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The FDA Must Stop Its Overreach and Start Respecting Consumer Freedom

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The Food and Drug Administration (FDA), unlike many federal agencies, is not cutting back on its significant federal overreach. Instead of undoing some of the Obama Administration's most harmful regulations, the FDA is implementing them and finding new means of federal intervention, at least when it comes to food and tobacco policy. This *Issue Brief* provides just four examples of this big-government mindset.

Menu Labeling Rule

The Affordable Care Act (Obamacare) includes a provision that requires restaurant chains to provide caloric and other nutritional information to customers on standard menu items.[1]

This provision is misguided. Restaurants, for example, which are in a very highly competitive industry, already have an incentive to provide nutritional information if consumers demand it.[2] Regardless of the policy problems with this provision, the FDA is required to issue a rule to implement it.

The menu labeling law[3] specifically applies to "restaurants and similar retail food establishments."[4] The Obama Administration's FDA interpreted this language to mean that even grocery stores, convenience stores, and movie theaters, among other non-restaurant businesses, are required to label their menus.[5]

A convenience store, for example, is not "similar" to a restaurant—they both might serve prepared food, but no reasonable person thinks they are in the same line of business. The FDA, though, took an unreasonably broad interpretation of the language and ignored the word "similar."

There may be limited situations where, for example, a grocery store could devote most of its floor space to selling prepared foods like a restaurant. In this context, the grocery store might reasonably be considered a retail food establishment that is "similar" to a restaurant.

There are approaches, such as examining a business's primary activity, use of floor space, or sources of revenue, which could help determine whether a business should be covered under the law. In fact, the FDA had considered and rejected such approaches in favor of its broad and unsupported interpretation of the statute.[6]

Instead of withdrawing this rule and issuing a new rule that would properly interpret the law, the FDA under the Trump Administration has moved forward with enforcing this Obama-era rule that is inconsistent with the plain language of the law.[7]

Produce Safety Rule

The Food Safety Modernization Act (FSMA),[8] signed into law by President Barack Obama in 2011, requires the FDA to address potential food contamination connected with the production and harvesting of fruits and vegetables. Specifically, the FDA must develop science-based minimum standards for the production and harvesting of fruits and vegetables that are raw agricultural commodities. Under FSMA, the FDA was required to develop a final rule based on known safety risks.[9]

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However, the FDA's 2015 final rule[10] developed standards for produce that are *not* associated with outbreaks of foodborne illnesses or otherwise connected to known risks. The FDA did not take a *broad* interpretation of FSMA's language; instead, it *ignored* FSMA's language by finalizing a rule that is not risk-based (focused on where there are likely risks).

The FDA argued that it was appropriate to cover commodities that have never caused an outbreak because those commodities could cause an outbreak in the future. In its economic analysis of the proposed rule, the FDA explained that "it is likely that at least some commodities that currently have never been implicated in an outbreak have a positive probability of being implicated in a future outbreak."[11]

A Mercatus Center report succinctly captured the absurdity of this logic: "This argument, if followed to its logical end, would not allow exemptions for any product for any health or safety rule ever."[12]

Unfortunately, the FDA is moving forward with the rule's implementation.

Milk Intervention

The FDA is not merely implementing Obama Administration overreach, but looking to create even more overreach. One of the most egregious examples[13] is the FDA's efforts regarding alleged consumer confusion over plant-based products that use dairy-related terms in their names, such as "almond milk."

Consumers *know* that almond milk does not come from cows. They are not confused and unable to distinguish between dairy products and plant-based products. The use of the word "almond" or "soy" before the word "milk" informs the consumer in a clear manner that the product is not milk from cows. (The whole point of listing words such as "almond" before "milk" is to indicate to the consumer that it is not milk from cows.)

