



# Carbohydrate Nutrient Content Claims: Proposals for FDA Action and Lessons for Regulatory Response to Emerging Consumer Trends

## Citation

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# **Carbohydrate Nutrient Content Claims: Proposals for FDA Action and Lessons for Regulatory Response to Emerging Consumer Trends**

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Class of 2006

April 2006

## **Abstract**

This paper considers the recent experience of the low-carbohydrate trend in nutrition. During the early years of this decade, thousands of new products claiming to be low in carbohydrates appeared on supermarket shelves in response to surging consumer demand. Despite the cooling of the fad, a substantial number of these products are still offered to consumers. While many of these foods make a variety of explicit and implicit claims on their labels about their carbohydrate content, the Food and Drug Administration (“FDA”) has not yet authorized definitions of nutrient content claims for carbohydrates. This paper argues that FDA must provide consumers and the food industry with a comprehensive regulatory framework for carbohydrate nutrient content claims in order to bring consistency to carbohydrate-related labeling and to ensure that claims are not false or misleading. This paper further argues that FDA should use the low-carbohydrate episode as an opportunity to evaluate how the agency and its food label regulations can most effectively respond to consumer needs in an era when changes in nutritional science are fast-paced, conventional diet wisdom is being challenged, and obesity in America has reached epidemic proportions.

# I.

## Introduction

Thirty years after the publication of his book *Diet Revolution*<sup>1</sup> and only shortly before his death,<sup>2</sup> Dr. Robert Atkins's vision of a new nutritional order became the reality of supermarket shelves and restaurant menus. *New Diet Revolution* was a bestseller,<sup>3</sup> Wall Street warmly embraced Atkins's company,<sup>4</sup> and other similar diet approaches rose to prominence.<sup>5</sup> The simple message of this new trend in nutrition: limit your intake of carbohydrates and you will permanently lose weight and increase energy levels.<sup>6</sup> Though Atkins and other proponents of low-carbohydrate diets had spread their gospel for decades,<sup>7</sup> in the 2000s the message had finally gained widespread interest in the popular imagination and increasing acceptance in the scientific community.<sup>8</sup>

The focus on low-carbohydrate eating came to prominence as the obesity crisis in America reached new heights.<sup>9</sup> And the Atkins low-carbohydrate approach has integrated this increasing public consciousness

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<sup>1</sup>See ROBERT C. ATKINS, DR. ATKINS' DIET REVOLUTION: THE HIGH CALORIE WAY TO STAY THIN FOREVER (1972).

<sup>2</sup>See Douglas Martin, *Dr. Robert C. Atkins, Author of Controversial But Best-Selling Diet Books, Is Dead at 72*, N.Y. TIMES, Apr. 18, 2003, at D9.

<sup>3</sup>See ROBERT C. ATKINS, DR. ATKINS' NEW DIET REVOLUTION (2002) [hereinafter ATKINS, NEW DIET REVOLUTION].

<sup>4</sup>In October 2003, an investor group led by private equity firms Parthenon Capital and Goldman Sachs Capital Partners paid \$231 million to take an eighty-percent equity stake in Atkins Nutritionals, Inc. See *Hunger Pangs*, DAILY DEAL, Aug. 15, 2005, 2005 WLNR 12744284. For Parthenon, in particular, the investment was a big bet on Atkins, since it represented approximately 20% of its fund's capital. See *id.*; see also Alan J. Wax, *Atkins Plan Looks Healthy To Investors*, NEWSDAY, Oct. 29, 2003, at A43.

<sup>5</sup>See, e.g., ARTHUR S. AGATSON, *THE SOUTH BEACH DIET: THE DELICIOUS, DOCTOR-DESIGNED, FOOLPROOF PLAN FOR FAST AND HEALTHY WEIGHT LOSS* (2003).

<sup>6</sup>ATKINS, NEW DIET REVOLUTION, *supra* note 3, at 4.

<sup>7</sup>Atkins's own diet system was adapted from work done on a no-carbohydrate diet by Dr. Alfred W. Pennington at Dupont during World War Two. See Martin, *supra* note 2.

<sup>8</sup>The benefits of the Atkins diet for weight control and general health are increasingly supported by scientific research. See, e.g., Mary Duenwald and Denise Grady, *Two Studies Indicate Atkins Diet May Help Heart*, N.Y. TIMES, May 22, 2003, at A20. Nevertheless, the diet's backers remain engaged in a heated debate with much of the nutritional establishment. For an interesting look at this battle, see Gary Taubes, *What If It's All Been a Big Fat Lie?*, N.Y. TIMES, July 7, 2002, § 6, at 22. This debate continues as new questions arise about the healthfulness of the low-carbohydrate diet's foil, the low-fat diet. See, e.g., Gina Kolata, *Low-Fat Diet Does Not Cut Health Risks, Study Finds*, N.Y. TIMES, Feb. 8, 2006, at A1.

<sup>9</sup>It has been hard to miss the heralding of the obesity epidemic in America with popular depictions such as documentarian

about obesity with the perpetual American fascination with fad diets and instant weight loss. Essentially Atkins tells consumers they need to give up their bagels and pasta – as beloved as they are – but in exchange they can consume virtually unlimited quantities of bacon, steak, eggs, and cheese.<sup>10</sup> Moreover, it is a nutritional approach that has, at least anecdotally, demonstrated weight loss results for many people.<sup>11</sup> It is thus not difficult to understand the popularity of low-carbohydrate eating and the consumer interest in low-carbohydrate products that emerged.

As consumers discovered low-carbohydrate eating and demanded products in accord with these new diet preferences, the food industry responded and reinforced the trend. By December 1, 2003, when Kraft Foods North America, Inc. (“Kraft”) submitted a petition to FDA under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (“FDCA”)<sup>12</sup> regarding the use of carbohydrate-related nutrient content claims, the company’s market research showed that sixty-eight percent of households were interested in limiting carbohydrates and forty-three percent were actually limiting carbohydrates at the present time.<sup>13</sup> Similarly, a survey cited by *Time* in May 2004 indicated that twenty-six million Americans were on strict low-carbohydrate diets and another seventy million were limiting carbohydrate intake without following a specific diet plan.<sup>14</sup> With this tremendous consumer interest came a bevy of low-carbohydrate products flooding the market, both from Atkins Nutritionals and other specialty low-carbohydrate food companies as well as from mainstream

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Morgan Spurlock’s 2004 film *Super Size Me*, lawsuits against McDonald’s, *see, e.g.*, *Pelman v. McDonald’s Corp.*, 237 F. Supp. 2d 512 (S.D.N.Y. 2003) (granting McDonald’s motion to dismiss), and media features such as *Time*’s June 7, 2004 cover story *Critical Condition: America’s Obesity Crisis*. The Food and Drug Administration’s (“FDA”) Obesity Working Group reported in its own March 12, 2004 report that sixty-four percent of Americans are overweight. FDA OBESITY WORKING GROUP, CALORIES COUNT: REPORT OF THE WORKING GROUP ON OBESITY (2004), <http://www.cfsan.fda.gov/~dms/owg-toc.html>.

<sup>10</sup>*See* ATKINS, *NEW DIET REVOLUTION*, *supra* note 3, at 19 (“Eating Atkins-style is a food lover’s dream come true – luxurious, healthy and varied.”).

<sup>11</sup>This is an appropriate place to disclose my personal experience with both the positive and negative aspects of low-carbohydrate dieting. I began to follow the diet outlined in *New Diet Revolution* in February 2004 and kept to it closely for nine months. With no increase in my level of physical activity over this period, I lost thirty pounds. By May 2005, I had returned to my pre-Atkins nutritional practices and by December 2005 had regained all thirty pounds.

