

be implemented. Some may require changes in law or regulation, and some may require substantial amounts of resources. The agency is now accepting public comment on the content of the proposals, as well as on which draft proposals should be given priority.

If the proposals were to be adopted and implemented, the FDA would make substantially more information about the regulatory process available to the public. The agency would disclose, among other things, when a drug or device is being studied and for what indication, when an application for a new drug or device has been submitted or withdrawn by the sponsor, whether there was a significant safety concern associated with the drug or device that caused the sponsor to withdraw an application, and why the agency did not approve an application. If a report that is published by a sponsor were to contain an incomplete picture about the safety or efficacy of a product, the FDA would be able to provide its analysis to contribute to the scientific discussion.

The task force believes that implementing some of the proposals would accelerate the development process for medical products by allowing companies

to learn from the successes and failures of other products. One proposal, for example, would allow the FDA to explain that an orphan drug whose application was abandoned or withdrawn by the sponsor for business reasons may nevertheless represent an important therapeutic advance for a rare disease. This information would be of substantial interest to patients with that disease, their families, and their clinicians. It could also encourage additional investment for development of that drug or provide another company with the incentive to purchase and continue with the application.

The task force is also proposing further public discussions on the appropriate release of certain raw data, without patient identifiers, to allow for additional study of, and new insights into, the safety and efficacy of drugs and devices.

Implementing other proposals would illuminate the agency's enforcement efforts by having the FDA post the classification of every facility inspection it performs. The final inspectional classification is based on the inspectors' observations and reflects the degree to which the establishment is out of compliance with laws and regulations de-

signed to ensure the safety of FDA-regulated products. Another proposal would have the FDA generate and share with the public information about the most common objectionable conditions or practices found by agency staff during inspections. This information could be very useful to consumers and purchasers of medical products and food.

More than 30 years ago, FDA Commissioner Donald Kennedy noted "a basic principle of our political system [is] that people affected by governmental decisions have a right to know the basis on which they are made." With the daily practice of medicine routinely affected by the decisions of the FDA, the medical community has a large stake in transparency at the agency. The full set of draft proposals can be found on the FDA's Web site (www.fda.gov/transparency). The agency is accepting comment on the proposals until July 20, 2010.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

Ms. Asamoah is the director of the FDA's Transparency Initiative, Silver Spring, MD, and Dr. Sharfstein is the FDA's principal deputy commissioner and chair of its Transparency Task Force.

This article (10.1056/NEJMp1005202) was published on May 19, 2010, at NEJM.org.
Copyright © 2010 Massachusetts Medical Society.

Health Care Reform in Action — Calorie Labeling Goes National

Marion Nestle, Ph.D., M.P.H.

Tucked away on page 455 of the 906-page health care reform act (Public Law 111-148) is a provision for listing calorie counts on the menu boards of

chain restaurants or adjacent to each food offered in vending machines and in retail stores. Establishments with 20 or more locations nationwide must post

calories "in a clear and conspicuous manner," along with "a succinct statement concerning suggested daily caloric intake" — presumably the 2000-kcal-per-day



standard that the Food and Drug Administration (FDA) uses for the “Nutrition Facts” on packaged foods. When the Nutrition Labeling and Education Act of 1990 went into effect in 1994, it required that nutrition labels be placed on food products but exempted restaurants. The new law removes that exemption.

The advocacy group Center for Science in the Public Interest (CSPI) organized support for this measure after having issued a 2003 report arguing that nutrition labeling would help to control the rising rates of obesity. The report summarized evidence that more people eat meals away from home than ever before, that U.S. children consume twice as many calories at restaurants as at home, and that nearly everyone underestimates the calorie content of restaurant meals.¹

In 2004, an FDA Obesity Working Group report, “Calories Count,” recommended providing nutrition information at the point of sale in restaurants. The FDA asked the nonprofit Keystone Center to review the status of such information. The 2006 report of

the Keystone Forum that was convened to develop recommendations on the topic indicated that about half of restaurant chains

provide calorie information but put it in places where it is unlikely to be seen. The forum urged that posting be more accessible and that research be conducted to investigate how calorie information is used,

affects restaurant management and sales, and works in practice. Although recognizing that variations in sources of ingredients, preparation methods, and portion sizes affect calorie determinations, the forum concluded that customers’ right to know the calorie counts of their foods outweighed other concerns.

Much evidence suggests that there is a potential value in posting calorie counts. Research has revealed widespread public interest in obtaining access to and using calorie information. Some preliminary studies found menu labeling to lead to slight reductions in the number of calories people purchase, particularly when such labeling is accompanied by a statement referring to a recommended intake of 2000 kcal per day. Other studies, however, found no effect or indicated that such posting might actually encourage young men, in particular, to eat more. Because these studies were largely conducted in classrooms or school cafeterias and used self-reports, cash-register receipts, or other such indirect measures

of food consumption, their overall significance is not easily interpreted.²

New York City was the first locality to require calorie labels. In 2006, the New York City Health Department proposed requiring quick-service chain restaurants with more than 15 outlets — those that were already providing calorie information — to post calorie counts on menu boards. The New York State Restaurant Association opposed the proposal on the grounds that calorie labeling would be impractical, expensive, and an unconstitutional violation of free commercial speech. It filed lawsuits and lobbied for preemptive legislation. After much legal wrangling, the courts ruled in favor of the city.³ The measure went into effect on July 19, 2008.