1. The Patient Protection and Affordable Care Act, Public Law 111–148, Section 4205, https://www.gpo.gov/fdsys/pkg/BILLS-111hr3590enr/pdf/BILLS-111hr3590enr.pdf (accessed October 25, 2018).
2. For more policy arguments against this provision, see Daren Bakst, "Obamacare's Menu Labeling Law: The Food Police Are Coming," Heritage Foundation *Issue Brief* No. 4008, August 6, 2013, https://www.heritage.org/agriculture/report/obamacares-menu-labeling-law-the-food-police-are-coming.
3. To learn more about the menu labeling law, see Daren Bakst, "Obamacare's Menu Labeling Law: The Food Police Are Coming," Heritage Foundation *Issue Brief* No. 4008, August 6, 2013, https://www.heritage.org/agriculture/report/obamacares-menu-labeling-law-the-food-police-are-coming, and Daren Bakst, "Government Control of Your Diet: Threats to 'Freedom to Eat,'" Heritage Foundation *Issue Brief* No. 4033, September 3, 2013, https://www.heritage.org/health-care-reform/report/government-control-your-diet-threats-freedom-eat.
4. The Patient Protection and Affordable Care Act, Public Law 111–148, Section 4205.
5. U.S. Food and Drug Administration, "Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments," *Federal Register*, Vol. 79, No. 230 (December 1, 2014), pp. 71155–71259, https://www.federalregister.gov/documents/2014/12/01/2014-27833/food-labeling-nutrition-labeling-of-standard-menu-items-in-restaurants-and-similar-retail-food (accessed October 24, 2018).
6. Ibid.
7. U.S. Food and Drug Administration, "Menu Labeling Requirements," https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm515020.htm (accessed October 24, 2018).
8. The Food Safety Modernization Act of 2011, Public Law No. 111–353, https://www.gpo.gov/fdsys/pkg/PLAW-111publ353/pdf/PLAW-111publ353.pdf (accessed October 25, 2018).
9. U.S. Food and Drug Administration, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," Final Rule, *Federal Register*, Vol. 80, No. 228 (November 27, 2015), pp. 74353–74672, https://www.federalregister.gov/documents/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption (accessed October 24, 2018).
10. Ibid.
11. U.S. Food and Drug Administration, "Analysis of Economic Impacts—Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption," https://www.fda.gov/downloads/food/guidanceregulation/fsma/ucm334116.pdf (accessed October 24, 2018).
12. Richard Williams, "Regulations Implementing the Food Safety Modernization Act," Mercatus Center *Working Paper*, August 2015, https://www.mercatus.org/system/files/Williams-FSMA-Regulations.pdf (accessed October 24, 2018).
13. News release, "Statement from FDA Commissioner Scott Gottlieb, M.D., on Modernizing Standards of Identity and the Use of Dairy Names for Plant-Based Substitutes," U.S. Food and Drug Administration, September 27, 2018, https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm621824.htm (accessed October 23, 2018), and U.S. Food and Drug Administration, "Use of the Names of Dairy Foods in the Labeling of Plant-Based Products, Request for Comments," Docket No. FDA-2018-N-3522, September 28, 2018, https://www.regulations.gov/document?D=FDA-2018-N-3522-0001 (accessed October 24, 2018).

An International Food Information Council Foundation survey in October 2018 found that consumers were generally not confused: "when looking at front labels of cow's milk and plant-based products, less than 1 in 10 [of respondents] believe that branded versions of soy milk, almond milk, cashew milk, and rice milk contain milk from cows."[14] These numbers reflect a representative survey of Americans; those who specifically seek out plant-based products, such as almond milk, are certainly unlikely to be confused.

Consumers also are very unlikely to assume that the nutritional profiles for different products are the same.[15] And, there is nutritional information right on the packages.

Unfortunately, the FDA is using its time—and taxpayer resources—to address this non-problem. The agency is taking initial steps[16] in potentially developing restrictions on the use of terms such as "almond milk." In September 2018, it published a request for information,[17] seeking public comments on the dairy-related names of plant-based products. Ironically, if the FDA does restrict the use of these names, it could create a situation where food companies have to develop new names that will lead to the very consumer confusion that the FDA claims it wants to prevent.

There would be one winner for this misguided overreach: the dairy industry, which is trying to stop plant-based products from using terms like "milk" in their names.[18] It is a useful way to limit competition and undermine innovative products that can better meet the needs of consumers.[19]

Tobacco Harm Reduction

In recent years, there have been innovations in the marketplace that give cigarette smokers a path to stop smoking. These products, such as e-cigarettes and heat-not-burn products,[20] appear to be much less harmful ways of delivering nicotine. For example, in a government-commissioned report, Public Health England estimated that using e-cigarettes could be 95 percent less harmful than smoking tobacco cigarettes.[21] To its credit, in a 2017 statement, the FDA apparently embraced the idea of tobacco harm reduction,[22] which is the idea that smokers should have access to products that meet their nicotine needs in ways that are less harmful than cigarettes.[23]