<sup>12</sup>Federal Food, Drug, and Cosmetic Act § 403(r)(4), 21 U.S.C. § 343(r)(4) (2004).

<sup>13</sup>Petition of Kraft to FDA, Nutrient Content Claims for the Carbohydrate Content of Foods 3 (Dec. 1, 2003) (No. 2004P-0105) [hereinafter Kraft Petition].

<sup>14</sup>Daniel Kadlec, *The Low-Carb Frenzy*, *TIME*, May 3, 2004, at 46.

consumer products companies.<sup>15</sup> Between 2002 and 2004, 1,558 new low-carbohydrate products came onto store shelves, with these products estimated to generate sales of \$30 billion in 2004.<sup>16</sup>

From where did these products appear so quickly? In some cases, they were on the shelves already – food companies relabeled naturally low-carbohydrate products as such, from obvious choices like meat and cheese products to condiments like mayonnaise to pork rinds. Along the same lines, products once marketed to diabetics, such as sugar-free chocolates, were rebranded to appeal to a wider, carbohydrate-conscious audience. Moreover, a number of entrepreneurial start-ups appeared quickly on the scene offering a panoply of specifically low-carbohydrate geared “diet” products. And food companies reformulated their existing products to reduce the carbohydrate content, either by removing carbohydrates or replacing them with some combination of dietary fiber, sugar alcohols, and non-caloric sugar substitutes.<sup>17</sup> The most prominent sugar substitute featured in the new regime has been sucralose, marketed as Splenda, a product whose popularity with consumers has made low-carbohydrate eating more feasible for many dieters.<sup>18</sup> Quickly, innovative low-carbohydrate products were available across the consumer spectrum, on grocery store shelves and restaurant menus, but also at vitamin shops and liquor stores.<sup>19</sup> Food companies that offered carbohydrate-heavy products and could not rapidly innovate suffered severe consequences.<sup>20</sup>

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<sup>15</sup>See Brian Grow, *The Low-Carb Food Fight Ahead: Atkins' Growing Product Line Is Raking It In. But Company Is Coming*, BUSINESSWEEK, Dec. 22, 2003, at 48 (noting emerging competition in marketing of low-carbohydrate products from mainstream consumer products companies).

<sup>16</sup>Kadlec, *supra* note 14. According to a higher count from ProductScan Online cited by the *New York Times*, over roughly the same period 3,737 new low-carbohydrate products were introduced. See Melanie Warner, *Is the Low-Carb Boom Over?*, N.Y. TIMES, Dec. 5, 2004, § 3, at 1 [hereinafter Warner, *Is the Low-Carb Boom Over?*].

<sup>17</sup>Though categorized as carbohydrates on the Nutrition Facts panel, fiber and sugar alcohols are not typically counted for the purposes of low-carbohydrate diets. Fiber passes through the body without impacting blood-sugar levels and some sugar alcohols have a minimal impact on blood sugar. See ATKINS, NEW DIET REVOLUTION, *supra* note 3, at 243.

<sup>18</sup>Sucralose is also endorsed by Atkins; he embraces its safety versus saccharin and the fact that it actually derives from sugar. See *id.* at 128-29.

<sup>19</sup>For example, Centrum introduced a “Carb Assist” version of its popular multivitamin, adjusting the quantity of some vitamins and minerals to supplement a low-carbohydrate diet. See Kurt Jetta and Jeff Elderton, *A Megacategory with Unique Traits*, CHAIN DRUG REVIEW, Feb. 27, 2006, at 31 (reporting on the recent downward sales trend of Carb Assist vitamins in the fickle nutritional supplement business). And Anheuser-Busch launched a trend-setting low-carbohydrate beer, Michelob Ultra, containing 2.6 grams of carbohydrates. After its rollout in 2002, when Anheuser-Busch sold 400,000 barrels of Michelob Ultra, in 2003 the company sold 2.5 million barrels in a year when beer sales were otherwise flat. See Rob Walker, *The Way We Live Now: 2-1-04: Consumed; Michelob Ultra*, N.Y. TIMES, Feb. 1, 2004, § 6, at 18.

<sup>20</sup>The nation’s number-one pasta company, New World Pasta, filed for Chapter 11 bankruptcy protection in May 2004. See *Chapter 11 Filing: New World Pasta Bankrupt*, NEWSDAY, May 10, 2004, at A25. Similarly, Krispy Kreme Doughnuts Inc.

How did consumers during this period know which products on grocery store shelves were consistent with a low-carbohydrate diet? How could they identify these 1,558 new products, and ensure that each was truly low in carbohydrates? Atkins's book guides consumers to the Nutrition Facts panel on products and suggests that they can subtract out the Dietary Fiber figure from the Total Carbohydrates figure to arrive at a level of carbohydrates that impacts blood sugar.<sup>21</sup> He also reminds followers of his diet approach to check the Nutrition Facts panel for the serving size of the product when considering the amount of carbohydrates they are consuming.<sup>22</sup> But as consumer demand for low-carbohydrate products skyrocketed, entrepreneurial start-ups and mainstream consumer products companies alike were not content to leave matters to the Nutrition Facts panel; instead they engaged in various maneuvers to signal on the front of food labels the low-carbohydrate nature of their products. Some of these companies explicitly advertised products as "low carbohydrate", "reduced carbohydrate", and "carbohydrate free", claims that directly violate the requirements of section 403(r) of the FDCA.<sup>23</sup> Others, including Atkins Nutritionals, used variations on the permissible term "net carbohydrates" to indicate what grams of carbohydrates should and should not be excluded from a low-carbohydrate dieter's count.<sup>24</sup> Finally, some brands, particularly the mainstream consumer products companies wary of the legal implications of using explicit "low carbohydrate" labels, implicitly indicated their products were low in carbohydrates by choosing a shrewd name like "Carb Clever"<sup>25</sup> or seeking an affiliation with a recognized low-carbohydrate diet, such as Atkins or South Beach, whose logo

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experienced a business decline, seeing its soaring stock price lose almost 90% of its value, as it fell from \$44.20 per share on January 1, 2002 to \$5.74 per share on January 1, 2006. See KKD: Basic Chart for Krispy Kreme Doughnut, Yahoo! Finance, at <http://finance.yahoo.com/q/bc?s=KKD&t=5y> (last visited Feb. 15, 2006). It should be noted that many industry experts are skeptical that these companies' business woes stem exclusively from the low-carbohydrate trend. See, e.g., John Schwartz, *Mutual Funds Report: Essay; What? Dieters Don't Buy Doughnuts and Twinkies?*, N.Y. TIMES, Oct. 10, 2004, § 3, at 26.

<sup>21</sup> ATKINS, NEW DIET REVOLUTION, supra note 3, at 243. Atkins also notes that this figure would be "a conservative one because most labels don't give you the additional info you would need to do further subtraction, such as the amount of sugar alcohol grams contained in the product." *Id.* He promises that his company's products do include the necessary additional carbohydrate information, including the amount of sugar alcohols. *Id.* at 244-45.

<sup>22</sup> *Id.* at 244.

<sup>23</sup> Federal Food, Drug, and Cosmetic Act § 403(r), 21 U.S.C. § 343(r) (2004).

<sup>24</sup> See, e.g., *infra* Appendix A (noting that Atkins Nutritionals' Morning Start breakfast bars have two grams of "net carbs").

