



GENERAL MILLS

July 14, 2011

*By Electronic Filing and Hand Delivery*

Federal Trade Commission  
Donald Clark, Secretary  
Room H-113 (Annex W)  
600 Pennsylvania Avenue, NW  
Washington, DC 20580

Re: **Interagency Working Group on Food Marketed to Children: FTC Project No. P094513  
Comments on Proposed Nutrition Principles and General Comments and Proposed  
Marketing Definitions**

Dear Mr. Clark:

General Mills, Inc. (~~General Mills~~) appreciates the opportunity to formally provide comments to the Interagency Working Group on Food Marketed to Children (~~IWG~~) regarding its proposal to set certain nutrition standards for food products that would be engaged in what the IWG would consider to be marketing to children or adolescents (the ~~Proposal~~). Though the IWG's request for public comments suggested that it may make sense for those submitting comments to submit two separate documents – one to address the proposed nutrition standards, and another to address the definitions of what would constitute ~~marketing to children~~ or ~~marketing to adolescents~~ – General Mills has found that its comments on both subjects are too intertwined to be pulled apart in this manner, and we are therefore submitting just one unified comment (the ~~Comment~~).

It is our sincere hope that this Comment will be useful to the IWG as it ponders its course following the close of the comment period on the Proposal, and that the IWG may draw on the points made in this Comment as it reflects back on its original mission and develops a study and report to Congress as required by the 2009 Omnibus Appropriations Act.

Without question, childhood obesity is a grave and complex public health problem in America, and there will be no easy solutions. General Mills fully supports the goal of combating childhood obesity and fostering public health and has been, for many decades, a true innovator and leader in providing some of the lowest-calorie, most nutrient-dense foods in existence to American youth. And we will continue to innovate and lead in this area. We will be, as we have been, part of the solution – and there is always more that we (and others in our industry) can do and will do.

That being said, it would be unreasonable to expect the IWG Proposal to be helpful in this regard, in part because its focus on food advertising is misplaced, and distracts badly needed attention from the declines in physical activity and other societal factors that *actually* are fostering the obesity crisis. Indeed, youth exposure to food advertising has been declining in recent decades, during the same period that obesity has been on the rise. Even worse, the Proposal's nutrition standards are such that they would ban the advertising of numerous foods that are extremely

beneficial to public health and key weapons in the war against obesity – including virtually all cereals. Literally *all* cereals marketed by General Mills would be barred from advertising – even cereals like Cheerios. Given the undisputed science that children who eat cereal (including sweetened cereals) are far less likely to be overweight (and have far better nutrient intakes) than children who do not eat cereal, banning advertising of cereal would be counterproductive and unfortunate public policy. And yet, because cereal is the individual food product most commonly advertised to children, a ban on cereal advertising would be the largest single impact of the Proposal, if implemented.

These are but a couple of numerous flaws with the Proposal – flaws in its fundamental premises, in its lack of scientific basis, in its arbitrariness and overbreadth, in its deep conflict with existing federal standards and dietary guidance, in its failure to consider its downstream consequences, in its unconstitutionality, in its impermissibility as an unauthorized expansion of regulatory power, and in its counterproductive and unneeded results – that ultimately render the Proposal irredeemable. As White House Chief of Staff William M. Daley commented during a recent discussion of questionable regulations, “Sometimes you can’t defend the indefensible.” This is one of those moments.

We would respectfully urge the IWG to withdraw the Proposal immediately and return to the more narrowly defined task actually given the IWG by Congress – namely, the task of studying the issue and reporting the results of such study to Congress. As part of such study, we would urge the IWG to focus its attention on the enormous strides that industry self-regulation has made in recent years through the Children’s Food and Beverage Advertising Initiative (“CFBAI”), and on the robust nature of CFBAI’s newly released uniform nutrition standards applicable to foods and beverages advertised to children. We believe that such study will compel the conclusion that further federal intervention would not be warranted or helpful.

Our detailed Comment follows below, beginning with a Table of Contents, an introduction, an executive summary and overview of the Comment as a whole, and finally a detailed discussion of each issue.

Before we proceed, however, we wish to make one final note about the overall tenor of this Comment. We believe strongly that this Proposal, more than perhaps any regulatory scheme we have seen proposed, is monumentally flawed. We mean no measure of disrespect by this assessment – and we know that people of good will and intent worked on developing this Proposal. But we feel it is our duty, as well as our duty to public health, to submit a Comment that reflects a candid analysis of the Proposal. And that is what follows.

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## INTRODUCTION

The IWG Proposal is intended to cause a huge shift in how food is produced, sold, consumed, and marketed in this country, imposing potentially billions of dollars in costs on American business, agriculture, and consumers. The IWG neither has the authority to effect such widespread changes in the American economy, nor has it established through competent evidence that the changes would yield *any* benefit to children. Through this Comment, General Mills urges the IWG to consider the causes of childhood obesity, and the means best suited to address the problem, which we believe will ultimately lead to the withdrawal of this Proposal.

In the 2009 Omnibus Appropriations Act, Congress created the IWG and provided it with a modest task: to “conduct a study and develop recommendations for standards for the marketing of food” to children, and to “submit to Congress, not later than July 15, 2010, a report containing [its] findings and recommendations.” As the Director of the FTC’s Bureau of Consumer Protection recently summarized, “[t]he Working Group’s job is to submit a report to Congress. That’s all.”

The IWG has vastly exceeded this mandate. Rather than act within the time provided by statute to provide recommendations to Congress – so that *Congress* could determine whether and how to act – the IWG has instead proposed its own sweeping restrictions on the types of foods that companies like General Mills can market to children (and overbroad definitions of what constitutes “marketing to children” in the first place), complete with a timetable that includes “interim” and “final” benchmarks for compliance. In a time of severe economic and budget crisis, the IWG has thus used congressionally appropriated tax dollars to assume the role of national regulator of food and marketing, usurping Congress’s prerogative to decide whether that is an appropriate exercise of federal power, or whether instead dietary decisions are best left to parents and family members who are the primary guardians of children’s health and well-being.

Aside from being unauthorized, the Proposal is also profoundly flawed – in terms of the staggering costs it would impose; the questionable reasoning and scientific “evidence” it deploys; its conflict and inconsistencies with existing federal regulations and dietary guidance; and its violation of well-established legal requirements and norms for government action.

**Costs.** The Proposal’s financial implications for American families and the U.S. economy are enormous. If all American children were to adopt the eating habits the IWG proposes, this would impose massive costs on American businesses, agriculture, and families. The annual cost of a diet consisting of the most commonly consumed foods that satisfy the Proposal’s nutrition standards is around 60% higher than the cost of the current diet. Even if no parents at all adopted the dietary changes themselves and only served their children the foods desired by the IWG, a full dietary shift by children alone would cost consumers over \$100 billion a year in additional food bills. And this does not even take into account the value of the time lost to preparing these “IWG-approved” foods – which are generally unprocessed, raw items that require far more preparation time than the foods in the current diet. There would be dramatic changes in agricultural production as well – including billions of dollars in reduced demand for American grain, and billions of dollars in increased reliance on imported fruits and vegetables.

The unrealistic limits to the sugar, sodium, and fat content of foods that can be marketed to children (and the unrealistic definitions of what constitutes “marketing to children”) would also drastically restrict the availability of information about products that are critical to children’s health

in the U.S., with the goal of suppressing consumption of these healthful products. Major changes to existing marketing practices would also be necessary, even where adults are the intended target of the marketing. For example, using a picture of an animated brand icon on a package (like the Pillsbury Doughboy) or an athlete who is highly popular with children is inconsistent with the Proposal. Companies would also be unable to sponsor charities where children constitute a significant portion of their beneficiaries (like Make-A-Wish or the March of Dimes), or even the U.S. Olympic team (where athletes are often under 18 years of age). These limitations would be both a disservice to consumers and an impermissible interference with commercial speech under the First Amendment.

***Absence of Scientific Basis and Effectiveness.*** For all the costs the Proposal would impose on American families and the economy, it would yield *no* discernable benefits in the battle against obesity. As the IWG admits, it lacks sufficient data to conclude that advertising of any foods to children has any effect on childhood obesity. There certainly can be no data that would tie *cereal* advertising to obesity – indeed, children who eat cereal frequently (whether sweetened cereal or not) are far less likely to be overweight (and also have better overall nutrient intakes) than children who do not. And since cereal advertising represents around half of all packaged food advertising directed to children, and since essentially all cereals would be barred from advertising under the Proposal, the single largest intended impact of the Proposal would be to suppress consumption of foods that are key weapons in the war against obesity and key allies in ensuring appropriate nutrient intakes by children. When the single largest impact of a policy is a result diametrically opposed to its mission, the policy is misguided.

Indeed, the IWG’s entire philosophy of what foods should and should not be promoted to children rests on faulty premises concerning the underlying causes of child obesity. Every agency that has considered the issue (including the IWG’s member agencies) has concluded that the most important factor contributing to weight loss is calories, *i.e.*, the balance of calories consumed through food and expended through exercise and metabolism. The Proposal, however, makes *no reference* to the calorie count or portion size of foods, despite Congress’s explicit instruction that the IWG consider both factors in its analysis. To the contrary, the Proposal would restrict advertising based solely on a food’s macronutrient content, such as the amount of sugar, sodium, or fat.

In addition to the flawed emphasis on macronutrients, the Proposal also errs in setting the proposed *amounts* of those nutrients at exceedingly low levels. Often, the amounts are lower than required by federal labeling laws to market a food as “healthy.” The proposed levels would consider as “foods of little or no nutritional value” foods that are indisputably healthy and part of a balanced diet – foods like salads, canned vegetables, cold and hot cereals, whole wheat breads, and yogurts. Even bottled water could not be advertised to children under the Proposal. Literally *all* of General Mills’ cereals, including Cheerios, Total, and Wheaties, would fail the Proposal’s standards. Cheerios bears FDA-authorized heart-health claims and is commonly recommended by pediatricians as a first finger food for infants and toddlers – and yet the Proposal labels it as inappropriate for children.

Altogether 88 of the 100 most commonly-consumed foods in the American diet fail the IWG standards. The Proposal unfortunately pays little heed to the fact that food needs to taste good before people will eat it, regardless of how effective an advertising campaign may be.

***Inconsistency with Other Federal Standards.*** The Proposal contradicts not only sound science, but also the government’s own prior statements and existing regulations. The IWG attempts to justify its departure from prior agency conclusions by misstating the prior standards or drawing

unwarranted inferences from them. For example, the proposed principles incorrectly state that the 2010 Dietary Guidelines released by the Departments of Agriculture and Health and Human Services recommend eating foods with as little added sugar as possible. To the contrary, the Guidelines merely recommend reduction of overall caloric intake, and conclude that added sugars are no more likely to contribute to weight gain than other sources of calories. Similarly, the IWG notes that the FDA permits use of the term ~~“healthy”~~ on any main dishes and meals that contain less than 600 milligrams of sodium, but sets an ultimate goal for industry of 300 milligrams of sodium per serving – merely because it is ~~“half”~~ of the federal labeling requirement. The IWG provides no scientific or other basis for taking one federal standard, devised in the food labeling context, transporting it to another context, and dividing it by two. With respect to fat intake, the IWG merely adopts the level that the FDA uses under labeling laws to permit companies to label products as ~~“low in saturated fat,”~~ but does not explain why it selected that level over others provided by the FDA (such as ~~“reduced saturated fat”~~). Similar factual errors, omissions, and leaps of faith permeate the proposed standards.

***Violation of Law.*** The deficiencies identified above and others discussed throughout this comment letter render the Principles ~~“arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.”~~ 5 U.S.C. § 706 (Administrative Procedure Act). A federal agency – or four of them, acting together – may not avoid and exceed assigned congressional responsibilities, impose billions of dollars of cost through dubious reasoning at odds with widely-accepted scientific evidence, and promulgate standards that conflict with existing, binding legislative standards adopted through full and proper notice and comment rulemaking. Nor may the government interfere with the First Amendment right of American business to provide information to consumers about their lawful products.

These deficiencies are not made more tolerable by the IWG’s claim that the Proposal’s standards are ~~“voluntary.”~~ In fact, it is the intent and effect of the Proposal to deter food companies from advertising their products, and to compel companies to withdraw or redesign food products that are healthful and popular. The agencies can be expected to wield their subpoena power to pressure companies toward compliance – continuing a pattern in recent years of burdensome subpoenas targeted at American food companies. It also is expected – and, perhaps, intended – that plaintiffs’ attorneys will seek to ~~“enforce”~~ the Proposal through baseless yet costly lawsuits which contend that the Proposal establishes a standard of care, the departure from which constitutes negligence, misrepresentation, or other violations of law.

As the Director of the FTC’s Bureau of Consumer Protection has acknowledged, ~~“the FTC Act explicitly forbids the Commission from issuing a rule restricting food advertising to children.”~~ The Proposal is an attempt to implement such restrictions through the back door.

\* \* \*

For these reasons, and for the reasons set forth in detail in this Comment, the IWG must fundamentally alter its approach. Specifically, and as required by statute, it should prepare a report to Congress that is based on sound scientific evidence and recognizes the role of calorie control (including lack of exercise) in contributing to childhood obesity. That report should acknowledge the healthful effects of foods like cereal and yogurt on children’s diets. And, it should give credit to the food industry for its existing voluntary efforts at producing and promoting healthful foods, rather than penalize food companies by making it more challenging to market and sell their products.

## **EXECUTIVE SUMMARY AND OVERVIEW**

### ***The Role of Food Advertising and Palatability in Public Health***

For decades, General Mills has played a central role in promoting public health (including healthy weights) for Americans of all ages through the marketing of our cereals, yogurts, vegetables, fruits, soups, and other products. From leading the cereal industry (since as early as the 1930s through the 1970s) to fortify cereals with key nutrients lacking in the diet (which has significantly improved the nutrient intake of America's children), to our addition of folic acid in the 1980s (which, along with broader fortification in other foods in the 1990s, has demonstrably reduced the incidence of neural tube defects in the U.S.), to our more recent efforts to dramatically improve America's intake of calcium and whole grains, General Mills has long been a leading force for improving public health.

These are just a few examples. One thing they all have in common is that ***none of them could have occurred absent our ability to advertise and market our products***. For one thing, these changes in product composition required massive investments that would have been utterly unaffordable absent an ability to effectively sell the resulting products. Beyond this, public health benefits cannot be achieved on a broad scale by products that people are unaware of and therefore do not buy or eat. It is advertising that enables these benefits. And this is not just about product changes – it can also be about brand new products that meet public health needs. For example, before we started advertising yogurts in the 1970s, yogurt was virtually unheard of in the United States. Today, it is an important source of calcium and Vitamin D in children's diets. Again, advertising enabled this.

***Another critical factor in allowing a food product to deliver public health benefits is taste.*** One can advertise a food all one likes, and people may try it once. But if they do not like the taste, it will not be purchased or eaten again. And if a food is not broadly eaten, it will be powerless to deliver a public health benefit. This is where small amounts of sugar or sodium can be absolutely critical in making certain foods palatable, a fact the federal government has consistently and repeatedly recognized over the years. As nearly any parent will attest, though a minority of children may eat unsweetened cereal or yogurt, most will not.

In its zeal to propose something dramatic – well-intentioned though it may be – the IWG Proposal leaves us with an impossible choice: either stop advertising healthful foods like cereals and yogurts to kids, or reformulate these healthful foods to make them unpalatable to kids. Neither choice is a valid recipe for promoting public health.

This is not to say that product innovations can never happen. They can and do. To meet consumer concerns about sugar, for example, General Mills has been gradually ratcheting sugar levels downward for years, and we recently announced a plan to reduce sugar in all of our cereals to no more than 9 grams. But there are limits on how much sugar can be reduced without unduly affecting palatability – and we are likely at the precipice of that limit at this point. In light of the significant benefits of cereal consumption, it would be a grave public health error to push past that precipice, though many activist groups who purport to be concerned about public health continue to push such an agenda. What they fail to understand – or, more likely, what they choose to ignore – is that ***sweetened cereals do not have more calories than unsweetened cereals***. Removing sugar from cereal does not necessarily result in a lower-calorie or more nutritious food. Cereal is a

carbohydrate-based food. Carbohydrates *always* have around 4 calories per gram, and the presence or absence of sugar does not alter this. This is why Lucky Charms (with 10 grams of sugar) and Cheerios (with 1 gram) are essentially identical calorically – and both provide similarly robust levels of key nutrients. And obesity is about an imbalance between calories consumed and calories expended, not sugar levels.

In contrast to our critics, General Mills has been a leader in applying science-based standards to the determination of what products should, and should not, be advertised to children. The overwhelming majority of our advertising to children is for our Big G cereal products, 100% of which are extremely dense in nutrients meeting key public health needs while being very low in calories. None of these products – and certainly none of the advertising of these products – is linked to obesity. In fact, to the contrary, numerous scientific studies have consistently demonstrated that ***children who eat cereal frequently are far less likely to be overweight than children who do not eat cereal.*** Because all cereals have essentially the same number of calories per typical 30-gram portion, it is not surprising that ***this same connection between cereal consumption and healthy body weights is found regardless of whether the cereals being eaten contain sugar.***

To be clear, the Proposal is not merely asking us to make our “kid cereals” less sweet – it is asking us to do so while also reducing sodium to unpalatable levels. Indeed, though the casual observer may assume that the IWG is focused solely on sugar, its sodium focus is perhaps even more extreme. In fact, in large degree due to the IWG’s incredibly low sodium standards, literally all of our cereal products (and those of others as well) would fail the IWG standards and could not be marketed to kids. And this result would obtain despite the fact that all these cereals meet FDA’s standards for labeling a food as “healthy” and despite the fact that many of these cereals bear FDA-authorized heart health claims. Even Cheerios fails the IWG standards and could not be advertised to kids. Nearly everyone would agree that such a restriction would make no sense.

Cereals confer huge public health benefits. But they do so only because people are aware of them and broadly consume them – and it is a combination of advertising and good taste that makes this happen. The elimination of either of these factors is bad public policy.

### ***The Role of Calories in Obesity***

It has been the consistent, unanimous, science-based verdict of all relevant federal agencies – including those involved here and others – that obesity is ultimately about the balance between calories consumed (“calories-in”) and calories expended (“calories-out”). As the Centers for Disease Control (“CDC”) succinctly puts in on its website dedicated to obesity:

When it comes to maintaining a healthy weight for a lifetime, the bottom line is – calories count! Weight management is all about balance – balancing the number of calories you consume with the number of calories your body uses or “burns off.”<sup>1</sup>

The Food & Drug Administration (“FDA”), which has devoted considerable resources to the study of the obesity problem, agrees: calories are the single most important consideration in weight

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<sup>1</sup> CDC, *Overweight and Obesity: Causes and Consequences*, at <http://www.cdc.gov/obesity/causes/index.html> (last visited July 6, 2011).

management. In order to focus Americans' attention on calories, rather than on "good" or "bad" foods, the FDA established a campaign called "Calories Count," in which it explained:

Fundamentally, obesity represents an imbalance between energy intake (e.g., calorie intake) and energy output (expended both as physical activity and metabolic activity . . . . Although there is much discussion about (1) the appropriate makeup of the diet in terms of relative proportions of macronutrients (fats [lipids], carbohydrates, and protein) that provide calories and (2) the foods that provide these macronutrients, **for maintenance of a healthy body weight it is the consumption and expenditure of calories that is most important.**<sup>2</sup>

Similar assessments have been made consistently, and up through the present day, by these and several other federal agencies as well – including the U.S. Department of Health and Human Services ("HHS"), the U.S. Department of Agriculture ("USDA"), and the National Institutes of Health ("NIH").<sup>3</sup>

Despite this chorus regarding the central role of the calorie-in/calories-out balance in obesity (and despite the fact that Congress, too, in authorizing the work of the IWG, emphasized explicitly that the IWG was to consider calories – listing it first in a broader list of considerations), the Proposal wholly ignores calories in setting its nutrition standards, focusing instead on a number of matters of less, or even dubious, relevance.

So, there is no attention to the "calories in" part of the equation here. Equally disturbing is the fact that the IWG is proposing an approach to obesity that completely ignores the "calories out" part of the equation as well. Given the clear recognition by IWG member agencies of the fundamental role of calories-in and calories-out, this lack of attention to both sides of the equation is truly striking.

If calories *had* actually been examined, the IWG would have seen from CDC and USDA data that caloric intake by American children has, since 1994 (*i.e.*, the period covering the lives of all children and adolescents in America today) remained essentially flat, actually dropping by 3%.<sup>4</sup> During this same period, obesity amongst children has risen 69%.<sup>5</sup> **Given that obesity is about calories-in vs. calories-out, and given that the calories-in number is lower than it was in 1994, the likely conclusion is that the recent rise in obesity relates to a decline in the calories-out number.**

And of course, common sense would dictate that as well. Children have always eaten food and consumed calories, but there is substantial reason to believe that children have become far more sedentary in recent decades – and therefore expend far fewer calories than they did formerly. For example, the degree to which daily physical education and recess has vanished from American schools is truly staggering. In addition to reporting a 33% decline in daily physical education among

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<sup>2</sup> FDA, *Calories Count: Report of the Working Group on Obesity* 3 (2004) (emphasis added).

<sup>3</sup> See *infra* Section II.A.1.a.

<sup>4</sup> USDA Agricultural Research Service, *1994-96 Continuing Survey of Food Intakes by Individuals and 1994-96 Diet and Health Knowledge Survey Data Tables* (1997); CDC and HHS, *National Health and Nutrition Examination Survey Data* [2000-2008] (hereinafter "NHANES Data").

<sup>5</sup> Ogden et al., *Prevalence and Trends in Overweight Among U.S. Children and Adolescents, 1999-2000*, JAMA 2002, 288(14):1728-1732; NHANES Data [2000-2008].

high school students from 1991-2003, HHS has reported that “[o]nly about one-third of elementary children have daily physical education, and less than one-fifth have extracurricular physical activity programs at their schools.”<sup>6</sup> Kids are physically inactive outside of school as well. CDC’s 2009 National Youth Risk Behavior Survey reported that 25% of students played video or computer games (or used a computer for something that was not school work) for three or more hours per day on an average school day.<sup>7</sup>

***Thus, by not considering calories, the IWG’s entire approach to addressing obesity is inherently flawed.*** A focus on advertising would only conceivably make sense if the rise in obesity were attributable to increased caloric intake traceable back to advertising. But the evidence does not support any part of this theory. And by focusing on advertising, the IWG is distracting public attention from the real causes of obesity on the “calories out” side of the balance. It is also, as noted earlier, working *against* public health by banning the advertising of foods that contribute markedly to public health and to the war on obesity.

### ***Overview of the Profound Problems with the Proposal***

For reasons that include (but that also go far beyond) those outlined above, General Mills believes the Proposal to be fundamentally and irredeemably flawed and urges its abandonment. The “Discussion” section below in this Comment will explore these points in detail. But it may be useful to provide an overview of these points at the outset.

***First, the Proposal is fundamentally flawed for the simple reason that it will do nothing to combat obesity.*** Though advertising is a convenient scapegoat for the obesity problem, the inconvenient reality is that there is no reason to believe it is responsible for the rise in obesity and every reason to believe it is not. And addressing a non-problem will not solve anything.

- For one thing, as noted above, caloric intake by kids today is essentially the same as it was a generation ago, while obesity among this age group has increased markedly – suggesting (along with compelling evidence that kids are far less physically active today) that the problem lies in reduced caloric expenditure and not in any increased caloric intake that some incorrectly assume must arise from advertising.
- If advertising caused childhood obesity, one would expect to see an increase in food advertising reaching children over the period that obesity has been rising. But nothing of the sort has happened. To the contrary, the FTC Bureau of Economics and other researchers have confirmed that children’s exposure to advertising has actually *dropped* over the past few decades, as obesity has been rising.
- If advertising caused childhood obesity, one would expect that child advertising bans in other countries (which have been in place for a long time in places like Quebec and Sweden) would have resulted in those jurisdictions having lower child obesity rates than similar provinces/countries that permit advertising to children. In fact, these advertising bans have *not* resulted in lower obesity rates.

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<sup>6</sup> Office of the Assistant Secretary for Planning and Evaluation, HHS, *Childhood Obesity*, at [http://aspe.hhs.gov/health/reports/child\\_obesity/](http://aspe.hhs.gov/health/reports/child_obesity/) (citing Youth Risk Behavior Surveillance System, NCCDPHP, CDC).

<sup>7</sup> CDC, *Youth Risk Surveillance – United States, 2009*, MORBIDITY AND MORTALITY WEEKLY REPORT 26 (June 4, 2010), available at <http://www.cdc.gov/mmwr/pdf/ss/ss5905.pdf>.

**Second, even if one made the questionable assumption that some sort of advertising ban could be justified, the advertising ban in the Proposal (the “Advertising Ban”) still could not be justified because its primary effect will be to ban the advertising of cereals, as well as yogurts and other healthful foods.** Suppressing consumption of foods like cereal and yogurt would be highly counterproductive – and may actually *promote* obesity and poor nutrient intakes to the detriment of public health.

- Cereal is the single food product most commonly advertised to children, representing around 49% of the packaged food advertising directed to children. Because essentially *all* cereals would be subject to the Advertising Ban – even unsweetened cereals like Cheerios – the primary intended impact of the Advertising Ban would be to suppress consumption of cereal by American youth. This is a truly unfortunate idea, due to the strong health credentials of cereal.
- As noted earlier, kids who eat cereal (including sweetened cereal) are far less likely to be overweight than those who do not, and they also have better overall nutrient intakes. If anything, a valid public health policy would be to promote *more frequent* consumption of cereal. Congress specifically directed the IWG to consider “evidence concerning the role of ... foods in preventing ... the development of obesity” among children. The IWG clearly did not consider this evidence.
- Another major impact of the Advertising Ban would be on yogurt, which provides an important source of calcium and Vitamin D to children.
- In both the case of cereal and yogurt, the IWG appears to fail to ask itself what it expects kids to eat in lieu of these items, and the impact of those substitutions on their health. In the case of yogurt, it might be any number of snack items which will almost certainly be nutritionally inferior. In the case of cereal, there is simply no other likely breakfast choice – and few, if any, other foods for that matter – that will be as dense in nutrients while being so low in calories.

**Third, the Proposal’s nutrition standards are arbitrary and conflict with both existing science and existing federal dietary policy and guidance – to the detriment of public health.**

The Proposal’s nutrition standards show a disregard for accepted science and policy en route to establishing a set of unjustifiable nutrition standards – with the perverse results of banning numerous foods that FDA labels as “healthy,” that bear FDA health claims, that USDA includes in its WIC food-assistance program, and that HHS and USDA promote for consumption under the U.S. Dietary Guidelines.

- By focusing on macronutrient composition and entirely ignoring calories, the Proposal’s nutrition standards arbitrarily ignore the mandate given the IWG by Congress as well as the long-standing (and unanimous) scientific determination of FDA, HHS, USDA, NIH, and CDC that obesity is about the calories-in/calories-out balance.
- Through frequent citations to FDA regulations and other federal dietary policy, the IWG cloaks its standards in the appearance of consistency with current policy, but closer examination of the items being cited reveals that they are being used for purposes having nothing to do with their intent – resulting in arbitrary and capricious standards that actually deeply conflict with current policy and established science.
- By seeking to suppress consumption of foods that FDA defines as “healthy,” foods that FDA, USDA, and other agencies encourage Americans to eat, and foods expressly

recommended by the American Academy of Pediatrics, the Proposal not only conflicts with current federal policy, it is harmful to public health.

**Fourth, the Proposal’s nutrition standards are impossibly strict and reflect a bias against prepared, non-raw foods and an unfortunate view that foods (and consumer tastes) can or should be reengineered to meet these impossible standards.** The IWG nutrition standards are so draconian that virtually no foods – even many that are universally recognized as healthful – meet the standards. Labeling these foods, as the IWG does, as foods of “little or no nutritional value” is not sound public health policy (and actually defames nutritious foods).

- As detailed in Section II.B.1, below, 88 of the 100 most commonly consumed foods in the American diet fail the IWG standards – including all grain and meat products amongst these “top 100” foods.
- The following are among the “top 100” foods that fail the IWG nutrition standards:
  - **Ready-to-eat cereals** (nearly all commonly consumed cereals – even unsweetened cereals like Cheerios – would be banned from advertising)
  - **Salads** (the most common form of salad is a leaf salad with low-fat dressing – and even this does not satisfy the IWG standards)
  - **Hot cereal** (the most common of these is sweetened oatmeal, but even plain oatmeal, if cooked according to standard package directions, fails the IWG standards)
  - **Bottled water** (pure water – unflavored and noncarbonated – fails the standards)
  - **Corn** (canned corn is the most common form of corn in the diet, and like all other canned vegetables, canned corn fails the IWG standards)
  - **Green beans** (canned)
  - **Peas** (canned)
  - **Whole wheat bread**
  - **Reduced-fat yogurt**
- **Rice**
- As a matter of public policy, the government would do well to affirmatively *promote* consumption of these healthful foods (and actually, the very agencies involved in the IWG do just that in their science-based pronouncements outside the IWG context)
- The 12 foods that meet the standards are primarily raw foods which, once prepared into a recipe or dish at home, would fail the standards.
- In reality, virtually all “recipes” or “processed foods” fail the standards, including nearly all recipes promoted by food industry critics – and even the recipes promoted by USDA as finalists in its recent “Recipes for Healthy Kids” contest. *Similarly, it will not be feasible to adjust our recipes (and reformulate our products) to meet the IWG standards while maintaining palatability.*
- The inherent bias against non-raw foods that underlies these standards ignores the critical role of fortified and packaged foods in public health.

**Fifth, if the Proposal’s Advertising Ban were actually to be fully implemented and achieve its objectives of suppressing consumption of “banned” foods and shifting consumption to foods that meet the IWG’s standards, the economic consequences for American consumers and American agriculture would be devastating.** The goal of a food advertising ban is necessarily to engineer a dietary shift toward foods not subject to the ban. Here, the few foods of which the IWG approves tend to be significantly more expensive and time-intensive (to prepare) than the commonly consumed foods in the current American diet. They also tend to be items (like fresh fruits and

vegetables) that are far more likely to be sourced from foreign agricultural sources. Since most grain products are “banned” by the IWG standards, and since grain products are almost exclusively sourced from American agriculture, the harm to American agriculture would be significant.

- We simply cannot afford to eat the way the IWG would like us to eat. All in all, if Americans actually shifted their diets to the foods the IWG hopes to promote, and away from the foods the IWG rejects, Americans’ food bills would rise by over 60% as described in Section III.A, below. Across the entire population, this would be an increase in food spending of over \$500 billion per year. Take into account the value of even a modest assumed increase in food preparation time (given that IWG-approved foods tend to be raw foods requiring more preparation time), and this “economic loss” felt by American consumers would rise to over \$1.1 trillion per year.
- The agricultural impact of such a dietary shift would be similarly dramatic. A full shift to this diet would result in \$30.3 billion in reduced demand for American grain, and the need for the American economy to expend an incremental \$489 billion on imported fruits and vegetables.
- To be sure, this level of dietary shift is unlikely. But if the IWG were successful in shifting even 20% of people’s diets to its approved foods, the economic impact would be staggering and utterly unaffordable. (In any event, if the best argument in favor of the Proposal is that it should be permitted to go forward because it will never achieve its desired (but catastrophic) dietary shift, that is hardly a ringing endorsement.)

**Sixth, in addition to promoting a diet that American consumers and American agriculture simply cannot afford, the Proposal would inflict wide-scale damage on the food industry, other sectors of the American economy, and the consuming public.**

- Obviously, the food industry will suffer, either from the inability to advertise its products upon which entire business models are currently built, or from the need to invest in costly product reformulations ultimately resulting in less palatable (and therefore less viable) products.
- In addition, as the food industry suffers, so will its raw material suppliers and other vendors and business partners, including grocery retailers who have whole aisles of their stores dedicated to products that the IWG now characterizes as having “little or no nutritional value” and bans from advertising (including in-store advertising).
- One of the harshest impacts of the proposed Advertising Ban will, of course, be felt by the media, entertainment, and advertising sectors of the American economy. Indeed, there are entire business models here that may simply cease to exist if the advertising ban is permitted to go forward. Advertising-supported children’s television is highly dependent on food advertising, to the point that it stands to lose over 20% of its advertising revenue if the advertising ban were to take effect.
- And the ultimate victims here will be American consumers. Not only will they likely lose access to free (advertising-supported) high-quality entertainment options for themselves and their children, but they will lose access to beneficial and innovative products that exist precisely *because* advertising enabled product improvements. As noted earlier, cereal has long been a force for meeting major public health challenges through product innovation (*e.g.*, through fortification in the 1970s, the addition of folic acid in the 1980s, calcium fortification in the 1990s, and the reformulation to deliver tremendous quantities of whole grains in the 2000s), and *none of these improvements could have happened without the ability to advertise*. Under an advertising ban, consumers will lose the benefits of further

product improvements. The products subject to the ban will become undifferentiated commodities – and competition and innovation will suffer.

**Seventh, even in the absence of the Proposal’s myriad flaws described above, the Proposal’s Advertising Ban is based on seriously overbroad definitions of activities that purportedly constitute “marketing to kids.”** Even if the advertising ban and its nutrition standards were otherwise appropriate – which they are not – the ban would still be unreasonable because its definitions of “marketing to kids” are impossibly vague and overbroad. Here are some of the activities that are deemed to constitute marketing to kids (such that food companies would be precluded in engaging in these activities, except with the rare product that meets the IWG’s standards):

- Sponsorship of charities where kids compose a significant portion of their beneficiaries (like Special Olympics, March of Dimes, Make-A-Wish, etc.).
- Sponsorship of a public entertainment event (like a sporting event or state fair) that may involve kid-oriented activities.
- Sponsorship of the U.S. Olympic Team (or any other team involving kids under 18).
- Use of the words “child” or “kid” on a package, even in communications to parents like “your child will love this bread.”
- Having a social media page, or YouTube video, where a mere 20% of the audience consists of kids.
- Using an animated depiction of a brand icon (like the Pillsbury Doughboy) on a package. *(Thus, the Proposal would strip companies of significant intellectual property assets, even on products that are not marketed to children.)*
- Using an animated figure, like Santa Claus or the Easter Bunny, on a package.
- Employing a celebrity or famous athlete that is “highly popular” with kids (people who will, of course, also be “highly popular” with adults).
- Advertising on television using kid-directed content, even on a show that is not a kid show.
- Advertising on shows with an audience of 30% children ages 2-11 or 20% adolescents ages 12-17. (Thus, up to 80% of the audience can be adults, and the advertising would still be banned. Even shows like SportsCenter can be off limits.)
- Advertising during a “daypart” or “programming block” containing kid shows, even if the ads run solely on shows that have a 100% adult audience.

**Eighth, the proposed Advertising Ban unconstitutionally restrains commercial speech in violation of the First Amendment.** As the U.S. Supreme Court noted just a few weeks ago in *Sorrell v. IMS Health*, “The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.” This decision is one in a long line of Supreme Court opinions over the past two decades strongly protecting commercial speech interests under the First Amendment. The IWG’s proposed Advertising Ban violates the First Amendment.

- Even under the case law preceding the *IMS Health* ruling, which primarily consisted of opinions where restraints on commercial speech were struck down following application of the so-called “*Central Hudson* test,” one has to look back quite a distance to find a commercial speech case where the government has prevailed. And *IMS Health* has just made the government’s burden in these cases even more difficult.
- Moreover, just two weeks ago, in *Brown v. Entertainment Merchants Ass’n*, the Court strongly reaffirmed its position that First Amendment rights do not diminish when children are involved. Aside from drawing isolated exceptions in the context of sexually indecent speech and commercial speech about products that are illegal for

children, the Supreme Court has consistently recognized ~~the~~ values protected by the First Amendment are no less applicable when government seeks to control the flow of information to minors.”

- The Advertising Ban at issue here is invalid even under the *Central Hudson* test. Under *Central Hudson*, a restriction on otherwise lawful commercial speech cannot survive First Amendment challenge absent a showing that the regulation (i) *materially advances a legitimate governmental interest*, and (ii) *is no more extensive than necessary to serve that interest*. Here, the Advertising Ban clearly fails both prongs of the analysis (due to its manifold deficiencies described throughout this Comment). And the *IMS Health* decision simply makes the unconstitutionality of the Advertising Ban that much more evident.

**Ninth, the Proposal represents an inappropriate expansion of regulatory power.** The degree to which the IWG has overstepped proper bounds certainly includes, but is by no means limited to, the unconstitutionality of its proposed Advertising Ban. Indeed, the level of ~~overstepping~~ here is striking.

- As a threshold matter, there is the question of the need, or propriety, of four federal agencies making the determination that American parents are not sufficiently able to carry out basic parenting duties. Virtually no grocery shopping is done by children. Rather, *parents are the ones who decide what foods they themselves will buy and serve to their children*. There is no basis for federal intervention in such private decision-making.
- Beyond this threshold issue, it should be remembered that the IWG was authorized simply to ~~conduct a study~~ and prepare a ~~report~~ to Congress. As far as we can tell, neither of these items has even been attempted. Rather, the IWG appears to have dispensed with the idea of completing any sort of study, ignored its obligations to merely report to Congress, and has moved instead to directly propose (entirely on its own) a comprehensive and unconstitutional set of restrictions on commercial speech.
- In addition to ignoring its congressional mandate, the IWG has also ignored President Obama’s recent Executive Order 13563 (January 18, 2011), which called upon regulations to ~~be~~ based on the best available science” and to ~~protect~~ public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.” There is little application of science – much less the best available science – to be found anywhere in the Proposal. And an advertising ban of healthful foods does not, by any means, promote public health, economic growth, innovation, competitiveness, or job creation.
- Indeed, the policy promoted here could never survive any sort of logical or scientific review, nor could it survive an economic impact assessment. As a result, the Proposal would never be able to make it through the normal rulemaking process, nor would it survive judicial review under the Administrative Procedure Act or the First Amendment.
- For the same reason, the IWG also violates the Data Quality Act, which requires federal agencies to maximize the integrity and quality of information upon which they rely. It also violates the National Nutrition Monitoring and Related Research Act.
- But the IWG seeks to avoid all of these deficiencies through the simple tactic of labeling the regulations as ~~voluntary~~ – even though they are backed up by the coercive power of four federal agencies, including those who wield the most discretionary power over our industry.
- It is one thing for a federal agency to issue voluntary guidance on an issue which, if the agency so chose, it could lawfully address with actual regulations. It is quite another for

four federal agencies to issue a comprehensive and burdensome set of standards that could never survive First Amendment or any other judicial review – and which the agencies utterly lack the authority to issue – and seek to achieve this by nominally labeling the standards as “voluntary.”<sup>8</sup>

- If this is permitted to move forward, the precedent set by this would be a dangerous one. Why would any agency ever go through normal rulemaking processes, or trouble itself with the Constitution, if a “voluntary” label is able to avoid any check on the agency’s power?

**Finally, the Proposal ignores the significant achievements of the food industry’s self-regulatory efforts.** For all of the reasons described above, the Proposal is deeply flawed as a matter of policy and as a matter of law. But it is not just a question of the Proposal being the wrong set of governmental regulations on what foods can or cannot be marketed to children and adolescents (and what it means to be marketing to children or adolescents). That would imply that there is a *right* set of such governmental regulations, and that the IWG just got it wrong. That would be a serious oversimplification of the problem here because *it overlooks the question of whether there should be any governmental intervention here at all.* Indeed, even if one uncritically accepts the unsupported assumption that advertising – and not reduced physical activity – is at the root of the recent rise in obesity, there would be no need for governmental intervention here given the significant successes of the Children’s Food and Beverage Advertising Initiative.

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<sup>8</sup> These rules are *not* actually voluntary:

(1) It is not possible for industry to simply ignore the will of its principal regulators, especially as codified publicly in a detailed set of rules developed over a period of years by these agencies. It is all but inconceivable that the agencies will simply “walk away” from this 5-year effort if industry chooses to not comply.

(2) Indeed, the FTC commented at the December 2009 IWG workshop that mandatory regulation would likely need to follow if the industry did not comply and later suggested at an Institute of Medicine workshop that FTC could bring enforcement actions against noncompliant companies. (Admittedly, FTC now appears to have backed away from these statements, but this appears to simply be a defensive move to avoid judicial review.)

