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TO PREVENT CHILDHOOD OBESITY

Public Health
Law Center
AT WILLIAM MITCHELL COLLEGE OF LAW

October 12, 2010

Dr. Margaret A. Hamburg, Commissioner
Department of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

**Re: Docket Nos.** **FDA-2010-D-0370**
**FDA-2010-N-0371**
**FDA-2010-D-0354**

Dear Commissioner Hamburg:

The undersigned national public health organizations appreciate the opportunity to submit comments to the Food and Drug Administration (FDA) regarding implementation of Section 4205 of the Patient Protection and Affordable Care Act of 2010 (PPACA).[1] Our comments address the Draft Guidance on implementation (Docket No. FDA-2010-D-0370), the Guidance on the effect of Section 4205 on state and local menu labeling laws (Docket No. FDA-2010-D-0354), and the Notice regarding voluntary registration (Docket No. FDA-2010-D-0371).

Our organizations are public health organizations that promote scientific and legally based approaches to public health policy, and provide legal technical assistance to local, state, and federal public health officials and attorneys across the country. Our comments address the following topics:

A. Implementation, focusing on how and where information should be disclosed
B. Promoting compliance and effective enforcement
C. Preemption of state and local laws

We hope that our comments will be useful in promoting the effective implementation and enforcement of Section 4205.

## A. Implementation: How and Where Information Should Be Disclosed

*Section III.C.5 Relating to Prominence of Calorie Disclosures on Menus and Menu Boards*

The Draft Implementation Guidance logically relies in part on objective standards to determine what is a "clear and conspicuous" calorie disclosure "adjacent to" a menu item. (21 U.S.C. § 343(q)(5)H).) We fully support the passage in the Guidance that directs that "[b]oth the number of

[1]We submit these comments on October 12, 2010, in accordance with the Federal Register notice for Docket No. FDA-2010-D-0370. *Guidance for Industry; Section 4205 of the Patient Protection and Affordable Care Act of 2010*, 75 Federal Register 164 (25 August 2010), pp. 52426-52427.

calories and the term 'Calories' or 'Cal' should be in a type size at least as large as the name or the price of the menu item, whichever is larger, with the same prominence, i.e., the same color and contrasting background as the menu item." Draft Implementation Guidance, Section III.C.5.

Size. By tying the type size to the larger of the name of the menu item or its price, the statute ensures that the calorie disclosure will be given prominence. But by not relying on external standards (or mandating a uniform standard), the provision also offers restaurants considerable flexibility in designing their menus and menu boards. The reference to the specific size of the price or item prevents any temptation to provide the disclosure in a type size that may be prominent but still smaller and thus less prominent than name or price information.

Font. One area not covered by the Draft Guidance that would benefit from clarification is the range of fonts or typefaces. Although *size* of type or font is covered, the font itself is not. In jurisdictions with local menu labeling laws, restaurants have complied with size and even prominence requirements while still obscuring the calorie information by putting the numbers in a thin and less visible font. This loophole can be closed by simply adding "font" to the Guidance's recommendation for addressing the problem.

*Section III.C.7 Relating to Disclosure of Trans Fat Information*

We fully support the FDA's conclusion that the written nutrition information should also include information about the amount of *trans* fats in standard menu items served at covered establishments.

*Section III.C.8 Relating to How Additional Nutrition Information Should Be Disclosed*

As FDA noted in the Draft Implementation Guidance, "[c]alorie and other nutrition information that is readily available at the point that consumers are making their food selections in restaurants … can help consumers make more healthful food choices." (Draft Implementation Guidance, Section II.) Consistent with this principle, the additional nutritional information (sodium, fats, etc.) must be available to customers where and when they are actually making their dietary decisions. For example, if the information is available only at the counter, or on poster in the restrooms, or at a computer kiosk at the back of the restaurant, or only upon verbal request, that does not meet the requisite standard – i.e., the information is not "readily available" in a way that will assist consumers in actually making, prior to their purchase, "more healthful food choices." The final Guidance and the Rule should make clear that whatever "written form" (21 U.S.C. § 343(q)(5)(H)(ii)(III)) is used, it must be available to customers *during the time that, and at the location where, they are making their decision about what to eat*.

