

ISSUE BRIEF

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FDA's Artificial Trans Fat "Ban": A Dangerous Step to Control Personal Dietary Choices

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In November 2013, the Food and Drug Administration (FDA) published its tentative determination¹ to revoke the Generally Recognized as Safe (GRAS) status for partially hydrogenated oils (PHOs), which are the primary dietary source of artificial trans fat. As explained in a recent FDA update, "If FDA determines that PHOs are not GRAS, it could, in effect, mean the end of artificial, industrially-produced *trans* fat in foods."²

The FDA would be taking the Federal Food, Drug, and Cosmetic (FD&C) Act of 1938 into novel areas that are unrelated to the food safety issues that the law is designed to regulate. It would do so by regulating nutrition and diet through limiting food choices. Thus, the agency is trying to conflate nutritional and dietary well-being with "safety." This action is extreme and unwarranted.

A Solution in Search of a Problem

In 2003, the average intake of trans fat from products containing PHOs was 4.6 grams per day per person, or 2 percent of energy based on a 2,000-calorie diet. This number plummeted to only 1 gram per day, or 0.5 percent of energy, in 2012, a massive 78 percent reduction.³ Further, there is no evidence of this

decline stopping, with a still very strong 23 percent reduction from 2010 to 2012.⁴

The American Heart Association recommends consuming less than 2 grams of trans fat a day (1 percent of a 2,000-calorie diet),⁵ which includes both artificial and natural trans fat consumption.⁶

Current artificial trans fat consumption is already about half of that number. Even if natural trans fat consumption—which the FDA estimated to be about 1.2 grams in 2003⁷—is added to the total, trans fat consumption would still be around the total recommended limit.

Even so, it is inappropriate to consider both natural and artificial trans fat together, because there is currently insufficient evidence that natural trans fat is associated with coronary heart disease. There is some research showing potential health problems with natural trans fat,⁸ but there is a significant amount of research that shows no association or even an inverse association.⁹

Research Does Not Demonstrate Harm at the Current Low Intake Levels

The FDA claims that trans fat consumption is harmful at any level, that any incremental increase in trans fat consumption increases low-density lipoprotein cholesterol (LDL-C, i.e. "bad cholesterol") concentrations, which is one of the major risk factors for coronary heart disease.

Current average consumption of artificial trans fat (0.5 percent of energy) and total trans fat (approximately 1 percent of energy) is much lower than at the levels where harm has been identified in the research. In its comment to the FDA, the Grocery Manufacturers Association argued:

This paper, in its entirety, can be found at
<http://report.heritage.org/ib4246>

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[T]he evidence does not support a conclusion that any increase in percent energy intake from *trans* fat (above zero) leads to a significant increase in LDL cholesterol. Observational and intervention data summarized here suggest that *trans* intake below 2% total energy does not appear to result in a significant impact on total and LDL cholesterol, the validated surrogate biomarkers for cardiovascular disease.¹⁰

Research Does Not Recommend Zero Consumption of Artificial Trans Fat

The Institute of Medicine's (IOM) 2005 *Dietary Reference Intake* report¹¹ and the *Dietary Guidelines for Americans, 2010*¹² both recommend that trans fat consumption should be as low as possible. Neither recommends that individuals should seek to consume zero trans fat, artificial or natural. Yet the FDA is trying to eliminate the consumption of artificial trans fat.

The IOM report, which the FDA heavily relies on, goes even further to indicate that a zero trans fat diet would have undesirable outcomes:

Because trans fatty acids are unavoidable in ordinary, nonvegan diets, consuming 0 percent of energy would require significant changes in patterns of dietary intake. As with saturated fatty acids, such adjustments may introduce undesirable effects (e.g., elimination of *commercially prepared foods*, dairy products, and meats that contain trans fatty acids may result in inadequate intakes of protein and certain micronutrients) and unknown and unquantifiable health risks.¹³

The IOM is referring to problems caused by eliminating *both* artificial trans fat (when mentioning commercially prepared foods) and natural trans fat (when mentioning dairy products and meats). Yet, in the tentative determination, the FDA describes the IOM quote cited above as indicating only that eliminating natural trans fat would be problematic, not artificial trans fat.

Unintended Consequences

It remains unclear which ingredients would replace artificial trans fat if they were eliminated. By not addressing the likely impact on food reformulation and individual diets, the FDA could very well be creating more health problems that it would allegedly be solving.

Consumers could choose different foods to eat as a result of reformulation making the products less palatable—trans fat improves taste, texture, and increases shelf life, among other benefits that the FDA ignores. The replacement products consumed by individuals could lead to an overall diet that is worse than their current diet.

There is also ever-changing knowledge regarding nutrition. Removing an ingredient from the food supply may later turn out to have been based on flawed science. Ironically, the current use of trans fat was a response to previous efforts to demonize alternative ingredients, such as saturated fats,¹⁴ by some activist groups. The federal government's experience making mistakes regarding dietary decisions (e.g., 1992 food pyramid encouraging carbohydrate consumption, not distinguishing between fats) should give the FDA pause.

What Congress Should Do

- Congress should not view this issue as merely about trans fat. This issue is much broader and is about the FDA's powers under the FD&C Act. While it is unlikely that the FDA would seek to ban caffeine, sugar, and sodium that is added to food, these added ingredients are likely to be targets of future regulation. It may start through voluntary measures, but that would be the first step toward mandatory regulation.
- Congress should amend the FD&C Act to clarify that the FDA is not authorized to regulate food ingredients based on chronic diseases connected to individual dietary choices and nutrition: *Unhealthy* is not the same as *unsafe*. When it comes to diet, chronic diseases may be caused by numerous factors that could have nothing to do with a specific food ingredient.