(3) The White House report on obesity (issued last year) similarly explicitly stated that FCC regulations should be changed to limit advertising in the event industry does not comply.

(4) Moreover, even if not “enforced” directly in this way by the government, these rules will be enforced in other ways: They will become the *de facto* statement of the federal government on what products are acceptable for kids to eat (or see ads about). They may become the model for school lunch regulations across the country, and may even become the model for international restrictions on advertising (in countries that do not protect commercial speech in the same way we do).

(5) The food industry’s ability to speak – even to adults about products they might want to purchase for their kids – will be chilled. How does the industry avoid the baseless class action lawsuits that will inevitably arise when it markets a product to parents to purchase for their kids, when the federal government has deemed these products to be unacceptable for kids? How does the industry avoid the baseless class action lawsuits alleging that its products have made kids obese (even if the industry does not advertise them) because the U.S. government has said so?

(6) Moreover, these standards will be enforced through activist pressure and public relations pressure to fall in line, pressure fed by defamatory assertions that incredibly healthful foods (like cereal and yogurt) marketed by the industry are, in the words of FTC’s Statement, foods of “little or no nutritional value.”

- As a result of CFBAI's efforts and the efforts of its 17 member companies, food advertising expenditures on children's television (adjusted for inflation) dropped from nearly \$600 million in 2004 to just over \$200 million in 2010, a decline of nearly two-thirds.
- Between 2004 and 2010, total food advertisements viewed by children on children's television programming fell by more than 50%. This same period also saw the following percentage declines in children's television advertising in the following categories:
  - cookies - 99%
  - soft drinks – 96%
  - frozen and refrigerated pizza -95%
  - breads, pastries, waffles and pancakes –nearly 100%
  - gum and mints - nearly 100%
  - snack bars - nearly 100%
  - snacks - 71%
  - candy - 68%
- Beyond these striking results, CFBAI member companies have been working diligently to strengthen their commitments even further, culminating in the recently announced CFBAI Uniform Nutrition Standards which are incredibly rigorous, science-based standards.
- Under these CFBAI member standards, approximately one-third of the food products currently advertised to children will need to be reformulated by the end of 2013, or they will no longer be able to be advertised under the new uniform standards.
- The IWG member agencies will undoubtedly have the opportunity to participate in the dialog leading up to any future changes to the CFBAI standards. But there is no need for the IWG to create its *own* standards – and certainly no reason to move any further to codify the non-science based, infeasible standards the IWG has just proposed.

## DISCUSSION

**I. The IWG has presented no evidence supporting the notion that its proposed Advertising Ban will have *any* beneficial impact on childhood obesity nor does any such evidence exist – indeed, all evidence is to the contrary (especially because the Ban’s largest impact will be on ready-to-eat cereal, which is a key weapon in the fight *against* obesity).**

**A. As a threshold matter, there is no reason to believe that banning advertising of any foods will reduce obesity rates – and every reason to believe it will not.**

Food advertising is a convenient scapegoat for obesity. Indeed, activist interest groups have openly, and with considerable stridency, accused the food industry of causing childhood obesity by advertising “junk food”<sup>9</sup> to children, and many have uncritically accepted those claims. But the inconvenient truth is this: There is no evidence to indicate that child-directed food advertising causes childhood obesity. Indeed, all evidence is to the contrary.

To be sure, there have been plenty of attempts to show such causation, but despite numerous attempts to do so – even those funded by the United States government – researchers have been unable to establish a causative relationship between advertising and obesity. In 2005, the Institute of Medicine was commissioned by Congress to identify a causal link between advertising and obesity. In their report, however, the authors could only reach the following conclusion: “[E]vidence is not sufficient to arrive at any finding about a causal relationship from television advertising to adiposity among children and youth.”<sup>10</sup> It is quite true that studies have been published which *purport* to establish a link between the advertising of certain foods and childhood obesity,<sup>11</sup> but the conclusions of these studies wither under closer scrutiny, because the studies themselves are hobbled by significant design or methodological flaws.<sup>12</sup>

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<sup>9</sup> We will leave aside, for the moment, the false and defamatory nature of the “junk food” characterization as applied to *any* of our products.

<sup>10</sup> Institute of Medicine, *Food Marketing to Children and Youth: Threat or Opportunity?*, at 379-80 (2006), available at <http://www.iom.edu/Reports/2005/Food-Marketing-to-Children-and-Youth-Threat-or-Opportunity.aspx>.

<sup>11</sup> See, e.g., Shin-Yi Chou, Inas Rashad & Michael Grossman, *Fast-Food Restaurant Advertising on Television and Its Influence on Childhood Obesity*, 51 J. OF LAW AND ECON. 599 (2008); Frederick J. Zimmerman & Janice F. Bell, *Associations of Television Content Type and Obesity in Children*, 100 AM. J. OF PUB. HEALTH 334 (2010); Tatiana Andreyeva & Inas Rashad Kelly, *Exposure to Food Advertising on Television, Food Choices and Childhood Obesity*, Working Paper (2010).

<sup>12</sup> See J. Howard Beales III and Robert Kulick, *Does Advertising on Television Cause Childhood Obesity? A Longitudinal Analysis* (publication forthcoming 2011); J. Howard Beales III, *Television and Obesity* (Oct. 2010), available at [http://www.gmaonline.org/file-manager/Health\\_Nutrition/Beales-Review-of-Recent-Studies.pdf](http://www.gmaonline.org/file-manager/Health_Nutrition/Beales-Review-of-Recent-Studies.pdf). The evidence that older children who spend more time watching television have higher BMIs does seem to have some support. But it has not been shown that such higher BMIs are due to increased TV ad exposure by children, and not the sedentary nature of the act of TV viewing itself. And although studies have attempted to show that children’s TV advertising is associated with higher BMIs in children, by comparing the BMI of children who watch videos instead of broadcast television, or who watch noncommercial television instead of commercial television (and thus, in both cases, would view fewer ads), their results either have been inconsistent with the hypothesis that television advertising increases BMI in

Not only is there no evidence to support the activist hypothesis that food advertising to children causes childhood obesity, there is incredibly compelling evidence that it does not.

*First*, CDC and USDA data regarding caloric intake by American youth establishes that caloric intake by youth in 2008 mirrors that from 1994 (and is even slightly lower), while obesity among American youth has climbed steeply. Because obesity is about the balance between caloric intake and caloric expenditure, the caloric intake data coupled with a rise in obesity would suggest there has been a decline in caloric expenditure among American youth. Due to the technological and other societal shifts occurring over this period, this hardly seems surprising. And it is apparent that food advertising can have nothing to do with decreased caloric expenditure. *Second*, food advertising to children has significantly *decreased* at the same time that childhood obesity rates have climbed in the United States – a trend that is the exact opposite of what one would have expected if advertising caused childhood obesity. *Third*, advertising bans have had no effect whatsoever on childhood obesity rates in those countries where they have been adopted – again showing that advertising has nothing to do with childhood obesity.<sup>13</sup>

As a consequence, neither this Advertising Ban, nor any other food advertising ban, will do anything to address childhood obesity.<sup>14</sup> It is simply the wrong approach for addressing the serious public health issue of childhood obesity.

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children, or reflected differences that were not statistically significant. In fact, what studies have tended to suggest is a much more complex set of factors associated with childhood obesity: total hours spent watching TV; cleanliness of the child's house (suggesting the degree of care taken in how the household is run); the child's caretaker's BMI; whether the child watches programming intended for adult audiences (suggesting insufficient adult supervision); and other environmental factors. While many of these factors are not susceptible of a quick legislative fix, they indicate that far more research needs to be conducted into the causes for childhood obesity, so that meaningful solutions can be devised to address them.

<sup>13</sup> Legally, the IWG does not have the option of ignoring this evidence. Rather, the law requires that agencies —examine the relevant data and articulate a satisfactory explanation for [their] action[s] including a rational connection between the facts found and the choice made.” *Motor Vehicle Mfrs. Ass’n of United States, Inc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). —Relevant data” includes all —important aspect[s] of the problem.” *Id.*; see also *Jicarilla Apache Nation v. U.S. Dep’t of Interior*, 613 F.3d 1112, 1114-15 (D.C. Cir. 2010) (—Because we are persuaded [the agency] failed to consider an important aspect of the problem . . . we reverse in part and remand . . .”). —If the agency has . . . entirely failed to consider an important aspect of the problem,” its action is arbitrary and capricious. *Id.*

<sup>14</sup> To be clear, this is not a simply a question of IWG simply devising the —right” kind of ban. It is true that we find the substance of this specific Advertising Ban particularly flawed in numerous respects. As described within this Comment, we find the nutrient standards endorsed by the Proposal to reflect a misunderstanding of, and to conflict in myriad respects with, existing federal dietary policy and regulations. We believe that IWG, in developing those standards, ignored the specific instructions of Congress, and that, if actually followed, these nutrient standards would actually *promote* obesity and poor nutrition in the United States. We further believe that the Advertising Ban reflects an uninformed view of how Americans procure, prepare, and consume food. And we are deeply concerned that full adoption of the Advertising Ban would have unintended but damaging consequences for the U.S. economy and for American communities and families. But setting these serious issues aside, the Advertising Ban is a fundamentally flawed concept from the very outset because no food advertising ban will do anything to curb childhood obesity in the United States, as described in detail in this Section I.A.

- 1. *The fact that caloric intake by kids has not dramatically increased (and is now actually lower than in the mid-1990s) during the same period that obesity has risen sharply, coupled with compelling data on the increasingly sedentary lifestyle of American youth, suggests that the rise in obesity is likely rooted in reduced caloric expenditure – which, of course, has nothing whatsoever to do with advertising.***

The entire Advertising Ban concept is premised on the idea that the recent rise in obesity is attributable to the “success” of advertising in getting children and teens to eat foods that contribute to obesity. Even as a matter of common sense, this assumption would not appear to ring true. Food has been advertised for an awfully long time, but obesity has spiked upward only recently. And the assumption becomes quite unreasonable if one pays attention to federal data on caloric intake by children and teens.

Though trends in caloric intake are difficult to detect due to the use of differing cross-sectional methods over the years, the best available data from USDA and CDC would indicate that kids between the ages of 2 and 19 were consuming around 2,002 calories per day (on average) in 1994-1996.<sup>15</sup> In 2007-2008 (the date of the most recent data on this point), average daily caloric intake by kids between 2 and 19 was around 1,937 calories.<sup>16</sup> Thus, during the current generation – the period that covers the lives of the kids 2 to 17 who are at issue in the Proposal – daily caloric intake by kids has actually ended up about 3% lower than where it began.<sup>17</sup>

And over this same period, obesity among kids in this age range moved from 10.0% (in 1988-1994) to 16.9% (in 2007-2008).<sup>18</sup> (See table below for further details.) This is a 69% increase in obesity that would be awfully difficult to explain by looking solely at caloric intake.

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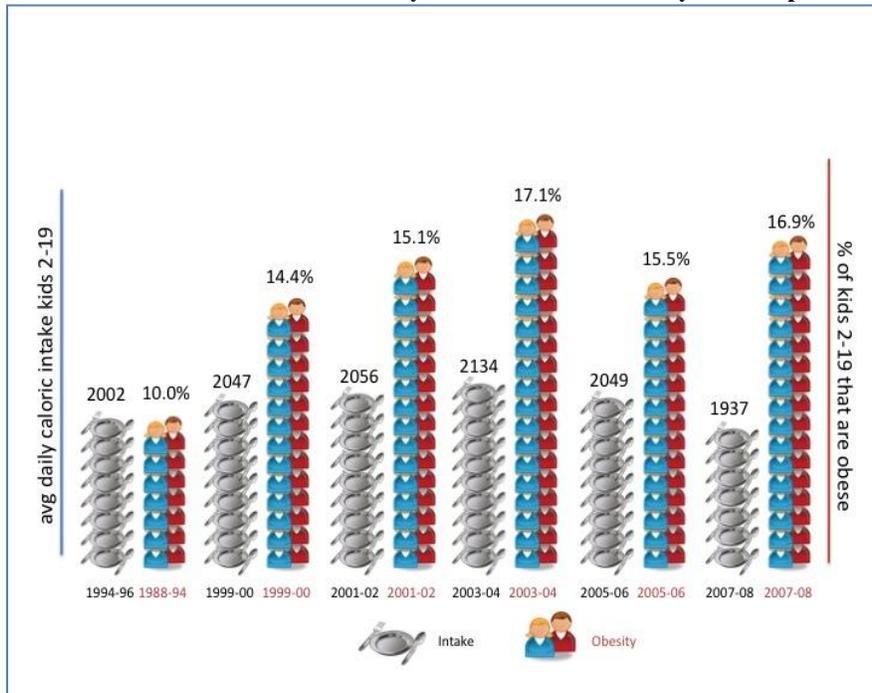
<sup>15</sup> USDA Agricultural Research Service, *1994-96 Continuing Survey of Food Intakes by Individuals and 1994-96 Diet and Health Knowledge Survey Data Tables* (1997); NHANES Data [2000-2008].

<sup>16</sup> *Id.*

<sup>17</sup> After analysis of caloric intake among children 6-11 between 1977 and 1996 (a period in which obesity nearly doubled for this age group), the Institute of Medicine similarly concluded that “no significant increased trends in energy intake were observed.” Institute of Medicine, *Preventing Childhood Obesity: Health in the Balance*, at 30 (2004), available at <http://www.iom.edu/Reports/2004/Preventing-Childhood-Obesity-Health-in-the-Balance.aspx>.

<sup>18</sup> Ogden et al., *Prevalence and Trends in Overweight Among U.S. Children and Adolescents, 1999-2000*, JAMA 2002, 288(14):1728-1732.

**Table: Youth Calorie Intake Relatively Flat While Youth Obesity Has Jumped 69%**



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All federal agencies addressing obesity – CDC, NIH, FDA, USDA, HHS – have uniformly agreed that weight gain is a matter of calories in versus calories out: when we consume more calories than we expend in our use of energy, we gain weight.<sup>20</sup> When we gain weight, it is because our “calories in” exceed our “calories out,” and our bodies store our excess calories as fat. This principle, though central to an understanding of the causes of obesity, does not appear to have been considered at all by the IWG in developing its Proposal.<sup>21</sup>

If the IWG *had* considered calories, including the federal data on caloric intake cited above, the IWG would have seen how questionable it is to assume a causal connection between child food advertising and child obesity. If food advertising were causing the sharp rise in obesity, such a cause – by definition – would have to be on the calorie intake side of the calories in/calorie out balance (because that is the only side of the equation that advertising could even theoretically affect). Given that caloric intake has not dramatically increased (ending up 3% lower by 2008) while obesity has risen by 69%, it seems dubious that a change in caloric intake is to blame – as opposed to a change in caloric expenditure.

<sup>19</sup> *Id.*; NHANES Data [2000-2008].

<sup>20</sup> *See supra* notes 1-3 and accompanying text.

<sup>21</sup> Strangely, the Advertising Ban addresses *neither* “calories in” *nor* “calories out.” *See* “Executive Summary and Overview” *supra*; *see also infra* Section II.A.1. That omission is contrary to the well-established requirement that agencies may not cavalierly disregard their longstanding policies and positions without adequate explanation. *FCC v. Fox Television Stations, Inc.*, 129 S. Ct. 1800, 1811 (2009). “An agency may not,” the Supreme Court has recently affirmed, “depart from a prior policy *sub silentio* or simply disregard rules that are still on the books.” *Id.*

So the net calorie change driving increasing obesity seems likely to be caused by the fact that children are simply not getting the same amount of physical activity that they did in the past. This conclusion is consistent with a published report of the Office of the Assistant Secretary for Planning and Evaluation at HHS (–HHS Report”): “Research indicates that a decrease in daily energy expenditure without a concomitant decrease in total energy consumption may be the underlying factor for the increase in childhood obesity.”<sup>22</sup>

That childhood obesity is likely caused by decreased calorie expenditure jibes with the considerable evidence we have regarding the increasingly sedentary lifestyle of American children and youth. As a recently issued White House Report observed, “[u]nfortunately, our young people live in a social and physical environment that makes it easy to be sedentary and inconvenient to be active.”<sup>23</sup> Technological development has produced a broad array of media for entertainment, communication, and social interaction to which children and adolescents have gravitated in great numbers, but whose use tends to require little in the way of energy expenditure. The time that youth devote now devote to the use of these media appears to come at the expense of time spent on physical activity. This phenomenon was noted in the White House Report:

Fewer than one in five high school students meet the current recommendation of 60 minutes of daily physical activity, and a recent study showed that adolescents now spend more than seven hours per day watching television, DVDs, movies or using a computer or mobile device like a cell phone or MP3 player.<sup>24</sup>

As the above statement suggests, American youth are spending their time in front of the screen or texting – and not on physical activity. CDC’s 2009 National Youth Risk Behavior Survey reported that 25% of students played video or computer games (or used a computer for something that was not school work) for three or more hours per day on an average school day.<sup>25</sup>

The HHS Report also points to research indicating a troubling decline in physical activity among children: –Physical activity trend data for children are limited, but cross sectional data indicates that one third of adolescents are not getting recommended levels of moderate or vigorous activity, 10 percent are completely inactive, and physical activity levels fall as adolescents age ...”<sup>26</sup> The same HHS Report grimly went on to observe:

This situation may actually be worse than these data describe. Activity measured by physical activity monitors tends to be significantly lower than what is reported on surveys.<sup>27</sup>

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<sup>22</sup> Office of the Assistant Secretary for Planning and Evaluation, HHS, *Childhood Obesity*, at [http://aspe.hhs.gov/health/reports/child\\_obesity/](http://aspe.hhs.gov/health/reports/child_obesity/).

<sup>23</sup> White House Task Force on Childhood Obesity, *Report to the President: Solving the Problem of Childhood Obesity Within a Generation*, at 66 n.5 (May 2010) (hereinafter —White House Report”).

<sup>24</sup> White House Report at 66.

<sup>25</sup> CDC, *Youth Risk Surveillance – United States, 2009*, MORBIDITY AND MORTALITY WEEKLY REPORT 26 (June 4, 2010), available at <http://www.cdc.gov/mmwr/pdf/ss/ss5905.pdf>.

<sup>26</sup> Office of the Assistant Secretary for Planning and Evaluation, HHS, *Childhood Obesity*, at [http://aspe.hhs.gov/health/reports/child\\_obesity/](http://aspe.hhs.gov/health/reports/child_obesity/) (citing Youth Risk Behavior Surveillance System, NCCDPHP, CDC).

<sup>27</sup> *Id.*

In addition to the physical activity decline associated with increased media use, American children and youth have been getting less in the way of physical activity in school. As again noted in this same HHS Report:

... schools are decreasing the amount of free play or physical activity that children receive during school hours. Only about one-third of elementary children have daily physical education, and less than one-fifth have extracurricular physical activity programs at their schools. Daily enrollment in physical education classes among high school students decreased from 42 percent in 1991 to ... 28 percent in 2003.<sup>28</sup>

A host of other environmental and sociological factors may be contributing to the decline in physical exercise among American children as well. For example, the percentage of trips to school that children walked declined from 20 percent in 1977 to 12 percent in 2001.<sup>29</sup> Neighborhood crime, unattended dogs, or lack of street lighting may also inhibit children from being able to walk safely outdoors.<sup>30</sup> HealthyPeople 2020, a consortium of government agencies, colleges and universities, businesses, and individuals, identifies other factors that may positively or negatively affect physical activity, including traffic density; access to neighborhood or school play area and/or recreational equipment; amount of time spent by parents in physical activity; and availability of family and friends' support for children's participation in physical activities.<sup>31</sup>

Although the various factors contributing to reduced physical activity among children are complex and certainly bear further study, it is clear that those factors are unrelated to advertising, and the Advertising Ban will, therefore, be useless in addressing those factors, and thus in curbing rising childhood obesity rates. The Advertising Ban is, therefore, a misguided public policy choice if the goal is to make a meaningful impact on this important public health issue. It is addressing a non-problem instead of the real problem.

**2. *In addition, the fact that food advertising to kids has declined during the spike in obesity is further proof that advertising is not the cause.***

As childhood obesity rates have climbed in the United States, American children actually have been seeing far fewer food advertisements than in prior decades – which indicates that advertising and childhood obesity are not related.

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<sup>28</sup> Office of the Assistant Secretary for Planning and Evaluation, HHS, *Childhood Obesity*, at [http://aspe.hhs.gov/health/reports/child\\_obesity/](http://aspe.hhs.gov/health/reports/child_obesity/) (citing YRBSS Fact Sheet: Physical Activity).

<sup>29</sup> *Id.* (citing R. Sturm, *Childhood obesity – What can we learn from existing data on social trends? Part 2*, PREVENTING CHRONIC DISEASE (2005)).

<sup>30</sup> *Id.*

<sup>31</sup> HealthyPeople 2020, *Physical Activity*, at <http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=33> (citing Van Der Horst K, Paw MJ, Twisk JW, et al., *A brief review on correlates of physical activity and sedentariness in youth* [Review], MED SCI SPORTS EXERC. 2007 Aug;39(8):1241-50).

According to a 2007 report of the Federal Trade Commission's Bureau of Economics, the number of ads viewed by children in 2004 declined 9% from the number of ads viewed in 1977.<sup>32</sup> And after 2004, the largest food manufacturers in the United States committed to self-regulatory restrictions on child-directed food advertising. In furtherance of that commitment, the Children's Food and Beverage Advertising Initiative ("CFBAI") was launched in 2006 by 10 food manufacturers, including General Mills, in partnership with the Better Business Bureau. Manufacturers who have signed on with CFBAI (which, at most recent count, number 17) have pledged to abide by a set of core principles regarding the content and nature of child-directed advertising.

The impact of the industry's self-regulatory efforts has been to dramatically reduce the amount of food and beverage television advertising viewed by children ages 2 to 11. For instance, advertising expenditures on children's television (adjusted for inflation) dropped from nearly \$600 million in 2004 to just over \$200 million in 2010, a decline of nearly two-thirds. Between 2004 and 2010, total food advertisements viewed by children on children's television programming fell by more than 50%. This same period also saw the following percentage declines in children's television advertising in the following categories:

- cookies - 99%
- soft drinks – 96%
- frozen and refrigerated pizza -95%
- breads, pastries, waffles and pancakes –nearly 100%
- gum and mints - nearly 100%
- snack bars - nearly 100%
- snacks - 71%
- candy - 68%<sup>33</sup>

But these dramatic drops in child-directed advertising have not been mirrored in declining U.S. childhood obesity rates. The fact that childhood obesity rates continued to climb, even though children were exposed to far fewer ads, is further proof that children's viewing of advertising does not cause their obesity. Again, there is no reason to believe that this Advertising Ban – or indeed any food advertising ban – will have any helpful effect on childhood obesity, and every reason to know it will not.

This evidence strikes at the heart of the IWG's Proposal. At a minimum, the IWG is obligated to consider and address this evidence. Its failure to do so falls short of the reasoned decision-making required by law.<sup>34</sup>

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<sup>32</sup> FTC, Bureau of Economics Staff Report, *Children's Exposure to TV Advertising in 1977 and 2004: Information for the Obesity Debate* (June 1, 2007).

<sup>33</sup> Georgetown Economic Services, *Preliminary Findings: Food and Beverage Advertising 2004 and 2010, Children's Impressions and Expenditures on Children's Programs* (April 2011), available at [http://www.gmaonline.org/file-manager/Health\\_Nutrition/ges\\_report\\_on\\_childrens\\_tv\\_advertising.pdf](http://www.gmaonline.org/file-manager/Health_Nutrition/ges_report_on_childrens_tv_advertising.pdf). It is also worth noting that, during the same period, children's tv ad views per average child for fruits and vegetable juices increased by 199%. *Id.*

<sup>34</sup> An agency's "failure to respond meaningfully" to objections to its proposals "renders its decision arbitrary and capricious." *PPL Wallingford Energy LLC v. FERC*, 419 F.3d 1194, 1199 (D.C. Cir. 2005). Indeed, "[u]nless the [agency] answers objections that on their face seem legitimate, its decision can hardly be classified as reasoned." *Canadian Ass'n of Petroleum Producers v. FERC*, 254 F.3d 289, 299 (D.C. Cir. 2001).

3. ***If advertising caused obesity, one would actually expect advertising bans to reduce obesity. But advertising bans in several other countries have achieved no reductions in obesity rates, further establishing that the rise in obesity is not attributable to advertising.***

Aside from the evidence presented above, further evidence that advertising is not responsible for the rise in obesity comes from empirical experience – advertising bans adopted in other countries appear to have had no effect on childhood obesity rates. For example, the Canadian province of Quebec imposed a ban on advertising to children under the age of 13 in 1980, more than three decades ago. Yet the rates of childhood obesity in Quebec remain similar to those in other Canadian provinces.<sup>35</sup> Similarly, in 1991 Sweden introduced a ban on advertising on children’s programming, and still childhood obesity rates in Sweden are consistent with those in the rest of western Europe.<sup>36</sup> In fact, Sweden has experienced higher rates of childhood obesity than the Netherlands, which has a robust food advertising environment.<sup>37</sup>

Thus, food advertising bans over the past several decades in other countries have produced no positive results. And there is no basis for concluding that results will be any different in the U.S. The IWG must explain why it thinks otherwise and must do so in a way that evidences reasoned decision-making, not mere conjecture. As the Supreme Court states, an “agency must cogently explain why it has exercised its discretion in a given manner,” and that explanation must be “sufficient to enable [a court] to conclude that the agency’s action was the product of reasoned decisionmaking.”<sup>38</sup> The IWG has not done this, nor can it be done.

- B. But even assuming (for the sake of argument) that some sort of advertising restriction would make sense, a ban aimed at suppressing consumption of ready-to-eat cereals, yogurts, and other beneficial foods makes no sense at all, would likely *promote* obesity and poor nutrient intakes, and would be harmful to public health.**

1. ***The single largest impact of the IWG Advertising Ban – a ban on advertising of nearly all cereals (even cereals like Cheerios) – is antithetical to the IWG’s mission to combat obesity and promote good nutrient intakes and should compel its abandonment.***

As demonstrated above, there is *no* reason to believe that advertising of food in general causes obesity, and every reason to believe it does not. So there is no reason to believe that the IWG’s proposed Advertising Ban will accomplish anything helpful. But even if one were to assume, purely

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<sup>35</sup> J.D. Willms, M.S. Tremblay, and P.T. Kazmarzyk, *Geographical and Demographic Variation in the Prevalence of Overweight Canadian Children*, 11 OBESITY RESEARCH 668 (2003).

<sup>36</sup> T. Lobstein & M.-L. Frelut, *Prevalence of Overweight Among Children in Europe*, 4 OBESITY REV. 195 (2003).

<sup>37</sup> D. Ashton, *Food Advertising and Childhood Obesity*, JOURNAL OF THE ROYAL SOCIETY OF MEDICINE 97(2): 51-52;2004.

<sup>38</sup> *State Farm*, 463 U.S. at 48; *Alpharma, Inc. v. Leavitt*, 460 F. 3d 1, 6 (D.C. Cir. 2006).

for the sake of argument, that some sort of advertising ban could be useful,<sup>39</sup> it is abundantly clear that *this* advertising ban (*i.e.*, the IWG’s proposed Advertising Ban) makes no sense at all. *This is because the primary effect of the ban would be to ban the advertising of essentially all ready-to-eat cereals.* Indeed, *all* cereals General Mills makes would be banned from advertising. This includes products like Cheerios, Total, Fiber One, and Wheaties.

Why do we say that this would be the “primary effect” of the Advertising Ban? Because ready-to-eat cereal accounts for far-and-away the largest share of advertising of individual foods to children – accounting for fully 49% of all packaged food advertising to children.<sup>40</sup> And all – or virtually all – of this 49% would be banned.

So it would be worthwhile to step back and ask about the utility of an Advertising Ban that has a complete ban on ready-to-eat cereal advertising as its single largest impact – especially when the Advertising Ban’s stated goals are “addressing the high rates of childhood obesity”<sup>41</sup> and “shifting children’s food marketing away from foods of little or no nutritional value.”<sup>42</sup> Ready-to-eat cereal is without question, an important weapon in the war *against* obesity as demonstrated consistently by all scientific studies of the connection between cereal consumption and reduced likelihood of obesity (discussed below), and we would defy anyone to establish that any cereal (whether sweetened or not) is a food of “little or no nutritional value.” To the contrary, one would be very hard-pressed to identify any non-cereal breakfast item that would be nutritionally superior for a child to eat (or lower in calories) than a bowl of *any* of our cereals. In fact, it could not be done. Cereals (whether sweetened or not) are lower in calories and denser in key nutrients than any other option one might likely consider, as discussed in greater detail below.

So the largest single result of the Advertising Ban is antithetical to its stated purposes. This alone should compel its abandonment.<sup>43</sup>

If anything, a valid public policy would be one that would promote *greater* consumption of ready-to-eat cereals. The Advertising Ban, obviously, is intended to do the opposite, because it is

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<sup>39</sup> One would have to assume away the existence of the First Amendment as well, solely for purposes of this exercise.

<sup>40</sup> Kantar Media data (calendar year 2010).

<sup>41</sup> Proposal at 1.

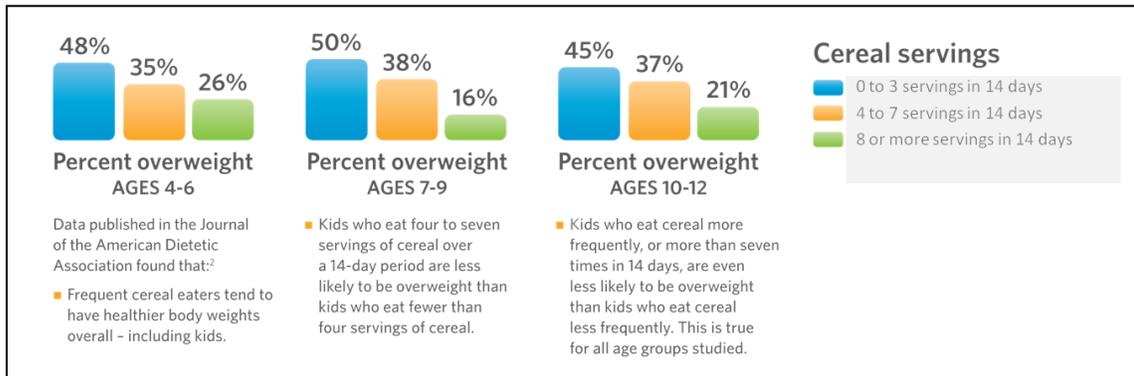
<sup>42</sup> FTC, *Statement of the Commission Concerning the Interagency Working Group on Food Marketed to Children Preliminary Proposed Nutrition Principles to Guide Industry Self-Regulatory Efforts*, at 1 (April 28, 2011), available at <http://www.ftc.gov/os/2011/04/110428foodmarketstmt.pdf>.

<sup>43</sup> It is also troubling to note that IWG must have known of this result, but moved forward with the Proposal anyway. The sweeping application of the Advertising Ban to cereal could scarcely have escaped IWG’s notice when it established its “nutrient standards” for foods. (These “nutrient standards” are the yardstick by which all foods are measured to determine their worthiness of being advertised to children; foods that fail to meet even *one* of these nutrient standards, regardless of what other benefits the food may confer, are subject to the Advertising Ban.) It is clear that IWG was focused on cereal, given that it chose to use cereal as its example for illustrating the application of the Proposal’s nutrient standards to foods whose normal serving size (or the “reference amount customarily consumed”) is 30 grams or less (a *special* rule that causes many cereals that would otherwise have passed the nutrient standards to fail). In the case of almost all cereals, the nutrient standard levels for sodium or added sugars (or both) are exceeded, causing the cereal to become subject to the Advertising Ban, solely because of this special rule. *See infra* Sections II.A.2.a.i and II.A.2.c.

necessarily designed to suppress consumption of products that, because of the ban, can no longer be advertised – and the largest percentage of that “banned” advertising is for cereal. The puzzling question, however, is why: *Why* would the IWG want to see the consumption of cereal decline, given the linkage between cereal consumption and reduced obesity and the superior nutrient-density-per-calorie provided by cereal? The answer is not clear. But the health credentials of cereal are incredibly clear, as detailed below.

- a. Kids who eat cereal frequently (including sweetened cereals) are far less likely to be overweight than those who do not, and they have better overall nutrient intakes as well.

Studies have consistently found that those who eat cereal frequently tend to have lower body weights, and in fact, the more frequently children eat cereal, the less likely it is that they will be overweight. According to data published in the *Journal of the American Dietetic Association*, for example, children aged 4 to 12 who eat eight or more servings of cereal over a 14-day period are significantly less likely to be overweight than those who eat four to seven servings of cereal over a 14-day period, who in turn are significantly less likely to be overweight than kids who eat zero to three servings of cereal during that same timeframe.<sup>44</sup> This result obtains for all age ranges. Pick just one specific set of data – for kids ages 7 to 9 – and one can get a sense of the huge magnitude of the difference between frequent cereal consumption and infrequent consumption. *Among this age range, frequent cereal eaters (8+ servings per 14 days) are over **three times** less likely to be overweight than infrequent cereal eaters.*<sup>45</sup>



And this is far from the only study establishing this relationship between increased cereal consumption and reduced obesity. A large study conducted by the NIH’s National Heart, Lung and Blood Institute, in which 2,000 girls were followed over a 10-year period, found that girls who demonstrated a consistent cereal-eating pattern had more healthful body weights and lower Body Mass Indexes than those who did not.<sup>46</sup> Although frequency of breakfast consumption and cereal

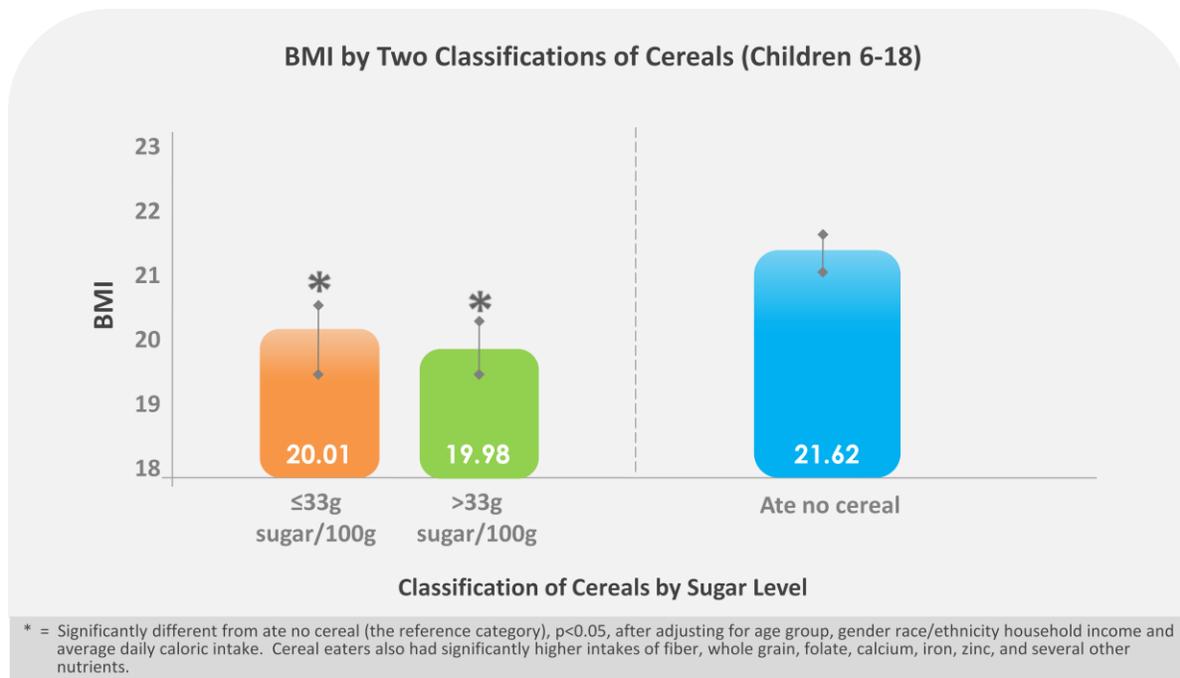
<sup>44</sup> Albertson AM et al., *Cereal Consumption: Its Relationship with BMI and Nutrient Intake of Children Aged 4 to 12 years*, J AM DIET ASSOC 2003;103:1613-1619.

<sup>45</sup> *Id.*

<sup>46</sup> Barton BA, Eldridge AL, Thompson D, Affenito SG, Striegel-Moore, RH, Franko DL, Albertson AM, Crockett SJ, *The Relationship of Breakfast and Cereal Consumption to Nutrient Intake and Body Mass Index: The National Heart, Lung and Blood Institute Growth and Health Study*, J AM DIET ASSOC 2005;105:1383-1389.

consumption declined with age, girls who continued to eat cereal frequently maintained a healthier body weight through adolescence, and had better overall nutrient intakes as well. And sugar content of the cereals did not alter the results – indeed, forty-one percent of the cereals consumed in the study were sweetened. The number of days eating cereal – including sweetened cereal – remained predictive of lower BMI and higher nutrient intakes.<sup>47</sup>

A 2009 study of children aged 6 to 18 similarly showed that *regardless of sweetness level*, cereal eaters have more healthful body weights than those who do not. In addition, they had significantly higher intakes of fiber, whole grain, folate, calcium, iron, zinc, and several other nutrients.<sup>48</sup>



And yet another study showed that cereal consumption was associated with a lower likelihood of weight gain and better nutritional status and among adolescent girls.<sup>49</sup> Although the frequency of breakfast eating declined with age, days on which the girls ate breakfast were associated with higher calcium and higher fiber intake.

<sup>47</sup> *Id.*

<sup>48</sup> Albertson AM et al., *The Relationship Between Ready-to-Eat Cereal Consumption Categorized by Sugar Content and Body Measures in American Children: Results from NHANES 2001-06*, FASEB JOURNAL (April 2009) 23 (Meeting Abstracts): 550.22; Albertson AM, Thompson DR, Franko DL, Holschuh NM., *Weight Indicators and Nutrient Intake in Children and Adolescents Do Not Vary by Sugar Content in Ready-to-Eat Cereal: Results from National Health and Nutrition Examination Survey 2001-2006*, NUTR RESEARCH Mar 2011. 31:229-236.

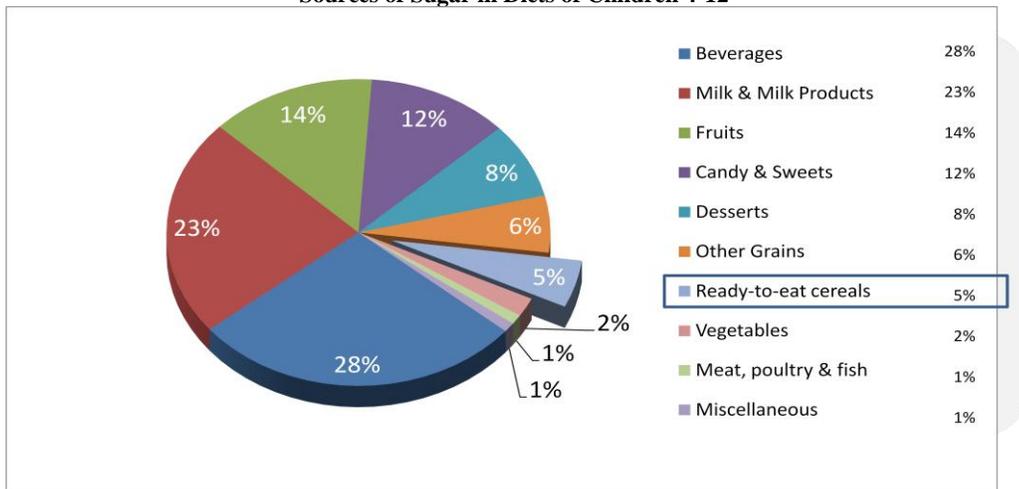
<sup>49</sup> Affenito SJ et al., *Breakfast Consumption in African-American and White Adolescent Girls Correlates Positively with Calcium and Fiber Intake and Negatively with Body Mass Index*, J AM DIET ASSOC 2005;105:938-945.