<sup>25</sup> See *infra* Appendix C.

they could emblazon on their products.<sup>26</sup>

With innovative products highlighting their carbohydrate content, a \$30 billion market thrived. But like all fads, the boom finally ended and a lot of the demand dried up by late 2004 and 2005. Companies suffered from a supply of low-carbohydrate products that far outstripped demand, a problem for any fad diet in its waning days, but compounded in the case of low-carbohydrate dieting by the “flash fire” of products that hit store shelves during the boom.<sup>27</sup> Atkins Nutritionals filed for bankruptcy in August 2005, after a rapid expansion via private equity funding at the height of the low-carbohydrate craze left the company with \$300 million of debt.<sup>28</sup> It looked as if Dr. Atkins’s legacy had been quashed.

Now that the fad is over, what is the relevance of this story of the low-carbohydrate boom and bust? On its face, the story sounds like any other diet fad, where demand skyrockets as consumers look for a silver bullet weight loss solution, consumer products companies rapidly respond and reinforce the demand for awhile, and then the market collapses. Are stories of pork rinds flying off supermarket shelves as diet foods in 2003 relegated to be merely historical nutrition relics like the oat bran craze of 1988, when Quaker Oats had to post apology letters in cereal aisles due to an inability to produce enough oat bran to keep pace with demand?<sup>29</sup>

Though it seems like just another food fad, the manner in which consumers, the food industry, and regulators have interacted in response to low-carbohydrate dieting remains highly relevant for three reasons. First, the story is still *directly* relevant, as a trip to any supermarket will show. Shelves remain stocked with at least some portion of the 1,558 low-carbohydrate products introduced at the height of the fad, and those that have survived seem to remain here to stay. And these persisting products are labeled in a variety of

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<sup>26</sup>See, e.g., *infra* Appendix E (indicating the South Beach logo on a Kraft product). Indeed, the most prominent example of this phenomenon has been Kraft’s relationship with South Beach. See *Company News; Kraft to Add South Beach Trademark to Some Products*, N.Y. TIMES, June 10, 2004, at C4.

<sup>27</sup>Warner, *Is the Low-Carb Boom Over?*, *supra* note 16.

<sup>28</sup>Melanie Warner, *Atkins Diet Saga Now at Chapter 11*, N.Y. TIMES, Aug. 3, 2005, at F2.

<sup>29</sup>Warner, *Is the Low-Carb Boom Over?*, *supra* note 16.

troubling ways. In particular, claims requiring FDA definitions (e.g., “low carbohydrate”) are being used with impunity, “net carbohydrate” and implicit labeling claims are not applied consistently, and food companies continue to market low-carbohydrate, but high-calorie and/or high-fat, products to consumers as diet and health foods. In this persistent low-carbohydrate product environment, continued dormancy of FDA in setting appropriate regulatory guidelines is problematic.

Second, the low-carbohydrate episode provides a clear case study of a regulatory process that does not always respond well to a consumer society where product demand is fast moving and niche marketing is prevalent, and where hope for a diet panacea leaves consumers vulnerable to manipulation. In the case of the low-carbohydrate fad, despite a flood of petitions asking for FDA direction on nutrient content claims relating to carbohydrates, FDA has remained inactive, leaving mainstream consumer products companies unable responsibly to market low-carbohydrate products and creating a vacuum in which up-start low-carbohydrate companies can engage in what Alison Kretser of the Grocery Manufacturers of America (“GMA”) has called a “wild west” of unchecked low-carbohydrate claims.<sup>30</sup> At the same time, the United States Department of Agriculture’s (“USDA”) Food Safety and Inspection Service (“FSIS”) and the United States Department of the Treasury’s Alcohol and Tobacco Tax and Trade Bureau (“TTB”) more quickly provided regulatory guidance for companies under their oversight.<sup>31</sup> Additionally, the Canadian government took action to regulate carbohydrate content claims and explicitly emphasized its policy at the height of the low-carbohydrate boom.<sup>32</sup> It is important to understand what FDA, FSIS, TTB and the Canadian government did well and poorly in response to the rapidly evolving consumer and industry interest in low-carbohydrate products.

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<sup>30</sup>Telephone Interview with Alison Kretser, Senior Director, Scientific and Nutrition Policy, GMA (Dec. 30, 2005).

<sup>31</sup>See FSIS, Statement of Interim Policy on Carbohydrate Labeling Statements (Dec. 22, 2003), <http://www.fsis.usda.gov/OPPDE/larc/Policies/CarbLabel.htm>; TTB, Rul. 2004-1, Caloric and Carbohydrate Representations in the Labeling and Advertising of Wine, Distilled Spirits and Malt Beverages (Apr. 7, 2004), <http://www.ttb.gov/alcohol/info/revrule/rules/2004-1.pdf>.

<sup>32</sup>See Canadian Food Inspection Agency, Information Letter: Carbohydrate Claims on Foods Sold in Canada (Aug. 31, 2004), <http://www.inspection.gc.ca/english/fssa/labeti/inform/choe.shtml>.

Third, the low-carbohydrate experience remains relevant because it represents something more than a short-term fad lacking in scientific basis. Though the Atkins diet approach had existed for thirty years, its reintroduction early in this decade came at a time when nutritional science began to question conventional low-fat wisdom and to reconsider the role of carbohydrate consumption and insulin resistance in our American struggle with obesity. Indeed, low-carbohydrate eating has sparked the first battle on the new frontier of nutrition, a reconceptualization that focuses on the physiological impact of foods rather than merely their chemical composition. While the carbohydrate-related trend has shifted from “doing Atkins” to today consuming foods with a low glycemic index, ultimately there is not much difference between the two approaches.<sup>33</sup> The approach is to look at the effect of foods on blood sugar rather than focusing solely on “calories in, calories out.” The upcoming challenge – and, incidentally, part of the delay in FDA action on carbohydrate-related nutrient content claims<sup>34</sup> – is to adapt the current regulatory scheme to fit new, competing concepts of proper nutrition in the shadow of the obesity epidemic. Thus, the low-carbohydrate story focuses our attention on the future regulatory debates to come.

This paper will argue that FDA cannot back away from the challenge of comprehensively regulating carbohydrate-related nutrient content claims. Even as the fad aspect of low-carbohydrate dieting has waned, many products remain on the shelves that mislead consumers and at the same time food companies have no guidance in marketing new and innovative low-carbohydrate foods to those who will continue to take this approach to nutrition. FDA should clearly distinguish what are low-carbohydrate products by setting a sufficiently low threshold for the use of the term “low carbohydrate” (and its implied synonyms) and by creating a clear continuum for the use of “low carbohydrate” relative to “good source of carbohydrates” and “excellent source of carbohydrates” claims. In addition, FDA should ensure that the term “net carbohydrate” is being used

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<sup>33</sup>Atkins’s approach does attempt to focus consumers on the glycemic index alongside basic carbohydrate content, but during the low-carbohydrate craze, it was the carbohydrate count that gained the greater focus. *See* ATKINS, NEW DIET REVOLUTION, *supra* note 3, at 78-84.

