The Heritage Foundation

ISSUE BRIEF

No. 4155 | FEBRUARY 28, 2014

Is the FDA Getting Out of Control?

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Acting on its own volition, the Food and Drug Administration (FDA) is using the regulatory process to gain unprecedented control of food policy and remove dietary choices from Americans. Similar to the Environmental Protection Agency (EPA), the FDA is pushing extreme policies to regulate in areas that have never been federally regulated. Recent examples highlight this disturbing trend.

Eliminating Trans Fat. In November 2013, the FDA issued a preliminary determination that partially hydrogenated oils, which are the major dietary source of trans fat in processed food, are not "generally recognized as safe" (GRAS).[1] This could be the first step in effectively banning artificial trans fat.[2] "If FDA determines that [partially hydrogenated oils] are not GRAS, it could, in effect, mean the end of artificial, industrially-produced *trans* fat in foods, says Dennis M. Keefe, Ph.D., director of FDA's Office of Food Additive Safety."[3]

As a result, the FDA would be making an extreme shift from protecting the public from *unsafe* food to banning a nutritionally *unhealthy* ingredient. It is a distinction not without difference. The FDA would be taking away choices, disrespecting the ability of Americans to make informed and voluntary choices regarding trans fat.

This would likely be just the start of what could be an attack on dietary decisions. Consuming *some* trans fat does not lead to serious illness or death, but of course, as with most things, the dose makes the poison. If individuals choose to consume a significant amount of trans fat over their lives, this may have an impact on their health, but that should be their choice.

Banning trans fat may result in higher food prices because of the potentially costly transition away from trans fat, and some companies may not be able to make the transition for some products. The newly formulated food may not match the taste, texture, and/or shelf lives of foods with trans fat.

This power grab is particularly egregious given the trends in trans fat consumption. According to the FDA, "consumption of trans fat from products containing partially hydrogenated oils has declined dramatically from 4.6 grams per day in 2003 to about 1 gram per day in 2012."[4] The public is already taking the FDA's desired action. In addition, the FDA has a trans fat labeling requirement in place.

Agency Action on Sodium. The FDA is going after sodium, which is an ingredient that is safe but can be unhealthy depending on consumption levels and individual health. The FDA's focus is on sodium added to food (as opposed to naturally occurring sodium). For practical reasons alone, it is unlikely that the FDA would ban added sodium, but the agency does have plans to take some sort of action to reduce sodium consumption beyond existing labeling requirements.

The FDA's Center for Food Safety and Applied Nutrition[5] lists the following objectives:

This paper, in its entirety, can be found at **http://report.heritage.org/ib4155**

Produced by the Thomas A. Roe Institute for Economic Policy Studies

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- "Advance plan for promoting broad, gradual reduction of added sodium in the food supply";

- "Complete a plan for implementation in 2015 to promote broad, gradual reduction of added sodium in the food supply."

The agency website states that the FDA "has not exercised its regulatory authority to limit the amount of salt added to processed foods; however, the agency is conducting research in this area."[6] In 2010, the FDA sponsored the Institute of Medicine report, *Strategies to Reduce Sodium Intake in the United States*,[7] and was reviewing the report's recommendations.[8] The primary recommendation was that the FDA "should expeditiously initiate a process to set a mandatory national standards [*sic*] for the sodium content of foods."[9]

Given the agency's overreaching proposed ban on trans fat, along with the FDA's recent efforts connected to sodium, the agency is likely going to try to regulate sodium content.

The Menu Labeling Rule. Obamacare requires restaurant chains to provide caloric and other nutritional information to customers on standard menu items.[10] Specifically, the law applies to "restaurants or similar retail food establishments."[11] By interpreting this statutory language very broadly, the FDA is proposing to impose the menu labeling rule on grocery and convenience stores,[12] creating greater costs and more intrusions into consumer decisions.

A retail food establishment is regulated under the FDA's proposed rule if it offers any food that is prepared and processed on site even if not intended for immediate consumption. The agency's interpretation is so extreme that if 99 percent of a grocery store's floor space is devoted to packaged goods but 1 percent is devoted to a deli counter, that 1 percent would allow the FDA to force the rule on the grocery store.[13]

Practically, the FDA is ignoring the word *similar*. A grocery or convenience store, by any reasonable interpretation, is not similar to a restaurant. This overboard interpretation will mean significant costs to regulated businesses, and those costs will certainly be passed on to consumers in the form of higher food prices. The FDA estimates that first-year compliance costs could be as high as $537 million for all regulated businesses covered under the rule, with recurring costs of as much as $64 million

