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April 26, 2017  
By electronic submission

Scott Gottlieb, M.D.  
Director  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Response to FDA Request for Comment on the Use of  
the Term “Healthy” in the Labeling of Human Food Products,  
81 Fed. Reg. 66562 (Sept. 28, 2016); FDA Docket No. 2016-D-2335

Dear Dr. Gottlieb:

The FDA has issued a Guidance for Industry on the “Use of the Term ‘Healthy’ in the Labeling of Human Food Products,” and opened a docket and invited public comments on how the FDA should allow words such as “healthy,” “health,” “healthful,” “healthfully,” “healthfulness,” “healthier,” “healthiest,” “healthily,” and “healthiness” to be used on food package labeling. The FDA asks what criteria should be used to consider whether a particular food product may be labeled as “healthy”; for example, whether it should be based only on nutrient content (as defined by the FDA’s *Dietary Guidelines*).

These comments are filed jointly on behalf of our clients, the Center for Medical Freedom, The Senior Citizens League, United States Justice Foundation, and Downsize DC Foundation.

### **Identity of Commenters**

The Center for Medical Freedom (“CMF”) ([www.centerformedicalfreedom.org](http://www.centerformedicalfreedom.org)) is a project of the Conservative Legal Defense and Education Fund, which was founded in 1985 as a nonprofit, non-partisan educational organization, incorporated under the laws of Virginia, and is tax-exempt under Section 501(c)(3) of the Internal Revenue Code (“IRC”). CMF’s mission is to educate members of the public about their right to make their own personal medical and healthcare choices, and their inherent right of self-defense to resist efforts by government at all levels to restrict and control those choices.

The Senior Citizens League (“TSCL”) ([www.tscl.org](http://www.tscl.org)) is a nonprofit, non-partisan social welfare organization incorporated under the laws of Colorado, and is tax-exempt under Section 501(c)(4) of the Internal Revenue Code of 1986. TSCL, headquartered in Alexandria, Virginia, is known as one of the largest U.S. nonprofit and nonpartisan organizations engaging in education and advocacy on behalf of senior citizens. Its mission is to educate the public and alert senior citizens about their rights and freedoms as U.S. citizens, to assist members and supporters regarding those rights, and to protect and defend the benefits senior citizens have earned.

TSCL has nearly one million senior citizen members and supporters. Its activities include monitoring developments in the United States with respect to the interests of senior citizens and defending those interests before government, developing educational materials designed to explain to senior citizens their various rights as U.S. citizens, raising the level of public awareness of senior citizens’ rights by conducting surveys and polls, and publishing and distributing informational newsletters to members, supporters, and the public.

The United States Justice Foundation (“USJF”), located in Ramona, California, is a legal defense and educational organization, founded in 1979, and is also tax-exempt under IRC Section 501(c)(3). More information about USJF can be found at [www.usjf.net](http://www.usjf.net).

Downsize DC Foundation is an educational organization supporting a smaller federal government as envisioned by the U.S. Constitution.

### Comments

The Food and Drug Administration (“FDA”) continues to operate as one of this country’s most notorious central planning agencies. This recent rulemaking reveals that the FDA believes that Americans will eat healthy, be healthy, and live long, happy lives — if only the FDA issues enough regulations.

The FDA generally couches its controls over Americans in terms of providing better information so consumers are free to choose, yet the rules it adopts regularly treat Americans as ignorant children needing parental FDA guidance. Moreover, the FDA’s regulations typically limit choices available to consumers — always allegedly for their own good:

FDA’s nutrition-related strategic goals include: Providing and supporting accurate and useful nutrition information **to consumers so they can choose** healthier diets consistent with the Dietary Guidelines for Americans.... To that end, on “May 27, 2016, [FDA] issued final rules updating the Nutrition Facts label and serving size information for packaged foods [named] Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion.” [*Fed. Reg.* at 66563.]

Year after year, FDA bureaucrats expand their control over Americans with new regulations, often working with other agencies such as the Federal Trade Commission (“FTC”) in asserting government control over everything from a banana<sup>1</sup> to a bandana,<sup>2</sup> and from a baklava to a balaclava.