<sup>34</sup>Interview with Alison Kretser, *supra* note 30.

consistently and that consumers are aware that “low carbohydrate” and “net carbohydrate” claims do not make products necessarily low in calories or appropriate for weight loss. But these regulations are only the beginning of the effort that is required. While rulemaking will ultimately help consumers in the short and medium term to have good information as they pursue low-carbohydrate diets, FDA must also consider how and when, in the future, it can more nimbly respond to rapidly changing nutritional interests and information with interim guidance for consumers and industry. Moreover, FDA and other regulators should use the low-carbohydrate issue as a long-term opportunity to reconceptualize the nutritional information that is presented to consumers more broadly, as our understanding of nutrition takes into account the physiological impact of food as much as foods’ chemical composition. The low-carbohydrate debate is part of a critical larger debate about emerging nutritional knowledge and FDA should not squander this opportunity for reflection.<sup>35</sup>

## II.

### The Continuing Importance of Regulating Carbohydrate Claims

#### A.

Supermarket Tour: South Nashua, New Hampshire, February 2006

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<sup>35</sup>One challenge will be for FDA to take advantage of these opportunities as resources within the agency are shifted away from traditional food labeling issues. In FDA’s fiscal year 2007 budget, spending at the Center for Food Safety and Applied Nutrition (“CFSAN”) is being reallocated to defense of the food supply and flu preparedness. See Jessica Lake, *CFSAN Shifts Priorities from Base Programs to Food Defense, Flu Prevention*, HEALTH DAILY NEWS, Feb. 7, 2006, at 1.

A visit to the average American supermarket indicates that low-carbohydrate marketed products are still ubiquitous, despite the waning nature of the dieting trend. In February 2006, I made several trips to the Shaw’s supermarket in Nashua, New Hampshire. The supermarket – chosen to approximate the average selection of products to which the American consumer is exposed – is owned by Albertson’s, Inc., of Boise, Idaho and is located in the busy shopping district of New Hampshire’s second largest city.<sup>36</sup> The visits demonstrated the continued presence on supermarket shelves of products that are labeled as low in carbohydrates either explicitly or through a variety of implicit winks and nods.

One preliminary observation recognized during my visits was that many of the products that highlight carbohydrate content no longer make carbohydrates a focal point of the label. First, many mainstream products that existed both before and after the fad note the factual total carbohydrate content on the front of the packaging, in simple and understated language. For example, Ken’s Foods, Inc. places a small banner on the front of the packaging for its Chunky Blue Cheese salad dressing announcing the product’s one gram of carbohydrates per serving, noting “still just 1g carbs per serving.” Basic factual carbohydrate claims are indeed a persistent part of the landscape of nutritional labeling. Along the same lines, some surviving post-fad low-carbohydrate products have started to integrate their carbohydrate labeling with other claims, no longer positioning products as strictly low in carbohydrates, but instead listing the carbohydrate content alongside other labeling. For example, even Atkins Nutritionals’ products, designed specifically to be low in carbohydrates, have shifted their labeling from focusing only on carbohydrates to noting other nutritional benefits alongside the carbohydrate claim. While the Atkins Morning Start breakfast bars used to simply note the two grams of net carbohydrates (after subtracting fiber and sugar alcohols) on the front panel,<sup>37</sup>

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<sup>36</sup>Though the choice may not be truly “average” because of the supermarket’s proximity to Boston and the relatively high socioeconomic status of Nashua’s population – indeed the “Wild Harvest” natural and organics section featured at Shaw’s is possibly exceptional – the national nature of the Albertson’s chain (soon to be operated by another national chain, Supervalu, based in metropolitan Minneapolis-St. Paul, Minnesota) corrects for some of the local deviation.

<sup>37</sup>See *infra* Appendix A.

since 2005 the bars have heralded “High Protein”, “No Sugar Added”, “Low-Glycemic Index”, and “Excellent Source of Calcium” alongside the two-gram count.<sup>38</sup> Many companies are also making clear that though the products are low in carbohydrates they are neither low in calories nor appropriate for weight control. The new Morning Start bars reflect this trend when they asterisk “Not A Low-Calorie Food.”<sup>39</sup>

In addition to the deemphasizing of carbohydrates, much product innovation that food companies carried out during the low-carbohydrate era remains on supermarket shelves, but indicates only the low-sugar nature of the foods rather than their low-carbohydrate characteristics. Some products – in many cases the identical formulas – have been rebranded from low-carbohydrate to low-sugar. As I visited the snack aisle, I noticed that the “CarbWell” Oreos I had eaten on my own low-carbohydrate diet are now Sugar Free SnackWell’s Oreos. An old cookie has simply been placed in a new box.<sup>40</sup>

However, many product labels I viewed still retain a decidedly low-carbohydrate oriented tone, while skirting the prohibition on explicitly labeling a product as “low” in carbohydrates without an FDA-provided definition mandated by the Nutrition Labeling and Education Act of 1990 (“NLEA”) amendments to the FDCA.<sup>41</sup> For example, many labels I viewed refer to the count of “net carbohydrates” in the products. These products typically exclude sugar alcohol and fiber from their carbohydrate count. Most of these products asterisk the net carbohydrate number and explain its calculation. For example, Del Monte’s “Carb Clever” pear chunks asterisk the claim of nine net carbohydrates with the explanation that “net carbs are calculated by taking the grams of total carbohydrates and subtracting the grams of fiber as found in the nutrition facts box as these have minimal impact on blood sugar.”<sup>42</sup>

While most products do explain their calculation of net carbohydrates in explicit arithmetic terms, some

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<sup>38</sup> See *infra* Appendix B.

<sup>39</sup> See *id.*

<sup>40</sup> See Delroy Alexander and Jeremy Manier, *For Every Fad, Another Cookie*, CHICAGO TRIBUNE, Aug. 23, 2005, at 1.

<sup>41</sup> See Federal Food, Drug, and Cosmetic Act § 403(r)(1)(A), (2)(A), 21 U.S.C. § 343(r)(1)(A), (2)(A) (2004) (mandating that nutrient content claims only be made when defined by regulation).

<sup>42</sup> See *infra* Appendix C.

explanations are more nebulous. For example, on Atkins Nutritionals' current Morning Start label, the two grams of net carbohydrates are no longer labeled as "Net Carbs" as they once were, but are labeled as "Net Atkins Count"; the word "carbohydrate" does not even appear in the claim.<sup>43</sup> And, instead of laying out the calculation of the two grams, the new packaging explains that "Atkins has developed a breakthrough method to . . . confirm the accuracy of Atkins net carb labeling claims. The term Net Atkins Count appears on product packaging to express this clinically tested number and to distinguish it from terms previously used, such as net carbs. There is no question that the Net Atkins Count is the most accurate number to consider when following a controlled-carbohydrate lifestyle."<sup>44</sup>

Another product I encountered that explains the net carbohydrate count opaquely comes from a rather unlikely place for low-carbohydrate products, the pasta aisle. "Dreamfields Healthy Low Carb Living" pasta, available in elbows, penne and spaghetti, heralds five grams of "digestible carbs" in each serving.<sup>45</sup> The alleged five net grams are not calculable from the Nutrition Facts panel however, since the total carbohydrate number of forty-two grams less four grams of dietary fiber arrives at thirty-eight grams of net carbohydrates by the conventional measure; instead, Dreamfields provides a separate "Carb Facts" panel below the standard panel that subtracts thirty-seven grams of "Controlled Carbs" from the total number to arrive at five grams.<sup>46</sup> The label goes on to explain how a product which looks and tastes like any other pasta product could be low in carbohydrates: "[u]nlike 'low carb' pastas that contain mostly soy protein and fillers, Dreamfields is authentic pasta made with premium durum wheat semolina, but our unique pasta recipe means fewer carbohydrates get absorbed into your system."<sup>47</sup>

Alongside these varied net carbohydrate claims, the other prominent NLEA-skirting approach I observed

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<sup>43</sup> See *infra* Appendix B.

<sup>44</sup> See *id.*

<sup>45</sup> See *infra* Appendix F.