### B. Promote Compliance and Effective Enforcement

The key to the success of any regulatory scheme is enforcement. Without a well-articulated and credible enforcement regime, no law can accomplish the purpose for which it was enacted. Because

the national menu labeling law supplants several actively enforced local regimes, the need to ensure proper enforcement of the federal menu labeling standard is especially acute. We urge the FDA to take the following measures to ensure that Section 4205 is fully and effectively implemented.

*Support Development of "Identical" State and Local Nutrition Labeling Requirements*

Assist state and local initiatives to enact "identical" requirements: Enforcement of the requirements contained in the national law may be accomplished through a variety of means. One effective measure is for state or local governments to enact new or amended labeling laws that are "identical" in substance to the federal law with respect to required nutritional disclosures, as a number of jurisdictions have done. For reasons of familiarity, tradition, and established practice, local and state authorities are much more likely to enforce their own laws, as opposed to a federal law. Thus, the FDA should encourage and facilitate state and local enactment of these laws, through the final Implementation Guidance, by offering to provide technical assistance to jurisdictions that are working to enact "identical" disclosure requirements in their laws. The FDA could offer to provide this assistance in various ways, including: 1) making staff available upon request to help assess proposed language for potential conflicts with the federal law; and 2) providing model legislation (as it does, for example, in the Model Food Code). The FDA should reiterate in these efforts that the language of the state or local measure need not be the same as the federal law in order for the relevant provisions to be considered "identical." *See* 21 C.F.R. 100.1(c)(4).

State and local enforcement mechanisms need not be "identical": Additionally, the FDA should include in the final Guidance and implementing regulations information that will facilitate enforcement of these state and local laws. For example, a significant benefit of these local regimes is that they allow states and local governments to make use of their existing inspection and enforcement apparatus. We recommend that language be added both to the Implementation Guidance and the Preemption Guidance that makes express an assumption that is implicit in the statute and draft Implementation Guidance: that enforcement provisions included in state or local menu labeling laws—for example, the administrative processes or remedies used to bring about compliance—are not affected by Section 4205 and need not be "identical" to those of the federal regime. Such a statement would be fully consistent with a statute that explicitly contemplates the parallel existence and operation of state and local menu labeling regimes.

*Support Compliance with, and Enforcement of, the Federal Requirements*

Not all states or locales can or will adopt requirements "identical" to the federal provisions. Although 21 U.S.C. §337 authorizes states to enforce the federal law in their own names in federal court, the efficacy of this method is doubtful. The procedural requirements coupled with the restriction to federal court make this enforcement option unattractive to state authorities. Indeed, it is our understanding that this provision has rarely, if ever, been used in the decades that it has been in existence.

Further, devolving enforcement responsibility onto state and local governments without consideration of their capacity or available resources would likely result—at best—in a patchwork of enforcement efforts, undermining the goals of uniformity and better protection. We recognize, however, that the FDA also has limited resources, and is not likely to have the capacity as it stands today to enforce the federal law in thousands of restaurants across the nation without state or local assistance. Thus, we suggest several options for promoting compliance and coordinating enforcement efforts between federal and state/local authorities to be considered as the final guidance documents and implementing regulations are developed.

To promote compliance with the federal law and "identical" state or local requirements, we urge the FDA to consider the following:

- The FDA should require that each covered food establishment register with the FDA, not only those voluntarily complying. (This could be similar to the requirement that food facilities register with the FDA under 21 U.S.C. §350d.) This database should be made readily available to the public, particularly to state and local authorities (for example, through the FDA's website). A local health inspector, particularly in a smaller city or town, is unlikely to know whether a local doughnut shop is part of a chain with only 3—versus 20— locations nationwide, for example. Having this kind of information collected in a database would help promote efficient enforcement.

