King County's Menu Labeling Strategy

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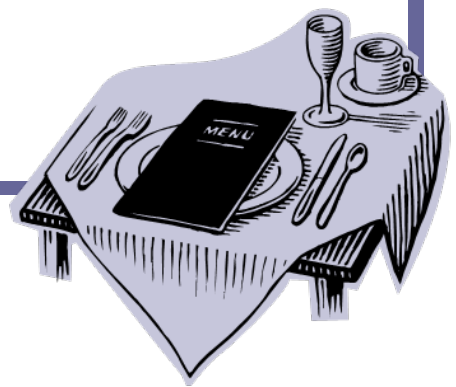


History:

- King County Board of Health adopted 2 regulations in July 2007:
  1. Restricting restaurant use of artificial trans fat
  2. Requiring chain restaurants to provide nutrition labeling of all standard menu items:
     - Calories
     - Trans fat
     - Saturated fat
     - Carbohydrates
     - Sodium

Requirements for Nutrition Labeling in Regulation adopted in July 2007:

- Labeling to be on menus next to all standard menu items, and in a font size and typeface similar to other information of standard menu items.
- Menu boards to have calorie information per standard menu item in font size and typeface similar to other information on menu board about the item. Other information to be available in a document plainly visible to consumer at point of ordering.
- Health officer may allow substantially equivalent methods of providing notice to consumers at the point of ordering.

Opposition by Restaurant Industry:

- Restaurant industry vocal in opposition, threatened litigation regarding nutrition labeling
- Principal legal arguments raised:
  - Free speech
  - Preemption
- Did not challenge artificial trans fat restriction

Commercial Free Speech Analysis: 3 Lines of Cases from Supreme Court:

1. Strictest (urged by restaurant association in NY) *United Foods*:
   - **Compelled Speech**. Supreme Court held that assessment on all mushroom producers to fund generic advertising violated the First Amendment because it compelled growers to subsidize commercial speech with which they disagreed—that all mushrooms should be consumed whether or not they are of a certain brand.

First Amendment

2. **Commercial Speech** — *Central Hudson*

   4 part test:

   1. Whether the expression concerns lawful activity and is not misleading;
   2. Whether the asserted governmental interest is substantial;
   3. Whether the challenged regulation directly advances the asserted interest; and
   4. Whether the challenged regulation is more extensive than necessary to serve the asserted interest.

First Amendment

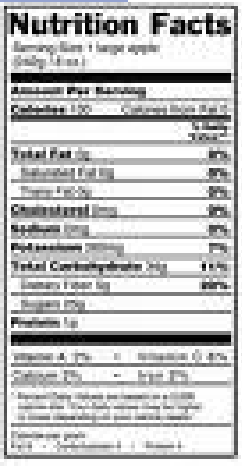
3. **Commercial Disclosure** — *Zauderer*
   - Test: disclosure requirement must be reasonably related to the State's interest in preventing deception to consumers. NY City argued this is appropriate analysis, and it was adopted as the proper standard of review by NY district court on the second round of NY case. Restaurant Association appealed the case to Second Circuit.
   - Jurisdictions in the Second Circuit (like NY) have advantage in that besides Supreme Court case, also has *Sorrell* as precedent.

Other Principal Argument Asserted against nutrition labeling: Preemption

- Nutrition Labeling and Education Act (NLEA) preempts state and local governments from requiring restaurants to provide nutrition information to consumers, depending on analysis applied.
- NLEA has two preemption provisions. One applies to restaurants and one does not. Thus it is critical in nutrition labeling preemption analysis which NLEA preemption provision applies.

Preemption by NLEA: Mandatory Nutrition Labeling

- NLEA designates as misbranded “food intended for human consumption and … offered for sale” unless its label bears certain nutrition information. The familiar “nutrition facts” panel on packaged foods is required by this section.
- NLEA expressly exempts restaurants from the preemption provisions applicable to this section.



Preemption by NLEA: Claims

- Voluntary nutrition content claims
  - NLEA also designates food as misbranded if "a **claim** is made in the label or labeling of food which expressly or by implication... characterizes the level of any nutrient" unless "the characterization of the level made in the claim uses terms which are defined" in FDA regulations.
  - State and local governments are preempted from requiring restaurants to make claims about nutrient levels.

Preemption: NY Case

- In 1st NY case, district court said that because the calorie count requirement only applied to restaurants that already voluntarily provide nutrition information, City was preempted from requiring calorie labeling; *i.e.*, mandatory nutrition labeling provision did not apply.
- NY City responded by changing regulation so applies to restaurants whether or not they voluntarily provide calorie information. NY City prevailed in second case, at least at the district court level. Case is on appeal.
- In friend of court brief to Second Circuit, FDA rejected voluntary v. mandatory distinction of district court.

Preemption: Is Nutrition Labeling a Claim?

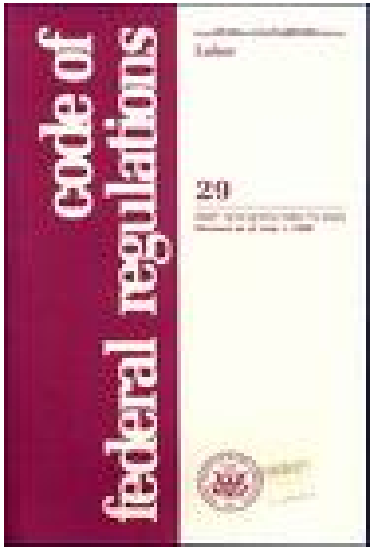
- Is lack of clarity whether disclosure of nutrient content is a “claim” such that state and local governments are preempted from requiring restaurants to provide it.
- 21 CFR 101.13(b)(1) provides that the statement “contains 100 calories” is a claim.
- The language is problematic, because it is a simple statement of how many calories are contained, now what commonly considered a claim.
- This leads to my policy recommendation.

Recommendation--Issue:

Should federal law be clarified as to what constitutes a “claim” under NLEA?

Recommendation:

FDA regulation should be amended to avoid any confusion that local or state requirement that restaurants provide consumers with information on the amount of a nutrient is not a “claim” that is preempted by NLEA.



Rationale for Recommendation:

Rationale: 21 CFR 101.13(b)(1) includes as an example of an expressed nutrient content claim in the statement “contains 100 calories.” Restaurants argue based on this regulation that all statements of the quantity of a nutrient are “claims” and thus state and local governments are preempted from requiring restaurants to provide such information to consumers. Amendment would avoid confusion based on this provision.

Back to History of King County regulation:

- Restaurant industry lobbied Washington legislature. Bill in legislature went through many changes: would have established a task force to study nutrition labeling, and prohibited local boards of health from adopting rules and regulations regarding nutrition labeling.
- Chair of House Committee requested representatives from King County and Washington Restaurant Association to negotiate an agreement. Agreement reached in March, just before adjournment of the Washington legislature.
- King County agreed to take action at a special meeting on the language that had been agreed upon with the restaurant association, while the Washington Restaurant Association agreed to request that the legislature not take action on the bill before it, and that it would not sue King County regarding the nutrition labeling requirement as adopted.

Current King County regulation

- Board of Health adopted regulation which allowed more flexibility, but held to the principle that nutrition information be made available to consumers at the point of ordering.
- Information can be made available via menu inserts, menu appendix, electronic kiosk, or as approved by the Health Department; also flexibility for menu boards.