<sup>46</sup> See *id.*

<sup>47</sup> See *id.*

at Shaw's was the use of implied low-carbohydrate claims, including endorsements by well-known low-carbohydrate diets as well as carbohydrate claims placed directly in the product's name. The subtlest implied labeling is that which features the seal of a diet, such as Atkins or South Beach. For example, Arnold's reduced-carbohydrate breads feature the Atkins seal while a variety of Kraft products, including the company's former "CarbWell" line, are endorsed by South Beach.<sup>48</sup> Implicit claims also make use of craftily descriptive names. In the wine aisle, I found a chardonnay that calls itself "One.6", referring to the fact that the wine contains 1.6 grams of carbohydrates per serving.<sup>49</sup> And, it seemed like down every packaged food aisle in Shaw's I found products containing the term "carb" in the name – from the "Carb Clever" pears and "Carb Options" Skippy peanut butter to low-carbohydrate breads from Arnold ("Carb Counting") and Pepperidge Farm ("Carb Style").

While a lot of the products I observed in Shaw's are marketed in an attempt to avoid the NLEA's prohibition on the use of an explicit "low carbohydrate" label by referring to net carbohydrates or using implicit product names, the term "low carbohydrate" does actually still appear on a number of labels. No product I viewed simply states "low carb" or "low carbohydrate", with the exception of separately regulated alcohol products such as Michelob Ultra beer, which permissibly uses the label "Low Carbohydrate Light Beer."<sup>50</sup> However, some non-alcohol products refer to a "low carb lifestyle", a "low carb diet", and "low carb living." For example, Dreamfields makes reference to "Healthy Low Carb Living" on the front of the package.<sup>51</sup> And Shaw's itself, within its Wild Harvest natural and organic aisle, directs customers with large signage to a "Low Carb Lifestyle" section. Even though it appears that most food companies have pulled back

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<sup>48</sup>See, e.g., *infra* Appendix E.

<sup>49</sup>This is not a particularly impressive claim, in light of the fact that Atkins measures 0.9 grams of carbohydrates in the average four ounce glass of white wine. See ATKINS, NEW DIET REVOLUTION, *supra* note 3, at 492.

<sup>50</sup>See TTB, *supra* note 31 (permitting the use of "low carbohydrate" with alcohol products containing less than three grams of carbohydrates per serving).

<sup>51</sup>See *infra* Appendix F; see also *infra* Appendix A (making reference to Atkins as "The Original Low-Carb Lifestyle"); Appendix D (suggesting Skippy "Carb Options" peanut butter is "For Use as Part of a Low Carb Diet!").

from the use of the basic claim “low carbohydrate” while waiting for FDA rules, the claim still remains in use indirectly, heralding low-carbohydrate “living” and “lifestyles” without so designating the products as specifically “low carbohydrate”.

Shopping in the Wild Harvest section also prompts a final observation. Among the products featured in Wild Harvest are various energy bar products, marketed to athletes. PowerBar, a popular energy bar brand, offers “PowerBar Performance,” a bar that has forty-five grams of total carbohydrates, including three of fiber (yielding forty-two net grams). This product’s marketing on the PowerBar website notes that the bar is “packing 25g of complex carbs.”<sup>52</sup> Neighboring the Performance bars on the shelves was a PowerBar product called “PowerBar ProteinPlus Carb Select.” This product has thirty grams of total carbohydrates including one gram of fiber and twenty-seven grams of sugar alcohol, netting to two grams of what PowerBar calls “Impact Carbs.” On the website, PowerBar comments that this product “[i]ncludes . . . only 1g of sugar.”<sup>53</sup> The energy bar selection at Shaw’s reflects another aspect of the carbohydrate-related trends in food selection – that not only are food companies offering products highlighting a *low* number of grams of carbohydrates, such as the “ProteinPlus Carb Select,” but also products featuring a *high* number of grams of carbohydrates, such as “PowerBar Performance.”

Though the low-carbohydrate craze has ended, supermarkets still offer myriad low-carbohydrate products. Some are foods naturally low in carbohydrate, such as blue cheese dressing, and are still so labeled, while others are creations of the low-carbohydrate era and are intended to serve the needs of the carbohydrate conscious. In both cases, the strongest products have survived the waning trend, and maintain an ongoing appeal to both hardcore low-carbohydrate dieters as well as the general population. Given the continued prevalence of these products, to the extent any of these products’ labeling claims are in tension with current rules or are otherwise false and misleading for consumers, FDA and other regulators must intercede. The

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<sup>52</sup>PowerBar Performance, at <http://www.powerbar.com/Products/Performance/> (last visited Feb. 15, 2006).

<sup>53</sup>PowerBar ProteinPlus Carb Select, at <http://www.powerbar.com/Products/ProteinPlusCS/> (last visited Feb. 15, 2006).

following section will argue that this is the case.

B.

#### Problems With Current Carbohydrate Labeling Practices

Having observed the range of carbohydrate information conveyed by products in the average American supermarket, even as the low-carbohydrate fad has waned, it is important to next ask whether this labeling, as currently constituted, hurts or helps consumers' nutritional choices. To evaluate this issue, however, requires one initial assumption: given the inconclusiveness of the scientific data related to the impact of low-carbohydrate eating on weight control and general health, in the short to medium term ideal food labels will convey information that will allow consumers to make *fully-informed* choices about products in light of this inconclusiveness.<sup>54</sup> Thus, as a general rule, effectively-presented carbohydrate claims need to provide consumers with balanced information – offer clear measures of carbohydrate content and give consistent signals of when products are truly low in carbohydrates while avoiding false and misleading labels as well as the implication that foods designed to be low in carbohydrates are necessarily healthy or low in calories. As my visits to Shaw's indicated, food companies are not yet effectively achieving this balance.

There are indeed some responsible, balanced food labels out there. Labels that indicate the product's total carbohydrate count do no more than reiterate the information already presented on the Nutrition Facts panel. Though this information does convey some implication that the product is positioning itself as low in carbohydrates, the claim is basically objective data presented to highlight the level of a macronutrient found in the product. Moreover, many food companies are generally responsibly labeling their low-carbohydrate

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<sup>54</sup>This is not to say that completely prohibiting carbohydrate-related labeling claims, as the Canadian government has done, is not also an option on the table. The benefits and drawbacks of this option will be explored below in Part III.G.2.

products. For example, when they provide net carbohydrate information, they explain their calculation, and they often note that their low-carbohydrate products are not necessarily low calorie or appropriate for weight control. In other words, they provide a balanced picture for consumers.

Most companies also tend to avoid explicit references to “low”, “reduced”, and “free”, claims that are prohibited without FDA definitions. However, properly defined by FDA, these claims would allow food companies to provide additional information that is consistent and helpful to consumers and might cut down on some of the irresponsible labeling described below, which is used to evade the prohibition on “low” and other such claims. In actuality, to avoid “low” and other forbidden claims, food companies have turned to a variety of labeling techniques that implicitly convey the low-carbohydrate nature of the product. Much of this labeling is troubling in its lack of consistency from product to product and its tendency to mislead consumers about the healthful and dietetic nature of the foods.