- The final Guidance and implementing regulations should require food establishments to provide to the FDA a copy of the written nutrition information required to be made available to customers, along with an explanation of the methods used to determine the nutritional information pursuant to 21 U.S.C. § 343(q)(5)(H)(iv). Requiring this information to be reported to the FDA would enhance compliance with the law, and is a logical extension of the FDA's authority to enforce the law. This nutrition information (including method of calculation) could be collected as part of the registration process suggested above, and also should be made publicly available either separately or as part of the registration database described above, to aid state and local enforcement of the federal requirements.

- As reflected in the statute and Draft Implementation Guidance (21 U.S.C. § 343 (q)(5)(H)(iv) and Draft Implementation Guidance, Section III.C.10), covered food establishments and vendors must have a reasonable basis to support their nutrient content disclosures. The final Guidance and regulations should clearly state that covered establishments and vendors are responsible for maintaining the accuracy of these disclosures, including keeping this information up-to-date as their menus change.

- The FDA could facilitate these compliance efforts, and ease the potential enforcement burden on state and local authorities, by developing a process for verifying the accuracy of the nutritional information provided by the 50 or 100 largest chains. Then, at least for these chains, state and local authorities would be able to focus their inspection and examination resources on checking that the information is being properly disclosed as required by Section 4205.

We believe that these approaches would not only enhance industry compliance, but would also promote more efficient enforcement. The FDA could also support state and local enforcement activities in the following ways:

- The FDA could use its authority under 21 U.S.C. § 372(a)(1)(A) to support enforcement activities by state and local authorities, including providing technical assistance and funding for these efforts.

- The FDA should set up a simple process for local health inspectors to report potential violations of the federal requirements—for example, by supplying them with postcards to be filled in and sent to the FDA, with a tear-off receipt to be left with the restaurant manager.

- The FDA should develop a system for collecting and storing these and other reports of violations in a database that would be accessible to state and local authorities, to aid enforcement efforts.

### C. Preemption of State and Local Laws

Preemption of state and local authority is disfavored, particularly in areas of law – like public health – where state and local governments historically and traditionally have had broad authority to regulate. Requiring retail food establishments to disclose nutritional information so that consumers can make informed choices falls squarely within this traditional realm of state and local authority. The FDA's August 24, 2010 Guidance regarding the preemptive effect of Section 4205 ("Preemption Guidance") correctly recognizes that while Congress has restricted state and local authority to impose menu labeling requirements on certain food establishments and vending machine operators, Congress clearly intended that state and local governments retain the remainder of their traditional authority in this area.

"Identical." As reflected in several of the comments submitted in response to the FDA's request for comments regarding how Section 4205 should be implemented (Docket No. FDA-2010-0298), there continues to be some confusion on this point. We therefore support the FDA's decision to clarify in the Preemption Guidance that only certain state and local menu labeling requirements not "identical" to the federal law are preempted, and that state and local governments retain their authority to impose non-"identical" labeling requirements on restaurants and other retail food establishments that (1) are not part of a national chain with 20 or more outlets and (2) have not agreed to comply with the federal law by registering with the FDA. Section 4205 (d) and Preemption Guidance, Sections 7 and 9.

However, we believe that the Final Guidance and Rule could more explicitly set forth the limitations on the preemptive effect of section 4205. Given the presumption against preemption in public health matters, and specifically in areas affected by this statute, the Guidance should contain a more explicit statement of non-preemption than what is currently included in Section C.7 of the Preemption Guidance. *See* Pub. L. No. 101-535, § 6(c)(1), 104 Stat. 2353, 2364 (21 U.S.C. § 343-1

note (NLEA "shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [21 U.S.C. § 343-1(a)] of the [FDCA]"); *NYSRA v. NYC Bd of Health*, 556 F.3d 114 (2nd Cir. 2009). *See also Memorandum for the Heads of Executive Departments and Agencies*, Office of the Press Sec'y, The White House, 2009 WL 1398319, at *1 (May 20, 2009).