Although bureaucrats rarely ever question whether a program they administer actually works, that question seems reasonable to ask. And the answer is startling. Despite all regulation to make them healthier, Americans continue to eat “unhealthier” than ever.<sup>3</sup> On average, 57.9 percent of their diet consists of “ultra-processed foods.”<sup>4</sup> Half of Americans drink 2.6 glasses of soda per day.<sup>5</sup> Less than half have a healthy BMI,<sup>6</sup> and 60 percent are “physically inactive.”<sup>7</sup> One in four has heart disease;<sup>8</sup> one in three has high blood pressure;<sup>9</sup> one in two regularly uses at least one prescription medication.<sup>10</sup>

In contrast, literally none of these problems existed at the turn of the Twentieth Century, before enactment of the 1906 Pure Food and Drugs Act. The stark reality is this: at best, most Americans are eating horrible diets and living incredibly unhealthy lifestyles **in spite of** the FDA’s constant intervention in our lives — at worst, it may be at least in part **because of** the FDA.

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<sup>1</sup> See [http://www.registrarcorp.com/fda-fce-sample/Preserved\\_Banana?lang=en](http://www.registrarcorp.com/fda-fce-sample/Preserved_Banana?lang=en).

<sup>2</sup> See [https://en.wikipedia.org/wiki/Sun\\_protective\\_clothing](https://en.wikipedia.org/wiki/Sun_protective_clothing) (“The FDA initially regulated sun protective clothing as a medical device, but later transferred oversight for general sun protective clothing to the FTC.”).

<sup>3</sup> See <https://www.theatlantic.com/health/archive/2016/03/less-than-3-percent-of-americans-live-a-healthy-lifestyle/475065/>.

<sup>4</sup> See <https://www.theatlantic.com/health/archive/2016/03/more-than-half-of-what-americans-eat-is-ultra-processed/472791/>.

<sup>5</sup> See [http://www.huffingtonpost.com/2012/07/25/half-of-americans-drink-soda-everyday-consumption\\_n\\_1699540.html](http://www.huffingtonpost.com/2012/07/25/half-of-americans-drink-soda-everyday-consumption_n_1699540.html).

<sup>6</sup> See <https://www.cdc.gov/nchs/data/nhanes/databriefs/adultweight.pdf>.

<sup>7</sup> See <http://www.nwregionalheart.com/americas-heart-disease-epidemic/>.

<sup>8</sup> *Id.*

<sup>9</sup> See <https://www.cdc.gov/bloodpressure/facts.htm>.

<sup>10</sup> See <https://www.cdc.gov/nchs/fastats/drug-use-therapeutic.htm>.

The purpose of these comments is to provide a “healthy” dose of skepticism about FDA’s efforts to micro-manage not just the nation’s food and drugs — but in recent years, exceeding its charter in regulating everything in any way related to human health.

**I. The FDA Has Demonstrated It Has No Idea Which Foods Are Healthy and Which Are Not.**

For many years under the FDA’s regulatory regime:

- Pop-Tarts can be marketed as “healthy” but “almonds” could not; and
- Kellogg’s Frosted Flakes can be marketed as “healthy” while avocados could not.<sup>11</sup>

That is because, currently, a food cannot be labeled and marketed as “healthy” unless “[t]he food meets the following conditions for fat, saturated fat, cholesterol, and other nutrients.” 21 C.F.R. § 101.65(d)(2). With respect to “a raw fruit or vegetable,” in order to be considered “healthy,” it must be “low fat,” meaning under 3 grams of fat per serving. 21 C.F.R. § 101.65(d)(2)(i); 21 C.F.R. § 101.62(b)(2)(i)(A).

This rule demonstrates that central planning can lead to absurd results. Avocados, for example, although widely considered one of the healthiest superfoods in existence, have 8 grams of fat per serving, and thus for many years under the FDA regime were not eligible to be marketed as “healthy.” Naturally, many objected. Meanwhile, sugar is not included as a disfavored category along with “fat, saturated fat, [and] cholesterol,” and thus a food can contain an unlimited amount of sugar and still be marketed as “healthy.”<sup>12</sup>

The FDA demonstrated the flaws of its central planning in March of 2015, when it audaciously sent a “Warning Letter”<sup>13</sup> to the company Kind, LLC, manufacturer of a line of quite healthy whole food snack bars, which contain “ingredients you can see and pronounce” — including “whole nuts, fruits and whole grains.”<sup>14</sup> The FDA’s letter claimed that, for Kind’s use of the word “healthy” in describing at least four of its snack bars, “none of your products listed above meet the requirements for use of the nutrient content claim ‘healthy’ that

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<sup>11</sup> See A. Gasparro, “FDA Seeks to Redefine ‘Healthy,’” *Wall Street Journal*, May 10, 2016, <https://www.wsj.com/articles/fda-seeks-to-redefine-healthy-1462872601>.