The first labeling problems arise with the use of the term “net carbohydrate”. As mentioned above, many products do clearly define the net carbohydrate calculation and tend to stick to a standard definition that subtracts out fiber and sugar alcohols. FDA has indeed indicated that it essentially accepts the use of net carbohydrate labeling. In a November 19, 2004 letter to the National Consumers League (“NCL”), Acting FDA Commissioner Lester Crawford wrote that FDA “has not generally objected to the use of ‘net carbohydrate’ type information on food labels if the label adequately explains how the terms are used so that it would not be false or misleading to consumers.”<sup>55</sup>

Yet, there are two fundamental problems with net carbohydrate labeling as it exists on the products I viewed.<sup>56</sup> First, labeling a product’s net carbohydrates may cause consumers to lose focus on the fact that

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<sup>55</sup>Letter from Lester M. Crawford, Acting Commissioner of Food and Drugs, FDA, to Linda F. Goldner, President, NCL 1 (Nov. 19, 2004) (No. 2004P-0105) [hereinafter FDA Letter to NCL].

<sup>56</sup>These problems are in addition to two other issues not analyzed above but appropriate to note briefly. First, there is a lack of a clear scientific consensus on what impact various sugar alcohols have on blood sugar levels. Dr. David Ludwig, director of the obesity program at Children’s Hospital in Boston, notes that some sugar alcohols may affect blood sugar equivalently to other carbohydrates, suggesting that “[i]t’s unclear whether the term [net carbohydrates] has any nutritional significance.” See Warner, *Is the Low-Carb Boom Over?*, *supra* note 16. Second, I would argue that in light of the potential laxative effect of

the product may not be low in calories or low in fat, but may instead take the net carbohydrate code as a signal that it is a diet product. As Kretser notes, when GMA submitted its petition on carbohydrate claims to FDA, the organization’s membership was of the opinion that however FDA determines to define “net carbohydrates”, it is important that food companies clearly present calorie information alongside net carbohydrate data since it is ultimately the product’s calories that count.<sup>57</sup>

In addition, and even more problematically, the “net carbohydrate” label is not applied consistently across products, making its use by consumers rife with trouble. As noted above, today most food companies do asterisk the net carbohydrate number and explain its calculation, a number that usually can be reconciled with the Nutrition Facts panel breakdown of carbohydrates.<sup>58</sup> However, some products, including prominent low-carbohydrate offerings, only define the count nebulously. Atkins Nutritionals’ products feature a “Net Atkins Count”, for example two grams for Morning Start breakfast bars, without ever referencing what nutrient it is even counting or how the calculation is being made, other than that it is “clinically tested.”<sup>59</sup> While Atkins Nutritionals thinks it is more accurately measuring blood sugar impact with this figure than when it uses a rough count that subtracts fiber and sugar alcohol, the “Net Atkins Count” provides consumers with an incomparable and unverifiable figure that is completely of Atkins Nutritionals’ own creation. As Nancy L. Schnell, a Deputy General Counsel at Unilever United States, Inc. (“Unilever”) argues in a letter to FDA, “Atkins’ effort to define and regulate its own, proprietary nutrient definition using a black-box scientific methodology undermines FDA’s use of consistent nutrient definitions on which food labeling claims are based.”<sup>60</sup>

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high amounts of sugar alcohols, it may be appropriate to require a warning on product labels about this issue.

<sup>57</sup>Interview with Alison Kretser, *supra* note 30.

<sup>58</sup>This is not always the case, however, even when the calculation is defined. Although dietary fiber is always listed on the Nutrition Facts panel, the break out of sugar alcohols is optional. *See, e.g., infra* Appendix A (explaining the various carbohydrates to exclude from the net figure yet not breaking all of them out in the Nutrition Facts panel). Thus, when sugar alcohols are not broken out but are part of the net carbohydrate calculation, the net carbohydrate number cannot be fully reconciled with the panel.

<sup>59</sup>*See infra* Appendix B.

<sup>60</sup>Letter from Nancy L. Schnell, Deputy General Counsel – Marketing and Regulatory, Unilever, to Michael M. Landa, Deputy Director for Regulatory Affairs, CFSAN, FDA 2 (Dec. 1, 2004) (No. 2004P-0298) [hereinafter Unilever Letter to Michael M.

Another perplexing example of this inconsistency in net carbohydrate claims is the Dreamfields label. Dreamfields uses the term “Digestible Carbs” and indicates that its products have five grams of digestible carbohydrates per serving.<sup>61</sup> Like Atkins Nutritionals’ use of the “Net Atkins Count,” Dreamfields has replaced a number calculable from the Nutrition Facts panel with authoritative-sounding yet non-comparable black-box clinical testing to arrive at a net carbohydrate number. However, more troubling than the approach of Atkins Nutritionals, Dreamfields attempts to draw consumer attention away from the Nutrition Facts panel to an imitation “Carb Facts” panel below that looks as reliable as the Nutrition Facts but summarily dismisses most of the forty-two grams of carbohydrates Dreamfields is required to list in the Nutrition Facts above.<sup>62</sup> Bonnie Liebman, Director of Nutrition at the Center for Science in the Public Interest (“CSPI”) disagrees with Dreamfields’ use of the term “Digestible Carbs”, writing humorously that “[i]f a serving of pasta sent 47 grams of undigested carbs to your large intestine, odds are you’d know it. So would everybody within 100 metres” given the flatulence that would occur.<sup>63</sup> Liebman believes Dreamfields is misguiding consumers by posting a net carbohydrate number while in reality basing its claim on the fact that the product has a low glycemic index.<sup>64</sup>

A second carbohydrate labeling practice that may mislead consumers is the use of implied claims, particularly those that appear in product names. In labeling a chardonnay wine as “One.6”, for example, food and beverage expert Phil Lempert suggests that the approach is “simple and smart” because he believes that providing a number in lieu of the product name means “people instantly get it.”<sup>65</sup> Consumers are likely to also immediately “get it” with products using the term “carb” directly *within* the name, signaling that products are low in carbohydrates when in reality no standard of comparison for “low” has been

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Landa].

<sup>61</sup> See *infra* Appendix F.

<sup>62</sup> See *id.*

<sup>63</sup> Bonnie Liebman, *Special Feature: Carb Claims on a Roll*, NUTRITION ACTION HEALTHLETTER, Jan./Feb. 2005, at 11, <http://www.cspinet.org/nah/01.05/carb-can.pdf>.

<sup>64</sup> *Id.*

<sup>65</sup> Theresa Howard, *Soon, You Can Raise a Toast to Low Carbs*, USA TODAY, May 11, 2004, at 1B.

set by FDA. In each case, consumers identify such products with low-carbohydrate eating based on the product's name without the necessity for any explicit claim of "low carbohydrate". Yet, as CSPI points out in its carbohydrate nutrient content claim petition to FDA, "the implied low-carbohydrate claims now appearing on foods ... are not subject to any limits on total carbohydrate content and are not required to be accompanied by qualifying disclosures."<sup>66</sup> Indeed, "Carb Options" peanut butter has five grams of total carbohydrates (three grams of net carbohydrates)<sup>67</sup> while "Carb Clever" pears chunks have ten grams of total carbohydrates (nine grams of net carbohydrates),<sup>68</sup> the kind of distinctions a consistent FDA rule is meant to synthesize. Moreover, employing implicit "carb" names – lacking any indication that a product is not low in calories and/or not intended for weight control – suggests to consumers at large, similarly to net carbohydrate labeling, that a product is healthful or weight loss-oriented even when it is not.

