunch and dinner, as is quite common), will have to find a way to constantly rotate the signage on each bin to match the food item, or, otherwise, create an enormous sign visible from the salad bar with every possible food item listed. (*Id*. ¶ 16.)

- Because calories must be posted for any food items regularly offered at covered stores, the rule will be particularly challenging for supermarkets and other food establishments that offer specialty items tailored to the particular geographic region (such as locally sourced bagels in New York) or that otherwise choose to offer fresh or innovative items that are not part of their permanent offerings. Those establishments will be required to either make separate calorie tabulations in those instances or, perhaps more likely, choose to forego offering specialty or innovative items. (*Id*. ¶ 17.)

- Convenience stores, which often have a small footprint, will have a difficult time complying with the law's requirement that information be posted "on a sign adjacent to and clearly associated with the corresponding food." *See* Regulation 81.50(b)(5) (Beckwith Decl. ¶ 13.)

- The lack of clarity as to the definition of a "menu," *see* Regulation 81.50(b)(7), may require Plaintiffs' members to post calorie information on promotional signage, which can be particularly challenging for convenience stores or other establishments with a small footprint. (*Id*. ¶ 14.)

As discussed, the FDA has committed to consider these and other issues between now and May 2018, but New York City is apparently content to foist these problems onto chains and

brands that have at least one New York City outpost. In other words, New York's regulation will effectively govern calorie count obligations and displays *nationally*, and in a manner that the FDA considered to be so problematic that more time was warranted to make revisions. Plaintiffs' members should not be forced to alter their business models, or be marked as lawbreakers, because of New York's decision to jump ahead of the national regulatory regime.

IV. THE PUBLIC INTEREST AND BALANCE OF THE EQUITIES FAVOR PLAINTIFFS

The public interest and balancing of the equities favor Plaintiffs, as well. Courts generally recognize that these factors follow automatically when there is a likelihood of success on a preemption claim. It is "clear that it would not be equitable or in the public's interest to allow the state . . . to violate the requirements of federal law." *Valle del Sol Inc. v. Whiting*, 732 F.3d 1006, 1029 (9th Cir. 2013) (quotations omitted).[3]

From a practical perspective, the public benefits from uniform regulation that makes it possible for food service businesses to operate on a national scale. Thus, whatever the local benefits that might accrue from premature implementation of Regulation 81.50, Congress and the FDA have expressly recognized that "the net benefits from national uniformity . . . outweigh the

[3] *See also, e.g., Ga. Latino All. for Human Rights v. Governor*, 691 F.3d 1250, 1269 (11th Cir. 2012) (holding that "enforcement of a state law at odds with the federal . . . scheme is neither benign nor equitable"); *Chamber of Commerce v. Edmondson*, 594 F.3d 742, 771 (10th Cir. 2010) (holding that "the public interest will perforce be served by enjoining the enforcement of the invalid provisions of state law") (quoting *Bank One v. Guttau*, 190 F.3d 844, 848 (8th Cir. 1999)); *accord E. Hampton Airport*, 841 F.3d at 155 n.20 (granting preliminary injunction in preemption case and noting that the opponent disputed only the likelihood-of-success factor, apparently conceding the remaining factors would follow from that determination).

loss in consumer protection that may occur as a result." *See* 58 Fed. Reg. at 2,462.[4] The Court should respect that considered judgment.

CONCLUSION

For the stated reasons, the Court should grant plaintiffs' motion and enjoin enforcement of Regulation 81.50 pending the completion of this litigation.

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Respectfully submitted,

STEPTOE & JOHNSON LLP

By: */s/ Charles Michael*

Charles Michael
1114 Avenue of the Americas
New York, New York 10036
(212) 506-3900
cmichael@steptoe.com

Counsel for Plaintiffs

Shannen W. Coffin
Osvaldo Vazquez
STEPTOE & JOHNSON LLP
1330 Connecticut Avenue, NW
Washington DC 20036
Pro Hac Vice Pending

Angelo I. Amador
RESTAURANT LAW CENTER
2055 L Street, N.W. Suite 700
Washington, D.C. 20036

[4] Of course, plaintiffs do not seek to upset the City's regulation of menu labeling for businesses not subject to the federal rule (*i.e*, those business with fewer than 20 locations that do not opt-in to the federal regulation). Thus, to the extent that the City asserts a public interest in regulating for the public health, its regulation will still apply where not preempted.