1. *Federal Register*, Vol. 78, No. 217 (November 8, 2013), pp. 67169–67175, https://www.federalregister.gov/articles/2013/11/08/2013-26854/tentative-determination-regarding-partially-hydrogenated-oils-request-for-comments-and-for (accessed February 12, 2014).
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," http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm372915.htm (accessed February 26, 2014).
3. Ibid.
4. Michael Taylor, "Trans Fat: Taking the Next Important Step," FDAVoice , November 7, 2013, http://blogs.fda.gov/fdavoice/index.php/2013/11/trans-fat-taking-the-next-important-step/ (accessed February 12, 2014).
5. FDA, "Center for Food Safety and Applied Nutrition (CFSAN) Plan for Program Priorities, 2013–2014," September 4, 2013, http://www.fda.gov/aboutfda/centersoffices/officeoffoods/cfsan/whatwedo/ucm366279.htm (accessed February 12, 2014).
6. FDA, "Lowering Salt in Your Diet," November 15, 2013, http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm181577.htm (accessed February 12, 2014).
7. Institute of Medicine of the National Academies, *Strategies to Reduce Sodium Intake in the United States*, April 4, 2010, http://www.iom.edu/Reports/2010/Strategies-to-Reduce-Sodium-Intake-in-the-United-States.aspx (accessed February 12, 2014).
8. FDA, "Lowering Salt in Your Diet."
9. Institute of Medicine of the National Academies, "Strategies to Reduce Sodium Intake."
10. See Daren Bakst, "Obamacare's Menu Labeling Law: The Food Police Are Coming," Heritage Foundation *Issue Brief* No. 4008, August 6, 2013, http://www.heritage.org/research/reports/2013/08/obamacare-s-menu-labeling-law-the-food-police-are-coming.
11. The Patient Protection and Affordable Care Act, Public Law 111–148, Section 4205.
12. *Federal Register*, Vol. 76, No. 66 (April 6, 2011), pp. 19191–19236.
13. Ibid. See the definitions of "restaurant or similar retail food establishment," "restaurant food," and "restaurant-type food," as well as the preamble that discusses the coverage of the rule, such as on p. 19198.

annually.[14] These numbers are likely very conservative. According to an industry estimate for supermarkets only, the rule could cost more than $1 billion in the first year alone, with recurring annual costs in the hundreds of millions.[15]

The menu labeling requirement also presumes that consumers make misinformed decisions and need government intervention.[16] This intrusiveness, along with the added cost, is especially troubling since the agency did not even quantify any benefits to its proposed regulation: "Food choice and consumption decisions are complex, and FDA is unaware of any comprehensive data allowing accurate predictions of the effect of the proposed requirements on consumer choice and establishment menus."[17]

Solutions to Address the Overreach. Congress should:

- **Rein in the FDA.** The FDA is interpreting and applying laws in a way that is inconsistent with the plain language and/or intent of Congress. Congress should reassert its power to rein in the agency.

- **Clarify that food safety does not mean restricting personal dietary choices.** It is now up to Congress to quickly get control of this situation before the FDA goes too far down the path toward government interference in personal food choices.

- **Ensure that the FDA does not divert resources from food safety to food control.** Ironically, the FDA is currently complaining that it does not have enough money to properly implement the Food Safety Modernization Act (FSMA), a sweeping and very flawed law.[18] Yet this is the same agency that is diverting resources and attention away from FSMA to its extreme food control agenda. FDA complaints about FSMA funding should not be taken seriously until the agency itself shows that it is focused on FSMA and not going on extreme tangents to push nutrition activist–type policies.[19]

An Arrogant Assumption. The FDA appears to be advancing a new public health paradigm that is based on the arrogant assumption that bureaucrats have the ability to accurately influence and even limit what people can eat. Food choices should be made freely by each individual based on his or her own preferences, not by bureaucrats in Washington, D.C.

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14. FDA, "Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments Notice of Proposed Rulemaking, Preliminary Regulatory Impact Analysis," March 2011, p. 44, http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/UCM249276.pdf (accessed February 18, 2014).
15. Food Marketing Institute, comment regarding Food and Drug Administration, "Food Labeling," November 21, 2011, p. 8, http://www.fmi.org/docs/newsletters-comments/omb-menu-labeling---omb-review-pursuant-to-executive-order-12866-and-13563.pdf?sfvrsn=2 (accessed February 18, 2014).
16. FDA, "Food Labeling," pp. 3–6.
17. Ibid.
18. Hearing, *Examining the Implementation of the Food Safety Modernization Act*, Committee on Energy and Commerce, U.S. House of Representatives, February 5, 2014, http://energycommerce.house.gov/hearing/examining-implementation-food-safety-modernization-act#video (accessed February 12, 2014). See also Lydia Zuraw, "Taylor: FDA Needs More Resources for FSMA Implementation," *Food Safety News*, February 6, 2014, http://www.foodsafetynews.com/2014/02/fda-needs-more-resources-for-fsma-implementation/#.UvuIqF8o7L8 (accessed February 12, 2014).
19. The substance of FSMA and the implementation schedule need to be carefully reviewed by Congress, and at a minimum, the law needs some reform.