The bottom line, as well articulated by Dr. Ronald Kleinman (Chief of the Pediatric Gastroenterology and Nutrition Unit at Massachusetts General Hospital; Professor of Pediatrics at Harvard Medical School; and former Chairman of the Committee on Nutrition for the American Academy of Pediatrics) is as follows: **“Research confirms an association between eating ready-to-eat cereal for breakfast and less overweight and obesity; also with better nutrient intake. This is true whether or not the cereal is pre-sweetened.”**<sup>50</sup>

It should be emphasized that the fact that sugar content has no impact on these compelling statistics should really come as no surprise. *As emphasized elsewhere in this Comment as well, obesity is about the calories-in/calories-out balance, and the sugar content of a cereal has no material impact on its caloric content. As carbohydrate-based foods, all cereals – whether unsweetened or sweetened – have around 4 calories per gram (because all carbohydrates have around 4 calories per gram).* For this reason, a typical 30-gram serving of any cereal – whether Cheerios or Kix or Lucky Charms – will have approximately the same number of calories, and all will provide similarly robust levels of key nutrients as well.

Indeed, cereal accounts for only 4% of caloric intake in the diets of children age 4 to 12,<sup>51</sup> while at the same time accounting for very sizeable percentages of key nutrients in children’s diets (as described in detail in subsection (b) below). And even if one were to (inappropriately) focus on sugar content instead of caloric content of cereals, government data establishes that cereal accounts for only 5% of children’s sugar intake, less than that provided by any other class of foods other than vegetables and meat.<sup>52</sup> By comparison, non-dairy beverages provide 28% of the sugar in children’s diets, and fruits provide 14%.<sup>53</sup>

Sources of Sugar in Diets of Children 4-12



Consider the remarks of Dr. Benjamin Caballero (Professor of International Health at the Johns Hopkins Bloomberg School of Public Health; Professor of Pediatrics at the School of Medicine,

<sup>50</sup> Presentation given to FTC Chairman Jon Leibowitz, *Cereal and Obesity*, at 9 (June 8, 2010), attached hereto as Attachment 1.

<sup>51</sup> NHANES Data [2005-06].

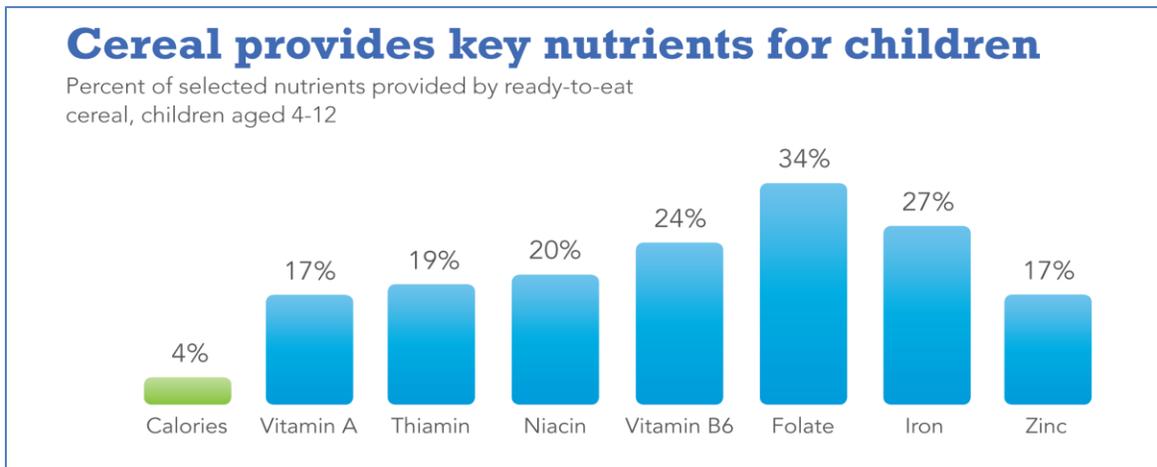
<sup>52</sup> See NHANES Data [2007-2008]. See also *infra* note 93 and accompanying text (discussing the Dietary Guidelines’ affirmation of the role of sugar in making nutritious foods palatable).

<sup>53</sup> See NHANES Data [2007-2008].

Johns Hopkins University; and a current member of the FDA’s Scientific Advisory Board) on this data: **“The study by Albertson et al, using NHANES data, confirms that breakfast cereals contribute only a very small fraction of daily refined sugars intake in 6-18 year old children. The study also found that children who consume cereal tend to have lower, not higher BMI than those who do not.”**<sup>54</sup> In failing to account for any of this in arriving at its Proposal, the IWG has failed in its legally required duty to consider all relevant data.<sup>55</sup>

b. Cereal is a critical source of key nutrients and whole grains for children.

Cereal provides an incredibly nutrient-dense meal for children – even more so when combined with fortified milk. Fortified cereals provide more iron, folic acid, zinc, B vitamin and fiber than any other conventional non-cereal breakfast choice. And fortified cereals also typically include vitamin A, thiamin, niacin, calcium, phosphorus, magnesium, and potassium. As noted earlier, cereals provide only 4% of the calories in children’s diets. But cereals deliver very significant percentages of key nutrients in children’s diets. For children 4-12, cereal is responsible for 17% of their vitamin A, 19% of their thiamin, 20% of their niacin, 24% of their vitamin B6, 34% of their folate, 27% of their iron, and 17% of their zinc intakes.<sup>56</sup>



Cereal is also a critical source of vitamin D and calcium, which are vitally important nutrients for the development and maintenance of strong, healthy bones in children.<sup>57</sup> Research shows that 96% of children aged 6 to 12 have insufficient vitamin D in their diet, and about 55% get insufficient calcium.<sup>58</sup> General Mills fortifies its entire line of children’s cereal with calcium and Vitamin D. And even beyond this fortification, since 91% of cereal is consumed with milk (which is also rich in

<sup>54</sup> Presentation given to FTC Chairman Jon Leibowitz, *Cereal and Obesity*, at 9 (June 8, 2010), attached hereto as Attachment 1.

<sup>55</sup> *State Farm*, 463 U.S. at 43.

<sup>56</sup> See NHANES Data [2007-2008].

<sup>57</sup> Vitamin D enables the body to absorb calcium, which helps to build strong bones and teeth. Recent studies also indicate that vitamin D may reduce the risk of a number of chronic diseases, including cardiovascular disease and diabetes.

<sup>58</sup> See NHANES Data [2007-2008].

calcium and vitamin D),<sup>59</sup> cereal does “double duty” in fostering consumption of these key nutrients. 41% of all of the milk in children’s diets is consumed with cereal.<sup>60</sup> For Hispanic children and African American children, that percentage rises to 48% and 54%, respectively.<sup>61</sup> As a consequence, 40% of the calcium in children’s diets comes from eating cereal.<sup>62</sup> Vitamin D can be found in foods other than cereal, such as herring, catfish, salmon, beef liver and eggs. But as a practical matter, if children find these foods unappealing, it may be difficult to get children to eat enough of them to obtain the vitamin D they need. Fortified cereal is a “win-win” food for kids because it not only delivers tremendous nutrition in a relatively small number of calories, but children actually like cereal and will eat it.<sup>63</sup> For instance, in a recent survey of Washington, D.C.-area mothers, more than 80 percent of mothers indicated that they serve cereal because they know their kids will eat it.<sup>64</sup>

As shown by the numbers in the preceding two paragraphs, were it not for cereal (and if cereal did not taste good to children), the nation’s children would be seriously deficient in all manner of key nutrients. Children would also have a much harder time getting sufficient quantities of whole grains in their diets. Whole grain consumption has been shown to promote heart health, to be consistent with healthful body weights, to reduce the risk of stomach and colon cancers, and to reduce diabetes risk by promoting healthful blood glucose and insulin levels. Yet whole grains are largely missing from most Americans’ diets. Only one in 10 Americans eats the minimum recommended amount of whole grain daily.<sup>65</sup> Market research shows consumption of whole grain did increase by 20 percent between 2005 and 2008<sup>66</sup> – an increase that coincided with General Mills’ 2005 decision to ensure that all of our cereals would deliver 8 grams of whole grain or more per serving. Today, General Mills delivers 37.5 million whole grain servings per day via its cereals alone – about 10 percent of the estimated whole grain consumed in America.<sup>67</sup> Ready-to-eat cereal is the leading whole grain source for Americans, and it is the top choice for children.<sup>68</sup>

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<sup>59</sup> *Id.*

<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

<sup>62</sup> *Id.*

<sup>63</sup> This is particularly critical for families whose food budgets are limited, and who cannot afford to buy foods that their children will reject.

<sup>64</sup> This survey, conducted on behalf of General Mills, polled 201 parents in the Washington, D.C. area between April 19 and 26, 2011.

<sup>65</sup> Cleveland L et al., *Dietary Intake of Whole Grains*, J AM COL NUTR 2000;19(3):331S-338S.

<sup>66</sup> Harnack L et al., *Dietary Intake and Food Sources of Whole Grains Among U.S. Children and Adolescents: Data from the 1994-1996 Continuing Survey of Food Intakes by Individuals*, J AM DIET ASSOC 2003;103:1015-1019.

<sup>67</sup> Bachman JL et al. *Sources of Food Group Intakes among the US Population, 2001-2002*. J AM DIET ASSOC 2008;108:804-814.

<sup>68</sup> Cleveland L et al., *Dietary Intake of Whole Grains*, J AM COL NUTR 2000;19(3):331S-338S; Harnack L et al., *Dietary Intake and Food Sources of Whole Grains Among U.S. Children and Adolescents: Data from the 1994-1996 Continuing Survey of Food Intakes by Individuals*, J AM DIET ASSOC 2003;103:1015-1019; Bachman JL et al., *Sources of Food Group Intakes Among the US Population, 2001-2002*, J AM DIET ASSOC 2008;108:804-814.

c. Cereal is also an incredibly low-cost, nutrient-dense food, and is especially critical to lower income and minority families.

As discussed repeatedly above, cereal is extremely dense in key nutrients. But it also is very efficient in delivering these nutrients – not just by doing so alongside very few calories, but also because it requires so little money and time. A typical bowl of cereal (with milk) costs under 50 cents and takes virtually no time to prepare. Cereal also has a long shelf life (which means that it does not tend to be wasted), is easy for parents to keep on hand, and easy for rushed families to prepare and serve. And, as noted above, because kids actually like to eat it, cereal is a win-win food for parents and kids – and even more so for lower income families who cannot afford to purchase food that their children will reject and not eat.<sup>69</sup>

Food insecurity is a major and growing problem within the United States. Feeding America, the nation's largest domestic hunger relief organization, reports (citing USDA data) that 17 million American children – more than one in five children – live in food insecure households.<sup>70</sup> Nutrient intake is of course a serious concern with respect to these children – and cereal is an important part of the solution. Data from a recent study of NHANES data from 2003-2008 suggests that the adverse nutritional effects of food insecurity can be mitigated through access to low-cost, nutrient-dense foods such as cereal.<sup>71</sup> Indeed, cereal consumption among food insecure children ages 4-12 was found to be associated with improved nutrient intake profiles.<sup>72</sup>

Moreover, in a separate study that attempted to rank foods according to nutrient density per unit cost (using a measure called the Nutrient Rich Foods Index (an algorithm of determining nutrient density of a food, which accounts for 9 nutrients to encourage (protein, fiber, vitamins A, C and E, calcium, iron, magnesium and potassium) and 3 nutrients to limit (saturated fat, added sugar and sodium)), fortified ready-to-eat cereals were among the very highest ranked foods.<sup>73</sup>

As a consequence, cereal is incredibly important to the health of low-income and minority populations in the United States. African American and Hispanic children (ages 2-18) who consume ready-to-eat cereal have significantly higher intakes of critical micronutrients and are more likely to meet overall nutrient intake requirements than children who consume other breakfast foods or skip breakfast.<sup>74</sup> *On the days that ready-to-eat cereal is consumed, these children receive over 30% of their day's intake of many vitamins and minerals from ready-to-eat cereal including 40% of their daily iron.*<sup>75</sup> Daily intake of milk is also significantly higher for the Hispanic and African American

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<sup>69</sup> See *supra* note 64 and accompanying text.

<sup>70</sup> Feeding America, *Child Hunger Facts*, at <http://feedingamerica.org/hunger-in-america/hunger-facts/child-hunger-facts.aspx> (last visited July 6, 2011).

<sup>71</sup> Tuttle C, Thompson d, Franko D, Albertson A, *Cereal Intake Is Associated with an Improved Nutrient Intake Profile Among Food Insecure Children in the United States: Results from NHANES 2003-08*, FASEB J March 17, 2011 25:769.19 (presented at FASEB Experimental Biology 2011).

<sup>72</sup> *Id.*

<sup>73</sup> Drewnowski A, *The Nutrient Rich Foods Index Helps to Identify Healthy, Affordable Foods*, AM J CLIN NUTR 2010;91 (suppl): 1095S-1101S.

<sup>74</sup> See NHANES Data [2007-2008].

<sup>75</sup> *Id.*

children who consume cereal.<sup>76</sup> As noted earlier, 48% of the milk consumed by Hispanic children, and 54% of the milk consumed by African American children, is consumed with cereal.<sup>77</sup>

d. Breakfast is important and cereal represents the best choice for breakfast.

One item of collateral damage of the proposed Advertising Ban's impact on cereal is that it would eliminate most advertising of breakfast to kids (which comes almost exclusively through cereal advertising). Studies have found that children who eat breakfast record higher test scores in school, have fewer discipline problems, and stay more alert than those who do not eat breakfast.<sup>78</sup> They also have better nutrient intakes and are less likely to be obese.<sup>79</sup>

We should *want* kids to eat breakfast. And among breakfast options, cereal is the lowest-calorie, most nutrient-dense food. By banning cereal advertising, the IWG is effectively either acting to limit breakfast consumption (a bad result) or to limit consumption of cereal at the expense of other breakfast options (also a bad result). Consider the foods most likely to replace cereal at breakfast, and none of the alternatives are attractive. Cereal generally has around 120 calories or less per serving (150 calories with skim milk) – a relatively low amount, particularly as compared with other breakfast choices: oatmeal with skim milk (170); doughnut (250); bagel with light cream cheese (315); two eggs, bacon, and toast (375); biscuit with sausage, egg, and cheese (580).<sup>80</sup>

Note that even *plain oatmeal* is higher in calories per serving. That might be surprising enough. But compare plain oatmeal with a common kid-oriented cereal like Lucky Charms from a nutrient delivery standpoint, and the benefits of ready-to-eat cereals become even more striking:

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<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

<sup>78</sup> Murphy JM et al., *The Relationship of School Breakfast to Psychosocial and Academic Functioning: Cross-sectional and Longitudinal Observations in an inner-city School Sample*, ARCH PEDIATR ADOLESC MED 1998;152:899-907; Wahlstrom KL and Begalle MS, *More than Test Scores: Results of the Universal School Breakfast Pilot in Minnesota*, TOP CLIN NUTR 1999;(1):17-29; Wesnes KA et al., *Breakfast Reduces Declines in Attention and Memory over the Morning in Schoolchildren*, APPETITE 2003;41:329-331.

<sup>79</sup> See Rampersaud et al., *Breakfast Habits, Nutritional Status, Body Weight and Academic Performance in Children and Adolescents*, J AM DIET ASSOC 2005; 105: 743-760; Nicklas TA et al., *Efficiency of Breakfast Consumption Patterns of Ninth Graders: Nutrient-to-Cost Comparisons*, J Am Diet Assoc 2002; 102(2); 226-33; Morgan KJ et al., *The Role of Breakfast in Diet Adequacy of U.S. Adult Population*, J AM COLL NUTR 1986; 5: 551-563.

<sup>80</sup> It is also worth noting that while some of these items would qualify for more lenient nutrition standards under the IWG approach, by virtue of the fact that they meet IWG's definition of what constitutes a "main dish" or a "real," cereal does not, which seems inappropriate given that it is eaten just as much as a "real" or "main dish" as any of these items.

 110 Calories		 Oatmeal 150 Calories	
<b>Iron</b>	<b>25% DV</b>	<b>Iron</b>	<b>10% DV</b>
<b>Thiamin</b>	<b>25% DV</b>	<b>Thiamin</b>	<b>10% DV</b>
<b>Riboflavin</b>	<b>25% DV</b>	<b>Riboflavin</b>	<b>2% DV</b>
<b>Folic Acid</b>	<b>50% DV</b>	<b>Folic Acid</b>	--
<b>Niacin</b>	<b>25% DV</b>	<b>Niacin</b>	--
<b>Vitamin B6</b>	<b>25% DV</b>	<b>Vitamin B6</b>	--
<b>Vitamin B12</b>	<b>25% DV</b>	<b>Vitamin B12</b>	--
<b>Zinc</b>	<b>25% DV</b>	<b>Zinc</b>	--
<b>Vitamin A</b>	<b>10% DV</b>	<b>Vitamin A</b>	--
<b>Vitamin C</b>	<b>10% DV</b>	<b>Vitamin C</b>	--
<b>Vitamin D</b>	<b>10% DV</b>	<b>Vitamin D</b>	--
<b>Calcium</b>	<b>10% DV</b>	<b>Calcium</b>	--

It is worth noting that plain oatmeal could be advertising under the Proposal whereas Lucky Charms could not. It is also worth noting that, while oatmeal is already more caloric per serving than Lucky Charms even when the oatmeal is served plain, it is highly likely that substantial quantities of sugar will be added to it at the time of consumption (especially if consumed by a child), resulting in a vastly more caloric breakfast than a bowl of Lucky Charms.

- e. To the detriment of public health, the IWG ignored Congress’s directive that it study and consider the benefits provided by foods such as cereal.

As discussed above, the IWG’s scheme for determining whether a food should be advertised to children is to apply an inflexible set of nutrient criteria to it, and a food’s failure to conform to any single criterion brings the food under the Advertising Ban. Perhaps the IWG was motivated by a desire to “keep it simple” – to come up with one set of standards that would apply across the board to all foods. If so, what unfortunately has resulted is a system that is not simple but *simplistic*, and consequently, ends up in many cases undermining the very goals the IWG set out to achieve. The rigid set of measures the IWG devised for evaluating foods *ignores* the fact that a food may be tremendously nutritious, or have powerful antioxidants, or be an excellent source of a hard-to-obtain micronutrient, even though that same food is a little higher (than the IWG permits) in sodium or fat or other macronutrient. Congress, however, did not wish the IWG to ignore these considerations. Rather, Congress expressly directed the IWG to consider both the negative *and positive* contributions of foods to diets of children, and to consider “*evidence concerning the role of consumption of ... foods in preventing ... the development of obesity among such children.*”<sup>81</sup>

<sup>81</sup> Congress’ directive provided as follows:

[T]he Working Group is directed to consider (1) *positive* and negative *contributions of* nutrients, ingredients, and *food* (including calories, portion size, saturated fat, trans fat, sodium, added sugars, and the presence of nutrients, fruits, vegetables, and whole grains) *to the diets of such children*; and (2) *evidence concerning the role of consumption of* nutrients, ingredients, and *foods in preventing* or promoting *the development of obesity among such children.*

Proposal at 2 (emphasis added).

There is no evidence that the IWG did either of those things in developing its standards. If it had, there would seem to be no way – based on all the compelling evidence provided above – that the IWG could have arrived at a proposal to ban the advertising of any, much less essentially all, ready-to-eat cereals. This error is no small matter. –When Congress says a factor is mandatory, that expresses its judgment that such a factor is important. In accordance with this principle, [courts] have held that the complete absen[c]e of any discussion of the statutorily mandated factor leaves [courts] with no alternative but to conclude that [the agency] failed to take account of this statutory limit on [its] authority, making the agency’s reasoning arbitrary and capricious.”<sup>82</sup>

Cereal is part of the solution here, not part of the problem. Seeking to suppress its consumption through an Advertising Ban is a misguided policy that will promote obesity and poor nutrient intakes. And since this is the principal impact of the entire Proposal, the Proposal is fundamentally flawed and should be withdrawn.

**2. *Another principal impact of the Advertising Ban would be to ban the advertising of most yogurts to kids, again contrary to the stated purpose of fostering public health.***

Among products that General Mills markets to children, cereal is far and away the most frequently advertised, and far and away the most frequently consumed. But cereal is not the only beneficial food that the government ought to be promoting – instead of demonizing. Yogurt is another example.

Yogurt accounts for about 10% of the advertising of individual food products to children,<sup>83</sup> and the Proposal would seek to ban nearly all of this. Though yogurt is not a commonly consumed staple like cereal – and therefore does not have the degree of consumption necessary to deliver public health benefits on a scale as broad as cereal does – yogurt is clearly very worthy of child consumption, and certainly should not be one of the major victims of an Advertising Ban.

For example, yogurt, like other dairy foods, delivers several essential nutrients, such as protein, phosphorus, potassium, certain B vitamins, and (of course) calcium. All of our yogurts are also fortified with vitamin D. It is worth pausing briefly to discuss the role of yogurt in providing these latter two (calcium and vitamin D) in greater detail.

Calcium is a vital nutrient that helps build strong bones and teeth. Bone is a living tissue that changes constantly, with small amounts of bone being removed and replaced by new bone. Peak bone mass is attained by age 30 in most individuals, with most bone mass accumulating during childhood and adolescence.<sup>84</sup> Up to 90 percent of peak bone mass is acquired by age 18 in girls and by age 20 in boys.<sup>85</sup> Achieving and maintaining high bone density reduces the risk of osteoporosis later in life.<sup>86</sup> Most Americans fall short of meeting the daily recommended amount of calcium.<sup>87</sup>

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<sup>82</sup> *Pub. Citizen v. Fed. Motor Carrier Safety*, 372 F.3d 1209, 1216 (D.C. Cir. 2004).

<sup>83</sup> Kantar Media data (calendar year 2010).

<sup>84</sup> National Institutes of Health, *Osteoporosis: Peak Bone Mass in Women*, at [http://www.niams.nih.gov/Health\\_Info/Bone/Osteoporosis/bone\\_mass.asp](http://www.niams.nih.gov/Health_Info/Bone/Osteoporosis/bone_mass.asp) (last visited July 6, 2011).

<sup>85</sup> *Id.*

<sup>86</sup> *Id.*

Over 75% of teenage girls and older females (51+ years) do not consume diets providing the recommended amounts of calcium.<sup>88</sup> Over 90% of children who eat yogurt meet their recommended intake for calcium.<sup>89</sup> In 2010, General Mills' Yoplait retail kid products provided over 156 million grams of calcium to consumers, which is enough to provide over 425,000 children with 100% of their recommended calcium intake for a whole year.

Vitamin D is a critical nutrient that enables the body to absorb calcium. Research also suggests that vitamin D is associated with decreased risk of several chronic diseases, including diabetes, hypertension and auto-immune diseases.<sup>90</sup> While vitamin D occurs naturally in many foods, such as herring, salmon, beef liver and eggs, it can be difficult for individuals, particularly children, to consume enough of these foods to meet recommended intake levels. Approximately 95% of Americans (and nearly 90% of children) have diets that fail to meet recommended intakes for vitamin D.<sup>91</sup> Fortified foods, such as yogurt, can help individuals fill this void. General Mills fortifies its entire line of yogurts with vitamin D, and its yogurts provide at least a good source of vitamin D. *Children who eat yogurt have higher intakes of vitamin D than those who do not.*<sup>92</sup> In 2010, Yoplait retail kid products shipped over 1.5 billion micrograms of vitamin D to consumers, which is enough to provide over 400,000 children with 100% of the recommended daily value of vitamin D for an entire year.

In providing calcium and vitamin D and other nutrients, yogurt is especially important for those who suffer from lactose intolerance, a condition that is most prevalent within the African American, Hispanic, Asian, and Native American populations in particular. These individuals experience varying degrees of discomfort (including diarrhea, abdominal pain, flatulence, or bloating) when they consume lactose, a sugar found in milk and other dairy products. As a result of this discomfort, lactose intolerant individuals avoid consuming dairy products, and ingest inadequate amounts of calcium, vitamin D, and other essential nutrients found in dairy products. Yogurt contains live and active cultures that can help lessen symptoms of lactose intolerance. For individuals who suffer from lactose intolerance, yogurt can be an important source of calcium and vitamin D because other dairy products may be less well-tolerated or accepted.

To be sure, yogurts marketed to children contain moderate amounts of sugar – typically moderate enough, in fact, that these yogurts would satisfy the IWG's sugar threshold (sometimes quite easily) but for the fact that the IWG employs a decades-old (and far from valid) assumption that yogurt portion sizes being consumed by kids are 8 ounces. Today, fewer than 2% of all yogurts are sold in 8-ounce containers, and yogurts marketed to kids come in either 4-ounce cups or 2.25-ounce tubes. There is no reason to believe that kids eat the multiple servings of these products that would

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<sup>87</sup> NHANES Data [2007-2008]; Institute of Medicine, *Dietary Reference Intakes of Vitamin D and Calcium* (Nov. 30, 2010), available at <http://www.iom.edu/Reports/2010/Dietary-Reference-Intakes-for-Calcium-and-Vitamin-D.aspx>.

<sup>88</sup> NHANES Data [2007-2008].

<sup>89</sup> *Id.*

<sup>90</sup> Hanley DA, Davison SK, *Vitamin D Insufficiency in North America*, J NUTR. 2005;135:332-337; Misra M et al., *Vitamin D Deficiency in Children and Its Management: Review of Current Knowledge and Recommendations*, PEDIATRICS 2008; 122; 398-417

<sup>91</sup> NHANES Data [2007-2008].

<sup>92</sup> *Id.*

result in them taking in more than the IWG's limit of 13 grams of sugar, but because the IWG assumes kids are eating 2 to 4 servings (8 ounces) of these products at one sitting, these yogurts fail the IWG's standards and are banned from advertising.

This is unfortunate, and in conflict with consistent federal dietary guidance recognizing the need for small amounts of sugar to make healthful foods (including reduced-fat dairy products like yogurt) palatable.<sup>93</sup> Sugar is especially important in the case of yogurt, because it masks the inherently sour taste of yogurt cultures in order to promote consumption of this food which, as described above, is clearly beneficial to public health.<sup>94</sup>

As noted at the very outset of this Comment, there are two necessary elements for a healthful food to "do its job" of delivering public health benefits: palatability and advertising. Yogurt is perhaps the prototypical example of the role of advertising in this process. Frequent kid consumption of yogurt is a relatively recent phenomenon. Not that long ago, American kids were not eating yogurt at all. General Mills sought to change that by making yogurt fun and appealing. We introduced Go-Gurt (a squeezable tube of yogurt suitable for snacking on the go) and Trix yogurt (a conventional cup yogurt branded in an appealing way), and supported these products with appealing advertising emphasizing an association between fun and yogurt. In addition to growing our brands, these initiatives helped drive competitive responses that developed yogurt as a popular snack for kids. In the past few decades, as our products and competitive products were being introduced and marketed, the frequency of yogurt consumption by kids ages 6 through 12 nearly quadrupled. Thus, effective marketing of these kid-oriented yogurt products has essentially created a product category that did not formerly exist, encouraging kids to more often choose nutrient-dense yogurt as a healthful snack.

Fortunately, the IWG Advertising Ban was not in place during this period or kids would likely be consuming far less healthful snacks in lieu of yogurt. Rather than banning the advertising of healthful products like yogurt to children, the IWG should recognize the important contribution yogurt makes to the American diet and the critical role that responsible advertising plays in encouraging consumers to choose products like yogurt. Yogurt is not a "food of little or no nutritional value" as it is being labeled by the IWG.

As with banning the advertising of cereal, banning the advertising of yogurt is counterproductive, and conflicts with the IWG's stated mission of promoting public health. As with cereal, the IWG appears to have ignored its congressional directive to consider the "positive contributions" of yogurt to the diets of children.

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<sup>93</sup> For instance the 2005 Dietary Guidelines published by USDA and HHS note that "[i]n some cases, small amounts of sugars added to nutrient-dense foods, such as breakfast cereals and reduced-fat milk products, may increase a person's intake of such foods by enhancing the palatability of these products, thus improving nutrient intake without contributing excessive calories." USDA and HHS, *Dietary Guidelines for Americans, 2005*, at 36-37. See also *infra* Section II.B.4.

<sup>94</sup> It should be noted that, since 2004, General Mills has been working to reduce the sugar content in its yogurts advertised to children under 12 – a huge challenge given the need to maintain the great taste that children have come to expect and enjoy from our products. Since 2007, we have lowered the average sugar content in Yoplait kid products by more than 21%. These sugar reductions have also been accompanied by a reduction in calories and fat: in 2008, we reduced the fat in our GoGurt products by 75% and calories by 12%, and reduced the fat in our Trix yogurt products by 33%.

## II. The Proposal's nutrition standards are arbitrary, capricious, and fundamentally flawed.

### A. The Proposal's nutrition standards conflict with existing (and long-standing, science-based) federal dietary policy and guidance – and would harm public health if actually implemented.

#### 1. *By focusing on macronutrient composition and ignoring calories, the proposed nutrition standards ignore the mandate given the IWG by Congress as well as the long-standing (and unanimous) scientific determination of FDA, HHS, USDA, NIH, and CDC that obesity is about the calories-in/calories-out balance.*

- a. It has been the longstanding determination of all relevant federal agencies – including the agencies involved here – that calories (and not macronutrient composition) are the key factor in obesity.

Federal agencies that have studied the problem, including the agencies that compose the IWG, have long been unanimous in affirming that obesity is a matter of calories in versus calories out, and yet the Proposal ignores that fundamental point. As recently as this year, the National Institutes of Health (NIH) reconfirmed the centrality of calorie intake/calorie expenditure to the obesity issue in its strategic plan for obesity research:

At a fundamental level, obesity develops because of a mismatch in “energy balance”: Calories taken in from food and beverage exceed those expended in activity and metabolic functions (including growth in children), with resultant excess adipose tissue (body fat) storage.<sup>95</sup>

In that same document the NIH took pains to underscore that the calories-in/calories-out balance, and not macronutrient composition, is the principal determining factor in affecting weight.

Recent intervention studies have examined a wide variety of topics, including lifestyle interventions for weight loss, maintenance of weight loss, and preventing comorbidities; diets varying in macronutrient composition for weight loss; increasing physical activity in schools; site-based and community approaches to weight control; bariatric surgery outcomes; and efficacy of weight-loss medications. Key conclusions have emerged: ***Both sides of energy balance – intake and expenditure – are important for obesity control. Macronutrient composition (i.e., percentage of fat, carbohydrate, and protein) is less important than calorie reduction for weight control*** after 1 year or more in randomized controlled trials among free-living adults. (emphasis added)<sup>96</sup>

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<sup>95</sup> HHS (NIH), *Strategic Plan for NIH Obesity Research: A Report of the NIH Obesity Task Force*, NIH Publication No. 11-5493, at 1 (March 2011), available at [http://obesityresearch.nih.gov/about/StrategicPlanforNIH\\_Obesity\\_Research\\_Full-Report\\_2011.pdf](http://obesityresearch.nih.gov/about/StrategicPlanforNIH_Obesity_Research_Full-Report_2011.pdf).

<sup>96</sup> *Id.* at 15. In addition, the National Heart, Lung, and Blood Institute (NHLBI), a health institute within the NIH and under the US Department of Health and Human Services (HHS), has similarly advised that weight management efforts need to focus on “energy balance” (calories from food and drinks (“energy in”) balanced with the energy used by the body for breathing, digesting, and being physically active (“energy out”)), rather than on the macronutrient composition of foods consumed:

The FDA, which has devoted considerable resources to the study of the obesity problem, agrees: *calories*, and not macronutrient composition, are the single most important consideration in weight management. In order to focus Americans' attention on calories, rather than on "good" or "bad" foods, the FDA established a campaign called "Calories Count," in which it explained:

Fundamentally, obesity represents an imbalance between energy intake (e.g., calorie intake) and energy output (expended both as physical activity and metabolic activity . . . . Although there is much discussion about (1) the appropriate makeup of the diet in terms of relative proportions of macronutrients (fats [lipids], carbohydrates, and protein) that provide calories and (2) the foods that provide these macronutrients, ***for maintenance of a healthy body weight it is the consumption and expenditure of calories that is most important.*** (emphasis added)<sup>97</sup>

Indeed, to this day, FDA continues to drive home its message that appropriate calorie balance is the key to avoiding overweight and obesity. For instance, in its recent proposed rulemaking on menu labeling, the FDA stated:

The primary risk factors for overweight and obesity in the general population are overconsumption of calories (i.e., eating more calories than are needed to maintain body weight) and physical inactivity (i.e., getting an amount of exercise below the amount required to burn excess calories consumed over the amount needed to maintain body weight).<sup>98</sup>

The Centers for Disease Control and Prevention (CDC) promote the same theme in their messages to the public on obesity: calories in/calories out are the key to weight management. As the CDC's website dedicated to obesity succinctly puts it:

When it comes to maintaining a healthy weight for a lifetime, the bottom line is – calories count! ***Weight management is all about balance – balancing the number of calories you consume with the number of calories your body uses or "burns off."*** (emphasis added)<sup>99</sup>

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***A calorie is a calorie is a calorie whether it comes from fat or carbohydrate. Anything eaten in excess can lead to weight gain. You can lose weight by eating less calories and by increasing your physical activity.*** Reducing the amount of fat and saturated fat that you eat is one easy way to limit your overall calorie intake. However, eating fat-free or reduced fat foods isn't always the answer to weight loss. This is especially true when you eat more of the reduced fat food than you would of the regular item. For example, if you eat twice as many fat free cookies, you have actually increased your overall calorie intake. (emphasis added)

NHLBI, *Aim for a Healthy Weight*, at 9 (Aug. 2005).

<sup>97</sup> FDA, *Calories Count: Report of the Working Group on Obesity*, at 3 (2004).

<sup>98</sup> Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. 19192 (proposed April 6, 2011).

<sup>99</sup> CDC, *Overweight and Obesity: Causes and Consequences*, at <http://www.cdc.gov/obesity/causes/index.html> (last visited July 6, 2011). This same website also cites to the U.S. Surgeon General's *Call to Action to Prevent and Decrease Overweight and Obesity* (2001), which likewise reached the same conclusion: —Actions should strive to help all Americans maintain a healthy or healthier weight through balancing caloric intake and energy expenditure." *Id.*

HHS and USDA have also joined the chorus of federal voices emphasizing that obesity and overweight are fundamentally an issue of calorie intake and expenditure. In their jointly prepared Dietary Guidelines for Americans issued earlier this year, the primary recommendation was for Americans to focus on balancing “calories they consume” with “calories they expend through physical activity,” in order to prevent further obesity and promote public health.<sup>100</sup>

As can be heard loudly and clearly from all of the above, federal agencies have spoken with one voice on this issue: to manage weight and prevent obesity, the focus should be on calories-in/calories-out.

The IWG cannot simply ignore this deep-rooted foundation of federal nutrition policy. The U.S. Supreme Court has repeatedly affirmed that an agency must “provide [a] reasoned explanation for its action” before it changes a policy.<sup>101</sup> This requirement “ordinarily demand[s] that [an agency] display awareness that it is changing position. An agency may not, for example, depart from a prior policy *sub silentio* or simply disregard rules that are still on the books.”<sup>102</sup>

In addition, the Supreme Court requires that an agency seeking to depart from established policy “provide a more detailed justification than what would suffice for a new policy created on a blank slate.”<sup>103</sup> That heightened burden arises when, “for example, [the agency’s] new policy rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests that must be taken into account.”<sup>104</sup> Both of those circumstances

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<sup>100</sup> The 2010 Dietary Guidelines provide as follows:

Maintain calorie balance over time to achieve and sustain a healthy weight. People who are most successful at achieving and maintaining a healthy weight do so through continued attention to consuming only enough calories from foods and beverages to meet their needs and by being physically active. To curb the obesity epidemic and improve their health, many Americans must decrease the calories they consume and increase the calories they expend through physical activity.

HHS and USDA, *Dietary Guidelines for Americans, 2010*, at ix (hereinafter “2010 Dietary Guidelines”). The Dietary Guidelines also emphasize the importance of consuming a nutrient-dense breakfast as a key principle for promoting calorie balance and weight management:

Eat a nutrient-dense breakfast. Not eating breakfast has been associated with excess body weight, especially among children and adolescents. Consuming breakfast also has been associated with weight loss and weight loss maintenance, as well as improved nutrient intake.

*Id.* at 19. Ironically, although the IWG guidelines were purportedly developed with the intent of reducing childhood obesity, the stringent criteria placed on ready-to-eat cereals (the most frequently consumed breakfast food by children) and dairy foods effectively bars almost all of these nutrient-dense foods from being advertised to children.

<sup>101</sup> *FCC v. Fox Television Stations, Inc.*, 129 S. Ct. 1800, 1811 (2009).

<sup>102</sup> *Id.*

<sup>103</sup> *Id.*; see *Motor Vehicle Mfrs. Ass’n of United States, Inc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 42 (1983) (“[I]n agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance.”).

<sup>104</sup> *Fox*, 129 S. Ct. at 1811; *Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. 735, 742 (1996) (“[C]hange that does not take account of legitimate reliance on prior interpretation may be arbitrary, capricious [or] an abuse of discretion.”) (internal citations omitted).

apply to the IWG, which has ignored the federal government's prior focus on caloric intake and the reliance of a significant portion of the economy on existing policy.<sup>105</sup>

The IWG, therefore, must engage and rebut (and not simply ignore) the federal government's long-running, multi-agency, trans-Administration focus on caloric intake. The consequences of failing to comply with the Supreme Court's requirements for adequate explanation are clear: ~~an~~ agency that neglects to do so acts arbitrarily and capriciously."<sup>106</sup> Indeed, even if the federal agencies were not unanimous in their focus on caloric intake, the IWG still could not ignore this important aspect of the obesity problem. It is indisputable that caloric intake is an important contributor to obesity. ~~Normally,~~ the Supreme Court has warned, ~~an~~ agency rule [is] arbitrary and capricious if the agency has . . . entirely failed to consider an important aspect of the problem."<sup>107</sup> Here, the IWG has ignored the evidence produced by numerous other federal agencies that supports the importance of calories to obesity. That alone is reason enough for the IWG to rethink the approach it adopted in the Proposal.<sup>108</sup>

- b. The IWG's mandate from Congress also required the IWG to consider calories as a key factor in obesity. The IWG's failure to do so not only violated its congressional mandate, it has also resulted in arbitrary and capricious standards that conflict with established science.

Not only have federal agencies concerned with the issue of obesity unanimously confirmed that calories, rather than macronutrients, are the key to obesity and overweight prevention, but Congress too specifically directed the IWG to consider calories in its report to Congress. In its charge to the IWG to evaluate the causes of childhood obesity and to submit a report to Congress with its findings, Congress stated:

The Working Group is directed to conduct a study and develop recommendations for standards for the marketing of food when such marketing targets children who are 17 years old or younger or when such food represents a significant component of the diets of children. In developing such standards, the Working Group is directed to consider (1) positive and negative contributions of nutrients, ingredients, and food (*including calories*, portion size, saturated fat, trans fat, sodium, added sugars, and the presence of nutrients, fruits, vegetables, and whole grains) to the diets of such children; and (2) evidence concerning the role of consumption of nutrients, ingredients, and foods in preventing or promoting the development of obesity among such children. (emphasis added)<sup>109</sup>

Note that ~~calories~~ is first in the list that Congress specifically tasked the IWG with considering in developing its standards.

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<sup>105</sup> See *infra* Section.III.

<sup>106</sup> *Jicarilla Apache Nation v. U.S. Dep't of Interior*, 613 F.3d 1112, 1119 (D.C. Cir. 2010).

<sup>107</sup> *State Farm*, 463 U.S. at 43; see *Jicarilla Apache Nation*, 613 F.3d at 1114-15 (~~Because~~ we are persuaded [the agency] failed to consider an important aspect of the problem . . . we reverse in part and remand . . .").

<sup>108</sup> *Id.* at 43 (~~an~~ agency rule is arbitrary and capricious if the agency has . . . offered an explanation for its decision that runs counter to the evidence before the agency").

<sup>109</sup> Proposal at 2 (emphasis added).

