The FDA Must Stop Its Overreach and Start Respecting Consumer Freedom

*Daren Bakst*

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 law3 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-retail 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
However, the FDA's 2015 final rule 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.”

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.”

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 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.)

---

4. The Patient Protection and Affordable Care Act, Public Law 111–148, Section 4205.
6. Ibid.
10. Ibid.
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.” 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. 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 in potentially developing restrictions on the use of terms such as “almond milk.” In September 2018, it published a request for information, 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. It is a useful way to limit competition and undermine innovative products that can better meet the needs of consumers.

**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, 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. To its credit, in a 2017 statement, the FDA apparently embraced the idea of tobacco harm reduction, which is the idea that smokers should have access to products that meet their nicotine needs in ways that are less harmful than cigarettes.

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

---


17. U.S. Food and Drug Administration, “Use of the Names of Dairy Foods in the Labeling of Plant-Based Products, Request for Comments.”


Proposed reducing nicotine in cigarettes to non-addictive or minimally addictive levels.\textsuperscript{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”\textsuperscript{25} (e-cigarettes) and published a notice\textsuperscript{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.\textsuperscript{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\textsuperscript{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.


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.