Since then, the FDA's actions and inactions do not reflect the sentiment expressed in the statement. The FDA has, for example:

14. The International Food Information Council Foundation, "Consumer Attitudes About Labeling Cow's Milk, Plant Based and Non-Dairy Alternatives," October 2018, https://www.foodinsight.org/sites/default/files/Milk%20Nomenclature_PDF_1.pdf (accessed October 24, 2018).
15. Judge Vince Chhabria, a California federal district court judge, nicely captured this point: "But a reasonable consumer (indeed, even an unsophisticated consumer) would not assume that two distinct products have the same nutritional content." *Gitson v. Trader Joe's*, Case No. 13-cv-01333-VC, (N.D. Cal. December 1, 2015), https://www.foodlitigationnews.com/wp-content/uploads/sites/12/2015/12/Gitson-v.-Trader-Joes-Co.-Order.pdf (accessed October 24, 2018).
16. News release, "Statement from FDA Commissioner Scott Gottlieb, M.D., on Modernizing Standards of Identity and the Use of Dairy Names for Plant-Based Substitutes," and U.S. Food and Drug Administration, "Use of the Names of Dairy Foods in the Labeling of Plant-Based Products, Request for Comments."
17. U.S. Food and Drug Administration, "Use of the Names of Dairy Foods in the Labeling of Plant-Based Products, Request for Comments."
18. Molly Roberts, "Big Dairy Is Going After Your Almond Milk," *The Washington Post*, July 24, 2018, https://www.washingtonpost.com/blogs/post-partisan/wp/2018/07/24/big-dairy-is-going-after-your-almond-milk/?utm_term=.c4c097a4d630 (accessed October 24, 2018).
19. For a helpful and brief discussion on the cronyism issue, see Senator Mike Lee (R–UT), "The War on Almond Milk," July 27, 2018, https://www.lee.senate.gov/public/index.cfm/2018/7/the-war-on-almond-milk (accessed October 24, 2018).
20. Guy Bentley, "Heat-Not-Burn Tobacco: The Next Wave of a Harm-Reduction Revolution," *Forbes*, https://www.forbes.com/sites/realspin/2017/03/15/heat-not-burn-tobacco-the-next-wave-of-a-harm-reduction-revolution/#655a005f6292 (accessed October 24, 2018).
21. Government of the U.K., Public Health England, "E-Cigarettes Around 95% Less Harmful Than Tobacco Estimates Landmark Review," August 19, 2015, https://www.gov.uk/government/news/e-cigarettes-around-95-less-harmful-than-tobacco-estimates-landmark-review (accessed October 24, 2018).
22. News release, "FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death," U.S. Food and Drug Administration, July 28, 2017, https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm568923.htm (accessed July 16, 2018).
23. To learn more about tobacco harm reduction and some of the obstacles for alternative nicotine-delivery products, see Daren Bakst, "FDA, Congress Should Not Block Critical Alternatives to Smoking," *The Washington Times*, August 20, 2018, https://www.washingtontimes.com/news/2018/aug/20/fda-congress-should-not-block-critical-alternative/ (accessed October 24, 2018), and Daren Bakst, "Rethinking Tobacco Policy: The Federal Government Should Stop Blocking Alternatives to Smoking," Heritage Foundation *Issue Brief* No. 4657, February 24, 2017, https://www.heritage.org/government-regulation/report/rethinking-tobacco-policy-the-federal-government-should-stop-blocking.

- **Proposed reducing nicotine in cigarettes to non-addictive or minimally addictive levels.**[24] Such a move would be, for all practical purposes, a ban on cigarettes. The government would be trying to force smokers to stop smoking cigarettes, even if they do not want to.

  Such a move would also have many unintended consequences. Most smokers are addicted to nicotine. If the alternatives for nicotine delivery are not appealing to some smokers, or worse, if the FDA restricts their availability, these smokers would likely find other ways to get their nicotine, such as through the black market. They might smoke even more cigarettes to get their nicotine fix, creating additional health problems.