Agencies cannot lightly ignore Congress's commands. When Congress speaks clearly, an agency is legally required follow the statutory mandate: "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."<sup>110</sup>

That rule extends to factors Congress enumerates for the agency's consideration in policymaking. An agency must consider such statutory factors, and must do so adequately, because "[w]hen Congress says a factor is mandatory, that expresses its judgment that such a factor is important."<sup>111</sup> In light of Congress's supremacy, and "[i]n accordance with this principle, [courts] have held that the complete absen[c]e of any discussion of a statutorily mandated factor leaves [courts] with no alternative but to conclude that [the agency] failed to take account of this statutory limit on [its] authority, making the agency's reasoning arbitrary and capricious."<sup>112</sup> The IWG's analysis fails to adhere to the cardinal rule that agencies must act in the manner established for them by Congress.

The IWG fails to consider calories in establishing the nutrition standards, and it fails to explain why. Aside from conflicting with its own congressional mandate, such failure to consider calories is, as discussed above, in direct conflict with established science confirming that excess calorie intake versus calorie expenditure (as opposed to macronutrient composition) is the key factor in determining obesity. As noted above at length, this science was established in part by the very agencies that constitute the IWG.

In view of the foregoing, the IWG's choice to not address calories in establishing the nutrition standards renders the nutrition standards arbitrary and capricious as a matter of law. The U.S. Supreme Court has held that an agency action is arbitrary and capricious if the agency has failed to "supply a reasoned analysis for [a] change," or "if the agency has . . . entirely failed to consider an important aspect of the problem . . . or offered an explanation for its decision that runs counter to the evidence before the agency."<sup>113</sup> Here, the IWG had every reason to know and understand that calories not only should be a consideration in setting its standards – Congress specifically directed it to do so – but that calories should be *the central* consideration in developing the standards. The IWG had its disposal all of the research which its member agencies (as well as other federal agencies concerned with the obesity issued) had developed which confirms that calorie balance is the *key* consideration in affecting obesity, and not macronutrient composition. By not addressing calories, the IWG thus "failed to consider an important aspect of the problem" and has not "offered an explanation for its decision that runs counter to the evidence" before it. This, according to the Supreme Court, is "arbitrary and capricious" agency action.

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<sup>110</sup> *Chevron USA, Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43 (1984).

<sup>111</sup> *Pub. Citizen v. Fed Motor Carrier Safety*, 374 F.3d 1209, 1216 (D.C. Cir. 2004).

<sup>112</sup> *Id.*

<sup>113</sup> *Id.*

2. ***Through frequent citations to FDA regulations and other federal dietary policy, the IWG cloaks its standards in the appearance of consistency with current policy, but closer examination of the items being cited reveals that they are being used for purposes having nothing to do with their intent – resulting in arbitrary and capricious standards that actually deeply conflict with current policy and established science.***

In order to bolster the credibility of the nutrition standards for foods that may be marketed to children, the IWG attempts, wherever possible, to create the illusion that the standards are based on longstanding nutrition guidelines by citing to FDA, USDA, and other federal dietary policy.<sup>114</sup> The IWG thereby pays lip service to the need for agencies to act consistently, a key requirement of reasoned agency action: “An agency must treat similar cases in a similar manner unless it can provide a legitimate reason for failing to do so.”<sup>115</sup> But illusion cannot mask reality: The Proposal deeply conflicts with current policy and established standards.

—As the United States Supreme Court has noted, APA rulemaking is required if an interpretation adopt[s] a new position inconsistent with . . . existing regulations.”<sup>116</sup> The IWG cannot by “voluntary” guidelines dramatically reshape the regulatory landscape concerning what does, and what does not, contribute to healthy eating and childhood obesity. Rather, notice-and-comment rulemaking, accompanied by potential judicial review, is the appropriate vehicle for such dramatic changes. As the following analysis shows, the IWG repeatedly announces standards inconsistent with prior regulatory guidance in the Proposal.

- a. The proposal’s “Principle B” nutrition standards, which set limits for saturated fat, trans fat, added sugars, and sodium in foods, are not supported by, and in some cases, are directly at odds with, existing federal regulations and dietary policy.

It is necessary to “walk through” the nutrition standards to understand the degree to which these standards lack any real basis in existing FDA regulation or policy – particularly those nutrition standards articulated under “Principle B” of the proposal. Principle B states that “[f]oods marketed to children should be formulated to minimize the content of nutrients that could have a negative impact on health or weight.” Listed under the caption “Nutrients with Negative Impact on Health or Weight” are the nutrition standards which the IWG developed in support of Principle B.<sup>117</sup> Foods that do not meet the standards for Principle B would fall under the IWG’s proposed advertising ban, and could not be marketed to children.

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<sup>114</sup> —In developing the proposed nutrition principles, the Working Group has been guided primarily by dietary recommendations developed by HHS and USDA as set out in the 2010 Dietary Guidelines for Americans (DGA), and by regulations promulgated by the FDA pursuant to the Nutrition Labeling and Education Act of 1990 (NLEA), and by USDA, governing nutrient content and health claims in food labeling.” Proposal at 3.

<sup>115</sup> *Indep. Petroleum Ass’n of Am. v. Babbitt*, 92 F.3d 1248, 1258 (D.C. Cir. 1996).

<sup>116</sup> *Air Transp. Ass’n of Am., Inc. v. FAA*, 291 F.3d 49,56 (D.C. Cir. 2002) (quoting *Shalala v. Guernsey Mem’l Hosp.*, 514 U.S. 87, 100 (1995)).

<sup>117</sup> Proposal at 16. IWG’s “Principle A” provides that “[f]oods marketed to children should provide a meaningful contribution to a healthful diet.” *Id.* at 15.

The IWG's "Principle B" nutrition standards ("Nutrients with Negative Impact on Health or Weight") provide as follows:

***Foods marketed to children should be formulated to minimize the content of nutrients that could have a negative impact on health or weight. With the exception of nutrients naturally occurring in food contributions under Principle A, foods marketed to children should not contain more than the following amounts of saturated fat, trans fat, sugar, and sodium.***

- Saturated Fat: 1 g or less per Reference Amount Customarily Consumed (RACC)<sup>##</sup> and 15% or less of calories for individual foods (per 100 g and less than 10% of calories for main dishes and meals)
- Trans Fat: 0 g (<0.5 g) per RACC<sup>##</sup> for individual foods (per labeled serving for main dishes and meals)
- Added Sugars: No more than 13 g of added sugars per RACC<sup>##</sup> for individual foods (per serving for main dishes and meals)
- Sodium: No more than 210 mg per serving for individual foods (450 mg per serving for main dishes and meals). §

§ This is an interim level and applies per serving only, not per RACC or per 50 g. Industry should work toward reducing sodium content by 2021 to 140 mg per RACC<sup>##</sup> for individual foods, and 300 mg per serving for main dishes and meals.

<sup>##</sup> For foods with a small RACC (30 g or less), the recommendations refer to the amount per 50 g of food.<sup>118</sup>

As discussed in detail below, none of the above standards is supported by existing federal regulations, existing federal dietary policy, or science.

- i. *The 50-gram criterion for foods with small "Reference Amounts Customarily Consumed" (RACCs) adopted by the IWG is not consistent with the meaning or intent of the regulations the IWG cites in support.*

For foods that have a small Reference Amount Customarily Consumed ("RACC") – 30 grams or less – the IWG applies its standards to the amount per 50 grams of food.<sup>119</sup> The IWG justifies this approach as being warranted by FDA regulations: "The adjustment for foods with a small RACC is a concept derived from federal food labeling regulations," citing 21 CFR 101.13, 101.14; 9 CFR 317.363, 381.463.<sup>120</sup> As discussed below, however, what the IWG has chosen to do is import an FDA food-labeling regulation – a rule solely intended to ensure that food labels provide information to consumers that is accurate and not misleading, and not to establish nutrition policy – and, to erroneously suggest that this rule mandates the standard that the IWG has articulated. This winds up being completely invalid, as closer examination of the cited regulations reveals.

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<sup>118</sup> *Id.* at 16.

<sup>119</sup> *Id.* at 14.

<sup>120</sup> *Id.*

In considering the FDA regulations being cited, it should first be noted that these regulations apply *solely* to food labeling, and even then, *only* where nutrient content claims and health claims are made. In general, these FDA regulations are designed to ensure that food labels do not overstate the health benefits or nutrition value of a certain product, do not otherwise mislead consumers, and are consistent across different food products and different manufacturers as to the meaning of a health or nutrient content claim. With that background in mind, let us consider what the FDA regulations actually provide:

If a food . . . contains more than 13.0 g of fat, 4.0 g of saturated fat, 60 milligrams (mg) of cholesterol, or 480 mg of sodium per reference amount customarily consumed, per labeled serving, or, for a food with a reference amount customarily consumed of 30 g or less or 2 tablespoons or less, per 50 g . . . then that food must bear a statement disclosing that the nutrient exceeding the specified level is present in the food as follows: —See nutrition information for \_\_ content” with the blank filled in with the identity of the nutrient exceeding the specified level, e.g., See nutrition information for fat content.<sup>121</sup>

This specific regulation applies only to foods that bear a “nutrient content claim” such as “low in saturated fat.”<sup>122</sup> The purpose of the regulation is to ensure that when such a claim is made, consumers are alerted to the fact that the food may contain other nutrients of which they should be aware. For instance, a food may indeed be low in saturated fat, but at the same time may be relatively high in sodium. This labeling regulation is intended to ensure that consumers are alerted to the “whole story” as far as that particular product is concerned. Similar rules apply when health claims are made.<sup>123</sup>

The 50-gram criterion is also intended to prevent food manufacturers from making health claims or nutrient claims for foods based on the fact that the serving size is small. For instance, the FDA wanted to make sure that food manufacturers could not claim that salted peanuts were low in sodium, simply because the portion size for peanuts is relatively small and, thus, so is the amount of sodium in that portion. The FDA employed the “50-gram” criterion to avoid that result:

[T]he agency conducted an analysis to assess the effect of deleting the weight-based criterion using food composition data of USDA (Ref. 5) in conjunction with the reference amounts in FDA’s final rule on serving sizes. The analysis showed that without a weight-based criterion, products such as sugar, grated parmesan cheese, and 25 percent fat cream could be labeled as “low calorie;” evaporated whole milk, nondairy creamer, green and ripe olives, and whipped dessert toppings as “low fat;” salted peanuts, butter, margarine, mayonnaise, ripe olives and mustard as “low sodium;”

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<sup>121</sup> 21 C.F.R. § 101.13(h)(1).

<sup>122</sup> See 21 C.F.R. § 101.13 (b).

<sup>123</sup> See 21 C.F.R. § 101.14(a)(4) (“Disqualifying nutrient levels means the levels of total fat, saturated fat, cholesterol, or sodium in a food above which the food will be disqualified from making a health claim. These levels are 13.0 grams (g) of fat, 4.0 g of saturated fat, 60 milligrams (mg) of cholesterol, or 480 mg of sodium, per reference amount customarily consumed, per label serving size, and, only for foods with reference amounts customarily consumed of 30 g or less or 2 tablespoons or less, per 50 g. For dehydrated foods that must have water added to them prior to typical consumption, the per 50-g criterion refers to the as prepared form. Any one of the levels, on a per reference amount customarily consumed, a per label serving size or, when applicable, a per 50 g basis, will disqualify a food from making a health claim unless an exception is provided in subpart E of this part . . .”).

and grated parmesan cheese and regular mayonnaise as “low cholesterol” (Ref. 6). —Low claims on these foods are contrary to recommendations made in the “Nutrition and Your Health; Dietary Guidelines for Americans,” issued jointly by the U.S. Department of Health and Human Services and USDA (Ref. 7) and would mislead and confuse the consumer.<sup>124</sup>

It bears noting here that the FDA initially set the 50-gram level at 100 grams. *But the FDA deliberately lowered the 100-gram level to 50 grams when it learned that the higher level would prevent claims on healthful products like cereal whose consumption the FDA wished to promote:*

Upon reconsideration, the agency acknowledges that the level it proposed, per 100 g, is too restrictive. While the proposed criterion would have prevented “low” claims on certain nutrient dense foods, *it also would have prevented some breads and other cereal grain products for which increased consumption is recommended in national dietary guidance from qualifying for “low” claims (Ref. 7). FDA has thus rejected maintaining the weight-based criterion as proposed.* (emphasis added)<sup>125</sup>

Thus, as seen in all of the above, this 50-gram “concept,” which the IWG co-opts from FDA regulations, is hardly FDA “standard operating procedure,” despite the IWG’s implication to the contrary. Rather, the 50-gram limiter applies *solely* to certain foods (in contrast to the IWG proposed standards) and *only* in the context of food labeling where a food manufacturer wishes to make a health or nutrient content claim (and not in the establishment of nutrition standards, which is the IWG’s mission). It certainly was never intended to be applied (as the IWG does) as a means for reducing consumption of cereal and other foods that FDA and other agencies promote through federal dietary guidance. Quite the contrary, in fact. The IWG, in the words of the Supreme Court, has “depart[ed] from a prior policy *sub silentio* [and] simply disregard[ed] rules that are still on the books,” without adequate explanation.<sup>126</sup>

The Proposal also cites to USDA regulations in support of the 50-gram criterion, which regulations were modeled after the FDA regulations, and similarly do not support the IWG’s position. Interestingly, the USDA nutrient content claim regulation comparable to 21 CFR 101.13 (*i.e.*, 9 CFR 317.313) does not contain the 50-gram criterion at all. But rather than concede that point, the IWG appears to have fished around and found something similar in 9 CFR 317.363. This USDA regulation applies *solely* to meat and meat food products bearing “healthy” claims – similar to the FDA regulations, which apply *solely* to products that make certain nutrient content or health claims. The USDA regulation provides:

The product shall not contain more than 480 mg of sodium per reference amount customarily consumed, per labeled serving size, and, only for foods with reference amounts customarily consumed of 30 g or less or 2 tbsp or less, per 50 g ....<sup>127</sup>

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<sup>124</sup> 58 Fed. Reg. 2302, 2315-16 (Jan. 6, 1993).

<sup>125</sup> *Id.* at 2318.

<sup>126</sup> *FCC v. Fox Television Stations, Inc.*, 129 S. Ct. 1800, 1811 (2009).

<sup>127</sup> 9 C.F.R. § 317.363(b)(3). IWG also cites to 9 C.F.R. § 381.463, which is the same but applies to poultry products rather than meat products.

As USDA made quite clear at the time, this regulation was intended simply to conform to the parallel FDA standards discussed above (which, as discussed above, similarly fails to support the IWG's position).<sup>128</sup>

Interestingly enough, although the IWG selectively cited the FDA and USDA regulations in support of its 50-gram criterion, it rejects other standards set forth in those same regulations where they do not support the IWG's desired outcome. For example, while the IWG purports to be relying on FDA regulations for this "50 gram" concept, it *rejects* the nutrient limits established by the FDA in those same regulations! What the IWG does instead is impose levels that are *far stricter* than the FDA's. For instance, the FDA's level for saturated fat is 4 grams in the cited regulations, while the IWG's is 1 gram. Similarly, the FDA's level for sodium is 480 mg, and the IWG's is 140 mg. One cannot help but conclude that the IWG chose to cherry-pick the FDA regulations to find support for its standards, and then to ignore those same regulations when they did not serve the IWG's needs.

And one might legitimately wonder whether there was an intention here to ensure that cereal advertising would be barred under the Proposal. After all, cereal is the only food product mentioned in its narrative justifying its use of the 50-gram criterion – so it is obvious that the IWG knew that it would be affecting cereal. In fact, it is the application of this criterion that makes it impossible for virtually any cereal to meet the IWG's standards, and thus be permitted to advertise.<sup>129</sup> Here is the sad irony: by manipulating existing FDA and USDA restrictions, the IWG seeks to ban the advertising of cereal, and thereby suppress consumption of one of the healthiest foods for children, and one that is consistently associated with healthful body weights in children. This is a result that runs directly counter to the public health mission assigned to the IWG by Congress.

ii. *The "added sugar" nutrition standard adopted by the IWG is similarly not supported by science or by federal regulations.*

The IWG seeks to ban the advertising to children of foods that have more than 13 grams of "added sugars" per RACC for individual foods (per serving for main dishes and meals)." In support of this standard, the IWG explains:

The Working Group's proposed target for limiting added sugars is similarly based on 2010 DGA [Dietary Guidelines for Americans] recommendations to choose prepared foods and beverages with as little as possible added sugars or caloric sweeteners. Added sugars can contribute to weight gain by providing excess calories or by diluting the nutrient density of the total diet.<sup>130</sup>

The first problem with the IWG's reliance on the Dietary Guidelines for Americans 2010 is that it misstates them. The Dietary Guidelines 2010 simply provide: "Reduce the intake of calories

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<sup>128</sup> USDA's issuing release accompanying the regulation stated as follows: "To ensure full compatibility with FDA's sodium criterion for individual foods, FSIS is providing identical allowances for foods with reference amounts of 30 g or less or 2 tablespoons or less ...." 59 Fed. Reg. 24228 (May 10, 1994).

<sup>129</sup> The IWG could have also addressed this problematic result by classifying cereal as a "main dish" or "meal," and thus allowing cereal to qualify for the more lenient nutrition restrictions applicable to those items. Cereal clearly is consumed as a main dish or meal. But the IWG did not classify it as such.

<sup>130</sup> Proposal at 12 (bracketed language added).

from solid fats and added sugars.”<sup>131</sup> First of all, this is a statement focused on *calories*, and does not call for “as little as possible added sugars,” as alleged by the IWG. Indeed, as described more fully below, it is exceedingly unlikely that the USDA would have desired that all foods and beverages be prepared with as little sweetener as possible, as federal agencies have long recognized the necessity and, in fact, the desirability of adding sweetener to certain foods in order to increase their consumption.<sup>132</sup> And despite the dearth of support in science or in regulation for its proposed standard, the IWG nonetheless chose to issue it with no support.

It is worthwhile to focus briefly on sugar (and so-called “added sugar”) at this point, because it is so often a source of confusion. We will highlight a few facts below.

- *Federal agencies have recognized that there is no scientific agreement on how much sugar people should or should not eat.*

There is no agreement among scientists or public health experts as to how much sugar people should or should not consume. The FDA – a member of the IWG – recognized this in 1993 when it promulgated final regulations for the labeling of foods making health claims. In its issuing release, the FDA addressed the public comments it had received requesting that the FDA establish a “disqualifying” level for added sugar – meaning that a food manufacturer would not be permitted to make a health claim about a product if the product had in excess of a certain number of grams of sugar. The FDA expressly declined that request:

The agency finds that it would not be appropriate to limit health claims on foods on the basis of added sugars either in terms of an absolute amount per serving or as a function of percent of calories per serving.<sup>133</sup>

In support of its refusal to establish a disqualifying level for added sugars, FDA explained that disqualifying levels are based on Daily Reference Values (DRVs), if such a value is able to be established for a given nutrient. In the case of fat, sodium, and cholesterol, the FDA was able to rely on published recommendations of public health experts as to levels for those nutrients that would promote public health, and therefore could establish DRVs. The FDA had no similar public health expert recommendations on which it could rely to establish a DRV for added sugars.<sup>134</sup>

In further support of its rejection of the public comment, the FDA went on to note *that public health literature did not support the contention that consuming sugar causes disease:*

Moreover, the public health community has not identified a dietary level above which consumption of sugars has been demonstrated to increase the risk of a disease. Thus, the agency finds that there is no sound basis on which to establish the requested DRV for sugars. Accordingly, the agency is declining to set a disqualifying level for added sugars at this time.<sup>135</sup>

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<sup>131</sup> 2010 Dietary Guidelines at x and 34.

<sup>132</sup> See, e.g., *supra* note 93 and accompanying text.

<sup>133</sup> 58 Fed. Reg. 2478, 2491 (Jan. 6, 1993).

<sup>134</sup> *Id.*

<sup>135</sup> *Id.*

There continues to be no scientific agreement that eating sugar causes poor health, as the Food and Science Board (under the Institutes of Medicine) confirmed as recently as last year. In its Phase I Report on the Examination of Front-of-Pack Nutrition Rating Systems and Symbol, the Food and Science Board concluded:

There is a lack of scientific agreement about the amount of sugars that can be consumed in a healthy diet and about potential adverse health effects of sugars beyond an effect on dental care. Thus, it is difficult to conclude that total sugars intake is of sufficient public health concern to be included in FOP [front-of package] rating systems.<sup>136</sup>

- *Federal agencies have expressly acknowledged that foods with added sugar are no more likely to lead to weight gain than other foods.*

The IWG's standards would ban the advertising of many existing foods having added sugar, even though federal agencies have concluded that there is no evidence that foods with added sugar cause weight gain. Rather, weight gain is caused by consuming excess calories. In other words, federal agencies have rejected the notion which the IWG embraces – that it is important to avoid foods with added sugars in order to avoid weight gain.

In their Dietary Guidelines 2010, USDA and HHS expressly *reject* the notion that foods containing added sugar, in particular, cause weight gain:

***Foods containing solid fats and added sugars are no more likely to contribute to weight gain than any other source of calories in an eating pattern that is within calorie limits.*** (emphasis added)<sup>137</sup>

In its report, the 2010 Dietary Guidelines Advisory Committee further confirmed that, to date, science does *not* support the hypothesis that added sugar causes weight gain:

A moderate body of evidence suggests that under caloric controlled conditions, added sugars, including SSB, are no more likely to cause weight gain than any other source of energy.<sup>138</sup>

Accordingly, the IWG's targeting of foods with added sugars is not only misguided, but directly contradicts what federal agencies have confirmed about foods with added sugars – that they are no more responsible for weight gain than other foods. The IWG is therefore violating the well-established rule that agencies cannot act inconsistently with the evidence before them.<sup>139</sup>

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<sup>136</sup> Institute of Medicine, *Examination of Front-of-Package Nutrition Rating Systems and Symbols: Phase I Report* 12 (The National Academies Press 2010) (bracketed language added).

<sup>137</sup> 2010 Dietary Guidelines at 28.

<sup>138</sup> USDA Agricultural Research Service, *Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010*, at 310 (May 2010).

<sup>139</sup> *Motor Vehicle Mfrs. Ass'n of United States, Inc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (stating that an agency may not act —~~court~~ to the evidence" before it).

- *The FDA, USDA and HHS all have rejected the distinction between “added sugars” and naturally occurring sugars – the body processes both exactly the same way.*

The IWG’s focus on ~~–added sugar~~” is also directly contrary to the determination of several agencies that ~~–added sugars~~” are indistinguishable, from a metabolic standpoint, from sugars that naturally occur in food. The FDA underscored the body’s inability to tell the difference between added sugars and naturally occurring sugars in declining to adopt public comments requesting that the FDA require food producers to specifically declare added sugars on the nutrition facts panel of food labels:

The agency is not persuaded that there is a need for mandatory disclosure of added sugars in place of, or in addition to, total sugars. There is no scientific evidence that the body makes any physiological distinction between added sugar molecules and those naturally occurring in a food.”<sup>140</sup>

For example, consider an 8 ounce glass of apple juice, which has 26 grams of naturally occurring sugar, and a glass of sugar water having exactly the same amount of sugar as added sugar. The human body would be unable to distinguish between the apple juice and sugar water in processing the sugar contained in those beverages, which is why the FDA concluded it made little sense to make such distinction in food labeling. However, the Proposal treats them quite differently: the apple juice could be advertised, while the sugar water could not. This is a highly questionable result.

In the Dietary Guidelines 2010, USDA/HHS confirmed the point that the body treats all sugars the same way:

[T]he body’s response to sugars does not depend on whether they are naturally present in food or added to foods . . . .”<sup>141</sup>

Therefore, since the body treats all sugar the same, there is no basis in science for making the proposed distinction, as the IWG’s member agencies have confirmed time and again. Yet the standards issued by the IWG cling to that distinction despite the evidence and without the explanation required by law.<sup>142</sup>

- *The FDA has indicated that the distinction between “added sugars” and naturally occurring sugars is not only wrong, it is misleading.*

The FDA has also gone so far to suggest that distinguishing between ~~–added sugar~~” and naturally occurring sugars could actually be misleading to consumers. In rejecting public comments requesting the FDA’s imposition of an ~~–added sugar~~” food labeling requirement, the FDA stated:

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<sup>140</sup> 58 Fed. Reg. 2079, 2098 (Jan. 6, 1993).

<sup>141</sup> 2010 Dietary Guidelines at 27.

<sup>142</sup> *State Farm*, 463 U.S. at 43 (stating that an agency may not act “~~–contr~~ to the evidence” before it); *FCC v. Fox Television Stations, Inc.*, 129 S. Ct. 1800, 1811 (2009) (stating that an agency must supply “~~–asoned~~ explanation” for changes in policy).

[D]eclaration of only added sugars may significantly underrepresent the sugars content of many foods that are high in naturally occurring sugars. For example, in some fruits canned in heavy syrup, added sugars may represent only about 50 percent of total sugars. Disclosure of only the added sugars could be misleading to consumers who are concerned with total sugar intake.<sup>143</sup>

In other words, the FDA is saying that if one is concerned about the sugar content of a food, one needs to consider naturally occurring sugars in exactly the same way that one considers added sugar. Again, this runs exactly counter to what the IWG has chosen to do, which is to treat naturally occurring sugars as if they are somehow better than added sugars, and thus may be ignored.

- *The FDA has expressly recognized that laboratory analysis cannot distinguish “added sugar” from other sugar, which makes it impossible for food manufacturers to comply with any law or regulation focused on “added sugar.”*

In declining to impose an “added sugar” labeling requirement for foods, the FDA identified and acknowledged the practicable impossibility of food manufacturers to identify added sugar. It is often naively believed by interest groups, and others unfamiliar with how food products are actually made, that food manufacturers prepare food labels by analyzing the “recipe” for that food. That is simply not the case.

Rather, the *only* way that food manufacturers are able to know with certainty the nutrients present in a food product is to have that food analyzed in a laboratory.<sup>144</sup> And, as the FDA clearly understood (and as the IWG repeatedly ignores), it is not possible for laboratories, when analyzing food, to distinguish naturally occurring sugars from added sugars:

When a product is sampled for compliance, laboratory analysis yields a value for total sugars. For most foods, as stated above, it is not possible to differentiate between added and naturally occurring sugars. Accordingly, the agency would not be able to determine the accuracy of a label declaration of added sugars.<sup>145</sup>

Using the example of apple pie, a food laboratory would not be able to determine how much of the total sugars came from the apples, and how much came from sugar or other forms of sweetener to sweeten the apples or the crust. However, the IWG chooses to ignore this practical difficulty, presumably with the intent of forcing food manufacturers to reformulate their products without sugar – itself a poor policy, as noted elsewhere in this Comment.

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<sup>143</sup> 58 Fed. Reg. 2079, 2098 (Jan. 6, 1993)

<sup>144</sup> Take for instance, a chocolate chip cookie. Indeed, the cookie maker may indeed use sugar in producing the dough to make the cookie. But let us assume that it has obtained the chocolate chips for the cookie from another producer, which does not sell those chips in retail grocery stores but to other food producers. Hence, the cookie maker does not have access to information concerning the sugar content of the chips. The only way that the cookie maker can really know how much sugar is in a cookie is to have the whole cookie analyzed in a laboratory, and the total sugars contained in the cookie – chocolate chips and dough – measured.

<sup>145</sup> 58 Fed. Reg. 2079, 2098 (Jan. 6, 1993).

- *“Added sugar” is an entirely arbitrary concept in and of itself, as demonstrated by the different meanings assigned to that term by federal agencies.*

The IWG’s decision to focus on ~~–~~added sugar” belies its failure to apprehend the arbitrariness of that entire concept. As those in the food industry well understand, it is far from clear just what constitutes ~~–~~added sugar.” One can only infer that the drafters of the proposal may believe it is simply a matter of looking at how much table sugar, or brown sugar, or corn syrup that the food producer includes in its ~~–~~recipe.” But it is a far more complex issue than that.

Apart from the practical difficulty that food manufacturers face in being able to access information regarding the amount of ~~–~~added sugar” in ingredients it sources from other producers, there are a host of subjective judgment calls in calculating ~~–~~added sugar.” For instance, when preparing our report in response to the recent FTC 6(b) Order, which required information concerning the ~~–~~added sugar” content of our advertised foods, General Mills was advised by FTC staff that the sugar content of added fruits would *not* count as added sugars. But the IWG’s proposed advertising ban’s discussion of ~~–~~naturally occurring nutrients” might suggest otherwise – unless 0.5 cups of fruit were added, in which case none of the sugar would count. For some products, it appears that adding small amounts of fruit might be fine, but adding a larger amount (but less than 0.5 cups) may well subject the product to the advertising ban. This purely arbitrary stance (and counter-intuitive result) well illustrates the complication here.

- *Though purportedly derived from federal guidelines, the 13-gram proposed limit on added sugars is based on unscientifically derived data and is therefore arbitrary.*

The IWG selected 13 gram of added sugars per RACC as the desired cap (with foods exceeding that cap being subject to the advertising ban) based on its interpretation of the Dietary Guidelines 2010 and FDA’s nutrient content claim regulations. The IWG explained:

The 2010 DGA [Dietary Guidelines for Americans] estimated that, in a 2,000 calorie daily diet, no more than 258 calories should come from SoFAS [solid fats and added sugars], which could include calories derived from solid fats and added sugars (and alcohol). If the entire 258 SoFAS calories came from added sugars, this would represent 64.5 grams of added sugars (4 calories per gram). Federal nutrient content claim regulations incorporate the principle that 20% or more of the daily value of a nutrient is considered high. Applying this principle to the 64.5 grams daily of added sugars, a food with 13 grams of added sugars would be considered high in added sugars.<sup>146</sup>

It is important to bear in mind, however, that the referenced Dietary Guidelines did not base this number on an evaluation of the scientific literature. Rather, this number was generated by the less-than-scientific method of looking at how many of the 2,000 daily calories remained after deducting foods in other categories:

SoFAS are calories from solid fats and added sugars. The limit for SoFAS is the remaining amount of calories in each food pattern after selecting the specified amounts in each food group in nutrient-dense forms (forms that are fat-free or low-fat and with no added sugars). . . .<sup>147</sup>

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<sup>146</sup> Proposal at 12 (bracketed language added)

<sup>147</sup> USDA Agricultural Research Service, *Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010*, at Appendix 7 (May 2010).

Thus, in other words, the number of calories allocated to SoFAS was simply the number left over once the Dietary Guidelines committee had, in a sense, “filled in the other boxes.” Therefore, if the committee had *started* with sugar, they may well have included a higher number of calories. There was nothing scientific about this determination.

But the IWG takes this number, and then applies another federal nutrient concept to it: “daily value,” which as we saw above, the FDA actually *rejected* as applicable to sugar, but which the IWG uses anyway – to make it seem as if its 13-gram added sugar limitation was scientifically derived and firmly rooted in existing federal regulations. In fact, it is not. As the above discussion shows, it is a purely arbitrary number.<sup>148</sup>

iii. *The saturated fat standard adopted by the IWG is not supported by the regulations the IWG cites.*

The IWG proposes to ban the advertising to children of foods that exceed the saturated fat target of 1 gram or less per RACC and 15% or less of calories for individual foods (per 100 grams and less than 10% of calories for main dishes and meals).<sup>149</sup> In support of its position, the IWG looks to the federal definition of “low saturated fat” in FDA regulations for food labeling.<sup>150</sup>

The use of this definition, however, suffers from the same problem we observed in the IWG’s establishment of the 50-gram criterion: namely, that the IWG has co-opted an FDA regulation that was established for an entirely different purpose – food labeling – and attempted to use it as support for its arbitrarily-chosen nutrition standard for permitting a product to be advertised. Here, the FDA regulation cited as support pertains to food labels that make nutrient-content claims regarding saturated fat, such as “low in saturated fat.” The FDA regulation provides that foods cannot make this claim unless they contain no more than 1 gram or less of saturated fatty acids per reference amount customarily consumed, and not more than 15 percent of calories from saturated fatty acids.<sup>151</sup>

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<sup>148</sup> In fact, the Institutes of Medicine had suggested that up to 25% of diet could be from added sugars:

The DRI committee concluded that evidence was insufficient to set a Tolerable Upper Intake Level (UL) for carbohydrates (IOM, 2002). However, a maximal intake level of 25 percent or less of total calories from added sugars was suggested by the panel. This suggestion is based on dietary intake survey data showing that people with diets at or above this level of added sugars were more likely to have poorer intakes of important essential nutrients.”

USDA Agricultural Research Service, *Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010*, at 287 (May 2010). A recent publication by Marriott et al. (2010) that re-evaluates added sugars and Body Mass Index (BMI) data indicates that individuals with the least intake of added sugars (5% of calories) or the most (35% of calories) had the highest BMI. Surprisingly, nearly 15% of those classified as obese consumed less than 5% of calories from added sugars. The publication concluded that (i) high levels of added sugar intake occur among only a small proportion of the population and cannot explain the existing problem of poor nutrient intake in the U.S. population as a whole and (ii) *a greater proportion of individuals classified as underweight and normal BMI reported higher levels of added sugars intake than individuals classified as overweight or obese.*

<sup>149</sup> Proposal at 16.

<sup>150</sup> Proposal at 11 (citing 21 C.F.R. § 101.62(c); 9 C.F.R. §§ 317.362 and 381.462).

<sup>151</sup> 21 C.F.R. § 101.62(c). IWG also cited to the USDA regulations which are the same as FDA’s. See 9 C.F.R. §§ 317.362 (“The terms low in saturated fat, low saturated fat, low contains a small amount of saturated

Thus, the IWG is taking an FDA standard for making a particular type of advertising claim (*i.e.*, a “low in saturated fat” claim), and then morphing it into a standard for allowing a product to be advertised at all! This is hardly what FDA intended.

The IWG’s choice of this food labeling regulation for establishing a saturated fat target is particularly inappropriate given that FDA expressly noted that it deliberately required an “especially low” level of saturated fat when allowing a food label to make a “low saturated fat” claim:

The agency continues to believe that this claim should enable consumers to easily identify the foods that contain *especially low* levels of saturated fat, and that the proposed definition achieves this purpose.<sup>152</sup>

The FDA acknowledged that this definition is stricter than that of the National Cholesterol Education Program (NCEP), but only because the definition applies only to foods that bear the “low in saturated fat” claim:

The agency acknowledges that this definition prevents this claim from appearing on some of the foods that NCEP recommends be used as substitutes for other foods in achieving a lower intake of saturated fat. For example, the NCEP recommends using skim or 1 percent fat milk as a substitute for whole milk, and 1 percent fat milk will not be able to make a “low in saturated fat” claim. The agency agrees with NCEP’s recommendations but does not believe that all such substitute foods, including 1 percent fat milk, are necessarily “low in saturated fat.”<sup>153</sup>

Note: the FDA did not reject the NCEP recommendations. It merely set the saturated fat level at an “especially low” level in order to ensure that the “low in saturated fat” claim would be truthful and not misleading. To be sure, FDA would support the notion that the NCEP foods could be part of a healthy diet, even if those foods do not meet the extremely strict definition of low saturated fat required for food labels that make saturated-fat claims, and clearly would support the advertising and marketing of such foods. The IWG, apparently, would not, given its inexplicable imposition of this demanding standard on all foods advertised or marketed to children.

The arbitrariness of the IWG’s chosen saturated fat standard is further evidenced by the fact that FDA has established *other* saturated-fat levels which the IWG did not choose, and the IWG neither identifies those levels nor explains why it did not choose them. That type of unexplained decision-making is forbidden by law.<sup>154</sup> Specifically, the IWG could have selected the FDA saturated fat “disqualifying level” (that is, the level at which a food label would not be permitted to

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fat, ‘low source of saturated fat,’ or ‘a little saturated fat’ may be used on the label or in labeling of products, except meal-type products as defined in Sec. 317.313(l) and main-dish products as defined in Sec. 317.313(m), provided that: (i) The product contains 1 g or less of saturated fat per reference amount customarily consumed and not more than 15 percent of calories from saturated fat; and (ii) If the product meets these conditions without benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.” (§ 381.462 is the same for poultry).

<sup>152</sup> 58 Fed. Reg. at 2339 (emphasis added).

<sup>153</sup> *Id.*

<sup>154</sup> *FCC v. Fox Television Stations, Inc.*, 129 S. Ct. 1800, 1811 (2009) (stating that an agency may not “depart from a prior policy *sub silentio*”).

make a health claim), which is set at 4g of saturated fat,<sup>155</sup> or the reduction level at which a food manufacturer would be able to make a “reduced saturated fat” claim, which requires a 25% reduction in saturated fat.<sup>156</sup> Accordingly, one can only conclude that the IWG’s selected standard for saturated fat was arbitrarily set.

iv. *The trans fat standard proposed by the IWG is similarly not supported by federal dietary guidance.*

The IWG proposed standards would ban the marketing to children of foods that contained more than 0 grams (<0.5 g) of trans fat per RACC for individual foods (per labeled serving for main dishes and meals).<sup>157</sup> The IWG describes its basis for the proposal as follows:

Because there is no daily reference value for trans fat, and because the 2010 DGA [Dietary Guidelines for Americans] recommends that trans fat intake be kept as low as possible, but does not specify a maximum intake level, the Working Group is proposing to set the target for trans at 0 (<0.5) grams per RACC for individual foods and 0 (<0.5) grams per labeled serving for main dishes and meals.<sup>158</sup>

Here, the IWG has chosen to parlay the absence of a daily reference value for trans fats (at present, food regulations simply require that nutrition facts panel discloses the level of trans fats, but do not attempt to set daily reference values for trans fats), and a dearth of federal guidance on trans fat levels, into a case for its decision to bar advertising of foods that contain anything more than trace amounts of trans fats.

The Dietary Guidelines recommendation that trans fat intake be kept “as low as possible” is simply not the same as zero. In the Guidelines, USDA and HHS never assert that Americans should eat no trans fats whatsoever. However, the IWG is apparently prepared to adopt that stance, and seeks to ban the advertising to children of foods that contain anything more than a tiny amount of trans fats.

v. *The sodium standard proposed by the IWG is not supported by the regulations the IWG cites and, in fact, directly conflicts with FDA’s thinking on the issue.*

The IWG seeks to ban the advertising to children of foods that have in excess of 210 mg of sodium per serving for individual foods (450 mg per serving for main dishes and meals).<sup>159</sup> However, the IWG observes that “[t]his is an interim level and applies per serving only, not per RACC or per 50 g. Industry should work toward reducing sodium content by 2021 to 140 mg per RACC for individual foods, and 300 mg per serving for main dishes and meals.”<sup>160</sup>

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<sup>155</sup> 21 C.F.R. § 101.14(a)(4).

<sup>156</sup> 21 C.F.R. § 101.62(c)(4).

<sup>157</sup> Proposal at 16.

<sup>158</sup> *Id.* at 11-12 (bracketed language added).

<sup>159</sup> *Id.* at 16.

<sup>160</sup> *Id.*

In support of its sodium target, the IWG explains:

The Working Group believes that the industry should work to significantly reduce the amount of sodium in food products, with the ultimate goal of achieving a sodium limit for foods marketed to children that parallels federal labeling regulations for low sodium –140 milligrams per RACC for individual foods. It also is proposing to set an ultimate goal of 300 milligrams per serving for main dishes and meals – half of the 600 milligrams of sodium established by federal labeling regulations for use of the term “~~healthy~~” on main dishes and meals.<sup>161</sup>

As the above language makes clear, the IWG rejects, without explanation, FDA’s higher levels for sodium as set forth in the definition of the “~~healthy~~” nutrient content claim.

In an attempt to sound reasonable, the IWG explains that it will phase in the sodium levels over time:

The Working Group also believes that, given the high proportion of foods currently in the marketplace that would not meet these limits, even with significant reformulation, interim targets are warranted. The Working Group is therefore proposing interim targets that represent amounts 50 percent greater than the ultimate targets. The interim target for individual foods would be 210 milligrams per serving, and the interim target for main dishes and meals would be 450 milligrams per serving. The Working Group recommends that industry should work to reduce sodium to the interim levels by 2016 and to the final levels by 2021.<sup>162</sup>

As explained below, there is nothing reasonable about the IWG’s sodium proposal at all. Furthermore, as described more fully below, the FDA had very good reasons for setting these higher sodium levels. Those reasons are based on lessons learned by the FDA when, in the 1990s, it attempted to set non-science-based “stretch goals” for the industry with respect to sodium levels in food, and then, to its embarrassment, was forced to retract them when it discovered that the lower levels it sought were, in fact, unattainable. This history (described immediately below) should serve as a cautionary tale for the IWG.