<sup>12</sup> This past January, one interest group has asked the FDA to restrict the use of the term “healthy” for foods that contain high levels of sugar. <https://www.law360.com/articles/885595/high-sugar-foods-can-t-be-healthy-fda-hears>.

<sup>13</sup> <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm440942.htm>.

<sup>14</sup> <http://www.kindsnacks.com/>.

are set forth in 21 C.F.R. § 101.65(d)(2).” Apparently the raw nuts Kind LLC was using in its bars pushed the total fat content of the product over the FDA’s arbitrary 3 gram limit.

Thus, the FDA letter demanded that Kind, LLC take steps to “cure” its “violations” of the use of the word “healthy.” After a response from Kind, LLC, the FDA sheepishly retracted its demand letter informally via email, stating that Kind could continue “to use ‘healthy’ in relation to its ‘corporate philosophy,’ [but] not as a nutrient claim.”<sup>15</sup> And, as Fortune Magazine reported, “[a]fter this article was published, the FDA contacted Fortune to contest the use of the word ‘reversal’ in the headline. Never wanting to admit to having made a mistake, the agency said it ‘it was not a reversal but rather a reevaluation.’”

The next year, in response to a petition by the American Heart Association, the FDA finally issued an “interim final rule” in December of 2016, “permit[ting] raw fruits and vegetables that fail to comply with the ‘low fat’ definition and/or the minimum nutrient content requirement to be eligible to bear the claim.”<sup>16</sup>

Separately, however, Kind LLC also submitted its own petition to the FDA in December of 2015, asking the agency to reevaluate its regulatory definition of healthy to permit certain clearly healthy foods like “nuts, avocados, olives, and salmon” to be marketed using the word “healthy” — even though those foods do not meet the FDA’s requirements and thus cannot be considered as healthy as Pop-Tarts and Frosted Flakes.

Now, in response to the Kind LLC petition, the FDA has proposed that it make further changes to its regulations, and has asked for comments on “the use of the term ‘healthy’ as a nutrient content claim in the labeling of human food products; and when, if ever, the use of the term ‘healthy’ may be false or misleading.” *Fed. Reg.* 66564.

The FDA has also asked for comments on a dozen other specific questions generally involving the use of the word healthy in the labeling of food.

## **II. The Cure for a Bad Regulation Is Not More Regulations.**

The FDA has demonstrated that, in spite of all of its expertise and scientific studies, it has absolutely no idea which foods are healthy and which are not. Yet the FDA is the agency entrusted with the responsibility of ensuring that consumers are provided accurate information so that they can make informed dietary decisions.

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<sup>15</sup> See <http://fortune.com/2016/05/10/kind-bar-healthy-fda/>.

<sup>16</sup> See <https://www.federalregister.gov/documents/2016/12/19/2016-29997/food-labeling-health-claims-dietary-saturated-fat-and-cholesterol-and-risk-of-coronary-heart-disease>.

The FDA's Kind LLC fiasco is a perfect example of "unhealthy" government bureaucracy. It highlights the problem with bureaucratic one-size-fits-all rules, not limited to the FDA's dietary recommendations, but also including NIH's "Recommended Daily Allowances,"<sup>17</sup> etc. Soon enough, one size doesn't fit all, and so the rules are tweaked with more rules. And when those new rules don't quite fit, the result is — more rules. Eventually, you are left with the FDA we have today — sporting an incredibly technical, complex — and expensive — bureaucracy that only lawyers can navigate, which leaves every corporation (such as Kind LLC) at the mercy of unelected, unaccountable bureaucrats, and which is not only wasteful of resources, but counterproductive. All that is really accomplished is that consumer prices increase because the government has made it more costly for companies to do business.