The Guidance and the Rule should, for example, explicitly reiterate that the word "identical" does not mean "identical" in language but rather in effect—i.e., that state or local requirements that are worded differently from the federal requirements may still be "identical" under Section 4205. *See* 21 C.F.R. 100.1(c)(4). This could be accomplished by adding the following sentence to section C.7 of the Preemption Guidance: "The specific words need not be the same—state or local requirements that are worded differently from the federal requirements may still be 'identical' under Section 4205."

Preemption applies only to menu labeling requirements. Further, we recommend that the Preemption Guidance contain an additional sentence or question-and-answer explaining that the preemption brought about by the federal law is limited to menu labeling in the covered establishments, such as the following:

> "Q: Does Section 4205 apply to areas other than menu labeling?
>
> A: The scope of the law's preemptive effect is coextensive with the law's nutrition labeling requirements. That is, the only state and local provisions that are preempted are those that explicitly require the type of menu labeling set forth in Section 4205 at a covered establishment."

This statement would avoid inadvertent preemption and thereby conform to the NLEA's bar on implied preemption. In the face of the obesity epidemic, state and local governments are motivated to implement a variety of systems, policy, and environmental changes to promote healthy eating and active living, and to make healthy behaviors the default choice. It is especially important that their freedom to experiment with policy interventions not be curtailed by an unnecessarily broad reading of Section 4205's preemptive language.

State/local enforcement mechanisms. The Preemption Guidance correctly recognizes that "warning statements, consumer advisories, and allergen labeling regarding the safety of the food or component of the food" are not nutrition labeling requirements, and thus are not affected by Section 4205. Preemption Guidance, Section C.8. As noted above, we recommend that language be added to Section C.7 of the Guidance that expressly states a conclusion that is implicit in the statute and Guidance: that enforcement provisions included in state or local menu labeling laws—for example, the administrative processes or remedies used to bring about compliance—also are not affected by Section 4205 because they are not nutrition labeling requirements. Such a statement would be in full compliance with a statute that explicitly contemplates the parallel existence and operation of state and local menu labeling regimes.

Vending machine operators. Finally, we suggest that statements about the preemptive effect of Section 4205 on state and local laws relating to vending machine should be modified or added to, to help avoid confusion. With regard to vending machines, the Guidance states that "no State or locality may have a requirement that is not identical to the federal requirements," regardless of the number of machines owned or operated. Preemption Guidance Section C.9. *See also* Notice Regarding Voluntary Registration , Section II.B. We recommend at least rephrasing the interpretation, as follows (for example): "The federal law does not affect state or local authority to impose nutrition labeling requirements on vending machine operators or owners, so long as these requirements are 'identical' (as explained above) to the federal requirements. This is true regardless of how many vending machines the operator owns or operates."

Furthermore, the FDA may wish to consider whether even that statement extends Section 4205's preemptive effect further than Congress intended. As noted above, there is a presumption against preemption in legal areas such as public health regulation. Congress has expressed its clear intent that the NLEA preempt only those provisions of state law that are expressly preempted by the terms of the act. Pub. L. No. 101-535, § 6(c)(1), 104 Stat. 2353, 2364 (21 U.S.C. § 343-1 note (NLEA "shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [21U.S.C. § 343-1(a)] of the [FDCA]"); *NYSRA v. NYC Bd of Health*, 556 F.3d 114 (2nd Cir. 2009). *See also Memorandum for the Heads of Executive Departments and Agencies*, Office of the Press Sec'y, The White House, 2009 WL 1398319 (May 20, 2009) (noting that "Throughout our history, State and local governments have frequently protected health, safety, and the environment more aggressively than has the national Government" and cautioning against overbroad agency preemption). Here, the "National Uniformity" section of the statute addresses only "a restaurant or similar retail food establishment"—notably excluding vending machines. Therefore, it is unclear to what extent Congress intended Section 4205 to preempt state and local regulation of smaller vending machine operators. We respectfully suggest that the FDA may wish to leave this issue, should it ever arise, for consideration by the courts.

We appreciate this opportunity to share our observations and recommendations regarding the guidance documents and proposed regulations that the FDA is preparing to help implement and enforce the federal menu labeling requirements. We would be pleased to provide any further information that may be helpful.

Sincerely,




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