In 1994, FDA issued the food labeling regulation relating to “~~healthy~~” claims, which established Tier I levels for sodium (480 mg) that applied until 1998, and Tier II levels for sodium (360 mg) that would go into effect after 1998. (Note how this approach mirrors the IWG’s: the IWG’s proposal establishes interim sodium levels that are higher for now, and then establishes reduced limits that will go into effect in 2016 and still further reduced limits that go into effect in 2021.) At the time FDA established these levels, FDA erroneously believed that food companies could easily reformulate their products to lower sodium levels if they were simply given a few years in which to do so. Fortunately, FDA began to realize it had made a mistake, and agreed to stay the effective date of the Tier II levels in response to a petition by ConAgra, which explained why meeting the Tier II levels would be impossible for the food industry.

In 2005, after a thorough analysis of relevant factors, FDA concluded that ConAgra, other food companies, and even public interest groups were correct that the stricter (Tier II) sodium levels it previously proposed were inappropriate, and it therefore eliminated them:

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<sup>161</sup> *Id.* at 13.

<sup>162</sup> *Id.* (footnotes omitted).

Comments from both industry and consumer advocates support the conclusion that implementing the second-tier sodium requirements would risk substantially eliminating existing —~~healthy~~” products from the marketplace because of unattainable nutrient requirements or undesirable and, thus, unmarketable flavor profiles. As a result of these comments, FDA has concluded that it can best serve the public health by continuing to permit products that meet the first-tier sodium level to be labeled as ~~healthy~~,” and thereby ensure the continued availability of foods that consumers can rely on to help them follow dietary guidelines not only for controlling sodium but also for limiting total fat, saturated fat, and cholesterol and consuming adequate amounts of important nutrients such as fiber, protein, and key vitamins and minerals.<sup>163</sup>

Remarkably, the FDA went so far as to publicly admit that setting unattainable stretch goals for food companies had not been a good decision:

The intent of the two-tiered sodium levels established by the 1994 final rule was to encourage industry to be innovative and further lower sodium levels in foods bearing the term healthy. However, based on comments and other data that have become available since 1994, FDA is concerned that this goal will not be realized and that implementing the second-tier sodium level requirements for the ~~healthy~~” claim could in fact result in a smaller selection of nutritionally desirable foods on the market. The agency agrees with the majority of comments that lowering the amount of sodium in healthy foods to the second-tier levels would run counter to public health goals if it discouraged manufacturers from producing healthy foods and consumers from eating them.<sup>164</sup>

There are many important lessons here for the IWG. *First*, as FDA learned, good intentions can sometimes backfire by creating unintended consequences. Here, FDA’s rule would have actually served to limit the number of healthy foods available to consumers – which was certainly *not* in the interest of public health, and *not* what FDA intended. The IWG’s stricter standard is even worse in this regard, and therefore even more detrimental to public health. *Second*, reducing salt in food is complicated. As FDA noted in the release that reversed its earlier ill-considered rulemaking, sodium serves many essential functions that must be kept in mind when attempting to regulate sodium out of food:

Many comments, particularly from industry, emphasized salt’s importance as a food ingredient. They stated that salt is essential for developing taste, and sometimes also for texture and microbiological stability. The comments said that no single substitute for the technical functions of salt was likely to be available soon. One comment explained that the tongue only recognizes sodium chloride (NaCl) as salty and that this makes creating palatable lower sodium versions of products difficult. An industry comment identified a number of manufacturing and technical issues with lowering the amount of salt in a product to the second-tier level. This comment said that hot dogs fall apart, processed meats have reduced microbial protection and lose their characteristic texture, and consumers will not eat certain products with sodium less than 360 mg because the products do not taste good or do not taste as expected. Several comments argued that because consumers will not buy products that meet the second-tier sodium levels, companies will have to discontinue their healthy products if the second tier sodium levels go into effect. As discussed in the response to comment 11 of this document, some comments submitted data to support this

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<sup>163</sup> 70 Fed. Reg. 56828 (Sep. 29, 2005).

<sup>164</sup> *Id.* at 56833.

argument. One comment stated that FDA recognized that the second-tier levels may be overly restrictive in soliciting comments in the 1997 ANPRM about the technological feasibility of reducing sodium and on consumer acceptance of products with reduced sodium.<sup>165</sup>

As FDA's explanation describes quite well, there are often excellent reasons to explain the presence of sodium in foods at the levels at which it is present. *Third*, it is important for federal regulatory agencies to listen to food companies that have the technical expertise regarding what is possible as far as reductions of sodium and other reformulations of food are concerned. The FDA acknowledged its error in assuming that its ambitious sodium reduction goals were feasible, when they in fact were not:

The agency acknowledges manufacturers' concerns about the technical importance of salt. The agency had anticipated that phasing in the lower second-tier sodium level requirement for the term "~~healthy~~" would allow the food industry time to develop technically and commercially viable alternatives to salt. Although it is unfortunate that no viable alternative has been found, FDA understands the manufacturing difficulties that are presented by the absence of a suitable substitute for salt and has taken them into consideration in deciding how to regulate the sodium content of foods bearing the ~~healthy~~" claim.<sup>166</sup>

Given the FDA's hard-learned lessons regarding federal regulatory attempts to set unrealistically low sodium levels, based on insupportable assumptions about the food industry's technological and commercial capabilities, the very public manner in which FDA was forced to retreat from such attempts, and the fact that FDA is a member of the IWG, the IWG's proposed sodium standards are highly inappropriate, certainly arbitrary, and positively unacceptable.

And as the above discussion makes abundantly clear, the IWG could have selected the sodium levels that FDA established for its ~~healthy~~" claim: 480 mg for individual foods and 600 mg for meals and main dishes.<sup>167</sup> Alternatively, it could have chosen FDA's disqualifying levels for nutrient content claims: 480 mg for individual foods and 720 mg for main dishes and 960 mg for meals.<sup>168</sup> Those levels are designed to help consumers construct a healthy diet.<sup>169</sup> Of course, in either case, the levels only apply when a company makes a nutrient content claim. FDA has not concluded that higher levels ~~are unsafe, dangerous, or bad.~~<sup>170</sup> Their sole function is to ensure that the nutrient content claims are truthful and not misleading.

Rather than selecting one of the above options, however, the IWG inexplicably chose 140 mg for individual food and 300 mg for meals and main dishes. The IWG merely stated that the 140 mg is FDA's limit for ~~low sodium~~" claims and the 300 mg limit is ~~half~~ of the 600 milligrams of

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<sup>165</sup> *Id.*

<sup>166</sup> *Id.* at 56833-34.

<sup>167</sup> 21 C.F.R. § 101.65(d).

<sup>168</sup> 21 C.F.R. § 101.13(h).

<sup>169</sup> As FDA has explained, ~~the~~ disqualifying levels represent the amount of these nutrients in a single food that would make difficult the construction of a diet that meets dietary guidelines. They in no way represent a finding by the agency that these levels will cause diet-related disease or that foods that contain nutrients at these levels are unsafe, dangerous, or bad." 58 Fed. Reg. 2478, 2492 (Jan. 6, 1993).

<sup>170</sup> *Id.*

sodium established by federal labeling regulations for use of the term ‘healthy’ on main dishes and meals.”<sup>171</sup> Once again, with respect to individual foods, the IWG has cherry-picked the FDA regulations to give the appearance that the Proposal is supported by current policy. With respect to meals and main dishes, the IWG was more direct – it expressly picked an amount that is ~~half~~ of the 600 milligrams of sodium established by federal labeling regulations for use of the term ‘healthy’ on main dishes and meals.” In that case, it did not even attempt to hide its departure from FDA policy.

b. The Proposal represents a back-door effort to impose new, arbitrary nutrient standards on the food industry.

As the above discussion demonstrates, the Proposal attempts to create the appearance that its nutrition standards are consistent with established food dietary policy, but they are anything but. Rather, they represent a back-door attempt by the IWG to establish new food dietary policy – by imposition of an advertising ban.

The IWG begins by providing assurances that the Proposal follows federal guidance. But then the IWG implies that it must diverge from that approach because it has a different purpose – ~~determining~~ “which foods are appropriate to market to children.” That suggests that the FDA, USDA and other federal regulations apply *only* to foods marketed to adults, which, of course, is simply untrue. And though the IWG cites to existing federal law and policy to support its nutrient standards, the IWG goes on to concede that it is pushing the envelope to set new, and more demanding, standards for the food industry:

The goal of the Working Group is to recommend principles that both improve the nutritional quality of foods marketed to children and can be feasibly implemented by industry with sufficient time to accomplish reformulation. The Working Group recognizes that, if the proposed nutrition principles were fully implemented by industry as proposed, a large percentage of food products currently in the marketplace would not meet the principles. The Working Group also recognizes that, while it may be feasible to reformulate some food products to meet the proposed nutrition principles, in many cases reformulation would require substantial changes in the nutritional profile of the food, such as significant reductions in added sugars or sodium content. Making substantial changes to the formulation of a food product may present both technical difficulties and challenges in maintaining the palatability and consumer acceptance of the product.<sup>172</sup>

The IWG, then, actually seems to recognize that it is setting a far higher bar for the food industry than what existing federal law would currently require – in the hopes of causing the food industry to reformulate its products in a dramatic way. The IWG suggests that, for some products, it is simply a matter of giving the food industry time to meet these more demanding standards<sup>173</sup> – and that the IWG is merely giving the food industry the ~~“hedge”~~ “it needs to get started. In other cases, the IWG admits that reformulation may not be possible – but seems to feel that that’s fine, too, without having closely examined which healthful foods might consequently be eliminated from being effectively marketed.”<sup>174</sup>

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<sup>171</sup> Proposal at 13.

<sup>172</sup> Proposal at 5.

<sup>173</sup> See *supra* Section II.A.2.a for a discussion of the FDA’s earlier misguided attempt to set ~~“stretch~~ “stretch goals” for the industry, which had the effect of eliminating the production of certain healthful, important foods.

<sup>174</sup> See *id.*

But because the IWG is advancing this agenda through a “voluntary” advertising ban, the IWG seems to feel it can set these standards at whatever arbitrary levels it chooses – even at levels that its own member agencies have explicitly rejected as unsupportable or inconsistent with public health. Worse, the IWG establishes these unsupportable standards with disregard for the economic and social consequences its arbitrarily-set standards will have on the food industry, not to mention the consequential effect on numerous other industries – retail grocery, advertising, television, transportation, etc., whose business will also be impacted. With all due respect, this is a very poor deployment of regulatory power and resources.

c. The Proposal is built on incorrect and inconsistently applied assumptions regarding portion sizes– yet another example of the arbitrary nature of the Proposal’s design.

In addition to the myriad deficiencies described above, the nutrition standards are also based on outdated and inconsistently applied assumptions about how much of certain foods children eat at one sitting. The result is that those assumptions wind up bringing certain foods within the advertising ban – even though these foods would almost never be consumed by children in the amounts that cause the foods to fail to meet the standards.

For example, the advertising ban would apply to many yogurt products, meaning that they could not be marketed to children. That is because, when the nutrient standard for “added sugar” is applied to yogurt using the decades-old RACC for yogurt – which assumes that yogurt comes in an 8-ounce cup – yogurt does not meet the standard. Today, however, less than 2% of all yogurt is sold in cups larger than 6 ounces, and yogurts advertised to kids exclusively come in 4-ounce or 2.25-ounce packages. But the IWG chooses not to consider the inappropriateness of the outdated RACC for yogurt, chooses to rely on it, with the consequence of banning the marketing of yogurt to children.

While clinging to outdated RACC standards for yogurt, the proposal then ignores the 30-gram RACC standard for cereal portion sizes, explicitly using the arbitrary 50-gram portion size instead, as discussed earlier. This is nearly two cups of cereal – and there is no legitimate support for assuming that kids (or adults, for that matter) would eat such a massive amount of cereal in one sitting. Because the IWG’s nutrient standards apply to an arbitrarily inflated assumed portion size for cereal, all ready-to-eat breakfast cereal winds up failing the IWG standards, and are therefore subject to the Advertising Ban.

To illustrate: A standard 30-gram serving of cereal will fail the criteria (and be banned from advertising) even if it has a mere 7.9 grams of sugar. This because the IWG’s nutrient standard for sugar applies to a 50-gram portion – and the amount of sugar in a 50-gram portion – again, far more cereal than any child would eat in one sitting – would exceed the IWG’s limit of 13 grams of sugar. The absurdity of that result – and the arbitrariness of the IWG’s action here – becomes even more apparent when one considers that a standard cereal *bar* meets the criteria, even if that cereal bar contains 13 grams of sugar. This is because a standard cereal bar has a 40-gram RACC – an amount that exceeds 30 grams, so that, unlike cereal, its portion size is not artificially inflated to 50 grams under the IWG’s portioning standards. This is simply illogical.

To be sure, the IWG was absolutely aware that, by applying its nutrient standards to 50-gram portion sizes for foods that have RACCs of 30 grams or less, cereal would be affected. Indeed, the IWG uses the example of cereal to illustrate the application of the standard!

[T]he 13 gram limit per RACC for added sugars would need to be adjusted down for a cereal with a RACC of 30 grams. As a result, the cereal would not meet the proposed principles for marketing to children if it contained more than 8 grams of added sugars in the 30 gram RACC.<sup>175</sup>

It is almost impossible to avoid concluding that the Proposal intended to target cereal in coming up with its 50-gram portion assumption for foods with small serving sizes. If so, the Proposal has intentionally promoted a most unfortunate public health policy.

- d. The IWG's entire approach of focusing on individual foods, rather than on diets, is fundamentally unsound and contrary to its congressional directive.

The design of the IWG's entire proposal is fundamentally unsound in that it focuses on the nutrition content of individual foods, instead of on *diets*. The error of the IWG's adopted approach is illustrated by the following example. Let us assume that an appropriate caloric intake is 2,000 calories per day, and that an average person eats, say, 20 items per day, for an average of 100 calories per item. Now, no one would contend that all foods containing more than 100 calories per serving should be banned from the diet. That would be ridiculous for the obvious reason that some higher-calorie foods (e.g., a piece of steak) would be balanced out by lower-calorie foods (e.g., a tomato). Clearly, there are foods that have many multiples of 100 calories per serving that can be a very sensible component of a healthful diet. Indeed, the IWG has acknowledged this point by establishing different levels for ~~meals~~" and ~~main dish~~" products.

But by subjecting all individual foods to the same arbitrary set of parameters, the IWG has adopted as flawed an approach as the ~~all~~ foods must be 100 calories or less" approach described above. As most people recognize, almost all individual foods can have an appropriate place in a sensible and healthy diet if eaten in moderation and with a balance of nutrients over several days.

The IWG's approach will admit to none of that. Under the IWG approach to standard-developing, there is no possibility of eating something that is high sodium in one sitting (such as a Caesar salad with anchovies), and low sodium in another (a piece of baked fish, plain baked potato, and sautéed spinach), in order to achieve a balanced diet. There is no such thing as having a small treat one day, which we then balance out the next two days by a little restraint. No, the IWG rejects the notion of constructing a balanced diet as a whole from many foods, any one of which may be a little high in one thing, but others of which are quite low, so that it is possible to achieve balance over time.

Under the IWG's approach, if an individual food does not meet the IWG's rigorous standards, it cannot be advertised – even if that food has recognized health benefits. This is well illustrated by the example of breakfast cereal. Many breakfast cereals would exceed, by a couple of grams, the arbitrary limit on sugars set by the IWG. Accordingly, under the IWG's approach, those cereals are *per se* bad, and cannot be advertised to children.

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<sup>175</sup> Proposal at 14.

So breakfast cereal is out, despite the fact that:

- Breakfast cereal is an important source of whole grains (General Mills cereals alone provide the nation with 10% of its whole grain consumption)
- Breakfast cereal is an important source of folic acid
- Breakfast cereal typically has only around 120 calories per serving
- It would be nearly impossible to get as much nutrition as cereal delivers, because cereal is fortified with numerous vitamins and minerals
- Children who consume cereal more frequently, including presweetened cereals, are far less likely to be overweight than those who consume cereal less often, and are more likely to have better nutrient intakes
- Children on average get 40% of their calcium through cereal consumption, as well as 17% of their vitamin A, 19% of their thiamin, 20% of their niacin, 24% of their vitamin B6, 34% of their folate, 27% of their iron, and 17% of their zinc intakes.
- Children on average get 5% or less of their sugar intake from cereal
- Children on average get 4% or less of their total calorie intake from cereal<sup>176</sup>

Not only does the IWG's approach make little sense, it is contrary to the directive it received from Congress, which was to consider the positive (and negative) contributions of foods in formulating its proposal.<sup>177</sup> The "one size fits all" disqualifying approach that the IWG has adopted runs exactly counter to that directive – no matter how beneficial a food otherwise is to public health, if it flunks the IWG's nutrient standards by the tiniest of amounts, it gets knocked out under the IWG's Advertising Ban.

Further, Congress directed the IWG to consider evidence concerning the role of consumption of nutrients, ingredients, and foods in preventing or promoting the development of obesity among such children.<sup>178</sup> But this is exactly what the IWG fails to do when it proposes to ban the advertising of all foods that fail to meet its arbitrarily set nutrient standards. For instance, as discussed *supra* in Section I.B of this Comment, breakfast cereal has a relatively low number of calories (and calorie balance is the key to maintaining a healthful body weight).<sup>179</sup> Furthermore, studies consistently show that children and adolescents who regularly consume ready-to-eat breakfast cereal for breakfast are far less likely to be overweight than those that do not.<sup>180</sup> However, the IWG's proposal would ban the advertising of all of General Mills' cereals (as well as those of other cereal makers).

The same is true for many frozen and canned fruits and vegetables that would fall within the advertising ban because they fail one of the IWG's standards, but which are consistent with the prevention of obesity. The Dietary Guidelines (2010) indicate that "a dietary pattern low in calorie density is characterized by a relatively high intake of vegetables [and] fruit," and "[s]trong evidence shows that eating patterns that are low in calorie density improve weight loss and weight

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<sup>176</sup> See *supra* Section I.B.1.

<sup>177</sup> See *supra* Section I.B.1.e; Proposal at 2.

<sup>178</sup> Proposal at 2.

<sup>179</sup> See *supra* Section II.A.1.a.

<sup>180</sup> See *supra* Section I.B.1.a.

maintenance.”<sup>181</sup> However, the IWG fails to consider the role that these banned fruit and vegetable products would play in ameliorating and helping to prevent obesity among children, and instead, subjects them to its rigid standard and finds them unsuitable for advertising.

Naturally, Congress did not intend such an unwarranted result, which is why it charged the IWG with considering the attributes of each individual food on its own. To do so, of course, would have required thorough study of individual foods by the IWG, which takes time and is a lot of work. But that kind of detailed due diligence, which the IWG failed to perform, is both necessary and appropriate: the IWG’s advertising ban has extremely significant consequences for public health, the economy, and American society.

The proposal does include some weak language which the IWG may have intended to serve as explanation for its ill-chosen approach. The IWG starts by indicating that it is conforming to existing dietary guidance in its proposal, and acknowledges that such guidance is focused on the diet as a whole – consistent with the Dietary Guidelines for Americans 2010. But the IWG goes on to imply that it is *diverging* from that guidance out of necessity:

The proposed principles should not be interpreted as a change in federal dietary guidance or nutrition policy or as a revision to any regulation defining health claims or nutrient content claims, such as ~~“healthy”~~ or ~~“low sodium,”~~ nor do the proposed principles signal any departure from the 2010 DGA [Dietary Guidelines for Americans]. The Working Group recognizes that the DGA provide science-based dietary recommendations for building healthy eating patterns and, thus, are focused on the total diet in a day, week, month, or longer, whereas food and nutrition labeling regulations are intended to provide information about the ingredients and nutrients in individual foods to enable consumers to make healthful dietary choices among foods. The Working Group’s proposed nutrition principles are designed for the specific purpose of guiding the industry in determining which foods are appropriate to market to children.<sup>182</sup>

Despite the IWG’s strained attempts to justify its approach, the fact remains that it has set nutrient standards at levels where one could construct an entire diet from FDA ~~“healthy”~~ foods, be in full compliance with the USDA Dietary Guidelines, and yet be eating high proportions of foods for which advertising would be banned. Any way one slices this, the advertising ban is at odds with existing policy about foods that form parts of healthful diets. This is neither logically nor legally defensible, and moreover, inexcusably flouts the explicit directive the IWG received from Congress.

- 3. By seeking to suppress consumption of foods that FDA defines as “healthy,” foods that FDA, USDA, and other agencies encourage Americans to eat, and foods expressly recommended by the American Academy of Pediatrics, the Proposal not only conflicts with current federal policy, it is harmful to public health.***

The Proposal would ban the advertising of foods whose consumption is expressly encouraged by the FDA, USDA and other agencies. Indeed, numerous foods that meet the FDA’s definition of ~~“healthy”~~ (including nearly all cereals) and/or the USDA/HHS’s Dietary Guidelines for 2010, as well as numerous foods that meet the standards of the USDA WIC program, fall within the scope of the

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<sup>181</sup> 2010 Dietary Guidelines at 16.

<sup>182</sup> Proposal at 5 (bracketed language added).

advertising ban. Such inconsistency is the hallmark of arbitrariness, because ~~an~~ agency must treat similar cases in a similar manner.”<sup>183</sup> Moreover, the Proposal bans the marketing to children of foods expressly encouraged by the American Academy of Pediatrics.

- a. The IWG standards would ban advertising of foods recommended in the USDA/HHS 2010 Dietary Guidelines.

Although the IWG attempts to characterize its standards as consistent with the 2010 Dietary Guidelines, they are in fact *inconsistent* with those guidelines. By taking this inconsistent position, the IWG fails to live up to a federal statutory mandate that the Dietary Guidelines ~~shall~~ be promoted by each Federal agency in carrying out any Federal food, nutrition, or health program.”<sup>184</sup>

For example, the IWG standards bar the marketing to children of whole grain foods like breakfast cereals, the consumption of which are encouraged by the 2010 Dietary Guidelines. The 2010 Dietary Guidelines recommend that people consume at least half of total grains as whole grains, and state that that can be accomplished in a number of ways, including by consuming whole-grain products that contain at least 8 grams of whole grains per ounce-equivalent. All General Mills Big G cereals contain at least 8 grams of whole grain per ounce-equivalent, and the FDA has specifically identified Cheerios as a whole grain food encouraged by the 2010 Dietary Guidelines.<sup>185</sup> Cereal is the number one source of whole grain in American diets for adults and children,<sup>186</sup> and the third most frequently consumed school breakfast item in elementary schools,<sup>187</sup> and yet the IWG’s nutrition standards effectively place an advertising ban on all cereals.

Cereal is also the primary source of folic acid, a nutrient whose consumption is expressly encouraged by the 2010 Dietary Guidelines. But the Proposal would ban the advertising of cereal, seemingly without regard to the potential decline in folic-acid consumption that may consequentially result.

The Proposal would also bar the marketing of many processed (canned or frozen) vegetables and fruits, even though the Dietary Guidelines recognize these forms of produce as desirable parts of a healthy diet. Processed fruits and vegetables are particularly important to the U.S. diet for a number of reasons. For one thing, they increase the consumption of fruits and vegetables because they are easier to prepare and less likely to spoil than fresh produce. This mitigation of spoilage is particularly important, because a high percentage of fresh produce is wasted by spoilage, thus making it a less cost-effective purchase than processed produce. Moreover, while fresh produce may be limited in certain

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<sup>183</sup> *Indep. Petroleum Ass’n of Am. v. Babbitt*, 92 F.3d 1248, 1258 (D.C. Cir. 1996).

<sup>184</sup> 7 U.S.C. § 5341(a)(1). ~~“Shall,”~~ of course, entails a ~~—mandatory”~~ duty. *Lopez v. Davis*, 531 U.S. 230, 241 (2001).

<sup>185</sup> See FDA, Labeling of Cheerios Toasted Whole Grain Cereal Q’s & A’s Regarding FDA’s Warning letter (May 14, 2009), at <http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm161795.htm> (“[T]he Dietary Guidelines for Americans encourages the consumption of whole grain foods, which includes whole oats found in products such as Cheerios.”).

<sup>186</sup> NHANES Data [2003-2004]; USDA Agricultural Research Service, *MyPyramid Equivalent Database, 2.0, for USDA Survey Foods, 2003-2004*.

<sup>187</sup> USDA, *School Nutrition Dietary Assessment—III* (Nov. 2007), at <http://www.fns.usda.gov/ora/menu/published/CNP/FILES/SNDIII-SummaryofFindings.pdf>.

locations or during certain times of the year, processed fruits and vegetables allow for a wider variety of produce to be available to consumers at all times.

As noted above federal law specifically provides that ~~any~~ Federal food, nutrition, or health program” must be carried out in a manner that promotes the Dietary Guidelines.<sup>188</sup> The IWG’s Proposal does not ~~promote~~” the Dietary Guidelines – it undercuts them.

b. The IWG standards would ban advertising of foods included in the USDA Women, Infant and Children program.

The IWG’s advertising ban would apply to foods expressly included in the USDA Women, Infants, and Children (WIC) program, including many whole grain breads and cereals that are currently part of the WIC program, as well as enriched grains, which are a primary source of folic acid and which are encouraged for pregnant women/teenagers to prevent neural tube defects in a developing fetus. All General Mills cereals within the WIC program are subject to the Advertising Ban.

c. The IWG standards would ban advertising of foods that the FDA defines as ~~healthy~~” or whose health benefits the FDA has expressly acknowledged.

Stunningly, numerous foods that meet the FDA’s food-labeling definition of ~~healthy~~” nonetheless fail to meet the IWG standards, and therefore could not be advertised to children. Below are a few representative of the huge number of General Mills products that meet the FDA’s ~~healthy~~” definition, and yet would be banned under the Proposal:

- All breakfast cereals, including Cheerios, Total, Total Raisin Bran, Wheaties, Fiber One, Rice Chex, Corn Chex, etc.
- Numerous varieties of Green Giant canned and frozen vegetables (e.g., steam garden medley, broccoli cuts, asparagus cuts, select baby peas, and many more)
- Old El Paso canned ~~heat and eat~~” black beans
- Old El Paso canned green chilies
- Most varieties of Progresso canned soups, including many ~~light~~” and reduced-sodium varieties
- Numerous Cascadian Farms organic canned and frozen vegetable varieties (e.g., asparagus, broccoli, whole green beans, and many more)
- Numerous Cascadian Farms organic frozen fruit varieties (e.g., frozen strawberries)
- Muir Glen fire-roasted diced tomatoes
- Numerous Yoplait fruit smoothie varieties
- Yoplait fat-free strawberry Greek yogurt and other Greek yogurt varieties

The IWG appears to not want American children to know about Cheerios or Green Giant baby peas.<sup>189</sup> The FDA may be fine with defining these foods as healthy, but the IWG is not. This result cannot be justified.

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<sup>188</sup> 7 U.S.C. § 5341(a)(1).

<sup>189</sup> See also *infra* Section II.B.1.

d. The IWG standards would ban advertising of numerous foods recommended by the American Academy of Pediatrics.

In addition, many foods recommended by the American Academy of Pediatrics (AAP) – including foods listed in the grain, protein, and dairy groups – would not meet the IWG proposed standards, including those described below:<sup>190</sup>

- Whole grains. Many whole-grain products recommended by the AAP fail the IWG standards (due to sodium or whole grain standards not being met). These include breads, crackers, cereals, pasta, brown rice, bagels, tortillas, corn bread, pita bread, bran muffins, English muffins, matzo crackers, pancakes, breadsticks, and pretzels.
- Proteins. It is unlikely that most cooked, canned beans (kidney beans, black-eyed peas, pinto beans, lentils, black beans), refried beans, peanut butter and reduced-fat deli meats within the AAP's protein recommendations would meet the IWG standards, because they would fail to fall within the IWG's sodium and sugar standards.
- Dairy. Practically all of the foods listed in the AAP's dairy recommendations, including low-fat milk, yogurt, cheese, string cheese, cottage cheese, pudding, custard, frozen yogurt, and ice milk, would fail to meet one or more of the IWG's sugar, fat and sodium standards.

Many of these foods – the “collateral damage” of the IWG standards – are essential to fostering public health, and particularly the health of children. The fact that the IWG standards would ban the advertising of these important foods reflects, at a minimum, a lack of careful design in the development of such standards.

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In sum, the Proposal abandons the recommendations of its member agencies, and ignores the guidance of professional pediatric organizations, with, not surprisingly, absurd results – perhaps the most striking of which is the banning of Cheerios advertising. Cheerios fails to pass muster under the IWG's arbitrary sodium standard, and thus, under the Proposal, not worthy of being marketed to American children. But consider the following about Cheerios:

- Cheerios is an important source of whole grains under the 2010 Dietary Guidelines and meets the recommendations of the American Academy of Pediatrics for whole grains
- FDA has specifically identified Cheerios on its website as a source of whole grains, which it has not done for any other cereal<sup>191</sup>
- Cheerios meets the FDA definition of “healthy”
- Cheerios is naturally cholesterol-free and has 1 gram or less saturated fat per serving
- Four out of five pediatricians recommend Cheerios as a “first finger” food<sup>192</sup>

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<sup>190</sup> See generally American Academy of Pediatrics, *Children's Health Topics*, at <http://www.aap.org/healthtopics/nutrition.cfm> (last visited July 6, 2011).

<sup>191</sup> See FDA, Labeling of Cheerios Toasted Whole Grain Cereal Q's & A's Regarding FDA's Warning letter (May 14, 2009), at <http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm161795.htm> (“[T]he Dietary Guidelines for Americans encourages the consumption of whole grain foods, which includes whole oats found in products such as Cheerios.”).

If even Cheerios – just one of many good foods that fall casualty to the IWG’s approach – cannot satisfy the IWG’s standards, then there is something very wrong about the thinking that has gone into those standards. In our view, it is clear that the standards should be withdrawn in their entirety and the IWG’s whole approach here reconsidered.

**B. The Proposal’s nutrition standards are impossibly strict and reflect a bias against prepared, non-raw foods and an unfortunate view that foods (and consumer tastes) can or should be reengineered to meet these standards.**

**1. *Almost no commonly consumed foods – even foods that are universally recognized as healthful – meet the IWG’s arbitrary standards.***

Out of the 100 most commonly consumed foods and beverages in America (as reported by The NPD Group, Inc., an independent market research company<sup>193</sup>), 88 would fail the IWG’s proposed standards.<sup>194</sup> The following are among the “top 100” foods that, in their common form, fail the IWG standards:

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<sup>192</sup> General Mills survey data (2009) (n=300).

<sup>193</sup> Source: The NPD Group, Inc. National Eating Trends® (NET®) in-home food consumption for the two years ending February 2011. NET® classifies all base dish foods into 88 standard categories; e.g. Vegetables, Fruits, Sandwiches, etc. (Base dish is defined as the final dish consumed). For this study, because there are differences between foods within given categories within the 88 standards categories, further sub-classifications of foods were required (e.g., ham sandwich vs. peanut butter & jelly sandwich; carrots vs. corn; etc.), resulting in over 400 expanded categories. For further information, see [Description of Methodology](#), note 194 below.

<sup>194</sup> Throughout this Comment, references to analyses of foods that do (or do not) meet the IWG standards are made with reference to the final (2021) standards.

Description of Methodology:

1. *List of “top 100” foods compiled by NPD.*

The list of over 400 commonly consumed foods, as provided by NPD (described in note 193 above), reflects not only the names of these foods, but their relative prevalence in the American diet, expressed in total share of “eatings.” From the final list of over 400 foods, ranked in order of prevalence, the determination could easily be made of the top 100 most commonly consumed food types. The “eatings” numbers, and the ranking of the foods themselves, are proprietary to NPD. However, an alphabetized list of the top 100 foods (stripped of ranking and prevalence data) is found in the Column A of Attachment 2 hereto. (NPD also offers similar data for the diets of children 2-17. The top 100 foods for this age range is very similar to that of the population as a whole, though the rank order of the foods differs. A parallel analysis of the top 100 foods for children 2-17 yielded the result that 86 out of the 100 most commonly consumed foods by children 2-17 fail the IWG standards.)

2. *Top 100 foods analyzed against IWG nutrition standards.*

In addition to providing the list of the top 100 most commonly consumed foods, ranked by prevalence in the diet, NPD was able to provide further detail about the most commonly consumed form of each food (with respect to those foods that may take a variety of forms). For instance, the NPD data establishes that most corn is from canned corn (vs. frozen or fresh) whereas most apples are fresh. This additional data makes it possible for the most commonly consumed form of given food types to be examined against the IWG requirements. This is precisely what was done. Column B of Attachment 2 reflects the precise form of each food that was used for the IWG analysis. This analysis is a simple exercise using the 2021 IWG standards and readily available nutrition information about the products listed in Column B. The results of this analysis are listed in Column C of

- **Ready-to-eat cereals** (nearly all commonly consumed cereals – even unsweetened cereals like Cheerios – would be banned from advertising)
- **Salads** (the most common form of salad is a leaf salad with low-fat dressing – and even this does not satisfy the IWG standards)
- **Hot cereal** (the most common of these is sweetened oatmeal, but even plain oatmeal, if cooked according to standard package directions, fails the IWG standards)
- **Bottled water** (pure water – unflavored and noncarbonated – fails the standards)
- **Corn** (canned corn is the most common form of corn in the diet, and like all other canned vegetables, canned corn fails the IWG standards)
- **Green beans** (canned)
- **Peas** (canned)
- **Whole wheat bread**
- **Reduced-fat yogurt**
- **Rice**

As a matter of public policy, the government would do well to affirmatively *promote* consumption of these healthful foods (and actually, as described earlier, the very agencies involved in the IWG do just that in their science-based pronouncements outside the IWG context). The idea that these foods should be subject to an advertising ban in the name of public health is simply insupportable.<sup>195</sup> As White House Chief of Staff William M. Daley commented during a recent discussion of questionable regulations, “Sometimes you can’t defend the indefensible.”<sup>196</sup> This is such a situation. A public policy that seeks to keep the existence of foods like salad and water a secret from America’s youth is indefensible by any standard.

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Attachment 2. A “yes” in Column C means the food meets the IWG standards whereas a “no” means the food fails the IWG standards. For those foods that fail the standards, one or more explanations for the failure are given in Column D. Please note that this is, in many cases, just a partial list of some of the more obvious reasons that the food fails the standards – it is not exhaustive in the case of many of the foods.

<sup>195</sup> Prior to its involvement in the IWG effort, FDA had historically recognized that setting overly strict nutrient standards can be counter-productive where the goal is to encourage healthy eating choices. For example, in 1993, FDA determined that setting overly strict “disqualifying levels” for fat, saturated fat, cholesterol, and sodium (i.e., levels beyond which health claims could not be made) was undesirable because to do so might “serve as impediments to providing consumers with important information on diet and health by precluding health claims for major food groups, such as fish and whole grain cereals, that can be significant foods in a balanced and healthy diet.” 58 Fed Reg. 2493 (1993). More recently, in the context of establishing sodium levels for the “healthy” claim, FDA reached a similar conclusion:

Comments from both industry and consumer advocates support the conclusion that implementing the [stricter] second-tier sodium requirements would risk substantially eliminating existing “healthy” products from the marketplace because of unattainable nutrient requirements or undesirable and, thus, unmarketable flavor profiles. As a result of these comments, FDA has concluded that it can best serve the public health by continuing to permit products that meet the [less-strict] first-tier sodium level to be labeled as “healthy,” and thereby ensure the continued availability of foods that consumers can rely on to help them follow dietary guidelines not only for controlling sodium but also for limiting total fat, saturated fat, and cholesterol and consuming adequate amounts of important nutrients such as fiber, protein, and key vitamins and minerals.

70 Fed. Reg. 56828 (Sep. 29, 2005).

<sup>196</sup> Peter Wallsten and Jia Lynn Yang, *White House’s Daley seeks balance in outreach meeting with manufacturers*, WASH. POST, June 16, 2011, at [http://www.washingtonpost.com/politics/white-houses-daley-seeks-balance-in-outreach-meeting-with-manufacturers/2011/06/16/AG177yXH\\_story\\_1.html](http://www.washingtonpost.com/politics/white-houses-daley-seeks-balance-in-outreach-meeting-with-manufacturers/2011/06/16/AG177yXH_story_1.html).

The advertising ban's nutrition standards are not only inappropriately strict – and (as described above) deeply inconsistent with the fact that many of the ~~–banned~~ foods meet FDA's definition of ~~–healthy~~, bear FDA-authorized health claims, satisfy USDA's standards for its Women, Infant, Children (WIC) food assistance program, are encouraged for consumption under the 2010 U.S. Dietary Guidelines, and are purchased for families using federal funds through the SNAP (food stamp) program – they are incredibly arbitrary. Though there is certainly nothing wrong with the twelve commonly consumed foods (out of the top 100) that actually meet the IWG standards (listed below) – they are no more healthful than the ~~–banned~~ foods listed above. This arbitrary and insupportable result is a direct consequence of the IWG's use of non-scientific standards in determining what makes the ~~–approved~~ list and what does not.

The twelve commonly-consumed foods that satisfy the standards are as follows:

- Raw bananas
- Raw apples
- Raw grapes
- Raw oranges
- Raw peaches
- Raw strawberries
- Raw carrots
- Fresh broccoli (cooked without salt or fat)
- Frozen mixed vegetables
- 100% fruit juice
- Applesauce
- Non-fat yogurt

Though there are fine foods on this list, they represent only small parts of three of the five food groups, as established by the U.S. Dietary Guidelines. No grain-based products and no meat products in the top 100 make the ~~–approved~~ list – they would all be subject to the advertising ban. The goal of any advertising ban of certain products, like that proposed by the IWG, is necessarily to limit consumption of products subject to the ban. Here, where the category of products involved does not involve discretionary items, but rather involves food (which obviously is required for human survival), the goal is necessarily to shift consumption away from ~~–banned~~ foods to foods that meet the IWG's standards. But there is simply no legitimacy to a public policy that suggests that there should be no grain products (like cereals and whole wheat breads) in our diet, and that these foods should be eliminated in favor of foods like applesauce and fruit juice. Again, these are perfectly acceptable foods – but they are not nutritionally superior foods. In fact, they are inferior to several of the ~~–banned~~ foods.

To be sure, it is unreasonable to assume that people will simply forgo eating grains entirely due to an advertising ban, but it *is* reasonable to assume that, if the ban has its desired effect, consumption of grains would drop significantly. And in particular, consumption of cereal would drop the most because (as noted earlier) cereal is the most heavily advertised food subject to the ban (and far and away the most heavily advertised grain product subject to the ban). For all the reasons described earlier, this is not what anyone should want from a public health standpoint. And what does the IWG expect people might eat in place of cereal for breakfast? Donuts? Bagels? Pancakes? Bacon? None of these – and no other food either – will be a worthy replacement.

Banning the advertising of the overwhelming majority of common foods, including numerous incredibly healthful options, is flawed public policy.

**2. Reformulation is not an option. Virtually no food, once prepared into a recipe or dish, can satisfy the IWG standards.**

As noted above, the list of common foods that satisfies the IWG standards is a sparse one, and most items on the list are raw, unprepared foods. This is because virtually no food, once prepared into a recipe or finished “dish,” can satisfy the IWG standards. Even the raw foods meeting the standards will, once incorporated into recipes prepared at home, end up being consumed as part of a food not meeting the standards. For example, uncooked oatmeal technically meets the standards, but when prepared according to package directions, it does not. An egg might also meet the standards, but unless it is hard-boiled or poached and unsalted, it will not meet the standards. *There is a double-standard at work here: the IWG is banning advertising of foods that are already processed in favor of foods that will be processed at home – seemingly in the naive belief that the home cook will add no salt, sugar, fat, or anything else to the whole food.* Home cooks will not “process” their food in this unpalatable manner.