These commenters believe that the FDA should get out of the business of regulating the use of the word "healthy" when it comes to food.

Most Americans likely fall into one of two categories. Either they trust the FDA's decisions as to what is healthy, in which case their health is put at risk by the FDA's bad advice, or else they ignore the FDA's guidance as to what is healthy, and they make their own informed determinations based on their own best judgment and other more reliable sources. Trusting the FDA's definition of "healthy" could have serious adverse health consequences. For example, a person could purchase and consume all sorts of unhealthy foods, including ones very high in sugar, all because they have been labeled as "healthy," and that marketing strategy has been given the FDA's stamp of approval. On the other hand, many Americans believe the government should not be dictating the nation's diet, and that government central planners cannot be trusted to make dietary decisions for the American people. Such persons conduct their own research and use their own common sense to develop a healthy and balanced diet. Perhaps they take 1,000 mg Vitamin C supplements because they know their body needs it — in spite of the "best scientific evidence" from the government that only 60 mg is recommended. Such persons rely not on government, but on a wide variety of resources, including blogs, websites, ingredient lists, food brands, grocery stores, etc.

For example, if Whole Foods decides to sell unhealthy foods in its store, its reputation and eventually its bottom line will suffer. But if the FDA misleads Americans into eating unhealthy foods, the agency's failure eventually will be used as justification for more regulation and increasing governmental powers over the marketplace.

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<sup>17</sup> For example, the Food and Nutrition Board of the Institute of Medicine currently recommends that adults consume between 75 and 90 mg of Vitamin C per day, and that this level is allegedly "sufficient to meet the nutrient requirements of nearly all (97%–98%) healthy individuals." <https://ods.od.nih.gov/factsheets/VitaminC-HealthProfessional/>. Of course, the original RDA for Vitamin C of 60 mg was "based on a mean requirement of 46 mg/d to prevent the deficiency disease scurvy" — as if the absence of a single disease means that a level of vitamin intake is adequate. <https://www.ncbi.nlm.nih.gov/pubmed/10357726>.

In short, for those consumers who seek healthy foods, a free marketplace of products and ideas will weed out unhealthy foods far better than any government bureaucracy. And for those consumers who do not care about consuming healthy food, it does not matter how many FDA guidelines or regulations are issued — such persons will continue to eat what they want — as is their right to do.

The FDA, then, imposes great costs on our economy and society, but provides few benefits in exchange, except for the bottom line of those select companies which are favored by FDA Regulations.

### **III. The FDA Has Been Ordered to Minimize Regulation, Not to Maximize It.**

On September 28, 2016, the FDA issued this request “to receive information and comments on the use of the term ‘healthy’ in the labeling of human food products.” Almost five months later, the President issued Executive Order (“EO”) No. 13,777 (Feb. 24, 2017), setting a regulatory reform agenda that “[i]t is the policy of the United States to alleviate unnecessary regulatory burdens placed on the American people.” Pursuant to this order, agency heads were instructed to establish Regulatory Reform Task Forces (“RRTF”) to “evaluate existing regulations” to make recommendations “to repeal, replace[], or modif[y]” regulations if found “outdated, unnecessary or ineffective” or “impose costs that exceed benefits.” Additionally, the task forces were instructed to “seek input and other assistance ... from entities significantly affected, ... including ‘small businesses and consumers’....” Finally, the EO instructed agency heads to “prioritize ... those regulations that the [RRTF] has identified as being ... unnecessary or ineffective” for repeal or modification.

As demonstrated above, the FDA’s regulations on what foods are “healthy” are most clearly “ineffective.” Based on the policies set forth in Executive Order 13,777, it appears a wise and economical use of resources for FDA to withdraw its Guidance for Industry and request for comments on the best way for the FDA to withdraw from the business of regulating use of the word “healthy.”

Alternatively, in light of the February 24, 2017 EO, these commenters recommend that the FDA request comment on the need, effectiveness, and cost/benefit of its regulation of the term “healthy,” under the EO reform policy, to alleviate the regulatory burdens upon American businesses and consumers.

Sincerely yours,

*/s/ Robert J. Olson*

Robert J. Olson

RJO:ph