Implied claims such as referencing a "low carb lifestyle" are no more helpful or constructive than calling a product "Carb Clever". They similarly imply that a product is low in carbohydrates. It is unimaginable that a consumer would compartmentalize that the Dreamfields brand is for "low carb living" but distinguish that the particular food in the box is not intended to be a "low carbohydrate" product. Shaw's shepherding of consumers into a "low carb" section of the store does an equal disservice. The placement of foods made largely with unpronounceable artificial ingredients in its Wild Harvest natural food section is ironic, but it is also questionable whether Shaw's should be setting a threshold for what is essentially "low carbohydrate" when FDA prohibits food companies from doing so.<sup>69</sup>

However, dealing with low-carbohydrate labeling issues in isolation is not the only relevant problem. As made clear by the two very different PowerBar products – one marketed as low in carbohydrates and one

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<sup>66</sup>Petition of CSPI to FDA, Nutrient Content Claims for Carbohydrates 2 (Apr. 7, 2004) (No. 2004P-0297) [hereinafter CSPI Petition].

<sup>67</sup>See *infra* Appendix D.

<sup>68</sup>See *infra* Appendix C.

<sup>69</sup>The danger of Shaw's signage is reflected in the inconsistent list on its website of a sampling of low-carbohydrate products found in the Wild Harvest section. This sampling of allegedly low-carbohydrate products ranges widely in net carbohydrate counts from zero grams up to eight grams per serving. See Shaw's Carbminder, *at* <http://www.shaws.com/learn/carbminder/WildHarvest/Index.html> (last visited Mar. 15, 2006).

marketed as high in carbohydrates – another challenge is posed by clearly defining both “low” and “high”<sup>70</sup> carbohydrate claims. Consumers see two products juxtaposed that communicate a very mixed message about carbohydrates, a message that confuses both the average consumer concerned about weight control as well as the serious athlete who may be interested in effective sources of energy for athletic competition.<sup>71</sup> It is critical that, if food companies are going to be allowed to make both high and low claims for carbohydrates – whether they are implied (such as “CarbSelect”) or explicit (such as “low carbohydrate” or “excellent source”) – the threshold for each claim is clear and consistent so as to effectively serve such diverse consumer constituencies.

A general observation about low-carbohydrate products that is more consumer protection than nutrition oriented is also in order. Consumers pay a premium for low-carbohydrate marketed products, when they sometimes should not. In the case of Pepperidge Farm “Carb Style” whole wheat bread, the cost per loaf is \$3.99 for a twenty-ounce package (\$0.20 per ounce) versus \$3.19 for a twenty-four ounce package (\$0.13 per ounce) of Pepperidge Farm’s regular whole wheat bread. Consumers are getting a reduction of carbohydrates from seventeen grams of net carbohydrates (twenty grams of total carbohydrates less three grams of fiber) for the regular bread to five grams of net carbohydrates (eight grams of total carbohydrates less three grams of fiber) for “Carb Style”, a pretty reasonable reduction relative to the increased price. However, some products are charging a very high premium for an unimpressive reduction in carbohydrates. A sixteen ounce jar of “Carb Options” Skippy proclaims its three grams of net carbohydrates per serving at \$3.59 per jar (\$0.22 per ounce) while Skippy’s regular creamy peanut butter contains five grams of net carbohydrates per serving for only \$2.19 per eighteen ounce jar (\$0.12 per ounce). On a per ounce basis, for a two-gram

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<sup>70</sup>This type of claim would ideally be asserted by food companies as “excellent source of carbohydrates” or “good source of carbohydrates.” “Excellent source” and “good source” are both subject to definition by FDA under NLEA. *See* Nutrient Content Claims for “Good Source,” “High,” “More,” and “High Potency”, 21 C.F.R. § 101.54 (2005).

<sup>71</sup>*See* Matt Brzycki, *No Corn on These “Carbs”: The Energy Lift in Sports*, COACH AND ATHLETIC DIRECTOR, Sept. 1, 2005, at 53 (providing advice about carbohydrates, as athletes and coaches waded through divergent nutritional information relating to high-carbohydrate eating to gain energy and low-carbohydrate eating for weight control).

carbohydrate reduction, the price is nearly *double* for the “Carb Options” peanut butter. As Bonnie Liebman exclaims tongue-in-cheek about Skippy’s dubious marketing strategy, “it’s worth every penny to slash those sugars to half a gram per tablespoon. After all, ordinary Skippy has a *whole* gram. So as you swallow each 100-calorie tablespoon of Carb Options – the same as regular Skippy – you can almost feel that half-gram of carbs just sloughing off your excess weight. Or is that the sound of loonies marching out of your wallet?”<sup>72</sup> Thus, consumers may be paying, in some cases, an excessive premium for a minor reduction in carbohydrate content.

To summarize, while the “wild west” of fly-by-night low-carbohydrate products arriving on grocery store shelves has receded, a vastly inconsistent cacophony of carbohydrate claims remains in the marketplace. As has been observed above, these products are impossible to compare one to another because helpful information has been replaced with reference to black-box laboratory testing. And in an attempt to signal that products are low in carbohydrates without illicitly labeling them “low carbohydrate”, food companies have adopted various maneuvers that imply a carbohydrate reduction yet have vastly different standards for the carbohydrate content. Moreover, many products continue to focus consumers on carbohydrate content to the exclusion of calories as well as other nutrients like fat. These low-carbohydrate labels lend the imprimatur of healthfulness, especially when they present the low-carbohydrate marketing without any qualifications. This problem matches that which occurred as the low-fat trend gained speed in the 1990s. Products marketed themselves as “low fat”, though the calorie count did not necessarily change, as fats were replaced with carbohydrates. Similarly, carbohydrates are now being replaced by fats, particularly saturated fats, as well as laxative sugar alcohols and artificial sweeteners.<sup>73</sup> Just as Liebman warned about the “Snackwell Syndrome” in the mid-1990s<sup>74</sup> – that as long as a product was low in fat consumers thought they could

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<sup>72</sup>Liebman, *supra* note 63 (emphasis in original). The loony is a colloquial name for Canada’s one-dollar coin.

<sup>73</sup>See *id.* at 10-11 (providing examples of ingredients that are being substituted for carbohydrates).

<sup>74</sup>See Gina Kolata, *The Nation; The Fat-Enabling Culture: Society Made Me Eat It!*, N.Y. TIMES, Dec. 1, 1996, at 4 (“For some reason, when people see fat-free on a label, they think: I will be fat free if I eat this,” Ms. Leibman [sic] said. ‘Some call it the Snackwell syndrome,’ she added, referring to a popular brand of fat-free cookies and snacks. ‘Ads for a lot of foods,’ she

eat unlimited quantities – low-fat Snackwell cookies were joined on supermarket shelves in the 2000s by a sister brand, Carbwell Oreos, that also encourages the same type of dangerous “dieting.”<sup>75</sup> It is into this environment that I argue FDA needs to enter.

C.

### The Consumer Perspective on Carbohydrate Food Labeling

While the current carbohydrate labeling practices employed by food companies *theoretically* may convey problematic information to consumers, the relevance of these issues would be diminished if consumers were not *in practice* misled by the current labels. A consumer survey recently released by FDA helps to elucidate whether this is the case. Between October 12, 2004 and January 21, 2005, CFSAN’s Office of Regulations and Policy sponsored a survey of 1,798 households in the 50 states and District of Columbia, selected from a nationally representative sample.<sup>76</sup> The survey – designed to provide background information from the consumer perspective to assist FDA rule makers in contemplating new regulations<sup>77</sup> – asked questions of consumers about their perceptions of fats (particularly trans fats) and carbohydrates as they relate to health and nutrition. The carbohydrate-related responses, while revealing that consumers are more savvy than we may think, reflect both a keen awareness of food companies’ carbohydrate labeling claims as well as abundant confusion about the meaning of many of these claims, pointing to a need for regulations defining carbohydrate nutrient content claims.

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said, ‘imply that you can eat the whole box and you won’t gain weight.’”) (internal quotation marks omitted).