There is perhaps no better demonstration of the above point than the fact that very few recipes, even those promoted as “healthy for kids,” meet the IWG standards. For example, consider the 15 recipes named by USDA as semi-finalists in its “Recipes for Healthy Kids” contest last month.<sup>197</sup> At least 12 of these 15 recipes promoted by USDA as “healthy,” kid-friendly recipes fail the IWG standards.<sup>198</sup> Similarly, consider the six recipes that White House chef Sam Kass has contributed to a story appearing on Oprah.com regarding healthy recipes “he serves the first family.”<sup>199</sup> Five of these six recipes would fail the IWG standards.<sup>200</sup> Consider, too, the assemblage of breakfast menus promoted in the back of the 2008 edition of Mark Bittman’s best-selling *How to Cook Everything* cookbook. Mr. Bittman (whose *New York Times* column has called for the Proposal to be enacted into mandatory standards immediately because cereal and other products constitute, in his opinion, “junk” that “does not deserve to be called ‘food’”)<sup>201</sup> proposes three breakfast menus using recipes from the main body of his book.<sup>202</sup> Neither the meals as a whole, nor the individual foods within any of these menus, would satisfy the IWG standards.<sup>203</sup> And, it bears noting, none would approach the dietary benefits per calorie of a bowl of Trix with milk.<sup>204</sup>

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<sup>197</sup> Let’s Move! in association with USDA, *Recipe Gallery*, at <http://www.recipesforkidschallenge.com/submissions> (last visited July 6, 2011).

<sup>198</sup> *See id.*

<sup>199</sup> Sam Kass, *White House Recipes*, at <http://www.oprah.com/food/Healthy-White-House-Recipes-from-Chef-Sam-Kass> (last visited July 6, 2011).

<sup>200</sup> *See id.*

<sup>201</sup> Mark Bittman, *Marketing Junk to Kids – Or Not*, N.Y. TIMES, May 9, 2011, at <http://bittman.blogs.nytimes.com/2011/05/09/marketing-junk-to-kids/>; Mark Bittman, *Junk Food ‘Guidelines’ Won’t Help*, N.Y. TIMES, May 9, 2011, at <http://opinionator.blogs.nytimes.com/2011/05/03/junk-food-guidelines-wont-help/?ref=opinion>.

<sup>202</sup> Mark Bittman, *HOW TO COOK EVERYTHING, COMPLETELY REVISED 971* (10th Anniversary Ed, 2008).

<sup>203</sup> *See id.*

<sup>204</sup> *See supra* Section I.B.1.a.

This is not to say that the recipes being promoted by USDA, or by professional cooks, are bad recipes. They are not. But it does point out the difficulties inherent in making palatable foods while still satisfying the IWG standards. Even for those setting out to create “healthy” recipes, and even for those who are highly critical of the food industry’s recipes for the products it sells, creating an IWG-compliant recipe is a rare feat. And these recipe creators have, compared to the food industry, all the freedom in the world in creating their recipes. They are not constrained by the limitations of existing production lines, nor any of the other constraints inherent in producing packaged foods on a mass scale. If they can dream it up, they can cook it and publish it. And still, they do not often produce recipes that satisfy the IWG standards because the standards are so highly intolerant of any of the items that typically are included in recipes to make foods palatable and appealing – such as fat, salt, and sugar.

It is generally agreed that human sense of taste can recognize four basic tastes – sweet, salty, bitter, and sour. The IWG has essentially taken even moderate sweetness and moderate saltiness off the table, leaving the food industry’s recipe creators with few options other than bitter, sour, and bland. Whether one is cooking for the readers of a best-selling cookbook, the first family, or the population of American consumers as a whole, these taste profiles are not workable, and nor is complying with the IWG standards.

**3. *The inherent bias against non-raw foods that underlies these standards is unfortunate and ignores the critical role of fortified foods in public health.***

As noted earlier, virtually all the foods that meet the IWG’s nutrition standards are whole, raw foods, whereas non-raw foods nearly always fail the standards. The IWG appears to assume that if people eat enough whole, raw foods, they will get the nutrients they need. But this is not at all the case. Foods contain different combinations of nutrients and no single food can supply all nutrients in the amounts people need. Even within a food group, there are natural variations and differences in the nutrient composition of the foods within the group. For example, bananas and cauliflower provide potassium but little vitamin C or A, and if people choose bananas and cauliflower as their “whole” fruit and vegetable servings, they will not get enough vitamin C or A. Therefore, if one were to choose to eat nothing but whole foods, one would have to work very hard to get an appropriate mix of nutrients, and it is simply not realistic for people to do this. To address this problem, fortification of commonly consumed processed foods has long been recognized as an appropriate and important means of delivering needed nutrients in the U.S. diet, and fortification has eliminated many nutrition deficiency-related diseases over the decades.<sup>205</sup>

General Mills has long been a leader in these efforts and has had a profound impact on improving public health, and a brief history of some of these fortification efforts is instructive.

In the late 1930s, Kix cereal became the first General Mills product to be “vitalized,” as it was called it then, with vitamins B and C, as well as iron and calcium. In 1940, General Mills launched Vibic Flour, which was enriched with Vitamin B, calcium, and iron, leading the industry into a fortification effort which, by a few years later, resulted in 75 to 80 percent of all-family flour

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<sup>205</sup> See generally Institute of Medicine, *Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification* Ch. 3 (The National Academies Press, 2003) (providing an overview of food fortification in the United States and Canada).

products being enriched throughout the industry. By 1943, a federal law was passed requiring bread to be enriched with vitamins. Reductions in several nutrition-related illnesses were attributed to these enrichment efforts. Fortunately for everyone, the IWG standards were not in place at the time.

At around the same time that Kix arrived on American breakfast tables, the high incidence of the bone-weakening disorder rickets was a blot on our national health record – as many as 50 percent of children in some areas had deformed bones. By 1953, the disease caused by vitamin deficiency had all but vanished in the U.S. The reason: the widespread fortification of milk with vitamin D – led by companies like General Mills who, through a revolutionary process, developed a way to make vitamin D easily available, inexpensive, and palatable, and was able to produce a vitamin D concentrate that could be added to milk. Today, General Mills fortifies its entire line of kids' cereals with vitamin D as well.

General Mills continued to blaze a trail in fortification in the middle and latter parts of the 20th century as well. By the mid-1940s, the company recognized that natural sources of Vitamin A – extractions from the livers of fish like cod, dogfish, and soupfin shark – were dwindling. To address this, General Mills, through a joint venture with the Eastman Kodak Company, developed the world's first commercial production of synthetic Vitamin A in 1947. Fortification with Vitamin A, which is essential for proper growth and vision, followed thereafter and is now an element of public health that we all take for granted.

In 1961, General Mills launched Total cereal – the first cereal to contain 100 percent of the minimum daily adult requirement for eight vitamins, as recommended by the U.S. government. And we began adding iron and B-vitamins to a wider range of cereals in the 1970s. These moves had a profound impact on addressing nutrient deficiencies. In 1985, General Mills began fortifying all cereals with folic acid – a B vitamin known to reduce the risk for neural tube defects in the developing fetus and therefore key to minimizing the risk of diseases like Spina bifida. Thirteen years later, the FDA recommended the fortification of many foods with folic acid to increase individual uptake. In all, the food industry's folic acid fortification efforts resulted in a 19 percent decline in neural tube defects in American children.

In 1999, calcium was added to several General Mills cereal brands. In addition to strong bones and teeth, calcium is essential for blood clotting, muscle contractions and relaxation (including heart muscles), and nerve transmission. At that time, a USDA study found that 72 percent of kids were not getting the calcium they needed. Meanwhile, surveys indicated that although moms understood the benefit calcium provided, they believed their kids were already getting enough. So General Mills set about raising awareness of calcium deficiency and the role our products could play in providing a solution to the problem. Our cereals, we explained, could be an easy way for kids to get the calcium they needed, since kids already loved eating them, and moms typically had cereal in the house. Eating cereal, it should be noted, has the added benefit of encouraging milk consumption. Over 40% of the milk consumed by American children (and 54% and 48%, respectively, of the milk consumed by African-American and Hispanic children) is consumed with cereal.

Ready-to-eat cereal is the leading source of iron and folic acid in children's diets and contributes significant amounts of fifteen essential nutrients, including fiber, vitamins A, C and D.<sup>206</sup> Children who eat cereal are not only far less likely to be overweight or obese than those who do not,

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<sup>206</sup> NHANES Data [2007-2008].

they also have far better overall nutrient intakes, which is critical for many aspects of their health. For example, cereal consumption accounts for 40% of children's calcium intake, 17% of their vitamin A intake, 19% of thiamin intake, 20% of niacin intake, 24% of vitamin B6 intake, 34% of folate intake, 27% of iron intake, and 17% of zinc intake – all while contributing only 4% of the calories in children's diets. Consumption of fortified ready-to-eat cereal has been shown to improve the overall nutritional adequacy of the diet, as well as provide key nutrients to targeted populations.<sup>207</sup> Again, it is an awfully good thing that the IWG standards have not been in place to block the delivery of these benefits.

This is not to say that whole foods are bad. But foods like fortified ready-to-eat cereals are of critical importance as well, and have been working for many decades to address important public health needs. Labeling them as “bad” and not worthy of being advertised or consumed is deeply misguided as a matter of public policy.

As a final illustration of this point, consider the following comparison between a bowl of plain oatmeal with a bowl of a fortified sweetened cereal like Lucky Charms. The oatmeal – at least in its uncooked form – meets the IWG standards, whereas the cereal does not. But, as shown below, Lucky Charms is less caloric per serving and far denser in key nutrients:

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<sup>207</sup> See Deshmukh-Taskar PR, et al., *The Relationship of Breakfast Skipping and Type of Breakfast Consumption with Nutrient Intake and Weight Status in Children and Adolescents: The National Health and Nutrition Examination Survey 1999-2006*, J AM DIET ASSOC. 2010 Jun;110(6):869-78; Albertson AM et al., *The Relationship of Ready-to-Eat Cereal Consumption to Nutrient Intake, Blood Lipids, and Body Mass Index of Children as They Age Through Adolescence*, J AM DIET ASSOC. 2009 Sep;109(9):1557-65; Williams BM, et al., *Are Breakfast Consumption Patterns Associated with Weight Status and Nutrient Adequacy in African-American children?*, PUBLIC HEALTH NUTR. 2009 Apr;12(4):489-96 (Epub 2008 May 27); Barton BA, et al., *The Relationship of Breakfast and Cereal Consumption to Nutrient Intake and Body Mass Index: The National Heart, Lung, and Blood Institute Growth and Health Study*, J AM DIET ASSOC. 2005 Sep;105(9):1383-9; Affenito SG, et al., *Breakfast Consumption by African-American and White Adolescent Girls Correlates Positively with Calcium and Fiber Intake and Negatively with Body Mass Index*, J AM DIET ASSOC. 2005 Jun;105(6):938-45; Cho S, et al., *The Effect of Breakfast Type on Total Daily Energy Intake and Body Mass Index: Results from the Third National Health and Nutrition Examination Survey (NHANES III)*, J AM COLL NUTR 22, 2003 296-302; Kostis RI, et al., *The Association Between Consumption of Breakfast Cereals and BMI in Schoolchildren Aged 12-17 years: the VYRONAS study*, PUBLIC HEALTH NUTR 2007 20, 1-7; Nicklas TA, et al., *Nutrient Contribution of Breakfast, Secular Trends, and the Role of Ready-to-Eat Cereals: a Review of Data from the Bogalusa Heart Study*, 2008 AM J CLIN NUTR 67(supp), 757S-763S; Sampson AE, et al., *The Nutritional Impact of Breakfast Consumption on the Diets of Inner-City African-American Elementary School Children*, 1995 J NATL MED ASSOC 87, 195–202; Gibson S, *Micronutrient Intakes, Micronutrient Status and Lipid Profiles Among Young People Consuming Different Amounts of Breakfast Cereals Further Analysis of Data from the National Diet and Nutrition Survey of Young People Aged 4 to 18 Years*, 2003 PUB HEALTH NUTR 6, 815-820.

Lucky Charms 110 Calories		Oatmeal 150 Calories	
Iron	25% DV	Iron	10% DV
Thiamin	25% DV	Thiamin	10% DV
Riboflavin	25% DV	Riboflavin	2% DV
Folic Acid	50% DV	Folic Acid	--
Niacin	25% DV	Niacin	--
Vitamin B6	25% DV	Vitamin B6	--
Vitamin B12	25% DV	Vitamin B12	--
Zinc	25% DV	Zinc	--
Vitamin A	10% DV	Vitamin A	--
Vitamin C	10% DV	Vitamin C	--
Vitamin D	10% DV	Vitamin D	--
Calcium	10% DV	Calcium	--

As the above illustrates, fortified “processed” foods like cereals provide extraordinary nutrient density – and yet they fail the IWG standards and could not be advertised. By contrast, if one wanted to achieve these same levels of vitamins and minerals in an IWG-approved breakfast based on plain oatmeal, one would have to add something like the following to the plain oatmeal: ½ medium raw baby carrot + 1 medium strawberry + 2 oz low-fat plain yogurt + 1 cup cooked spinach (without salt or fat) + 2 oz fresh yellowfin tuna (cooked without salt or fat) + 2.5 oz extra lean pork chop (cooked without salt or fat) + 1 oz fresh salmon (cooked without salt or fat) + 1 small, raw, eastern oyster.

**Added calories and cost of potential IWG-approved additions to plain oatmeal to achieve same levels of key nutrients as bowl of Lucky Charms**

Lucky Charms	Oatmeal + Additional Foods																																																
 <table border="1"> <tr><td>Iron</td><td>25% DV</td></tr> <tr><td>Thiamin</td><td>25% DV</td></tr> <tr><td>Riboflavin</td><td>25% DV</td></tr> <tr><td>Folic Acid</td><td>50% DV</td></tr> <tr><td>Niacin</td><td>25% DV</td></tr> <tr><td>Vitamin B6</td><td>25% DV</td></tr> <tr><td>Vitamin B12</td><td>25% DV</td></tr> <tr><td>Zinc</td><td>25% DV</td></tr> <tr><td>Vitamin A</td><td>10% DV</td></tr> <tr><td>Vitamin C</td><td>10% DV</td></tr> <tr><td>Vitamin D</td><td>10% DV</td></tr> <tr><td>Calcium</td><td>10% DV</td></tr> </table>	Iron	25% DV	Thiamin	25% DV	Riboflavin	25% DV	Folic Acid	50% DV	Niacin	25% DV	Vitamin B6	25% DV	Vitamin B12	25% DV	Zinc	25% DV	Vitamin A	10% DV	Vitamin C	10% DV	Vitamin D	10% DV	Calcium	10% DV	 <table border="1"> <tr><td>Iron</td><td>15% DV</td></tr> <tr><td>Thiamin</td><td>15% DV</td></tr> <tr><td>Riboflavin</td><td>23% DV</td></tr> <tr><td>Folic Acid</td><td>50% DV</td></tr> <tr><td>Niacin</td><td>25% DV</td></tr> <tr><td>Vitamin B6</td><td>25% DV</td></tr> <tr><td>Vitamin B12</td><td>25% DV</td></tr> <tr><td>Zinc</td><td>25% DV</td></tr> <tr><td>Vitamin A</td><td>10% DV</td></tr> <tr><td>Vitamin C</td><td>10% DV</td></tr> <tr><td>Vitamin D</td><td>10% DV</td></tr> <tr><td>Calcium</td><td>10% DV</td></tr> </table>	Iron	15% DV	Thiamin	15% DV	Riboflavin	23% DV	Folic Acid	50% DV	Niacin	25% DV	Vitamin B6	25% DV	Vitamin B12	25% DV	Zinc	25% DV	Vitamin A	10% DV	Vitamin C	10% DV	Vitamin D	10% DV	Calcium	10% DV
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<p>110 Calories</p> <p><b>Total \$0.31</b></p>	<p>150 Calories + Additional Foods</p> <p><b>451 Calories</b></p> <p><b>Total \$5.29</b></p>																																																

The resulting breakfast, composed solely of “unprocessed” foods approved by the IWG and designed to be perhaps the lowest calorie way to achieve the same nutrient levels and the “processed” cereal, would have around 451 calories (vs. 110 for Lucky Charms). It would also cost vastly more – like around 17 times more. And it would be quite unrealistic to expect people to be able to construct

such a diverse diet of foods necessary to achieve the mix of nutrients that are already offered in a very turn-key way by fortified foods. The IWG must consider facts like this before labeling essentially all common fortified foods as foods unworthy of consumption by American youth.

**4. *The IWG standards reflect a lack of appreciation for the need for healthful foods to be made palatable.***

Another fundamental flaw in the Proposal lies in its failure to appreciate the necessary role that taste plays in encouraging people to eat healthful foods. As discussed earlier, the IWG standards are so harsh that even reformulating products like children's cereals using recipes similar to those of ~~adult~~ cereals would not help, given that virtually no adult cereals satisfy the standards either. But even if that would have worked, it would be a bad result for public health, because kids would not eat unsweetened cereals with the prevalence with which they eat children's cereals today – and for all of the reasons described elsewhere, we should *want* kids to eat cereals.

The IWG's failure to recognize the need for moderate amounts of sugar and sodium to maintain palatability and promote consumption of healthful foods stands in stark conflict with the longstanding recognition of this in federal dietary policy. For instance the 2005 Dietary Guidelines published by USDA and HHS note that ***“[in] some cases, small amounts of sugars added to nutrient-dense foods, such as breakfast cereals and reduced-fat milk products, may increase a person's intake of such foods by enhancing the palatability of these products, thus improving nutrient intake without contributing excessive calories.”***<sup>208</sup> Similarly, the 2010 Dietary Guidelines note that:

calories [from solid fats or added sugars] are best used to increase the palatability of nutrient-dense foods rather than to consume foods or beverages that are primarily solid fats, added sugars, or both. ***A few examples of nutrient-dense foods containing some solid fats or added sugars include whole-grain breakfast cereals that contain small amounts of added sugars.***<sup>209</sup>

As discussed in detail earlier, FDA has similarly recognized the need for moderate levels of sodium in promoting the palatability and consumption of healthful foods: ~~“L~~owering the amount of sodium in healthy foods to [overly strict levels] would run counter to public health goals if it discouraged manufacturers from producing ~~healthy~~ foods and consumers from eating them.”<sup>210</sup>

The IWG has failed to take any of this guidance into account, and the results are both arbitrary and perverse: a ban on advertising of healthful foods – or, viewed another way, a mandate to reformulate healthful foods to make them unpalatable. Either way, public health will suffer.

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<sup>208</sup> USDA and HHS, *Dietary Guidelines for Americans, 2005*, at 36-37 (emphasis added).

<sup>209</sup> 2010 Dietary Guidelines at 46 (emphasis added); *see also* Institute of Medicine, *School Meals: Building Blocks for Healthy Children* 97 (The National Academies Press, 2009) (“With careful menu planning, enough discretionary calories should be available to cover flavored fat-free milk in place of plain fat-free milk as a daily option, some flavored low-fat yogurt, and some sweetened ready-to-eat cereals. These are highly nutritious foods that are very popular with many schoolchildren and that are identified in the AHA statement as potentially having a positive impact on diet quality. Fruits in light syrup contain about 10 grams of added sugars per half cup serving. The omission of those sweetened foods might result in decreased student participation as well as in reduced nutrient intakes.”)

<sup>210</sup> 70 Fed. Reg. at 56833 (Sept. 29, 2005); *see supra* Section II.A.2.a.iv.

### III. Implementation of the Proposal would lead to serious adverse consequences for consumers, agriculture, and the American economy as a whole.

#### A. If the Proposal met its desired goal of shifting food consumption away from “banned” foods toward foods that meet the IWG’s standards, the economic consequences for American consumers and American agriculture would be devastating.

The goal of any advertising ban is, by definition, to suppress consumption of products that can no longer be advertised. Of course, if the ~~–banned~~ products are nonessential items like tobacco, the goal would be to shift behavior away from consuming *any* products within the product category at all. But here, the Advertising Ban takes on food – a product category that is essential for human life. Thus, the IWG’s goal is not to suppress consumption of all foods – rather, the IWG’s goal is to engineer a shift in the diet away from foods that fail the IWG nutrition standards (~~–banned~~ foods) toward foods that meet the IWG standards.

As the IWG recognized, noting that ~~–a~~ large percentage of food products currently in the marketplace would not meet” the standards,<sup>211</sup> this would be a radical shift in the American diet. Indeed, as noted in Section II.B of this Comment (immediately above), *88 of the 100 most commonly consumed foods in the American diet fail the IWG’s nutrition standards, and only 12 meet them.*<sup>212</sup> Attempting to engineer a shift away from 88% of the diet is, by any standard, a radical move.

It would also be an incredibly costly move. As discussed at length in Section II.B above, and as shown on Attachment 2 to this Comment, foods that meet the standards are nearly all ~~–raw~~ foods like fresh fruits and vegetables, whereas foods that fail the IWG standards are typically non-raw ~~–processed~~ foods. All commonly consumed grain-based and meat-based foods within the ~~–top 100~~ fail the IWG standards. Not only are fresh fruits and vegetables and other ~~–raw~~ foods typically more expensive than ~~–processed~~ foods (even if one does not take into account the added cost caused by the frequency with which fresh produce is discarded due to spoilage), they also take substantially more time to prepare (cleaning, peeling, chopping, cooking, etc.). And fresh fruits and vegetables – in contrast to meats and grains (which are almost always sourced from American agriculture) – are much more commonly imported from foreign agricultural sources.

To be sure, there is nothing wrong with fruits and vegetables. General Mills sells an awful lot of both. In fact, we are one of the very largest sellers of vegetables in the U.S. But if the IWG were actually successful in moving the American diet to a diet composed primarily of raw produce and the few other foods that meet its impossibly strict nutrient standards, the economic consequences – for American consumers and American farmers – would be devastating. The cost of feeding the American population would skyrocket, and American agricultural producers would suffer devastating losses at the hands of foreign imports.

We will get into the numbers below. But even at the outset, it is worth preemptively rebutting the likely retort that the IWG does not really expect to fully achieve its desired dietary shift. That is undoubtedly correct – in part due to the numbers we are about to discuss below, which show how

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<sup>211</sup> Proposal at 5.

<sup>212</sup> See *supra* Section II.B.1.

unaffordable even a partial shift in the diet toward IWG-approved foods would be for most Americans – but that is no defense. First of all, as the numbers below will show, if the IWG were successful in engineering even a more modest 20% shift in the American diet, the economic damage would be catastrophic. And even more fundamentally, if the best argument in favor of a governmental policy is that the catastrophic results of its successful implementation will never occur – because the policy will never be successfully implemented – that is hardly a legitimate justification for the policy.

1. ***If the IWG were successful in engineering its desired dietary shift away from “banned” foods toward foods that meet the IWG’s standards, the cost borne by American families for their food, and the cost to the American economy as a whole, would increase by a staggering amount.***

As noted in Section II.B, above, there is an elitist notion at work here that we should all be avoiding “processed” foods (like cereal) in favor of items like fresh mangos and steel-cut Irish oats. In Section II.B, we have already debunked the myth that these foods are nutritionally superior to processed foods like cereal. They are not. But even beyond this, the fact remains that *American families cannot afford to eat the way IWG would like them to eat.*

Based on a recent study comparing the cost of 2,000 calories under the current American diet with the cost of a 2,000 calorie daily diet composed of the most prevalently-consumed IWG-approved foods (the “IWG Diet”), a shift by an average American to the IWG Diet would conservatively increase that individual’s average annual food spending by **\$1,632**.<sup>213</sup> This is a 60.3% increase over the cost borne by the average American under the current diet.<sup>214</sup>

If the entire U.S. population were to fully adopt the IWG Diet, the increased cost of feeding the population would rise by **\$503 billion** per year.<sup>215</sup> And this is an extremely conservative number, because this is based on *current* pricing of IWG-approved foods – not the pricing that would ensue after a massive increase in demand for IWG-approved foods.

Moreover, this would not even represent the full economic cost to consumers of a shift to the IWG Diet because, as noted above, such a shift would also necessarily result in substantial increases in food preparation time inherent in the shift toward raw, unprocessed foods. Using a modest assumption that food preparation time would increase by a mere 20 minutes per day for American adults, this translates to a loss of 28.4 billion hours per year, which at prevailing wage rates reported by the U.S. Department of Labor would equate to **\$643 billion** in economic loss each year.<sup>216</sup>

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<sup>213</sup> Georgetown Economic Services, *An Analysis of the Economic Impact of the Dietary Specifications of the Interagency Working Group on Food Marketed to Children* at 3, available at <http://www.uschamber.com/sites/default/files/issues/environment/files/GES%20IWG%20Powerpoint%20July%202011.pdf> (also attached hereto as Attachment 3) (hereinafter —“GES Report”). See the GES Report for details on methodology for all analyses mentioned in this Section III.A.

<sup>214</sup> *Id.*

<sup>215</sup> *Id.*

<sup>216</sup> *Id.* at 8.

Conservatively, this brings the estimated cost of a full shift to the IWG Diet to **\$1.15 trillion** per year.<sup>217</sup> Obviously, this is utterly unaffordable. And as noted above, there is no doubt that the IWG would not expect to be able to achieve a 100% dietary shift like this. But even if it were 20% successful in achieving this dietary shift, the costs would be enormous. A 20% adoption rate for the IWG Diet would cost American consumers, in the aggregate, \$229 billion each year.<sup>218</sup>



2. ***If the IWG were successful in engineering its desired dietary shift away from “banned” foods toward foods that meet the IWG’s standards, the economic damage done to American agriculture (at the expense of foreign agriculture and a massive trade deficit) would be devastating.***

Beyond being utterly unaffordable for American consumers, a full shift to the IWG Diet would have a devastating impact on American agriculture, due to the increased prevalence of fruits and vegetables in the IWG Diet and the relatively small role of grain-based foods. A review of USDA data on U.S. production, consumption, and imports of agricultural products establishes that 99% of grain consumed in the U.S. is sourced from American agriculture, whereas fruit and vegetable demand is met less commonly by U.S. sources – to the point where incremental fruit and vegetable needs would have to be met through importation.<sup>219</sup>

Playing out this analysis – looking at the relative prevalence of fruits, vegetables, grains, etc. in the current diet according to U.S. Department of Commerce data and comparing this with the relative prevalence of these items in the IWG Diet<sup>220</sup> – a recent study concluded that a full shift to IWG Diet would have the following impacts:

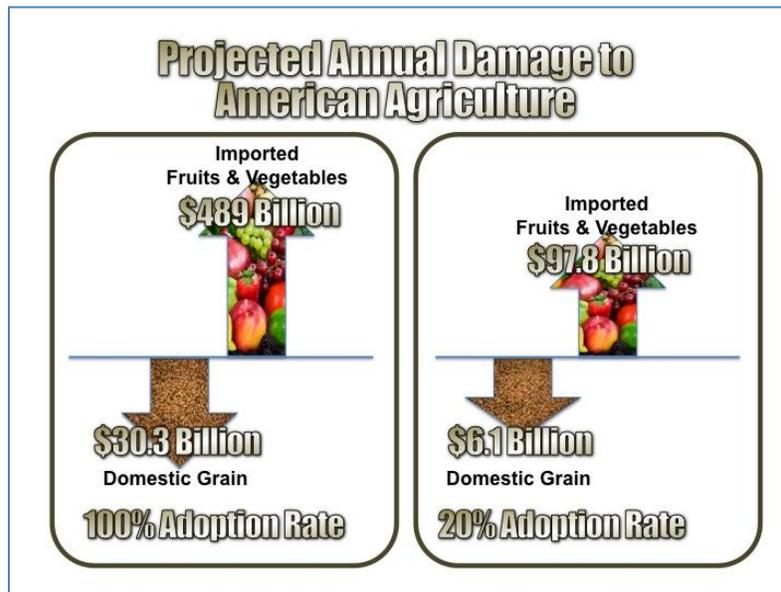
<sup>217</sup> *Id.* at 3

<sup>218</sup> *Id.*

<sup>219</sup> *Id.* at 15-18.

<sup>220</sup> See *id.* for a detailed summary of methodology. As a brief summary, we would note that this analysis was done using the NPD data on the prevalence of “eatings” of foods in the American diet (referred to in Section II.B, *supra*). It was assumed that, if consumers shifted their diets to the IWG Diet, the relative frequency of consumption of IWG-compliant foods *as compared with each other* would remain the same as in the current diet. In other words, if raw apples were eaten twice as frequently in the current diet as carrots, it was assumed that this 2:1 eating frequency ratio would carry forward to the IWG Diet. GES determined the 27

- Demand for U.S. grain for domestic food use would decline by 71.8%, which would result in a **\$30.3 billion** decline in the value of grain produced for food consumption by U.S. growers.
- Demand for fruits and vegetables would increase by 1009% and 226%, respectively, and the American economy would need to expend an additional **\$489 billion** to import fruits and vegetables.
- Even at a lesser rate of adoption of the IWG Diet, the impacts are severe and unaffordable. At a 20% adoption rate, for example, demand for U.S. grain for domestic food use would decline by \$6.1 billion annually.



There does not appear to be any evidence that the IWG engaged in any sort of economic or agricultural impact analysis in formulating its Proposal. It should have done so.

**B. The economic consequences for the food industry, the media industry, and their employees and business partners would also be severe**

In addition to the heavy economic burden that would be borne by American consumers and farmers as a result of a “successful” re-engineering of part or all of the American diet by the IWG, there would of course be serious economic damage done to the food industry and its other business partners. The FTC, in its 2008 Report to Congress on food industry marketing expenditures directed to children and adolescents (*i.e.*, marketing expenditures that the IWG would *define* as being directed to children and adolescents even though, as described in Section IV below, many of these activities are adult-directed), reported that the 44 food companies from whom it had collected data had spent \$1.6 billion during 2006 on “marketing to kids.”<sup>221</sup> That number does *not* cover any of the marketing

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most commonly consumed foods in the IWG Diet and used their relative prevalence scores to allocate percentages of the IWG Diet to types of foods and food groups.

<sup>221</sup> FTC, *Marketing Food to Children and Adolescents: A Review of Industry Expenditures, Activities, and Self-Regulation, A Report to Congress*, at 7 (July 2008).

activities by the thousands of other food businesses and restaurants that would also fall within the definition of “marketing to kids.” And quite honestly, the number does not even cover all of the “marketing to kids” activities of the 44 responding companies either, because many companies reached various informal agreements with FTC staff on not reporting expenditures for activities that were clearly adult-directed – but which fell within the overbroad definitions.

If these definitions become codified as part of the Advertising Ban, it is safe to assume that all or nearly all of this activity would be “banned” activity because, as described above, nearly all foods fail the IWG standards. Right there, we have at least \$1.6 billion in economic activity going up in smoke, and this does not even take into account the economic impact on the food companies that are unable to effectively market their products through now-banned activities, or on the food retailers who have whole aisles of their stores dedicated to products that the government now inappropriately classifies as “foods of little or no nutritional value” and for which effective marketing would be banned.

Consider first the media partners of the food industry. In calendar year 2010, food advertising accounted for around 21% of all advertising on children’s television<sup>222</sup> – \$345 million worth of advertising. Nearly all (if not all) of this would vanish due to the Advertising Ban. This would not be an easy loss to absorb for media outlets. And this is only television. The economic blow becomes even larger when one considers all the other restrictions – on the 19 other categories of marketing activities covered by the IWG’s definitions of “marketing to kids.” As noted above, the number becomes at least \$1.6 billion, even without considering the numerous smaller industry participants who were not part of the FTC’s analysis.

Consider, too, the people who design, create, and produce these advertising elements and other marketing initiatives, including advertising agencies, interactive marketing agencies, animators, website designers, package designers, promotion marketing firms, etc. – \$1.6 billion in economic activity cannot disappear without an impact on people’s jobs and livelihoods. (And this does not even count the impact on the people who create the entertainment and informational programming that is supported by this advertising activity.) There will be severe impacts and ripple effects here. And to what end? Making sure that cereal, yogurt, water, salads, etc. are kept secret from American youth, even those old enough to drive?

In a piece published on an FTC website on July 1, the Director of the FTC’s Bureau of Consumer Protection appeared to implicitly concede that there is no reliable evidence establishing that advertising causes obesity, but then commented that “[i]t doesn’t really matter whether you’re convinced that food marketing has played a role in obesity” before going on to suggest that we should all be able to rally behind this Proposal regardless of that lack of scientific evidence of adverse effects.<sup>223</sup> Such an approach flies in the face of the guidance provided by President Obama’s recent executive order on “improving regulation.”<sup>224</sup> That executive order provides, among other things, that “[o]ur regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.”<sup>225</sup> It also provides that regulatory activity must

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<sup>222</sup> Kantar Media data (calendar year 2010).

<sup>223</sup> David Vladeck, Director, Bureau of Consumer Protection, *What’s On the Table* (July 1, 2011), at <http://business.ftc.gov/blog/2011/07/whats-table> (hereinafter —“Vladeck Remarks”).

<sup>224</sup> Exec. Order No. 13,563, 76 Fed. Reg. 3,821 (Jan. 28, 2011).

<sup>225</sup> *Id.*

be based ~~on~~ the best available science.”<sup>226</sup> An assertion that the lack of sound scientific justification ~~doesn’t really matter,~~ and that it’s okay to proceed without it to harm ~~economic growth, innovation, competitiveness, and job creation~~ through regulation, is completely at odds with President Obama’s executive order.

As noted earlier, a review of ~~the best available science~~” would not only have established that food advertising in general has not caused the recent spike in obesity – but that encouraging *increased* consumption of foods like cereal (including sweetened cereals) would be a far more sound public health policy than what is being proposed. If that had been done, the IWG’s proposed Advertising Ban would not have moved forward at all. But even if it had, it would be irresponsible to not consider the grave economic impacts of the Advertising Ban, and there is no evidence that the IWG has considered this.

**C. Ultimately, even beyond economic consequences, the Proposal would be harmful to the health and lifestyle of American families**

As noted elsewhere in this Comment, advertising fuels product sales, which in turn fuels investment and innovation. General Mills has long been a true leader in product innovation designed to advance public health, including the following:

- Led the cereal industry (since as early as the 1930s through the 1970s) to begin to fortify cereals with key nutrients lacking in the diet, including iron and B-vitamins.
- Launched the first fortified flour in 1940, enriched with Vitamin B, calcium, and iron.
- Led the effort to fortify milk with vitamin D in the mid-20th century (which virtually eliminated the bone-weakening disorder rickets).
- Led the industry with the addition of folic acid to cereals in the 1980s (which, along with broader fortification in other foods in the 1990s, has demonstrably reduced the incidence of neural tube defects in the U.S.).
- Led the fortification of cereals with calcium in the 1990s.
- Dramatically improved America’s intake of whole grains in the 2000s through ensuring that all of our cereals contain at least 8 grams of whole grain per serving and often more. Today our cereals account for 10 percent of all whole grains consumed in the U.S.
- Fortified our entire line of yogurts with vitamin D. Approximately 95% of Americans (and nearly 90% of children) have diets that fail to meet recommended intakes for vitamin D, but children who eat yogurt have higher intakes of vitamin D than those who do not.

These are just a few of our significant achievements through product innovation. Other food companies would have their own lists as well. The impact on the health of American families has been significant. But none of this innovation could have happened without costly investment by food companies, and none of that could have happened absent the industry’s ability to advertise the products borne of its investment. An advertising ban, especially for healthful products like cereal, yogurt, and the numerous other products being inappropriately ~~banned~~ here, will crush innovation and harm the health of American families.

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<sup>226</sup> *Id.*

Moreover, just as the IWG appears to have wholly failed to consider the alternatives that people may eat in lieu of cereal (when it decided to propose an Advertising Ban on essentially all cereals),<sup>227</sup> the IWG has similarly failed to consider what sorts of advertising will fill the void left when food advertising vanishes from children-oriented and family-oriented media. Most likely, a sizeable portion of what will fill the void will be advertisements for video games, movies, DVDs, toys, and other television shows – since these are some of the largest non-food advertisers to kids. If the IWG believes, as it suggests it does, that advertising contributes to obesity, then surely an increase in advertising for sedentary activities would seem to be a problem, especially given the compelling data (discussed in Section I.A.1, above) that it is the decrease in caloric expenditure that is at the root of the recent upward spike in child obesity.

Finally, the IWG does not appear to have considered the impact of its proposed Advertising Ban on the basic quality of life for American families. Very few American parents would wish to do without quality entertainment programming for their children. But when one takes away 21% of the advertising revenue that supports this programming, it is unreasonable to assume that advertising-supported children's and all-family programming can continue to survive as if nothing happened. The entire business model is under threat. Ultimately, this may either lead to lower-quality "adertainment" programming designed around video games and the like, or it may lead to programming for which parents must pay (either through subscription "premium channel" payments or through costs passed along by cable and satellite operators for non-advertising-supported channels). Either way, parents and families lose. And, indeed, lower-income parents and families may simply be unable to afford quality entertainment programming for their children.

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<sup>227</sup> See *supra* Section I.B.1.d.

**IV. The Proposal’s definition of what constitutes “Marketing to Kids” is extraordinarily overbroad – banning communications that are primarily aimed at (or that primarily reach) adults and banning the use of iconic trademark and trade-dress elements.**

Even if the Advertising Ban were otherwise appropriate – which it is not for all of the reasons outlined in this Comment – the Advertising Ban is still fundamentally flawed because its definitions of “marketing to children/adolescents” (“Marketing Definitions” or “Definitions”) are incredibly overbroad, as well as impossibly vague and unworkable. The IWG was specifically charged with developing “a set of principles to guide industry efforts to improve the nutritional profile of food marketed directly to children ages 2-17.”<sup>228</sup> But as shown in this Section, the IWG has reached far beyond its mandate to unduly restrict marketing messages that are clearly intended for (or that primarily reach) adults.

**A. As an initial matter, the Marketing Definitions have not been “vetted” by industry as asserted by the IWG.**

The IWG’s Proposal incorporates by reference the categories and definitions of marketing activities set out by the FTC in conjunction with its 2008 “Marketing Food to Children and Adolescents: A Review of Industry Expenditures, Activities, and Self-Regulation” report.<sup>229</sup> These definitions are intended to form the basis of the Advertising Ban. The IWG explains that it chose to rely on this framework because this framework had already been “vetted” by industry:

The Working Group proposes to use the existing FTC template for defining marketing to children and adolescents because it has already been vetted through public comment in connection with the 2006 study. The participating companies in the FTC study represented a significant majority of the food, beverage, and restaurant companies engaged in marketing to children. Those companies were required to apply the FTC’s definitions in compiling and submitting marketing data for the study. The Working Group therefore believes that the proposed definitions have already been tested and appear to provide a workable framework for defining marketing to children and adolescents.<sup>230</sup>

It is easy to understand why the IWG found it convenient to simply adopt an existing template. But in so doing, the IWG completely ignores the fact that this “template” was designed for, and applied by industry in, a completely different context. It has absolutely *not* been “vetted” for present purposes.

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<sup>228</sup> FTC, *Statement of the Commission Concerning the Interagency Working Group on Food Marketed to Children Preliminary Proposed Nutrition Principles to Guide Industry Self-Regulatory Efforts*, at 1 (April 28, 2011), at <http://www.ftc.gov/os/2011/04/110428foodmarketstmt.pdf> (emphasis added).

<sup>229</sup> While IWG explicitly cites to these 2008 definitions in its Proposal, this citation is presumably an error, since the FTC subsequently refined its 2008 definitions in its 2010 “Order to File Special Report” (the responses to which will serve as the basis for the FTC’s forthcoming updated report on marketing food to children and adolescents). See “Order to File Special Report,” FTC Matter No. P064504 (August 12, 2010), at [http://www.ftc.gov/os/6b\\_orders/foodmktg6b/P094511/P094511order.pdf](http://www.ftc.gov/os/6b_orders/foodmktg6b/P094511/P094511order.pdf). We are also making this assumption because of IWG’s assertion that these definitions have been supposedly “vetted.” Accordingly, in this Comment, we are citing to the FTC’s refined definitions included in its “Order to File Special Report” (hereinafter “Marketing Definitions”).

<sup>230</sup> Proposal at 17.

