

## MEMORANDUM

**From:** Steven B. Steinborn  
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**Date:** April 5, 2018

**Re:** **FDA Commissioner Gottlieb Announces New Nutrition Innovation Strategy**

On March 29, 2018, Food and Drug Administration (FDA or the agency) Commissioner Scott Gottlieb, M.D., delivered a nutrition-related policy address. <sup>1/</sup> The Commissioner emphasized FDA's role in helping Americans improve their nutrition as a step towards reducing chronic disease, with a particular focus on sodium reduction. The Commissioner's address provides important insight into the shape that FDA nutrition and health policy can be expected to take in the next few years.

### Role of FDA in Helping Americans Improve Their Diets

Commissioner Gottlieb opened his address with a discussion of the importance of prevention in managing chronic disease. Dr. Gottlieb likened the steps the agency has taken to reduce smoking rates to abate cancer, to the potential steps FDA could take to improve nutrition and diet in order to reduce the rates of chronic disease like obesity, heart disease, diabetes, and cancer. While the Commissioner acknowledged that there "are many contributing factors" to the increase in chronic disease, he believes nutrition plays a central role, citing an American College of Cardiology estimate that over 20 percent of deaths in 2015 were attributable to poor dietary factors. The Commissioner also stated that about 75 percent of the population has a diet low in vegetables, fruits, dairy, and healthy oils, and high in sugars, saturated fats, and sodium. When it comes to improving the diet and nutrition of Americans, the FDA, as the agency regulating 80 percent of the U.S. food supply, "has a critical role to play to help make this happen."

### Current Trends

Commissioner Gottlieb also discussed current consumer trends among Americans, including greater demand for healthful foods and access to information about the foods they eat. These trends have prompted food manufacturers to use innovative technology and reformulate products to increase fiber content, limit additives, and reduce sodium or sugar content. Dr. Gottlieb noted, however, that while consumer preferences for foods that are "minimally processed, lower in sugar, and produced with wholesome ingredients" have prompted industry change, this change has not been evenly distributed across socioeconomic lines, with some Americans lacking access to even a basic supermarket.

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<sup>1/</sup> A transcript of the speech is available at <https://www.fda.gov/NewsEvents/Speeches/ucm603057.htm>.

## The Nutrition Innovation Strategy

In order to facilitate improvements in the diet and nutrition of Americans, Dr. Gottlieb announced a multi-year Nutrition Innovation Strategy <sup>2/</sup> that will build on the 2018 Strategic Policy Roadmap released by FDA in January of this year. <sup>3/</sup> This strategy aims to “take a fresh look at what can be done to reduce preventable death and disease related to poor nutrition.”

The highlights of the strategy include:

- **Modernizing Claims**

Dr. Gottlieb emphasized the importance of claims on food packages – both as quick signals for consumers about the benefits of a food or beverage, and in encouraging manufacturers to reformulate products to improve their healthy qualities. Given this importance, the agency will work to modernize the claims regulatory framework in several ways. First, FDA intends to adopt a more streamlined review of health claims and qualified health claims by triaging requests according to public health significance.

Second, the agency will continue its efforts to update the regulatory definition of the term “healthy.” FDA intends to reduce the focus on specific nutrients, in favor of a more expansive dietary pattern approach that ties the regulatory definition to food groups. The agency will also consider a standardized display for “healthy” claims, such as an icon or symbol, to assist consumers in finding this information on food labels. More broadly, the agency will seek input on other possible changes to nutrient content claims that could facilitate innovation to promote healthful eating patterns. Recall that when FDA revamped the Nutrition Facts Panel it stated that it would next revisit regulation of nutrient content claims.

And finally, FDA will soon “have more to say” on “natural” claims. The agency acknowledges that consumers trust this term despite the lack of clarity around it. Moving forward, the FDA intends to consider the widely differing views on what criteria should apply to a “natural” claim, and aims to achieve a result that is “based in science.”

- **Modernizing Ingredient Labels**

Under the new strategy, FDA is currently considering what changes could make ingredient information more consumer-friendly. In addition to readability, this includes considering whether simpler alternative names for certain ingredients could be used so they are more understandable (for example, “vitamin B6” instead of “pyridoxine,” and alternative names for “potassium chloride”). Consumers want “clean labels,” and both manufacturers and the agency will have a role in their development.

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<sup>2/</sup> More information on the FDA’s Nutrition Innovation Strategy is available at <https://www.fda.gov/Food/LabelingNutrition/ucm602651.htm>.

<sup>3/</sup> The Strategic Policy Roadmap is available at <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM592001.pdf>. A Hogan Lovells memorandum regarding food priorities of the Strategic Policy Roadmap is available at [https://www.hfoodlaw.com/wp-content/uploads/sites/357/2018/02/HL-Memo-FDA\\_s-2018-Strategic-Policy-Roadmap.pdf](https://www.hfoodlaw.com/wp-content/uploads/sites/357/2018/02/HL-Memo-FDA_s-2018-Strategic-Policy-Roadmap.pdf).

- **Implementing the Nutrition Facts Label and Menu Labeling**

FDA intends to finalize its draft guidance for menu labeling requirements “soon,” in anticipation of the May 7, 2018 compliance date. With respect to the updated Nutrition Facts Panel requirements, Dr. Gottlieb did not indicate when the proposed compliance date of January 1, 2020 for large manufacturers would be finalized. FDA will be launching a “major educational campaign” for consumers surrounding the new nutrition information, with a focus on helping consumers understand daily caloric needs and providing suggestions on “simple swaps” (such as swapping out lemonade for a lower calorie seltzer with lemon) to reduce calories.

- **Modernizing Standards of Identity**

Although FDA believes that standards of identity continue to serve an important purpose in facilitating consumer knowledge of what is in standardized products, the agency aims under its new strategy to take a fresh look at existing standards in light of marketing trends and the latest nutritional science. Dr. Gottlieb gave the examples of (1) examining current restrictions in the cheese standards of identity on the use of salt substitutes that could be used to reduce sodium; and (2) the requests to modernize the yogurt standard of identity to support innovations occurring in the category. FDA will also look to eliminate unnecessary standards. The Commissioner emphasized that public health will remain the priority, but that the agency wants to allow industry more flexibility for innovation.

- **Sodium Reduction**

Stating that there is “no single more effective public health action related to nutrition than the reduction of sodium in the diet,” Dr. Gottlieb announced FDA’s plans to advance the short-term voluntary sodium reduction targets initially proposed in 2016 via a draft guidance document. FDA intends to align its approach with the Dietary Reference Intake (DRI) being conducted by the National Academies. The DRI is anticipated to be finalized in 2019 and FDA plans to release its updated short-term targets the same year.

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Dr. Gottlieb’s address sheds light on how the agency intends to use available resources to maximize FDA’s ability to improve dietary practices that are associated with disease-related risks. Food companies and other stakeholders will be well-served to carefully study the merits and implications of the various FDA initiatives.

We will continue to monitor FDA’s actions related to nutrition and labeling. Please contact us if you have any questions.