

## The Trans-Fat Ban — Food Regulation and Long-Term Health

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**T**rans fats naturally exist in small amounts in the fat in meat and milk, but most trans fats in the food supply have been added by food manufacturers. Since 1911, when Procter and Gamble introduced

Crisco, companies have used artificial trans fats because of their commercially favorable properties, such as long shelf life, stability during deep frying, and palatability. These fats have therefore been incorporated into a great many foods, including snack and deep-fried foods, baked goods, margarines, and crackers (see graph). The primary dietary source of artificial trans fat is partially hydrogenated oils, created by adding hydrogen to vegetable oils.

In the early 1990s, studies began revealing negative health effects of trans fats, and by the mid-2000s, it was clear beyond doubt that trans fats increase the risk of coronary heart disease, proba-

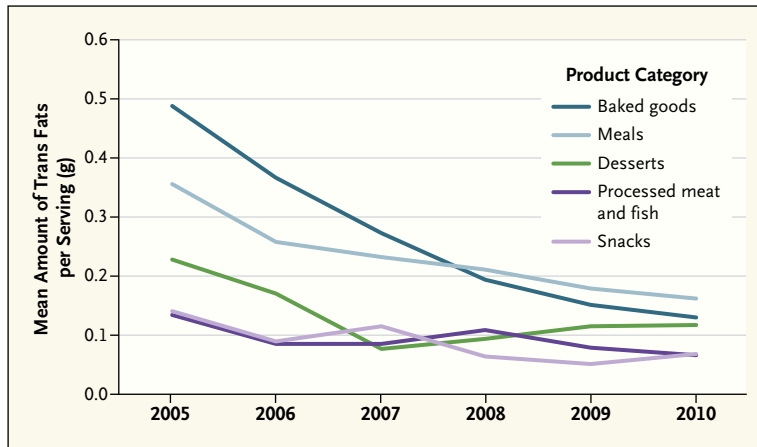
bly through their deleterious effect on low-density lipoprotein and high-density lipoprotein cholesterol levels.<sup>1</sup> Denmark banned partially hydrogenated oils in 2003, and several other countries followed suit; in the United States, New York City passed such a ban for restaurant foods in 2006, and the state of California did the same in 2008.

Now, more than a decade after the first ban, the Food and Drug Administration (FDA) has proposed a regulation that would declare partially hydrogenated oils unsafe and allow only a small amount of remaining artificial trans fats in foods sold in the United States.<sup>2</sup> A strong argu-

ment can be made for eliminating artificial trans fats entirely<sup>3</sup>; the Centers for Disease Control and Prevention estimates that this action could prevent as many as 20,000 coronary events and 7000 deaths from coronary causes each year in the United States. Still, the FDA action represents a significant advance.

Essentially banning artificial trans fats would be a public health victory, made possible in part by limited resistance from the food industry. When New York City proposed its ban, the restaurant industry resisted, claiming that foods would cost more and taste worse and that consumer choices would be restricted because the supply chain could not produce alternative fats in sufficient amounts. None of these predictions were borne out, and industry has adapted.

What may have worried indus-



**Amount of Trans Fats Found in Products with the Highest Trans-Fat Content, 2005–2010.**

Data are calculations from the U.S. Department of Agriculture Economic Research Service, which are based on data from the Mintel Global New Products Database.

try more was the precedent being set by governments claiming interest in and authority over the long-term health consequences of food. And indeed, that precedent makes the FDA action historic: banning artificial trans fats will save lives, but it also portends future government actions regarding the food supply that will affect human health much more broadly.

Americans have long granted federal, state, and local governments the authority to reduce the acute risks posed by unhealthful foods, particularly when it comes to avoidance of foodborne illnesses. No one raises concerns about government overreaching when authorities step in to contain disease caused by contaminants such as *Escherichia coli* or salmonella. Since elements of our diet contribute in substantial ways to the leading causes of death (including cardiovascular disease and cancers), it is important to understand how the regulatory authority of government might be part of an overall strategy to improve our nutrition.