The Marketing Definitions were crafted to accompany subpoenas for information about past child-marketing expenditures. And as with any subpoena, the scope of these subpoenas' requests was heavily negotiated with FTC staff on a company-by-company basis. Industry may have been ~~required~~ to apply the FTC's definitions," but industry's application of these definitions was not based on their plain language alone. That would have been impossible (given the myriad complexities inherent in them<sup>231</sup>). Rather, companies applied the definitions following negotiations with FTC staff and in line with FTC guidance not found in the Definitions themselves. Indeed, FTC found it necessary to issue several rounds of guidance, and some of that guidance required companies to seek approval ~~on~~ a case by case basis" for specific methodologies used.<sup>232</sup> Outside of this subpoena context – *in a context where negotiation is not possible and 100% compliance is expected* – the Marketing Definitions are impossibly vague and unworkable.<sup>233</sup>

## **B. The Marketing Definitions unduly restrict adult-directed communications.**

The biggest flaw with the Marketing Definitions, however, is not the fact that they are unworkable. The Marketing Definitions – *no matter how they are applied* – are tremendously overbroad and would affect the marketing of almost all food products, because they go far beyond restrictions on child- and adolescent-directed communications. Even if advertising to kids were a contributing factor to childhood obesity (which it is not – *see* Section I above), the Definitions are a sledge hammer that would smash much more than their intended target, seriously impairing food

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<sup>231</sup> The Marketing Definitions are subject to a near infinite number of interpretations. They cannot be applied in a black-and-white fashion (thus, the need to negotiate with FTC staff to ensure compliance on a company-by-company basis). Many of the Definitions rely entirely on subjective analyses of creative executions. How to judge, for example, whether a given marketing activity promotes "—adolescent-oriented themes"? *See, e.g.*, Marketing Definitions at C3. Moreover, even many of the Definitions that rely on "—objective" definitions are subject to variety of different interpretations, because they do not take into account the complexities of calculating the supposedly objective measures. Take the Definitions for television advertising that rely on audience composition. *See, e.g., id.* at B2, C2. Contrary to what the Definitions suggest, it is impossible to accurately predict viewership in advance. This is because calculating viewership has many variables. Audience composition varies on when and where a program airs (i.e., daypart and regional (market) differences). Also, media buys are much more complicated than simply purchasing ad time on the national broadcast of first-run programming. Most media is actually purchased on a local "—spot" basis in numerous markets – the audience for each "—spot" varying on a daypart and market basis. For example, under the Definitions, how should advertisers treat an ad that runs during a 1:00 a.m. showing of "—SpongeBob Squarepants" in Cleveland? And what about an ad scheduled to run on ABC's "—Family Night Movie," when audience composition depends on the actual movie playing? Doing an audience composition analysis for each television program in each local market for each particular time slot would not only be extremely burdensome, it would lead to wildly inconsistent approaches among advertisers. Indeed, for this and most of the other Definitions, assumptions are required and methodologies can and will differ.

<sup>232</sup> *See, e.g.*, Attachment 4 ("—Frequently Asked Questions" – Amended Guidance to 6(b) Order Recipients") at 6.

<sup>233</sup> To state the obvious, the language of the Marketing Definitions was drafted to capture past expenditure data related to kid marketing, not with a view of defining future restrictions on marketing activities. *See generally* Marketing Definitions. On their face, then, the Marketing Definitions do not make sense. They would have to be completely reworked in order to have any application here, and companies would be likely to rework the definitions in different ways.

manufacturers' ability to market many products to any age group, including adults. Not only would this have a hugely detrimental economic impact on food companies and the businesses that support them (including advertising agencies and media companies), but it would also violate the First Amendment (*see* Section V below).

The IWG's Proposal incorporates all twenty of the FTC's categories of advertising, marketing, and promotional activities, essentially encompassing all possible marketing communications. And the Definitions of what constitutes "marketing to children/adolescents" in each category are consistently overbroad, though each category presents unique issues. While it is beyond the scope of this Comment to discuss the problems with every single definition in each category and for both "child" and "adolescent" communications, the following is a sampling of activities that are – incredibly – deemed "marketing to kids," such that food companies would be precluded in engaging in these activities, except with the rare product that meets the IWG's standards:

- **Sponsorship of charities where kids compose a significant portion of their beneficiaries.**

Under the Marketing Definitions, companies would be precluded from advertising in conjunction with philanthropic endeavors where 30% (children 2-11) or 20% (adolescents 12-17) or more "of the participants in, or attendees or beneficiaries of, the organization, program, or event" were under 12 or 17, respectively.<sup>234</sup> This is also true for any programs or events that simply involve child- or adolescent-oriented "themes [or] activities."<sup>235</sup> This means that companies could not sponsor programs benefitting important charities and initiatives like Special Olympics, March of Dimes, Make-A-Wish – even if their messaging was completely adult targeted. General Mills' Betty Crocker brand, for example, sponsors a program that benefits the Make-A-Wish Foundation solely in conjunction with the marketing of adult-oriented products. How does precluding this type of sponsorship possibly get at the IWG's stated goals, and how can the IWG justify the negative repercussions for non-profits that depend on corporate philanthropy to help address important child-related issues?



- **Sponsorship of a public entertainment event (like a sporting event or state fair) that may involve kid-oriented activities.**

Sponsoring events that feature child or adolescent "themes" or "activities" are also out of bounds.<sup>236</sup> This has a wide-reaching impact. Companies could not sponsor, or engage in marketing activities around, any type of "all family" event, as such events inherently involve kid activities.

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<sup>234</sup> *Id.* at B16-17; C15-16.

<sup>235</sup> *Id.*

<sup>236</sup> *Id.* at B8, C8.

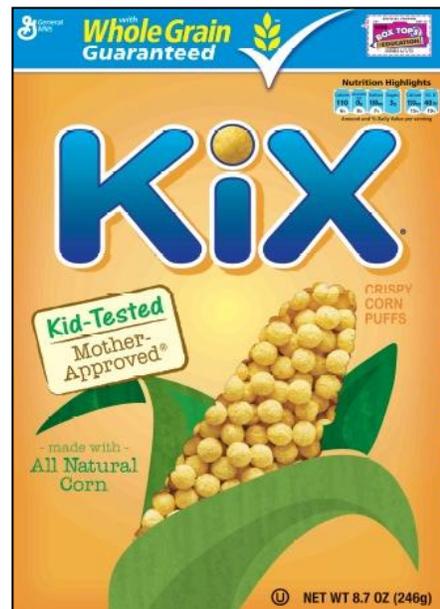
Accordingly, state fairs, many sporting activities, block parties, and other family-friendly events may all be off limits.

- **Sponsorship of the U.S. Olympic Team (or any other team involving kids under 18).**

Additionally, Companies could not sponsor the U.S. Olympic team, because it has many members under the age of 18.<sup>237</sup> This would essentially bar food companies from engaging in any Olympics-related marketing activities.

- **Use of the words “child” or “kid” on a package, even in communications to parents like “your child will love this bread.”**

The Marketing Definitions go so far as to preclude companies for using even words like “~~kid~~” on product packaging, no matter what the context. Specifically, packaging is deemed “~~marketed to kids~~” if packaging or labeling: “~~use[s] language, such as “~~kid~~,” “~~child~~,” “~~tween~~,” or similar words, or prominently depicted performers, models, or characters who were, or appeared to be, under age 12, in order to indicate that the product was intended for children.~~”<sup>238</sup> A similar definition exists for adolescents.<sup>239</sup> This means that companies would be precluded from communicating with parents – messaging to parents about birthday parties or other kid-related activities, as well as messaging about kid appeal like “~~your child will like this~~,” would be prohibited. For example, the packaging shown at right for General Mills’ Kix cereal would be barred due to its longstanding “~~Kid-Tested, Mother-Approved~~” tagline, even though this product is only marketed to adults and the use of “~~kid~~” here is clearly in the context of a parent-directed communication.



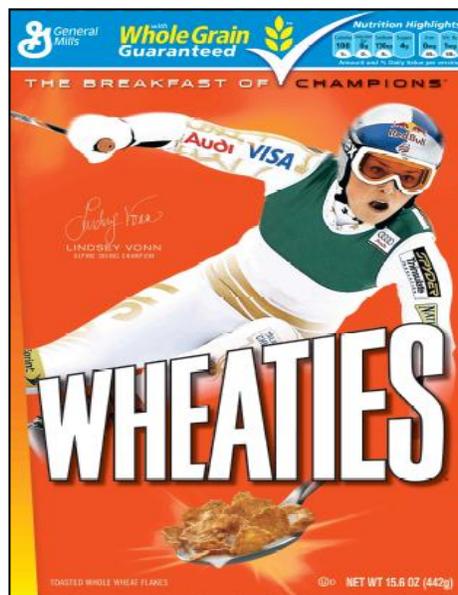
<sup>237</sup> *Id.* at B12, C11 (precluding sponsorships when members of the sponsored team include children and/or adolescents).

<sup>238</sup> *Id.* at B5-6.

<sup>239</sup> *Id.* at C5.

- **Employing a celebrity or famous athlete that is “highly popular” with kids.**

Under the Marketing Definitions, any activity that employs celebrities or athletes “highly popular” with children or adolescents is per se marketing to them.<sup>240</sup> Again, the Definitions go too far. Many celebrities and athletes appeal to *both* kids and adults. And just because a celebrity or athlete is popular with both crowds should not mean that he or she cannot be used in adult-directed marketing communications. Yet, the Definitions would essentially preclude companies from engaging with almost any major celebrity or athlete, because those celebrities or athletes with general market appeal are undoubtedly “highly popular” with all age groups.



- **Advertising on shows with an audience of 30% children ages 2-11 or 20% adolescents ages 12-17.**

When it comes to television advertisements, if children 2-11 make up as little as 30% of a program’s audience, or if adolescents 12-17 make up as little as 20%, any commercial that airs during that program will be deemed kid advertising.<sup>241</sup> To state the obvious, this means that a whopping 80% of a program’s audience may be adults, and any marketing communication directed to this adult audience – even if the message has nothing to do with children or adolescents – will be considered intended for kids. This mandate that companies have a guaranteed audience of greater than 80% adults before being able to speak to them raises significant First Amendment concerns (*see generally* Section VIII below).

In its Proposal, the IWG defends this overreaching by stating that “audience share is based on a percentage that is approximately double the proportion of that age group in the U.S. population” and that it “believes that these audience shares are likely to ensure capturing most programming or publications targeted to children or adolescents, which not also including substantial amounts of adult fare that happen to have some young people in the audience.”<sup>242</sup> But there is no inherent logic in the IWG’s position. The same show that has a 20% adolescent audience (which as the IWG says, is double the percentage of adolescents in the population) might have 30% of its audience between

<sup>240</sup> *Id.* at B13-15, C11, C13-14.

<sup>241</sup> *Id.* at B2, C2.

<sup>242</sup> Proposal at 18.

ages 30 and 35 (triple the percentage of this age group in the population). The IWG would say the show and its advertising is, by definition, targeted to adolescents. But is it not more targeted to the 30-35 age group?

There are many instances where multiple age groups are “overrepresented” in a television audience, but if one of them happens to be kids, it does not matter which overrepresented group the food advertiser is trying to reach – even if the goal is to reach adults, the IWG determines by fiat that the advertiser is advertising to kids. This arbitrary framework yields, like with the other Definitions, a restriction on advertising to adults in primarily adult-directed media. Indeed, under the Definitions, companies would be precluded from delivering adult-directed messages in, for example, NFL broadcasts, sitcoms with universal appeal like “Malcolm in the Middle,” and broadcasts of “all family” movies.

- **Advertising during a “daypart” or “programming block” containing kid shows, even if the ads run solely on shows that have a 100% adult audience.**

Further illustrating their arbitrary nature, the Marketing Definitions go even beyond individual television programs to preclude advertising products during “dayparts” or entire “programming blocks,” if a daypart of programming block contains any kid programming.<sup>243</sup> This means, for example, that a company could not advertise a product during the evening news, if the news was, say, preceded by a kid program (or an adult program that just happened to have 20% adolescents in the audience).

- **Advertising on television using kid-directed content, even on a show that is not a kid show.**

Though the Proposal chooses to emphasize only the portions of Marketing Definitions (as applied to television advertising) that define advertising to children or adolescents as advertising on programs with child audience shares of 30% or more, or adolescent audience shares of 20% or more,<sup>244</sup> the actual Marketing Definitions go much farther and restrict food companies from running advertising on *any* program if the advertising is “intended to reach children” and/or “intended to reach adolescents” among perhaps multiple targets for the advertisement.<sup>245</sup> Thus, if a food manufacturer developed an “all-family” advertisement for an “all-family” product like Honey Nut Cheerios, this could not be aired on *any* program – even programs with child or adolescent audience shares falling far below the 30% or 20% levels and with a comparatively enormous adult audience.<sup>246</sup>

- **Having a website or social media page, or placing content on a website or social media page, where a mere 20% of the audience consists of kids.**

If children 2-11 or adolescents 12-17 make up as little as 20% of an Internet audience, any marketing in conjunction with that audience is deemed directed to them.<sup>247</sup> Like with the Definitions

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<sup>243</sup> Marketing Definitions at B2, C2.

<sup>244</sup> See Proposal at 18.

<sup>245</sup> See Marketing Definitions at B2, C2.

<sup>246</sup> *Id.*

<sup>247</sup> *Id.* at B5, B14 C4, C13.

concerning television audience composition, this goes too far in restricting companies' ability to connect with adult consumers, as it is nearly impossible to ensure that an Internet audience will be *over 80% adult*.

**C. Use of iconic trademarks and trade-dress elements would be banned under the Marketing Definitions.**

Perhaps the most significant aspect of the Marketing Definitions' overreach, however, is in the realm of animated characters. Under the Marketing Definitions, the presence of an animated character on product packaging is definitive proof that the product is being ~~marketing~~ "to kids." The Definitions state that packaging or labeling is deemed per se directed at children or adolescents if it ~~prominently~~ features child- [or adolescent-] oriented animated or licensed characters."<sup>248</sup> Accordingly, on its face, the Advertising Ban would extend beyond licensed third-party equity characters to include companies' *own* characters, as well as ~~characters~~ "like Santa Claus and the Easter Bunny. And as with the other examples cited above, this would apply regardless of whether the product is intended to be marketed to kids, to gatekeepers as a treat for their kids, or even to adults themselves.

The impact of this prohibition would be significant. Seasonal merchandising – Christmas (Santa Claus), Easter (Easter Bunny), Halloween (Ghouls), etc. – would essentially be precluded in its entirety. But most importantly, Companies would have to abandon longstanding animated brand icons like the Pillsbury Doughboy, even when used on adult-targeted products:



At the end of the day, the IWG's Proposal would strip companies of significant intellectual property assets. The economic impact of this ~~taking~~" would be extraordinary – and it cannot be justified, especially since it is not even limited to child- and adolescent-targeted products and thus has absolutely no connection to the IWG's stated goals.

These examples of problematic components of the Marketing Definitions are not meant to be exhaustive. But they well illustrate some of the major issues with the IWG's Proposal as a whole. By extending its reach far beyond kid-directed advertising to include adult-directed messages, not only does the IWG's Proposal run afoul of the First Amendment (*see generally* Section VIII below), it proceeds on the untenable premise that the government – not parents – are in the best position to decide what foods should be purchased for, and consumed by, American families (*see generally* Section VI below).

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<sup>248</sup> *Id.* at B5, C5.

## V. The Proposal unconstitutionally restrains commercial speech in violation of the First Amendment.

Commercial speech has received robust constitutional protection in recent decades, with the Supreme Court consistently recognizing the serious threat to important First Amendment values posed by the suppression of advertising for lawful products and services. In the last fifteen years, the Supreme Court has invalidated *all* governmental suppression of commercial advertising to have come before it, always on the grounds that those regulations violate the First Amendment right of free expression.<sup>249</sup> Indeed, as recently as a few weeks ago in *Sorrell v. IMS Health*, the Supreme Court reminded us that “The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.”<sup>250</sup> As this Section will demonstrate, the IWG’s Proposal violates the First Amendment.

(For a more expansive discussion of how the IWG’s Proposal violates the First Amendment, see Prof. Martin H. Redish’s white paper entitled “Childhood Obesity, Advertising and the First Amendment,” attached hereto as Attachment 5 and incorporated herein by reference. The following is largely an excerpted summary of Professor Redish’s points (used with permission), supplemented with a few additional comments and updates.)

### A. To begin with, the supposed “voluntariness” of the IWG’s Proposal does not make it immune from First Amendment challenge.

By framing its Proposal as merely “voluntary,” the IWG effectively seeks to gain the benefit of its suppression of lawful expression while simultaneously insulating that suppression from judicial review. But government cannot be permitted to establish a regulatory framework, *the sole intent and effect of which will be to suppress speech*, while such framework remains immune from judicial review. To the contrary, this Proposal will be ripe for judicial review as soon as it is finally recommended (if it ever is). As discussed in Section VI below, the IWG’s Proposal is *not* voluntary for at least the following reasons:

- (1) It is not possible for industry to simply ignore the will of its principal regulators, especially as codified publicly in a detailed set of rules developed over a period of years by these agencies. It is all but inconceivable that the agencies will simply “walk away” from this 5-year effort if industry chooses to not comply.
- (2) Indeed, the FTC commented at the December 2009 IWG workshop that mandatory regulation would likely need to follow if the industry did not comply and later suggested at an Institute of Medicine workshop that FTC could bring enforcement actions against noncompliant companies. (Admittedly, FTC now appears to have backed away from these statements, but this appears to simply be a defensive move to avoid judicial review.)

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<sup>249</sup> See, e.g., *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001); *Greater New Orleans Broad. Ass’n v. United States*, 527 U.S. 173 (1999); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996); *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995).

<sup>250</sup> *Sorrell v. IMS Health, Inc.*, No. 10-779, slip op. at 22 (2011) (quoting *44 Liquormart* at 503).

- (3) The White House report on obesity (issued last year) similarly explicitly stated that FCC regulations should be changed to limit advertising in the event industry does not comply.
- (4) Moreover, even if not ~~enforced~~ directly in this way by the government, these rules will be enforced in other ways: They will become the *de facto* statement of the federal government on what products are acceptable for kids to eat (or see ads about). They may become the model for school lunch regulations across the country, and may even become the model for international restrictions on advertising (in countries that do not protect commercial speech in the same way we do).
- (5) The food industry's ability to speak – even to adults about products they might want to purchase for their kids – will be chilled. How does the industry avoid the baseless class action lawsuits that will inevitably arise when it markets a product to parents to purchase for their kids, when the federal government has deemed these products to be unacceptable for kids? How does the industry avoid the baseless class action lawsuits alleging that its products have made kids obese (even if the industry does not advertise them) because the U.S. government has said so?
- (6) Moreover, these standards will be enforced through activist pressure and public relations pressure to fall in line, pressure fed by defamatory assertions that incredibly healthful foods (like cereal and yogurt) marketed by the industry are, in the words of FTC's Statement, foods of ~~little~~ or no nutritional value."

The above threats – *in and of themselves* – would render the IWG's proposal sufficiently non-voluntary and ripe for judicial review. But ripeness is even clearer here because the Proposal restricts free expression in violation of the First Amendment (as shown in the sections that follow). It is well established that regulatory threats to freedom of expression justify facial challenges due to the chilling effect on speech created by the specter of government sanction.<sup>251</sup> Judicial fears of self-censorship have led to recognition of a far more lenient approach to ripeness requirements when First Amendment rights are implicated.<sup>252</sup> Indeed, the Supreme Court has long recognized the common sense reality that government pronouncements about the legitimacy of speech inevitably have a coercive effect. For example, in *Bantam Books v. Sullivan*, the Supreme Court invalidated the government's practice of notifying publishers that certain books met the definition of obscenity.<sup>253</sup> That decision squarely rejected the government's argument that mere agency exhortations, unaccompanied by ~~formal~~ legal sanctions," did not violate the First Amendment where the targets of the governmental statements inevitably felt compelled to alter their speech activities.<sup>254</sup> *Bantam Books* is consistent with a long line of cases holding that the government cannot use its regulatory

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<sup>251</sup> See, e.g., *N.Y. Times Co. v. Sullivan*, 376 U.S. 254, 278–79 (1964) (expressing concerns about speech regulations that lead to ~~self-censorship~~"); *Wolfson v. Brammer*, 616 F.3d 1045, 1058–1059 (9th Cir. 2010) (reviewing numerous cases holding that ~~one~~ need not await ~~the~~ consummation of threatened injury before challenging a statute restricting speech, to guard against the risk that protected conduct will be deterred).

<sup>252</sup> Martin H. Redish, 15 Moore's Federal Practice ¶ 101.61[5][b] (3d ed.; rev'd 2010).

<sup>253</sup> *Bantam Books v. Sullivan*, 372 U.S. 58, 66–67 (1963).

<sup>254</sup> See also *Entertainment Software Ass'n v. Blagojevich*, 469 F.3d 641, 651–52 (7th Cir. 2006) (invalidating labeling requirements for ~~violent~~ video games because government was attempting to suppress speech by imposing the government's opinion).

authority and police power as a veiled threat to discourage speech.<sup>255</sup> There can be no doubt that the regulations here will suppress speech in the same manner – *indeed, that is their entire point.*

Moreover, preventing companies which have been subjected to supposedly voluntary regulations from bringing a constitutional challenge until explicitly mandatory regulations have actually been promulgated would cause substantial hardship to those companies. Once mandatory regulations have been promulgated, the affected companies would be placed in the precarious position of choosing between declining to exercise their First Amendment rights until they are able to obtain legal relief on the one hand, and risking incurring penalties for failure to comply with those mandatory regulations, on the other hand. The existence of such potential hardship from delayed adjudication has long been recognized as an appropriate ground on which to find a suit ripe for adjudication.<sup>256</sup> The threat to free speech rights caused by promulgation of the voluntary regulations therefore constitutes an imminent and cognizable violation of the advertiser’s First Amendment rights.

The Supreme Court recognized in *Bantam Books* that “[i]t is characteristic of the freedoms of expression in general that they are vulnerable to gravely damaging yet barely visible encroachments.”<sup>257</sup> Government cannot be permitted to establish a regulatory framework in which the constitutional rights of the subjects of its regulation are infringed as a practical matter, while that framework remains immune from judicial review. The inherently coercive nature of the regulatory process is in no way diluted by labeling the regulations “voluntary.” Under established precedents, the nominally voluntary nature of the regulations will not prevent immediate judicial review of their constitutionality.

**B. The First Amendment prohibits government from suppressing truthful advertising for lawful products in an effort to keep consumers ignorant about their economic choices.**

The First Amendment’s protection of commercial speech, no less than its protection of other categories of expression, is designed to prevent government from manipulating citizen behavior through the selective suppression of speech advocating lawful action. Such indirect manipulation of private choices is inherently inconsistent with the essential premises of our democratic society. When government acts in such a manner, it undermines the ability of citizens to make lawful choices, not by imposition of legislatively authorized restrictions on conduct or through processes of free and open debate, but rather indirectly by the manipulative and selective suppression of truthful expression.

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<sup>255</sup> See, e.g., *Rattner v. Netburn*, 930 F.2d 204, 209 (2d Cir. 1991) (finding triable issues as to whether a local official’s disapproval of advertisement constituted an “immin[ent] threat that some form of punishment or adverse regulatory action would follow” absent compliance); *White v. Lee*, 227 F.3d 1214 (9th Cir. 2000) (holding that informal government actions violate the First Amendment when likely to chill free speech and enjoining a government investigation); *Rossignol v. Voorhaar*, 316 F.3d 516, 526 (4th Cir. 2003) (finding that the need for business owners to maintain good relations with local police resulted in intimidation from police presence designed to suppress speech); *Playboy Enters., Inc. v. Meese*, 639 F. Supp. 581 (D.D.C. 1986) (enjoining Attorney General from publicly disseminating a list of publications that purportedly constituted pornography).

<sup>256</sup> *Abbott Laboratories v. Gardner*, 387 U.S. 136, 149 (1967) (holding that hardship is to be important consideration in deciding ripeness question). See also Martin H. Redish, 15 Moore’s Federal Practice ¶101.76.

<sup>257</sup> 372 U.S. at 66.

The Supreme Court has consistently recognized the relevance of this foundational precept of liberal democratic theory to the protection of commercial speech:

The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish. Some of the ideas and information are vital, some of slight worth. But the general rule is that the speaker and the audience, not the government, assess the value of the information presented.<sup>258</sup>

In his opinion for the plurality in *44 Liquormart v. Rhode Island*, Justice Stevens wrote that bans of truthful advertising of lawful products designed to protect consumers from commercial harms rarely do. “Instead,” Justice Stevens noted, “such bans often serve only to obscure an underlying governmental policy” that could be implemented without regulating speech.”<sup>259</sup> He added that “[i]n this way, these commercial speech bans not only hinder consumer choice, but also impede debate over central issues of public policy.”<sup>260</sup> Justice Stevens found such regulations unconstitutional because they:

usually rest on the offensive assumption that the public will respond ‘irrationally’ to the truth. The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good. That teaching applies equally to state attempts to deprive consumers of accurate information about their chosen products.<sup>261</sup>

This basic tenet of First Amendment jurisprudence – that we must be “especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good” – was just strongly reaffirmed and quoted by the Court in the *Sorrell v. IMS Health* case.<sup>262</sup>

The IWG’s Proposal sweeps far and wide to significantly disrupt consumers’ ability to learn about lawful economic choices. Its restrictions reach advertising aimed at minors who are fully capable of rationally making their own lawful choices,<sup>263</sup> as well as advertising seen primarily by adults.<sup>264</sup> Moreover, there is no requirement that the advertisements in question first be found false

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<sup>258</sup> *Sorrell v. IMS Health, Inc.*, No. 10-779, slip op. at 23-24 (2011) (quoting *Edenfield v. Fane*, 507 U.S. 761, 767 (1993)).

<sup>259</sup> 517 U.S. 484, 502–03 (1996) (citation omitted).

<sup>260</sup> *Id.* at 503.

<sup>261</sup> *Id.* (internal citation omitted). *See also Thompson v. Western States Medical Center*, 535 U.S. 357, 374 (2002) (“We have . . . rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information.”).

<sup>262</sup> *See generally Sorrell v. IMS Health, Inc.*, No. 10-779, slip op. at 22 (2011).

<sup>263</sup> The fact that the IWG’s Proposal purports to suppress only advertising directed at children does not affect this First Amendment analysis. Just last month, in *Brown v. Entertainment Merchants Ass’n*, the Supreme Court strongly reaffirmed its position that First Amendment rights do not diminish when children are involved. Aside from drawing isolated exceptions in the context of sexually indecent speech and commercial speech about products that are illegal for children, the Supreme Court has consistently recognized the values protected by the First Amendment are no less applicable when government seeks to control the flow of information to minors.

<sup>264</sup> *See generally* Section VII *supra*.

or misleading for the ban to be triggered. The IWG's Proposal directly contravenes the core premises of commercial speech protection recognized by the Supreme Court. It is unambiguously inconsistent with the First Amendment's protection of commercial speech.

**C. The Proposal fails to satisfy even the Supreme Court's *Central Hudson* test for the protection of commercial speech.**

In its recent decision in *Sorrell v. IMS Health, Inc.*, the Supreme Court further signaled a shift away from use of the intermediate scrutiny standard of its *Central Hudson* test when government seeks to suppress truthful advertising for a lawful product or service in an effort to protect consumers from what it deems 'wrong' choices.<sup>265</sup> The Court has now made clear that such paternalistic regulations are categorically unconstitutional. But even if a court were to rely on the *Central Hudson* test in lieu of finding the IWG's Proposal categorically invalid, there is little doubt that the Proposal would be found unconstitutional.

The Court in *Central Hudson* established a four-step process by which to determine whether commercial speech could constitutionally be regulated or suppressed.<sup>266</sup> First, where the speech promotes sale of an unlawful product or service or is found to be false or misleading, the regulation of commercial speech is to be automatically upheld. Assuming the speech in question has passed this first hurdle, the next three questions scrutinize the nature of the regulation of that speech. For the regulation of commercial expression to be upheld, it must pass *all three* of the remaining prongs; failure to satisfy *any one* of these requirements results in a finding of unconstitutionality.

Under the second prong of the test, government must establish that its regulation of commercial speech serves a "substantial" governmental interest.<sup>267</sup> Once that test has been satisfied, the court must determine "whether the regulation directly advances the governmental interest asserted...."<sup>268</sup> The regulation will be invalidated if the regulations "only indirectly advance the state interest involved."<sup>269</sup> Moreover, the regulation must *materially* advance the interest. Government has the burden of establishing, beyond mere speculation, that its regulation does so.<sup>270</sup> Even if the first three requirements have been satisfied, the regulation must still be found to be "[no] more extensive than is necessary to serve [the substantial governmental] interest." Although in the early years of the test's use one might have been able to accurately characterize the Court's protection of commercial speech as somewhat inconsistent, there is no doubt that over at least the last 15-20 years the Court has enforced the test vigorously, consistently invalidating regulations of commercial speech for their failure to satisfy the third prong, the fourth prong, or a combination of the two. The IWG's proposed restrictions of advertising for supposedly "low nutrition" foods – especially when applied to nutrient-dense foods like ready-to-eat breakfast cereals and yogurts – clearly fail both the third and fourth

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<sup>265</sup> See generally *IMS Health*, No. 10-799.

<sup>266</sup> *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 55 (1980).

<sup>267</sup> 447 U.S. at 566.

<sup>268</sup> *Id.*

<sup>269</sup> *Id.* at 564.

<sup>270</sup> *Edenfield v. Fane*, 507 U.S. 761, 770–71 (1993) ("This burden is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.").

prongs of the *Central Hudson* test, and are therefore unconstitutional. This is so, even in the event the Court were ultimately to reject reliance on a categorical invalidation of paternalistically motivated suppression of truthful commercial speech in line with the recent *Sorrell vs. IMS Health* case.

**1. *The Proposal fails materially to advance the government’s interest in reducing childhood obesity.***

The Court’s rationales for invalidating regulations of commercial speech under *Central Hudson*’s third prong generally fall into one of two categories: (1) the regulation leaves unregulated so large a portion of the problem sought to be remedied that it cannot be deemed to “materially” advance the government’s interest in preventing the asserted harm;<sup>271</sup> or (2) the government is unable adequately to support the proposition that the regulated speech gives rise to the problem sought to be remedied.<sup>272</sup> Careful scrutiny of the IWG’s Proposal demonstrates that while it is definitely designed to foster a “substantial” governmental interest (i.e., avoidance of childhood obesity), it cannot be deemed to “materially” advance that interest. This is particularly true when the Proposal is applied to advertising for ready-to-eat breakfast cereals and other nutrient-dense foods like yogurt, but ultimately the Proposal will be found to violate the First Amendment in *all* of its potential applications. The simple fact is that – as demonstrated in Section I above – there is no evidence to indicate that child-directed food advertising causes childhood obesity.

Specifically, the Proposal fails to satisfy the requirement of *Central Hudson*’s third prong for three reasons already established by this Comment: (1) Strong evidence exists to support the proposition that reductions in exercise by children bears significant responsibility for the recent increase in childhood obesity (*see generally* Section I above); thus, even the total success of the proposed ban on advertising would leave substantial portions of the childhood obesity problem unaffected. (2) Whether or not reduced exercise is the primary cause, no persuasive evidentiary basis

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<sup>271</sup> See, e.g., *Greater New Orleans Broad. Ass’n v. United States*, 527 U.S. 173, 190 (1999) (invalidating federal law prohibiting “some, but by no means all, broadcast advertising of lotteries and casino gambling” because “[t]he operation of [the challenged statute] and its attendant regulatory regime is so pierced by exemptions and inconsistencies that the Government cannot hope to exonerate it.”); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 506 (1996) (emphasis in original) (invalidating prohibition of liquor price advertising as a means of promoting the government’s interest in temperance because “the State has presented no evidence to suggest that its speech prohibition will significantly reduce marketwide consumption.”); *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995) (federal law prohibiting beer labels from displaying alcohol content held unconstitutional because under the law distilled spirits are permitted to display their alcohol content); *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410 (1993) (invalidating ban on commercial news racks on city streets in the city by an attempt to improve aesthetics, because the remaining non-commercial newspaper racks rendered “marginal indeed” the aesthetic benefits gained from the regulation); *Bad Frog Brewery, Inc. v. N.Y. State Liquor Auth.*, 134 F.3d 87, 99–100 (2d Cir. 1998) (state’s prohibition of beer label with frog extending its middle finger could not be justified as an effort to protect children from obscenities, because of continuing wide-spread availability of obscenities in society).

<sup>272</sup> See, e.g., *Edenfield v. Fane*, 507 U.S. 761 (1993) (state ban on in-person solicitation by certified public accountants held unconstitutional because accountants “are not trained in the art of persuasion” there was no danger of overbearing or misleading in-person solicitation). See also *Bad Frog Brewery, Inc.*, 134 F.3d at 100 (“The truth of these propositions [that the regulation of speech will advance the government’s substantial interest] is not so self-evident as to relieve the state of the burden of marshalling some empirical evidence to support its assumptions.”).

exists to support the recent view that advertising by the food industry aimed at children has contributed significantly to the increase in childhood obesity (*see also generally* Section I above); thus, suppression of such expression would fail to materially advance the asserted governmental interest. (3) Ready-to-eat cereals represent the largest share of food advertised to children and therefore would be the category of products most affected by the Proposal; yet the proposed regulatory restriction on the advertising of these cereals would fail miserably in advancing the interest in reducing childhood obesity, for the simple reason that cereals do not contribute to the obesity problem (*see generally* Section II above).<sup>273</sup> Indeed, overwhelming evidence establishes that children who eat ready-to-eat cereals more often are far more likely to have healthier body weights than those who eat cereal less often.<sup>274</sup> Thus, far from materially advancing a government interest, banning the advertising of cereal would work directly *against* the governmental interest in reducing obesity. In and of itself, this fact sounds the death knell for the Proposal under *Central Hudson*'s third prong.

**2. *Even assuming that the Proposal materially advances the government's substantial interest in reducing childhood obesity (which it does not), the Proposal is far more extensive than necessary to serve that interest.***

Even if one were to suspend disbelief and somehow conclude that the Advertising Ban actually would materially advance the governmental interest in reducing childhood obesity, it is nevertheless clear that it contravenes *Central Hudson*'s fourth prong, which demands that the regulation of truthful commercial speech be no more extensive than necessary to serve that interest. On a number of occasions, the Supreme Court has invalidated commercial speech regulations either because alternative non-speech means of achieving the government's goal were available or because the regulation swept too far, impinging upon protected speech that failed to give rise to the harm sought to be prevented.<sup>275</sup> Here, IWG's Proposal fails *Central Hudson*'s fourth prong on both grounds: first, means far less invasive of free expression exist to achieve the goal of reducing childhood obesity; second, the Proposal sweeps well beyond the limited goal of restricting advertising seen by children and adolescents, substantially disrupting the free speech rights of commercial advertisers to communicate with adults, and adults to receive those communications.

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<sup>273</sup> Similarly, yogurt is one of the products advertised most frequently to children, and nearly all such advertising would be banned by the proposed regulations. Yet there is no evidence whatsoever that yogurt contributes to obesity. To the contrary, yogurt is a nutrient dense food that provides important nutrients (protein, calcium, magnesium, vitamin A, and vitamin D) that children need for normal growth and development. Fewer than half of the children ages 2-12 get the calcium they need each day. However, kids who eat yogurt are twice as likely to meet the calcium intake recommendation as kids who do not eat yogurt. *See NHANES DATA [1999-2002]*.

<sup>274</sup> *See supra* Section I.B.1.

<sup>275</sup> *See, e.g., 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 507 (1996) (invalidating prohibition on price advertising of liquor because "[i]t is perfectly obvious that alternative forms of regulation that would not involve any restriction on speech would be more likely to achieve the State's goal of promoting temperance...."); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 565 (2001) (state's restrictions of outdoor advertising of tobacco violate fourth prong of *Central Hudson*); *Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 632 (1995) (quoting *Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 417 n.13 (1993)) ("[T]he existence of numerous and obvious less-burdensome alternatives to the restriction on commercial speech . . . is certainly a relevant consideration in determining whether the 'fit' between ends and means is reasonable.").

a. Numerous less-invasive means of advancing the goal of reducing childhood obesity are available.

In its recently issued report, the White House Task Force on Childhood Obesity described a wide variety of potential means to battle the problem of childhood obesity other than the restriction of advertising. These included (1) increased provision of health care services,<sup>276</sup> (2) improvement in nutritional value of school meals,<sup>277</sup> as well as of other foods offered in school and in afterschool programs,<sup>278</sup> (3) improvement in the provision of access to quality foods or eradication of ~~food~~ deserts,<sup>279</sup> (4) altering existing governmental food subsidy policies,<sup>280</sup> and (5) increasing physical activity in schools while simultaneously encouraging a general increase in childhood physical activity.<sup>281</sup> In addition, as the Supreme Court has recognized in other contexts,<sup>282</sup> the availability of educational campaigns to inform the public of the dangers of childhood obesity and the means to fight the problem renders the direct suppression of commercial speech unconstitutional.<sup>283</sup>

There has been absolutely no showing that the government has seriously attempted any, much less all, of these alternative measures prior to its effort to suppress advertising. Although it is true that, in order to satisfy *Central Hudson*'s fourth prong, the regulation of speech need not be shown to be the absolute least restrictive alternative, it does require the government to first make meaningful attempts to deal with the problem using methods that do not threaten free expression. Yet to this point, the government has failed to demonstrate that it has made sufficient efforts to implement any of these recently recommended alternatives. Thus, a reviewing court would necessarily find the Proposal unconstitutional, in accordance with the Supreme Court's explicit holding that government may not suppress commercial expression when narrower restrictions ~~would~~ serve its interest as well.<sup>284</sup>

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<sup>276</sup> White House Task Force on Childhood Obesity, *Report to the President: Solving the Problem of Childhood Obesity Within a Generation*, at 33-34 (May 2010).

<sup>277</sup> *Id.* at 37-46.

<sup>278</sup> *Id.* at 46-48.

<sup>279</sup> *Id.* at 49-50.

<sup>280</sup> *Id.* at 58-59.

<sup>281</sup> *Id.* at 65-73 (—**S**chools are a key setting to focus on, given the significant portion of time children spend there. Schools can undertake a combination of strategies and approaches to help children be more active....”).

<sup>282</sup> See, e.g., *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 571 (2001); *44 Liquormart v. Rhode Island*, 517 U.S. 484, 530 (1996).

<sup>283</sup> See also White House Report at 68 (—**M**ost physical activity for students can be provided through a comprehensive school-based physical activity program.... complemented by activities before, during, and after school, as well as in recess, other physical activity breaks, intramural and physical activity clubs, interscholastic sports, and walk and bike to school initiatives.”).

<sup>284</sup> *Central Hudson*, 447 U.S. at 565.

b. The Proposal unduly restricts the First Amendment right of commercial advertisers to communicate with adults.

Let us assume, solely for purposes of argument, that the government could satisfactorily establish that (1) restricting advertising aimed at children would materially advance the government's interest in reducing childhood obesity, and (2) the beneficial impact of these restrictions could not be achieved by alternative means less invasive of free speech rights.<sup>285</sup> Even under these dubious assumptions, the constitutionally fatal flaw in the Proposal is that, in addition to affecting communication seen by young children, it intentionally sweeps within their reach substantial amounts of commercial communication seen by adults or minors who are of sufficient age to make independent choices.

On numerous occasions – involving both commercial speech regarding products that are illegal for minors and so-called “indecent” speech – the Supreme Court has unambiguously held that regulations of expression designed to protect children may not simultaneously disrupt communication between speakers and adult listeners or viewers.<sup>286</sup> Yet the Proposal here suffers from the very same constitutional defect. While they purport to restrict only advertising aimed at children, they nevertheless extend their reach to advertising on shows where up to 80% or more of the audience is made up of adults, as described earlier.<sup>287</sup> In addition, the Proposal restricts numerous forms of advertising and marketing in a variety of other contexts, negatively impacting adults' access to the communication. For example, the definitions of the types of activities that supposedly constitute “marketing to children” (and that therefore would be constrained by the Proposal) include the use of the word “child” on a food package to indicate that the product is “intended for children.”<sup>288</sup> The fact that a product may be intended *for* children does not mean that it is being marketed *to* children. For example, many products are marketed to parents as products “your child will love.” But the Proposal would include within its prohibitions this sort of marketing to parents, even though the speech in this case is directed exclusively to adults.

Clearly, the government may not bootstrap its assumed justification for restricting communication to children into a near-pervasive restriction on communication seen by substantial numbers of adults.<sup>289</sup> Moreover, to the extent that the Proposal is grounded in a concern that children

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<sup>285</sup> As prior discussion has clearly demonstrated, however, these assumptions would be wholly inaccurate, both as to the regulations on their face and even more starkly when applied to ready-to-eat cereals. See *supra* Section I.