The strong opposition suggested that restaurants were unlikely to post calorie counts voluntarily. Yet by 2009, California, Oregon, and Maine required calorie labeling, as did a dozen or more U.S. counties and cities. Similar bills were under consideration in at least 30 other regions. Confronted with a cacophony of differing laws, the restaurant association dropped its opposition, thereby paving the way for a national law that supersedes local and state laws.

New York City has now had calorie labeling in place for 2 years, and it is worth asking whether this initiative has improved customers’ purchases, induced restaurants to reduce the caloric content of their foods, or educated the public about the calories in foods and diets. One study examined the first question; the others have not yet been addressed. Shortly after the label-

ing began, investigators collected cash-register receipts and survey responses from more than 1100 fast-food customers in low-income New York City neighborhoods and in Newark, New Jersey, a city with comparable low-income neighborhoods but no menu labeling. Although nearly 28% of New York customers said they noticed and were influenced by calorie labeling, this group purchased about the same number of calories as everyone else.⁴ This result might be expected, since these outlets were located in areas with little choice in restaurants and where residents might be likely to seek low-cost foods that are high in calories.

Encouraging chains to reformulate their products or reduce portion sizes might be one potential benefit of labeling requirements, but a comparison of current numbers to those in my collection of 2007 nutrition brochures yields no clear trend. McDonald's, for example, decreased the calories in large orders of french fries by 30 but increased those in small orders by 20. Starbucks has decreased the calories in many of its drinks, but some Subway sandwiches have more calories now. The New York City Health Department's more systematic evaluation, as yet unpublished, suggests that calorie reductions of about 10% have been common.

My personal observations raise several concerns about the implementation of this policy. In some chains, the calorie numbers are posted in print too small or too obscure to be read easily. Some chains post amounts to the ab-

surdly precise single calorie — 497 for a club sandwich at Cosi, for example. Calorie numbers are best rounded off to the nearest 10 or 25; they are ballpark figures. One comparison of actual measurements to posted amounts revealed wide deviations, sometimes by as much as a factor of two.⁵ Some chains, such as Le Pain Quotidien, do not post counts at all but provide calorie information on menus by request. Chains that allow customers to select their own quantities of food post calorie counts in uninterpretable ranges: 170 to 780 for a salad at Chipotle, or 330 to 890 for ice cream at Cold Stone Creamery. FDA regulations will need to deal with such issues.

Despite such logistic problems and modest benefits, calorie labeling is well worth the trouble. Here, at last, is help for explaining the relationship of food energy to body weight. Calories are otherwise impossibly abstract; they cannot be seen, smelled, or tasted. Almost everyone underestimates the number of calories in away-from-home foods, especially when portions are large or the foods are promoted as healthful. Few nonbiochemists understand that “calories” are actually kilocalories, and 1 kcal is the amount of heat needed to raise the temperature of a liter of water from 14.5°C to 15.5°C at 1 atmosphere of pressure. It is much easier to explain how posted calorie counts in fast-food meals fit into a 2000-kcal diet.

Calorie labeling demonstrates that larger portions have more calories. Judging by reactions to my lectures about portion size

and the *Mindless Eating* studies of Cornell University professor Brian Wansink, this relationship is apparently not intuitively obvious. Many people find it difficult to believe that any food contains more than 200 or 300 kcal. Watching the calorie counts of McDonald's french fries go from 230 (small order) to 380 (medium) to 500 (large) may be instructive to anyone who is paying attention. That not everyone will look at calorie postings is a given. For those who do look, calorie labeling provides an incentive to avoid large portions — and to share the 670-kcal Le Pain Quotidien cookie with three friends.

Disclosure forms provided by the author are available with the full text of this article at NEJM.org.

From the Department of Nutrition, Food Studies, and Public Health, New York University, New York.

This article (10.1056/NEJMp1003814) was published on April 7, 2010, at NEJM.org.

1. Anyone's guess: the need for nutrition labeling at fast-food and other chain restaurants. Washington, DC: Center for Science in the Public Interest, November 2003. (Accessed April 6, 2010, at <http://www.cspinet.org/restaurantreport.pdf>.)
2. Larson N, Story M. Menu labeling: does providing nutrition information at the point of purchase affect consumer behavior? Princeton, NJ: Robert Wood Johnson Foundation, June 2009. (Accessed April 6, 2010, at <http://www.rwjf.org/files/research/20090630hermenulabeling.pdf>.)
3. Farley TA, Caffarelli A, Bassett MT, Silver L, Frieden TR. New York City's fight over calorie labeling. *Health Aff (Millwood)* 2009; 28:w1098-w1109.
4. Elbel B, Kersh R, Brescoll VL, Dixon LB. Calorie labeling and food choices: a first look at the effects on low-income people in New York City. *Health Aff (Millwood)* 2009; 28:w1110-w1121.
5. Urban LE, Dallal GE, Robinson LM, Ausman LM, Saltzman E, Roberts SB. The accuracy of stated energy contents of reduced-energy, commercially prepared foods. *J Am Diet Assoc* 2010;110:116-23.

Copyright © 2010 Massachusetts Medical Society.