The FDA has primary authority over the labeling and safety of the processed food supply in the United States. The agency first addressed trans fats by requiring the disclosure of the trans-fat content of food on nutrition labels beginning in 2006. Food manufacturers reformulated some food products to reduce or eliminate trans fat, thereby avoiding having to declare it as an ingredient, but studies showed that some subpopulations continue to have high intake because of their use of trans-fat-based products such as margarine and highly processed foods, such as some baked goods, that could be produced with alternative sources of fat.<sup>2</sup>

Partially hydrogenated oils have been considered safe by the food industry and are used in foods on the basis of that classification. However, the FDA has the authority to issue a notice proposing to determine that a substance is not “generally recognized as safe” (GRAS) and as a result is subject to further regulation.<sup>4</sup> In 2013, the FDA determined that there is “no longer a

scientific consensus” that partially hydrogenated oils are safe for their intended use in food, made a tentative determination that they are no longer GRAS “under any condition of use in food,” and issued a request for comments on its proposal.<sup>2</sup>

The FDA is expected to remove GRAS status for partially hydrogenated oils and reclassify them as “food additives.” Unlike GRAS ingredients, food additives are not presumed to be safe and thus require premarketing approval.<sup>5</sup> As a result, manufacturers would no longer be allowed to sell partially hydrogenated oils directly or use them as ingredients in food products. The FDA action would apply to packaged foods found in stores but would also have broader reach. State and local governments have primary authority to regulate restaurants, but irrespective of their actions, partially hydrogenated cooking oils would no longer be permissible for sale.

Other constituents of the food supply such as added sugars, salt, caffeine, and saturated fat might also be addressed by government, using trans fat as the precedent. The FDA has the authority to require labeling of constituents such as added sugars and caffeine, and it can establish safe thresholds for use through its authority to eliminate problematic ingredients. As in the case of trans fat, the legal mechanism open to the agency for regulating a constituent of food is to remove GRAS status and have the constituent declared a food additive. For example, the FDA now grants GRAS status to caffeine up to the amount typically added to colatype beverages, but it could reconsider this threshold, chal-

lenge manufacturers of products such as energy drinks who have determined themselves that caffeine is safe at much higher levels, and ultimately regulate the amount of caffeine permitted in products.

Whether states have authority on these issues is an important question. Federal law does not expressly preempt states from making their own determinations of GRAS status. However, a state taking such an action could place itself in conflict with federal law and be vulnerable to legal challenges based on arguments, for example, that state actions are preempted by federal law. States do have authority to use their police power to enact regulations directed at food-service establishments such as restaurants in order to support public health. States could, for example, require restaurants to



An audio interview with Dr. Brownell is available at NEJM.org

tions directed at food-service establishments such as restaurants in order to support public health. States could, for example, require restaurants to

reduce sodium levels in prepared foods, as New York City did with trans fat, and could require warning labels for foods.

Over the past few decades, food-safety concerns have expanded from issues of foodborne illness and contaminants such as lead to include the effects food ingredients have on chronic diseases such as heart disease. The government's rightful role is to continue examining food ingredients to determine safe conditions for their use. The government has the authority and responsibility to regulate the unhealthful aspects of the food supply, and artificial trans fat is likely to be an important frontier. The fact that a regulatory arm of the U.S. government is now following the lead of other countries and some U.S. cities and states with regard to trans fat suggests that a watershed has been reached; regulatory recon-

sideration of ingredients such as sugar, caffeine, and salt may well be next on the agenda.

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

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1. Mozaffarian D, Katan MB, Ascherio A, Stampfer MJ, Willett WC. Trans fatty acids and cardiovascular disease. *N Engl J Med* 2006;354:1601-13.
2. Department of Health and Human Services. Tentative determination regarding partially hydrogenated oils; request for comments and for scientific data and information. *Fed Regist* 2013;78:67169-75.
3. Dietz WH, Scanlon KS. Eliminating the use of partially hydrogenated oil in food production and preparation. *JAMA* 2012;308:143-4.
4. Code of Federal Regulations. 21 CFR 570.38 — determination of food additive status.
5. Code of Federal Regulations. 21 CFR 570.30 — eligibility for classification as generally recognized as safe (GRAS).

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## Insourcing Health Care Innovation

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Many health care professionals find it irritating when management gurus recommend solving health care's problems with approaches they would "copy and paste" from unrelated industries — a former chief executive of a manufacturing company claims that the same simple lessons that enabled him to transform his own industry can improve value in health care, or a business-school professor offers an eight-point leadership plan that she's translated into health care as easily as if she'd trans-

lated it into French. Many people who work in health care value outside perspectives and are open to new approaches — and yet bristle at facile recommendations emerging from these translations.

At the same time, health care improvements can come from people who don't know the field asking, genuinely, "Couldn't you do it a different way?" — where insiders might be less able to imagine alternatives. Principles guiding high-impact innovation are evolving faster outside health care than inside. So it makes

sense not to give up on the management gurus entirely, but we can distinguish between those who follow good innovation practices and those who don't. Health care is not a single problem but thousands of problems, and rather than seeking a solution derived from other fields, we'd do better to find a solution *process* to use from within.

The challenge of health care innovation lies in combining contextual understanding with fresh perspectives. We — a physician, a business-school professor, a