<sup>286</sup> See, e.g. *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 653–64 (2001) (state law designed to protect minors from tobacco advertising held unconstitutional because it interfered with communication between tobacco seller and adult purchasers); *Reno v. ACLU*, 521 U.S. 844, 875 (1997) (prohibition on indecent communications on the Internet held unconstitutional); *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 74 (1983) (prohibition of commercial mailings concerning use of prophylactics to prevent venereal disease held unconstitutional, despite possibility that minors might view the advertisements); *Butler v. Michigan*, 352 U.S. 380, 383 (1957) (government cannot constitutionally “reduce the adult population . . . to reading only what is fit for children.”); see generally Eugene Volokh, *Freedom of Speech, Shielding Children, and Transcending Balancing*, 1997 SUP. CT. REV. 141.

<sup>287</sup> See *supra* Section IV.B.

<sup>288</sup> See *id.*

<sup>289</sup> It should be noted that the government may not constitutionally justify its suppression of speech as a time-place-manner regulation, for two reasons. First, the regulation by its nature is content-based, and

who view the advertisements will lack sufficient cognitive development to comprehend the differences between an advertisements and normal programming, the fact that in many instances it prohibits commercial communication to minors up to the age of 17 clearly demonstrates the extent to which the Proposal reaches far beyond its purportedly legitimate purpose. It is therefore indisputable that even if the Proposal survives scrutiny under other aspects of commercial speech protection, it fails the fourth prong of the *Central Hudson* test.

The First Amendment protection of commercial speech clearly dictates that government must pursue options for dealing with the problem of childhood obesity that do not trample on rights guaranteed by the Constitution. Instead of pursuing constitutionally harmful and socially futile remedies, governmental agencies should focus their attention and resources on finding constitutionally permissible alternatives by which to achieve their worthy goal of ameliorating the problem of childhood obesity. The IWG has failed to do this. Suppressing the promotion of lawful products is not the answer. The Proposal is plainly unconstitutional.

## **VI. The Proposal represents an inappropriate expansion of regulatory power.**

Apart from the grave constitutional issues posed by the Proposal's advertising restrictions, the IWG Proposal also represents an enormous government intrusion into decisions affecting business practices, agriculture, marketing, health, nutrition, and childrearing that ought to be made in the first instance by American parents, consumers, and industry. At the heart of the Proposal is the dubious assumption that American parents are not able to carry out their basic responsibilities, *i.e.*, instilling good eating habits. But it is *parents*, not children or the federal government, who must ultimately decide what groceries to buy and what is served at the kitchen table for breakfast, lunch, and dinner. Most would agree there is no need for four federal agencies to intervene in this private decision-making process and dictate to parents what foods will be available to serve their children. And there is certainly no need to dictate these private decisions by reshaping the American economy in a way that would cause substantial economic harm to agriculture, food producers and distributors, and media and advertising concerns.

Moreover, there is no *legal justification* for this expansion of regulatory power. Congress's charge to the IWG was modest and straightforward; it was to "conduct a study" and "develop recommendations for standards for the marketing of food" to deliver in a report to Congress.<sup>290</sup> As David Vladeck, the Director of the FTC's Bureau of Consumer Protection recently commented, "[t]he Working Group's job is to submit a report to Congress. That's all."<sup>291</sup>

The IWG has far exceeded that mandate. Rather than conduct a study, it has instead cobbled together its Proposal by making selective use of pre-existing government standards developed in other contexts, while ignoring other government data that conflicts with its preferred conclusions – such as

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therefore disqualified as a time-place-manner regulation. Second, even if one were (incorrectly) to view the suppression purely as a time-place-manner regulation, where the asserted justification for that regulation is inapplicable to 80% of those participating in the expressive activity the regulation cannot be constitutionally justified.

<sup>290</sup> Proposal at 2 (quoting 2009 appropriations act).

<sup>291</sup> David Vladeck, Director, Bureau of Consumer Protection, *What's On the Table* (July 1, 2011), at <http://business.ftc.gov/blog/2011/07/whats-table>.

the mountain of evidence and governmental pronouncements connecting obesity to the calories-in/calories-out balance. And rather than make recommendations to Congress, the IWG has proposed its own sweeping industry standards, along with a timeline for market participants to reach interim and final benchmarks for compliance. It has thus both ignored and significantly overstepped Congress's mandate.

In the process, the IWG has made factual and scientific assertions about health, nutrition, and marketing that could never pass muster under the legal standards that govern agency decision-making – such as the Administrative Procedure Act (“APA”), the Data Quality Act, presidential Executive Orders, and economic impact review by the Office of Information and Regulatory Affairs (“OIRA”). It is undoubtedly in part to avoid these procedural requirements, and to attempt to avoid judicial review, that the IWG has decided to propose purportedly “voluntary” industry standards, rather than engage in full notice-and-comment rulemaking. As discussed above, however, the agencies’ subpoena power, potential for future enforcement actions, and other pressures are intended to coerce regulated entities to comply with these standards, even though they were proposed without congressional authorization and fail to satisfy basic standards for reasoned agency decision-making.

#### A. Congress did not authorize the IWG to promulgate the Proposal.

“[A]n agency’s power is no greater than that delegated to it by Congress.”<sup>292</sup> Accordingly, agencies may not act “in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.”<sup>293</sup> Indeed, “[i]t is central to the real meaning of the rule of law [and] not particularly controversial that a federal agency does not have the power to act unless Congress, by statute, has empowered it to do so.”<sup>294</sup> The four federal agencies that drafted and promulgated the Proposal failed to observe the rule of law by exceeding the mandate that Congress gave them when it formed the IWG.

As the Proposal itself notes, Congress created the IWG as part of an omnibus appropriations bill, tasking it with “conduct[ing] a study and develop[ing] recommendations for standards for the marketing of food when such marketing targets children who are 17 years old or younger or when such food represents a significant component of the diets of children.”<sup>295</sup> In conducting that study, the IWG was instructed to consider, among other things, the “negative contributions of nutrients, ingredients and food,” including “calories” and “portion size,” on the “diets of . . . children.”<sup>296</sup> It was further instructed to consider “evidence concerning the role of consumption of nutrients, ingredients, and foods in preventing or promoting the development of obesity among such children.”<sup>297</sup> Congress concluded by directing that the IWG “shall submit to Congress, not later than July 15, 2010, a report containing the findings and recommendations of the Working Group.”<sup>298</sup>

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<sup>292</sup> *Lyng v. Payne*, 476 U.S. 926, 937 (1986).

<sup>293</sup> 5 U.S.C. § 706(2)(C).

<sup>294</sup> *Transohio Sav. Bank v. Dir., Office of Thrift Supervision*, 967 F.2d 598, 621 (D.C. Cir. 1992) (internal quotation marks omitted); *Catholic Health Initiatives v. Sebelius*, 617 F.3d 490, 497 (D.C. Cir. 2010) (Brown, J., concurring) (“This is a cardinal principle of administrative law that an agency may act only pursuant to authority delegated to it by Congress.”).

<sup>295</sup> Proposal at 2 (quoting 2009 appropriations act).

<sup>296</sup> *Id.* (emphasis added).

<sup>297</sup> *Id.*

<sup>298</sup> *Id.*

The IWG has both ignored and exceeded this modest mandate. It has *ignored* the mandate in that it has failed to conduct a “study” of the role that various nutrients and foods play in children’s diet; instead, it has relied on misstatements and selective quotations derived from pre-existing government documents – such as the USDA’s 2010 Dietary Guidelines.<sup>299</sup> For example, the IWG recommends limiting the amount of “added sugar” in food to the maximum extent possible, whereas the Dietary Guidelines suggest only that people reduce *caloric intake* from added sugar, noting that sugar consumption in and of itself does not meaningfully contribute to weight gain.<sup>300</sup> Similarly, the IWG ignored Congress’s charge that it consider the effect of “calories” and “portion size” on children’s diets. That is a glaring omission in light of the fact that the Dietary Guidelines, on which the IWG purports to rely, confirms that calorie control (through moderate food intake and exercise) is the most important contributor to successful weight loss.<sup>301</sup> And of course, the IWG has ignored Congress’s mandate to deliver it a report by July 15, 2010 – instead opting to propose industry-wide standards of its own creation.

In this way, the IWG has also *exceeded* Congress’s mandate by using the appropriations bill as a pretext for a sweeping attempt to remake the food industry in a manner that conflicts with existing federal rules and regulations and would prove enormously expensive to the national economy. Rather than merely “conduct[] a study” and provide Congress with “recommendations for standards,” the IWG has instead set forth its *own* industry standards, replete with timetables for companies to meet interim and final benchmarks. In so doing, the IWG has effectively usurped Congress’s intended role of determining to what use (if any) the agencies’ findings and recommendations should be put.

The IWG agencies’ newly-minted federal nutrition standards also violate the National Nutrition Monitoring and Related Research Act of 1990, which provides that “[a]ny federal agency that proposes to issue any dietary guidance for the general population or identified population subgroups shall submit the text of such guidance to the Secretaries” of HHS and USDA.<sup>302</sup> The statute defines the term “dietary guidance for the general population” specifically to exclude “any rule or regulation issued by a Federal agency” – thus, the Proposal, which does not purport to be a rule, is covered by the statute.<sup>303</sup>

When an agency intends to propose “dietary guidance,” the Secretaries of HHS and USDA must “assure that the guidance either is consistent with the Dietary Guidelines for Americans’ or that the guidance is based on medical or new scientific knowledge which is determined to be valid by the Secretaries.”<sup>304</sup> Critically, if either Secretary finds that the new guidance is *not* consistent with the Dietary Guidelines, it must be published in the Federal Register and submitted for public comment.<sup>305</sup> If the Secretaries choose to approve the new guidance, despite its inconsistency with the Dietary Guidelines, they must provide “an explanation of the basis and purpose for the final

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<sup>299</sup> See *supra* Section II.A.2.a.ii.

<sup>300</sup> See *id.*

<sup>301</sup> See *id.*

<sup>302</sup> 7 U.S.C. § 5341(b)(1).

<sup>303</sup> *Id.* § 5341(b)(3).

<sup>304</sup> *Id.* § 5341(b)(2)(A).

<sup>305</sup> *Id.*

guidance which addresses significant and substantive comments as determined by the proposing agency.”<sup>306</sup>

The Proposal, for the reasons discussed above, is neither consistent with the Dietary Guidelines nor based on medical or new scientific knowledge validated by the Secretaries. Nor has the Proposal been published in the Federal Register for public comment; indeed, there is no evidence it has been submitted to the Secretaries of the required agencies. The IWG’s Proposal therefore conflicts with Congress’s judgment that agencies must openly acknowledge conflicts between new dietary principles and the Dietary Guidelines, submit such principles for public comment, and explain the basis for any deviation between newly-approved guidance and the Dietary Guidelines.

It would seem that, from the start of this process, the IWG has had an outsized view of its role, and has aggressively created new dietary policy from whole cloth. But the IWG’s aggressiveness does not come without cost. As noted above, if the IWG’s hoped-for dietary shift were fully implemented, the proposed principles would result in a staggering increase in Americans’ food bills.<sup>307</sup> And there would also be dramatic changes in agricultural production – including vastly reduced demand for American grain, and the need for an unaffordable amount of imported fruits and vegetables.<sup>308</sup> Last but not least, many foods and beverages that are staples of Americans’ diets (and that are undeniably ~~–healthy~~”) would be forbidden to kids under the Proposal – such as cereals, salads, reduced-fat yogurt, and bottled water.<sup>309</sup>

If Congress intended such radical and far-reaching changes, it would have made those changes itself, or at least made an *explicit* delegation of such authority to an agency. –Congress ... does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions – it does not, one might say, hide elephants in mouseholes.”<sup>310</sup> That principle applies here, where implementation of the Proposal would be exorbitantly costly, requiring farmers, manufacturers, communications providers, and advertisers to radically shift their business models, product lines, and existing relationships. A congressional mandate to prepare a report making marketing recommendations has been converted into *de facto* regulations that would impose billions of dollars of costs on American industry. And it is doing so without the protections of full notice-and-comment rulemaking and the assurance of judicial review. Congress did not intend that, and the member agencies of the IWG are not authorized to do it.

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<sup>306</sup> *Id.* § 5341(b)(2)(B).

<sup>307</sup> *See supra* Section III.

<sup>308</sup> *See id.*

<sup>309</sup> *See id.*

<sup>310</sup> *Whitman v. Am. Trucking Ass’ns, Inc.*, 531 U.S. 457, 468 (2001); *see Gonzales v. Oregon*, 546 U.S. 243, 267 (2006); *In re Any & All Funds or Other Assets*, 613 F.3d 1122, 1130 (D.C. Cir. 2010) (–Congress does not typically hide elephants in mouseholes.”).

**B. The Proposal ignores norms for reasoned agency decision-making under the Administrative Procedures Act.**

Even if the IWG *were* authorized by Congress to promulgate the Proposal, the analysis it contains and the conclusions it reaches fail to satisfy the standards for reasoned agency decision-making under the APA. As set forth more fully in Section II.A., *supra*, the Proposal violates numerous fundamental norms for agency action:

*First*, agencies must act consistently.<sup>311</sup> In many places, the IWG’s member agencies contradict their own prior statements and regulations. For example, the Proposal’s restrictions on “~~added~~ sugars” conflict with prior statements, including the USDA’s 2010 Dietary Guidelines, that added sugars do not contribute any more to weight gain than calories from other sources.<sup>312</sup> In addition, the Proposal contains standards for marketing food to children that deviate from the FDA’s regulations concerning what foods may be labeled as “~~healthy~~” under the Federal Food, Drug, and Cosmetic Act.<sup>313</sup> Many foods that are “~~healthy~~” under FDA regulations (such as Cheerios) could not be marketed to children under the Proposal.

*Second*, agencies must provide reasoned explanations for their actions.<sup>314</sup> The IWG often makes choices without explaining the basis for its decision. For example, after observing that the FDA permits use of the term “~~healthy~~” on any main dishes and meals that contain less than 600 milligrams of sodium, the IWG sets an ultimate goal of 300 milligrams per serving for main dishes and meals – merely on the basis that it is “~~half~~” of the federal labeling requirement.<sup>315</sup> Taking a regulatory standard and dividing it by two is not “~~reasonable~~” decision-making – particularly since any company that was relying on the FDA regulations would have to dramatically alter its ingredients, food processing, and existing marketing practices if it wants to comply with the Proposal.

*Third*, agencies must consider all important aspects of a problem.<sup>316</sup> The IWG fails to do so. Despite overwhelming evidence of the connection between calorie intake and obesity, the Proposal makes no effort to account for calorie consumption in its analysis.<sup>317</sup> Nor does the IWG consider the opposite side of the coin – the role of activity and exercise (or lack thereof) in burning calories and reducing the likelihood of child obesity. (This omission is particularly noteworthy in light of the name

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<sup>311</sup> *E.g., Indep. Petroleum Ass’n of Am. v. Babbitt*, 92 F.3d 1248, 1258 (D.C. Cir. 1996) (“~~A~~ agency must treat similar cases in a similar manner unless it can provide a legitimate reason for failing to do so.”).

<sup>312</sup> *See supra* Section II.A.2.a.ii.

<sup>313</sup> *See* 21 C.F.R. § 101.65.

<sup>314</sup> *FCC v. Fox Television Stations, Inc.*, 129 S. Ct. 1800, 1811 (2009).

<sup>315</sup> Proposal at 13.

<sup>316</sup> *See Motor Vehicle Mfrs. Ass’n of United States, Inc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 42 (1983) (“~~N~~ormally, an agency rule [is] arbitrary and capricious if the agency has . . . entirely failed to consider an important aspect of the problem. . . .”).

<sup>317</sup> Proposal at 20 (“~~T~~he proposed nutrition principles do not include limits on portion size or calories for foods marketed to children. Should the Working Group recommendations address portion size or calories directly . . . ?”).

of the First Lady's childhood obesity initiative, "Let's Move," which focuses on the effects of physical activity on weight loss.<sup>318</sup>)

*Fourth, and finally*, agencies must consider reasonable alternatives to their chosen approach.<sup>319</sup> The IWG repeatedly fails to do so. For example, it arbitrarily selected a level of saturated fat that the FDA uses in the labeling context to permit companies to label products as "low in saturated fat."<sup>320</sup> The IWG might have selected instead the FDA's saturated fat "disqualifying level" (that is, the level at which a food label would not be permitted to make a health claim), or the "reduction level," or the level at which a food manufacturer would be able to make a "reduced saturated fat" claim.<sup>321</sup> The IWG nowhere explains why it selected one saturated fat level rather than another. This failure to consider alternatives or to explain its choices is arbitrary and capricious.

### C. The Proposal also does not meet the standards for reasoned agency decision-making set forth in recent executive orders.

The Proposal also ignores the directives in President Obama's recent executive order on "improving regulation."<sup>322</sup> That executive order provides, among other things, that "[o]ur regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation."<sup>323</sup> It also provides that, "[w]here relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, each agency shall identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public."<sup>324</sup> Finally, the executive order states that regulation must be based "on the best available science" and that "each agency shall ensure the objectivity of any scientific and technological information and processes used to support the agency's regulatory actions."<sup>325</sup> The IWG's Proposal fails to meet any of these standards.

*First*, the Proposal fails to "protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation." For example, the Proposal would ban healthful foods produced by American agriculture and the food industry, thereby harming "public health" and hindering "economic growth." The Proposal would effectively ban the awareness of cereals, even though children who eat cereal are more likely to be healthy.<sup>326</sup> In

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<sup>318</sup> See generally Let's Move, <http://www.letsmove.gov> (last visited July 6, 2011).

<sup>319</sup> *Chamber of Commerce v. SEC*, 412 F.3d 133, 145 (D.C. Cir. 2005) ("[T]he [proposed] alternative was neither frivolous nor out of bounds and the Commission therefore had an obligation to consider it."); see *Laclede Gas Co. v. FERC*, 873 F.2d 1494, 1498 (D.C. Cir. 1989) ("[W]here a party raises facially reasonable alternatives . . . the agency must either consider those alternatives or give some reason . . . for declining to do so.").

<sup>320</sup> See *supra* Section II.A.2.a.iii.

<sup>321</sup> See *id.*

<sup>322</sup> Exec. Order No. 13,563, 76 Fed. Reg. 3,821 (Jan. 28, 2011).

<sup>323</sup> *Id.*

<sup>324</sup> *Id.* at 3,822.

<sup>325</sup> *Id.*

<sup>326</sup> Albertson AM et al., *Cereal Consumption: Its relationship with BMI and nutrient intake of children aged 4 to 12 years*, J. AM. DIET. ASSOC. 2003;103:1613-1619; Barton BA et al., *The Relationship of Breakfast*

addition, the Proposal would effectively ban awareness of yogurt, a critical source of calcium and Vitamin D for the millions of children who rely on these products.<sup>327</sup> The Proposal would also label salads, hot cereals, canned vegetables, and even bottled water as inappropriate foods.<sup>328</sup>

Second, the Proposal is not “based on the best available science.” To the contrary, the Proposal ignores well-established nutritional science published by the federal government, and is notable for its lack of scientific support. On the most fundamental level, there is no evidence, nor does the IWG provide any, that nutrient intake, as opposed to the calories-in/calories-out balance, is responsible for the obesity crisis, and certainly there is no evidence that advertising is responsible for the recent rise in obesity. Indeed, all evidence is to the contrary.<sup>329</sup> The IWG actually admits that there is insufficient evidence that advertising contributes to poor nutrition or obesity – a concession it perhaps had to make, as it was the conclusion of the government’s own Institute of Medicine.<sup>330</sup> But this concession is damning to the IWG’s entire project of attempting to regulate industry’s marketing efforts as a means for combating obesity.

Third, the Proposal does not “identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public.” Rather, the Proposal does the exact opposite, increasing the burdens on consumers shopping for food by restricting information in the marketplace. Moreover, the Proposal, if fully implemented, would prevent companies from sponsoring charities where children comprise a significant portion of their beneficiaries (like the March of Dimes), or even the U.S. Olympic team (where athletes are often under 18 years of age).<sup>331</sup> The Proposal would even preclude companies from advertising their products on shows where up to 80% of the viewing audience is adult.<sup>332</sup> The Proposal would likewise increase burdens on industry, which would have to attempt to comply with government standards that conflict with the Proposal, such as FDA labeling regulations.<sup>333</sup>

Fourth, and finally, by promulgating the Proposal as “voluntary” guidelines without full notice-and-comment rulemaking, it appears that the IWG may be attempting to sidestep economic impact review by OIRA. That is inappropriate. In a recent memorandum issued to the heads of executive agencies, the Director of the Office of Management and Budget made clear that the OIRA review process has historically extended to, and should continue to include, review of “significant policy and guidance documents.”<sup>334</sup> That memorandum clarified the scope of executive orders from President

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*and Cereal Consumption to Nutrient Intake and Body Mass Index: The National Heart, Lung and Blood Institute Growth and Health Study, J AM DIET ASSOC 2005;105:1383-1389.*

<sup>327</sup> See *supra* Section I.B.2.

<sup>328</sup> See *supra* Section II.B.

<sup>329</sup> See *supra* Section I.A.1.

<sup>330</sup> See *supra* note 10 and accompanying text.

<sup>331</sup> See *supra* Section IV.B.

<sup>332</sup> See *id.*

<sup>333</sup> See *generally* Section II.A.2.

<sup>334</sup> See Peter R. Orszag, Memorandum for the Heads and Acting Heads of Executive Departments and Agencies, *Guidance for Regulatory Review* (Mar. 4, 2009).

Clinton and President Obama stating that significant agency actions are subject to OIRA review.<sup>335</sup> President Obama's new Executive Order specifically reaffirms this commitment.<sup>336</sup> That review requires agencies to provide OIRA with ~~a~~ reasonably detailed description of the need for the regulatory action and an explanation of how the regulatory action will meet that need," ~~[a]~~n assessment of the potential costs and benefits of the regulatory action," and ~~an~~ explanation of the manner in which the regulatory action is consistent with a statutory mandate."<sup>337</sup> OIRA can then review the proposed filing to determine whether it is consistent with applicable law and the cost-saving principles set forth in the executive orders.<sup>338</sup> A proposal with the scope, ambitions, and magnitude of the IWG's proposed standards should be submitted for OIRA review, pursuant to the OMB's 2009 memorandum. And for the reasons stated above, the IWG's Proposal could never survive such an economic impact review.

#### **D. The Proposal does not comply with the Data Quality Act.**

For the same reasons, the Proposal's factual and scientific assertions also fail to satisfy the standards set forth by Congress in the Data Quality Act (~~D~~QA"). The DQA requires federal agencies to ~~allow~~[ ] affected persons to seek and obtain correction of information maintained and disseminated by [an] agency that does not comply with the" standards established by the individual agencies to ~~ensur~~[e] and maximiz[e] the quality, objectivity, utility, and integrity of information."<sup>339</sup> The Proposal fails to comply with *any* of the IWG member agencies' information quality standards under the DQA. Accordingly, General Mills hereby requests that the IWG member agencies correct their erroneous statements, and provide the factual bases for their conclusions, pursuant to the agencies' respective DQA guidelines.

The FTC's guidelines, for instance, provide that when the agency disseminates ~~infl~~uential scientific, financial, or statistical information," it ~~shall~~ make underlying data and methods, including, where appropriate, sources and assumptions employed, available to the public to the greatest extent feasible and appropriate in order to facilitate the reproducibility of such information, either before or after its dissemination, by qualified parties."<sup>340</sup> The HHS's guidelines go even further, providing that ~~[w]~~ith regard to analysis of risks to human health, safety and the environment, maintained or disseminated by agencies, agencies shall either adopt or adapt the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996 (42 U.S.C. 300g-1(b)(3)(A) & (B))."<sup>341</sup> The FDA and CDC, in adapting the quality principles set forth in the Safe Drinking Water Act, have stated that they will use ~~the~~ best available science and supporting studies conducted in accordance with sound

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<sup>335</sup> See, e.g., Exec. Order No. 12,866—Regulatory Planning and Review, 58 Fed. Reg. 51,735, 51,738 (Sept. 30, 1993), 76 Fed. Reg. at 3,821.

<sup>336</sup> See 76 Fed. Reg. at 3,821.

<sup>337</sup> See 58 Fed. Reg. at 51,741.

<sup>338</sup> See *id.*

<sup>339</sup> See Pub. L. 106-554 (Dec. 21, 2000).

<sup>340</sup> See FTC Data Quality Act Guidelines at Part VIII, available at <http://www.ftc.gov/ogc/sec515/FTC515Guidelines.shtm>.

<sup>341</sup> See HHS Data Quality Act Guidelines at Part D.2, available at <http://aspe.hhs.gov/infoquality/Guidelines/part1.shtml#d4e>.

and objective scientific practices, including peer reviewed science and supporting studies when available.”<sup>342</sup> Finally, the Department of Agriculture provides that, “[t]o the extent possible, . . . [the Department] will identify the source of the information [contained in Department releases] so that the public can assess whether the information is objective.”<sup>343</sup>

The factual and scientific statements in the Proposal fail to meet the standards for accuracy and objectivity set forth in the IWG member agency’s data quality guidelines. For example:

- The Proposal incorrectly states that the 2010 Dietary Guidelines recommend consumption of ~~pre~~prepared foods and beverages with as little as possible added sugars or caloric sweeteners.”<sup>344</sup> To the contrary, the Dietary Guidelines merely recommend reduction of *overall caloric intake* of added sugars and fats.<sup>345</sup>
- The Proposal incorrectly states that ~~a~~added sugars can contribute to weight gain by providing excess calories or by diluting the nutrient density of the total diet.”<sup>346</sup> To the contrary, as stated in the 2010 Dietary Guidelines, ~~f~~oods containing solid fats and added sugars are no more likely to contribute to weight gain than any other source of calories in an eating pattern that is within calorie limits.”<sup>347</sup>
- After stating that the FDA permits use of the term ~~healthy~~” on any main dishes and meals that contain less than 600 milligrams of sodium, the Proposal sets an ultimate goal of consumption of 300 milligrams of sodium per serving for main dishes and meals – merely on the basis that it is ~~half~~” of the federal labeling requirement.<sup>348</sup> The reason for dividing the FDA’s 600-milligram goal by two is not disclosed, nor does it appear to be based on scientific evidence of any kind.
- The Proposal incorrectly assumes that reduced consumption of particular ingredients, such as sugar, saturated fats, and sodium, will reduce the problem of obesity. To the contrary, the unanimous, science-based verdict of all federal agencies to have considered the issue is that controlling obesity ultimately comes down to controlling calories – by balancing calories consumed and calories expended through exercise.

As the FTC has recognized, the public comment process ~~pro~~vides an opportunity for interested parties . . . to corroborate or dispute the objectivity, utility, or integrity of . . . information or data” relied on by IWG in promulgating the Proposal.<sup>349</sup> Therefore, General Mills respectfully requests that the IWG correct the factual inaccuracies in the statements listed above, and/or provide the public with

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<sup>342</sup> See FDA Data Quality Act Guidelines at Part VII.C, available at <http://aspe.hhs.gov/infoquality/guidelines/fda.shtml>; CDC Data Quality Act Guidelines at Part VII, at <http://aspe.hhs.gov/infoquality/Guidelines/cdcinfo2.shtml#vii>.

<sup>343</sup> See USDA Data Quality Act Guidelines, available at [http://www.ocio.usda.gov/qi\\_guide/](http://www.ocio.usda.gov/qi_guide/).

<sup>344</sup> Proposal at 12 (bracketed language added).

<sup>345</sup> Dietary Guidelines at x and 34.

<sup>346</sup> Proposal at 12.

<sup>347</sup> Dietary Guidelines at 28.

<sup>348</sup> Proposal at 13.

<sup>349</sup> See FTC Data Quality Act Guidelines at Part VI, available at <http://www.ftc.gov/ogc/sec515/FTC515Guidelines.shtml>.

the factual bases for its conclusions, which must reflect ~~the~~ best available science and supporting studies conducted in accordance with sound and objective scientific practices, including peer reviewed science and supporting studies when available.” Given the enormous impact that the Proposal may have on American businesses and consumers, it is imperative that the IWG’s guidelines be grounded in science that is accurate and transparent.

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This is not the federal government’s first attempt to overstep its proper bounds and attempt to regulate food advertising directed at children. In 1978, the FTC proposed a rule that would have imposed significant restrictions on food advertising during television shows targeted at children.<sup>350</sup> The goal was to reduce the amount of sugar that children consumed.

The proposal, however, sparked a firestorm of criticism. The Washington Post editorial page lambasted it as a ~~preposterous~~ intervention that would turn the agency into a great national nanny.”<sup>351</sup> The Post explained that ~~the~~ proposal, in reality, is designed to protect children from the weaknesses of their parents – and the parents from the wailing insistence of their children.”<sup>352</sup> ~~That,~~” the Post concluded, is one of the roles of a governess.” ~~It is not,~~” however, ~~a~~ proper role of government.”<sup>353</sup> Rather, ~~[a]~~ flat ban on commercials involving, as it would have to, certain judgments a government shouldn’t be encouraged to make or enforce, would make parents less responsible, not more.”<sup>354</sup>

Congress likewise saw the proposal as an unwarranted expansion of the FTC’s power, and took the exceptional step of explicitly suspending the rulemaking for the proposed restrictions. It declared such restrictions beyond the agency’s authority. See Pub. L. No. 93-637 § 11 (May 28, 1980) (codified at 15 U.S.C. § 57a(h)) (~~The~~ Commission shall not have any authority to promulgate any rule in the children’s advertising proceeding pending on the date of the enactment of the Federal Trade Commission Improvements Act of 1980 or in any substantially similar proceeding on the basis of a determination by the Commission that such advertising constitutes an unfair act or practice in or affecting commerce.”).

The IWG is following the same course that met with such disastrous results over 30 years ago, even though the federal government remains entirely unsuited to the task of dictating the foods that children may become aware of and eat. As First Lady Michelle Obama noted at a White House forum on childhood obesity in April 2010, ~~the~~ solution to this challenge has to come from the bottom up. The government can’t be in a position telling people to do – what to do in their own homes, and that generally doesn’t work.”<sup>355</sup>

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<sup>350</sup> See 43 Fed. Reg. 17,967 (Apr. 27, 1979).

<sup>351</sup> Editorial, *The FTC as National Nanny*, WASH. POST, Mar. 1, 1978, at A22.

<sup>352</sup> *Id.*

<sup>353</sup> *Id.*

<sup>354</sup> *Id.*

<sup>355</sup> Remarks by the First Lady at *“It’s Move” Town Hall Event* (Apr. 7, 2010), at <http://www.whitehouse.gov/the-press-office/remarks-first-lady-lets-move-town-hall-event>.

The Proposal is an attempt by the IWG to circumvent Congress's prohibition on food marketing regulation by claiming that the proposed standards are merely "voluntary." But in truth, the Proposal will have an unmistakable – and intended – coercive effect. Because the Proposal reflects the input of four federal agencies that wield broad discretionary and coercive power over the food industry, companies in the industry will feel obliged to adhere to the proposed standards as a practical matter, out of fear of antagonizing regulators. The FTC has already issued burdensome subpoenas to food companies on their practices and expenditures concerning advertising to children. It is reasonable to believe that the FTC will continue to use its subpoena power to track industry's compliance with the Proposal, backed by the possibility of enforcement actions.

In addition, the Proposal also will be used as a predicate for baseless lawsuits against food companies, as plaintiffs' lawyers will claim (erroneously) that it provides the appropriate standard of care under various theories of liability. The IWG itself has given legs to this potential argument by mistakenly claiming that its Proposal is consistent with existing federal regulations and defining "banned" foods as foods of "little or no nutritional value." Its failure to acknowledge the discrepancies between the Proposal and existing regulations will sow confusion, as the plaintiffs' bar seeks to place the imprimatur of the federal government on ill-founded suits against a reputable industry.

As Abraham Lincoln observed, "The legitimate object of government is to do for a community of people whatever they need to have done, but cannot do at all, or cannot so well do, for themselves, in their separate and individual capacities. In all that the people can individually do as well for themselves, government ought not to interfere."<sup>356</sup> The IWG agencies should take a page from history and decline the temptation to interfere with the private decisions of parents and families across the nation. The Proposal is inconsistent with federal prohibitions on restricting marketing to children, could never survive arbitrary and capricious review under the APA, economic impact review by OIRA, or scrutiny under the First Amendment. The IWG may not impose burdensome standards on industry based on faulty science that could cost billions of dollars for no benefit, through the mere expedient of placing a "voluntary" label on restrictions that Congress did not authorize it to adopt.

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<sup>356</sup> 1 COMPLETE WORKS OF ABRAHAM LINCOLN 180 (Nicolay and Hay, eds.) (remark from July 1, 1854).

## VII. The Proposal ignores the significant achievements of the food industry's self-regulatory efforts.

For all of the reasons described at length above – and for many others that are beyond the scope of this Comment – it is clear that the Proposal is deeply flawed as a matter of policy and as a matter of law. But it is not just a question of the Proposal being the wrong set of governmental regulations on what foods can or cannot be marketed to children and adolescents (and what it means to be marketing to children or adolescents). That would imply that there is a *right* set of such governmental regulations, and that the IWG just got it wrong. That would be a serious oversimplification of the problem here because *it overlooks the question of whether there should be any governmental intervention here at all.*

The question of whether governmental intervention is actually needed presumably would have been part of the “study” the IWG was asked to complete – but did not complete. And for all of the reasons described in Section I above, such study – if carried out objectively and on the basis of actual evidence – would have compelled the conclusion that governmental intervention into advertising activities (as opposed to steps the government *could* take to foster greater participation in physical activity) would not in any way be appropriate or warranted for the simple reason that there is no reason to believe that advertising is at the root of the recent spike in child obesity rates, and certainly no reason to believe an advertising ban will have any impact on obesity rates. Moreover, an analysis of *any* Supreme Court commercial speech precedent over the past 15 years would also compel the conclusion that this sort of governmental intervention – in addition to being unwarranted – is also not lawful.

But even assuming away these realities for the moment, a determination that there is a need for governmental intervention would also necessarily hinge on a conclusion that the food industry is not, on its own, moving enough with its own self-regulatory efforts. There is no way to reach this conclusion. Indeed, in light of the significant successes of the Children’s Food and Beverage Advertising Initiative, even the most irrational critic should concede (albeit reluctantly, no doubt) that the food industry has taken *huge* steps in altering the mix of products it advertises directly to children.

As noted earlier, manufacturers who have signed on with CFBAI (which, at most recent count, number 17) have pledged to abide by a set of core principles regarding the content and nature of child-directed advertising. The impact of the industry’s self-regulatory efforts has been to dramatically reduce the amount of food and beverage television advertising viewed by children ages 2 to 11. For instance, food advertising expenditures on children’s television (adjusted for inflation) dropped from nearly \$600 million in 2004 to just over \$200 million in 2010, a decline of nearly two-thirds. Between 2004 and 2010, total food advertisements viewed by children on children’s television programming fell by more than 50%. This same period also saw the following percentage declines in children’s television advertising in the following categories:

- cookies - 99%
- soft drinks – 96%
- frozen and refrigerated pizza -95%
- breads, pastries, waffles and pancakes – nearly 100%
- gum and mints - nearly 100%
- snack bars - nearly 100%
- snacks - 71%
- candy - 68%<sup>357</sup>

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<sup>357</sup> Georgetown Economic Services, *Preliminary Findings: Food and Beverage Advertising 2004 and 2010, Children’s Impressions and Expenditures on Children’s Programs* (April 2011), at [http://www.gmaonline.org/file-manager/Health\\_Nutrition/ges\\_report\\_on\\_childrens\\_tv\\_advertising.pdf](http://www.gmaonline.org/file-manager/Health_Nutrition/ges_report_on_childrens_tv_advertising.pdf).

During this same period, the average number of views per child of fruit and vegetable juice advertisements on children's television *increased* by 199%.<sup>358</sup>

It is awfully difficult to look at these dramatic changes over such a short time period without concluding that the industry has taken huge strides, and at an impressive pace, to meet concerns about certain foods marketed to children.

At the same time, CFBAI member companies have been working diligently for years to strengthen their commitments even further, culminating in the recently announced CFBAI Uniform Nutrition Standards. These uniform standards, which are replacing existing company-specific standards, are undeniably rigorous – imposing significant challenges on the 17 participating companies and requiring reformulation (by the end of 2013) of approximately one-third of the food products these companies currently are able to advertise to children (or else these products will no longer be able to be advertised). *In contrast to the IWG standards, however, these standards are potentially feasible, and they are consistent with established science and existing government standards.*

The standards speak for themselves, and we will not attempt to summarize every detail here. But it is worth mentioning that the new criteria, in addition to being uniform, strengthen currently applicable standards as a general matter in five ways, as described by CFBAI as follows:

First, the new criteria eliminate a product qualifying based solely on meeting a “reduced” claim (i.e.,  $\geq 25\%$  less sodium). Second, they eliminate a product qualifying solely because it is packaged in a portion controlled, 100 calorie pack. Third, they include calorie limits for all categories. Fourth, they include nutrients to limit (NTL) criteria for key items; saturated fat, *trans* fat, sodium and total sugars. Fifth, they include nutrition components to encourage (NCTE) (food groups and/or nutrients) for all product categories. Currently, not every participant has a standard for each item – calories, NTL and NCTE – so the new criteria fill those gaps.<sup>359</sup>

For a fuller description of the CFBAI Uniform Nutrition Standards, see CFBAI's website.<sup>360</sup> Note also that CFBAI has committed to continue to review the criteria periodically, such as after the issuance of 2015 Dietary Guidelines for Americans, to ensure consistency with dietary guidance and to determine the appropriateness of any further strengthening.<sup>361</sup>

Naturally, there would be opportunities for the IWG member agencies to participate in the dialog leading up to any future changes. But there is no need for the IWG to create its *own* standards – and certainly no reason to move any further to codify the standards the IWG has just proposed or to imply that these flawed standards are the “gold standard” to which industry should aspire.

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<sup>358</sup> *Id.*

<sup>359</sup> Children's Food and Beverage Advertising Initiative (CFBAI), *White Paper on CFBAI's Uniform Nutrition Criteria*, at 2 (July 2011).

<sup>360</sup> CFBAI's website is: <http://www.bbb.org/us/children-food-beverage-advertising-initiative/>

<sup>361</sup> CFBAI White Paper at 3.

## CONCLUSION

General Mills has long been a true leader in promoting public health through its cereals, yogurts, vegetables, fruits, soups, and other products. But as discussed throughout this Comment, our ability to provide the public with nutrient-dense, low-calorie foods is contingent on our ability to effectively encourage people to be interested in our foods through *advertising* and to promote continued interest in our products through *good taste*. The Proposal presents us with an untenable choice between making our healthful foods unpalatable or refraining from advertising them. Neither is a valid recipe for fostering public health.

Childhood obesity is a grave problem, but the Proposal is not a valid solution. It seeks to suppress the consumption of numerous products – including essentially *all* ready-to-eat cereals on the market today – that we should be *encouraging* children and adolescents to eat, and which the member agencies of the IWG actually *do* promote for consumption in their science-based pronouncements outside of the IWG context. Indeed, nearly no commonly consumed foods (other than a short list of foods consisting mostly of raw fruits and vegetables) meet the IWG’s impossibly strict standards – not even numerous foods that qualify as “healthy” under FDA regulations, and that the 2010 Dietary Guidelines promote for consumption. This is due, in large part, to the IWG’s decision to deviate markedly from its own member agencies’ assessments of science – and to instead formulate a series of contradictory pronouncements.

The IWG has also deviated from the norms of proper rulemaking in proposing these purportedly “voluntary” (but inherently coercive) restrictions, has swept within its scope all manner of communications that are received by (and even directed to) adults, and has ultimately arrived at a proposal that would not survive constitutional review. And this is not some benign folly – but a policy that will have serious economic impacts and, indeed, a policy that is on balance harmful to public health. As well-intentioned as the Proposal undoubtedly is, it should not be permitted to go forward.

Respectfully submitted,  
**GENERAL MILLS, INC.**

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