Inevitable Overreach

Individuals do not need the FDA to protect them from themselves. This is precisely what the de facto artificial trans fat ban is trying to accomplish. When trying to address chronic disease connected to dietary choices through regulation, the FDA would inevitably be forced to restrict or limit food availability and the personal choices that individuals freely make on their own. No government body or agency should ever have that kind of power.

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Endnotes:

1. *Federal Register*, Vol. 78, No. 217 (November 8, 2013), pp. 67169–67175.
2. According to the FDA, “*Trans* fat wouldn’t be completely gone...because it also occurs naturally in small amounts in meat and dairy products. It is also present at very low levels in other edible oils, such as fully hydrogenated oils, where it is unavoidably produced during the manufacturing process.” U.S. Department of Health and Human Services, Food and Drug Administration, “FDA Targets *Trans* Fat in Processed Foods,” November 7, 2013, <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm372915.htm> (accessed March 6, 2014).
3. The FDA used this same comparison. The 2003 number, though, is based on FDA data for individuals 20 years of age or more, whereas the 2012 intake number is based on data for individuals two years of age or more. In footnote 8 of the tentative determination, the FDA explains, “While we did not calculate a mean intake for ages 20 years or more, based on the similarity in the intakes calculated for children aged 2–5 years, teenage boys, and persons aged 2 years or more (Ref. 8), we believe there would not be a significant difference between the intake estimated for persons ages 2 years or more and that for persons ages 20 years or more.”
4. The 2010 and 2012 estimates are both based on intake for individuals two years of age or more. See Michael Taylor, “*Trans* Fat: Taking the Next Important Step,” U.S. Food and Drug Administration, November 7, 2013, <http://blogs.fda.gov/fdavoices/index.php/2013/11/trans-fat-taking-the-next-important-step/> (accessed July 2, 2014).
5. American Heart Association, “*Trans* Fats Q&A,” November 8, 2013, http://www.heart.org/HEARTORG/GettingHealthy/FatsAndOils/Fats101/Trans-Fats_UCM_301120_Article.jsp (accessed July 2, 2014).
6. According to the Centers for Disease Control and Prevention, “Naturally occurring *trans* fat is found in small amounts in the fatty parts of meat and dairy products. Artificial *trans* fat comes from foods that contain partially hydrogenated oil and is formed when hydrogen is added to liquid oil turning it into solid fat.” See this CDC web page on *trans* fat at <http://www.cdc.gov/nutrition/everyone/basics/fat/transfat.html> (accessed July 1, 2014). As explained in footnote 1, artificial *trans* fat can also occur at very low levels in other edible oils, such as fully hydrogenated oils. For purposes of the tentative determination, the FDA is focusing on artificial *trans* fat from PHOs.
7. This is apparently the latest data that the FDA has on natural *trans* fat consumption.
8. Ingeborg A. Brouwer, Anne J. Wanders, and Martijn B. Katan, “Effect of Animal and Industrial *Trans* Fatty Acids on HDL and LDL Cholesterol Levels in Humans – A Quantitative Review,” *PLoS ONE*, Vol. 5, No. 3 (March 2010), <http://www.plosone.org/article/fetchObject.action?uri=info%3Adoi%2F10.1371%2Fjournal.pone.0009434&representation=PDF> (accessed July 2, 2014).
9. “Human consumption of naturally occurring [*trans* fatty acids] from ruminants is generally low and there is evidence to suggest that it does not adversely affect health.” Shauna Downs, Anne Marie Thow, and Stephen R. Leeder, “The Effectiveness of Policies for Reducing Dietary *Trans* Fat: A Systematic Review of the Evidence,” *Bulletin of the World Health Organization*, Vol. 91, No. 4 (April 2013), pp. 262–269, <http://www.ncbi.nlm.nih.gov/pubmed/23599549> (accessed July 2, 2014). See also Sarah K. Gebauer et al., “Effects of Ruminant *trans* Fatty Acids on Cardiovascular Disease and Cancer: A Comprehensive Review of Epidemiological, Clinical, and Mechanistic Studies,” *Advances in Nutrition*, Vol. 2 (July 2011), pp. 332–354, <http://advances.nutrition.org/content/2/4/332.long> (accessed July 2, 2014). Also, only recently has there been a focus on distinguishing between artificial and natural *trans* fat. According to the article, “Traditionally, intake of total TFA was considered independent of the origin (ruminant [natural] vs. industrially produced); however, more recent studies have separately estimated intake of rTFA [natural *trans* fat].”
10. Grocery Manufacturers Association, “Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information; Extension of Comment Period,” public comment to the Food and Drug Administration, March 7, 2014, p. 31, <http://www.regulations.gov/#!documentDetail;D=FDA-2013-N-1317-0172> (accessed July 1, 2014). There are many other comments in the docket that address this issue as well.
11. National Research Council, *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients)* (Washington, DC: National Academies Press, 2005), http://www.nap.edu/catalog.php?record_id=10490 (accessed July 2, 2014).
12. U.S. Department of Agriculture, *Dietary Guidelines for Americans, 2010*, January 31, 2011, <http://www.cnpp.usda.gov/DGAs2010-PolicyDocument.htm> (accessed July 2, 2014).
13. National Research Council, *Dietary Reference Intakes*. Emphasis added.
14. See, e.g., Mike Ciandella, “Networks Ignore CSPI’s Hypocrisy in *Trans* Fat Controversy,” *NewsBusters*, November 13, 2013, <http://newsbusters.org/blogs/mike-ciandella/2013/11/13/network-ignore-cspi-hypocrisy-trans-fat-controversy> (accessed July 2, 2014).