- **Threatened in a FDA statement to "curtail the marketing and selling of flavored products"**[25] (e-cigarettes) and published a notice[26] seeking public comment on issues, such as whether the agency should prohibit flavors for tobacco products, including for the less-harmful alternative products. While the FDA may reasonably be concerned with how flavors impact youth usage of alternative products, restricting or prohibiting flavors could make the products less appealing to adults who want to quit cigarette smoking; flavors can help entice adult smokers to use alternative products.[27]

What the FDA Should Do

The FDA's work should reflect the overarching goals of the Trump Administration to reduce federal overreach and respect the rule of law, while taking appropriate steps to protect public health and safety. The FDA should:

- **Repeal the menu labeling rule and issue a new rule properly defining what types of businesses should be covered under the law.** This means generally excluding grocery stores, convenience stores, movie theaters, and other businesses that are not similar to restaurants.

- **Repeal the FSMA final rule and issue a new rule that is risk-based as required by the law.** Specific changes[28] should include:

  - Regulating only those commodities that have caused a foodborne-illness outbreak over the past 10 years.

  - Clarifying that such an outbreak should be directly caused by on-farm practices, because outbreaks, even if it can be shown that they are caused by a specific commodity, could be attributed to off-farm activities such as transportation, retail practices, or actions taken by the consumer.

- Requiring that independent, peer-reviewed risk assessments be used in determining which commodities should be regulated.

- **Stop trying to address alleged consumer confusion over whether plant-based products with dairy-related terms in their names, such as almond milk, are dairy products.** This is a classic example of a solution in search of a problem.

24. U.S. Food and Drug Administration, "Tobacco Product Standard for Nicotine Level of Combusted Cigarettes," Proposed Rule, *Federal Register*, Vol. 83, No. 52 (March 16, 2018), pp. 11818–11843, https://www.federalregister.gov/documents/2018/03/16/2018-05345/tobacco-product-standard-for-nicotine-level-of-combusted-cigarettes (accessed October 24, 2018).
25. News release, "Statement from FDA Commissioner Scott Gottlieb, M.D., on New Steps to Address Epidemic of Youth E-Cigarette Use," U.S. Food and Drug Administration, September 12, 2018, https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm (accessed October 24, 2018).
26. U.S. Food and Drug Administration, "Regulation of Flavors in Tobacco Products," Advance notice of proposed rulemaking *Federal Register*, Vol. 83, No. 55 (March 21, 2018), pp. 12294–12301, https://www.federalregister.gov/documents/2018/03/21/2018-05655/regulation-of-flavors-in-tobacco-products (accessed October 24, 2018).
27. See, for example, Michelle Minton, "For Sake of Public Health, FDA Should Not Ban E-Cigarette Flavors," Competitive Enterprise Institute, July 16, 2018, https://cei.org/blog/sake-public-health-fda-should-not-ban-e-cigarette-flavors (accessed October 24, 2018).
28. For more recommended changes and discussion on FSMA, see Daren Bakst, "How Congress Can Stop the FDA's Attempt to Micromanage Farming Through the Food Safety Modernization Act," Heritage Foundation *Issue Brief* No. 4741, July 25, 2017, https://www.heritage.org/agriculture/report/how-congress-can-stop-the-fdas-attempt-micromanage-farming-through-the-food.

- **Embrace tobacco harm reduction.** This means removing unnecessary obstacles that block adult smokers from having access to alternative nicotine delivery products. It also means directly addressing the specific and concrete problems of youth access to such products without undermining the nature and potential of the products that can help cigarette smokers stop smoking.

What Congress Should Do

Congress should pass legislation to ensure that the FDA is interpreting the law as Congress intended, and not creating unwarranted obstacles for consumers. The FDA recommendations listed above should be codified in statute, and the appropriations process should be used to achieve these objectives, if necessary.

Even if the FDA makes the necessary changes, a future Administration might revert back to the old policies. Through legislation, Congress can help to stop this from happening.

Conclusion

There are major issues at play connected to this FDA overreach, beyond whether the agency will properly interpret the law. There is a choice between two vastly different approaches on food policy: (1) the nation's food policy could be governed by a big government approach where federal bureaucrats think they know better than consumers what consumers should eat (the food police mentality), and (2) food policy could recognize that individuals should be allowed to make their own personal dietary decisions. Just because some Americans do not make the government's "preferred dietary decisions" does not make their individual choices wrong.

For one of the biggest public health issues (cigarette smoking), the federal government could prevent the market from providing solutions to help smokers, or it can remove obstacles so that a wide range of alternatives are available to adult smokers, while addressing any concerns regarding youth usage of these alternative nicotine delivery products.

Quite simply, these major issues are about whether food and tobacco policy will respect personal freedom and markets, or place its faith in federal bureaucratic control.

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