<sup>75</sup>Kretser, in her telephone interview, also found the comparison to the low-fat era apropos. She noted that just as people lost sight of the caloric content of foods in focusing on fat in the 1990s, people today are losing sight of the caloric content of foods in focusing on carbohydrates. See Interview with Alison Kretser, *supra* note 30.

<sup>76</sup>See Office of Regulations and Policy, CFSAN, FDA, FDA Health and Diet Survey – 2004 Supplement: Topline Frequency Report (November 2005), <http://www.cfsan.fda.gov/~comm/crnutri3.html#nutria> [hereinafter FDA Health and Diet Survey].

<sup>77</sup>See E-mail from Jordan Lin, Office of Regulations and Policy, CFSAN, FDA, to Andrew Cooper (Dec. 27, 2005) (on file with author).

According to the survey results, there is a high level of awareness in the marketplace regarding carbohydrate-related claims on foods. 67% of consumers have heard of the term “net carbs” or “net carbohydrates”, 67% have seen food products that highlight the amount of carbohydrates on their packaging, and 71% have seen food products that include the term “carb” or “carbohydrate” in the product name.<sup>78</sup> Moreover, 89% of consumers have seen or heard of a food product that claims to be “low carbohydrate” or “low carb” and 59% of these respondents have tried a product claiming to be low-carbohydrate.<sup>79</sup> The 89% awareness of low-carbohydrate claims is particularly notable because, since explicit “low carbohydrate” claims are currently prohibited, it is likely many of these consumers are seeing net carbohydrate labels or products with “carb” in their name and inferring the low-carbohydrate notion from these implied claims.

Though consumers are very much aware of the presence of these claims, skepticism about nutritional claims generally shades respondents’ opinions. In addition, despite a flood of products that claim to be low in carbohydrates, the fad has not fundamentally swayed consumers from the conventional nutritional wisdom that calories are key. According to the survey, 59% of consumers believe manufacturers decide when a product can say “low carb” while 32% believe the government decides.<sup>80</sup> On a related note, in an e-mail correspondence, Jordan Lin of CFSAN notes that in a 1995 Health and Diet survey conducted by FDA, most consumers surveyed “thought only some or almost none of the terms such as light, lean, reduced, or healthy were accurate.”<sup>81</sup> Thus, any concern about consumers being misled by labeling claims should be tempered by recognition that the average grocery shopper is not completely ignorant. Moreover, the survey also revealed that consumers are generally aware of the conventional wisdom that calories count more than anything else. 62% of those surveyed said that eating fewer calories is relatively more important if one wants

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<sup>78</sup>FDA Health and Diet Survey, *supra* note 76.

<sup>79</sup>*Id.*

<sup>80</sup>*Id.*

<sup>81</sup>*See* E-mail from Jordan Lin, Office of Regulations and Policy, CFSAN, FDA, to Andrew Cooper (Jan. 20, 2005) (on file with author) [hereinafter E-mail from Jordan Lin, Jan. 20, 2005].

to lose weight, while only 25% said eating fewer carbohydrates was more important.<sup>82</sup> Lin, who is CFSAN's primary contact on the survey results, finds this personally to be the most notable carbohydrate-related result of the survey. He suggests that "most consumers seem to be not swayed by the low-carb fad and still recognize fat or calories is more important in losing weight than carb[s]... [T]he huge disparity between the response percentages in [this question] suggests most consumers do recognize that, despite the new products they may see in the marketplace, calories are still one of the key factors on people's weight."<sup>83</sup>

Nevertheless, though many consumers believe calories are more important than carbohydrates, 59% of respondents have tried a product that claims to be low-carbohydrate, and as observed above, awareness of these claims runs even higher.<sup>84</sup> Therefore, it is still critical to evaluate whether consumers feel confused as they wade through carbohydrate-related nutrition claims. First, the survey shows that consumers are unsure about what the term "low-carbohydrate" means in relation to calories, with 55% of respondents thinking that a low-carbohydrate claim means the product could be either high or low in calories and another 25% not knowing if low-carbohydrate means high or low in calories.<sup>85</sup> Lin believes that "in the context of other carb-related responses, . . . many consumers are unsure about whether low carb products are high or low in calories."<sup>86</sup> In addition, consumers seem perplexed by the relationship among low-carbohydrate claims, net carbohydrate claims, and foods' total carbohydrates. 48% of consumers surveyed do not know whether a low-carbohydrate claim means the product is low in total carbohydrates, net carbohydrates, or could be low in either, with an additional 35% responding that it could be low in either net or total carbohydrates.<sup>87</sup> On a related note, while 67% of consumers are aware of net carbohydrate claims as mentioned above, at the same time 62% of these respondents do not know whether net carbohydrates have a different or the same

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<sup>82</sup>FDA Health and Diet Survey, *supra* note 76.

<sup>83</sup>E-mail from Jordan Lin, Jan. 20, 2005, *supra* note 81.

<sup>84</sup>FDA Health and Diet Survey, *supra* note 76.

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

<sup>86</sup>E-mail from Jordan Lin, Jan. 20, 2005, *supra* note 81.

<sup>87</sup>FDA Health and Diet Survey, *supra* note 76.

effect on a person's weight as total carbohydrates.<sup>88</sup>

The survey also confirms that, to the extent consumers are purchasing and consuming low-carbohydrate products, the problems described in Part II.B above are relevant to them. First, among consumers who have tried to limit their carbohydrates, 79% follow no diet plan in so limiting their carbohydrate intake, while 21% follow a plan such as Atkins or South Beach.<sup>89</sup> Thus, if most consumers are not relying on diet plans to identify products that are low in carbohydrates, they are most likely relying on the claims products themselves make. In addition, among these same consumers, 54% are limiting their carbohydrate intake for the purpose of weight control while another 6% are limiting carbohydrates for both weight control and another purpose.<sup>90</sup> These 60% of consumers are vulnerable to products that may be low in carbohydrates but are not necessarily low in calories or for weight control. This is particularly problematic since 79% of these people are not following a diet plan, which might have potentially made recommendations about both carbohydrate as well as caloric intake.

The consumer survey shows that consumers are aware of food companies' low-carbohydrate, net carbohydrate, and implied claims. In addition, they are confused by much of the terminology and vulnerable to many of the claims. This consumer perspective thus underscores the appropriateness of regulatory action in standardizing carbohydrate labeling claims and in stringently requiring that such labels not be false or misleading.

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<sup>88</sup> *Id.*

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

<sup>90</sup> *Id.*

### III.

## Proposals for the Regulation of Carbohydrate Labeling Claims

### A.

#### Prelude: Where Does the Process Stand Today?

At the end of 2003, as the low-carbohydrate trend took its hold, large food companies interested in capitalizing on consumer interest in products with lower carbohydrate content petitioned FDA under section 403(r)(4) of the FDCA, seeking a regulation to define the terms “low”, “reduced”, “free”, “good source”, and “excellent source” as they relate to carbohydrates. Kraft filed a comprehensive carbohydrate-labeling petition on December 1, 2003<sup>91</sup> and Pepsico, Inc. (“Pepsico”) sent a letter to FDA requesting a “reduced” claim on December 19, 2003.<sup>92</sup> Over the course of 2004, additional petitions and related correspondence on this issue came in to FDA from other food companies including Unilever and Nestle USA (“Nestle”), trade groups including the GMA and the American Bakers Association (“ABA”), and consumer groups including CSPI and NCL. All asked for FDA action on the labeling of products oriented toward carbohydrate-conscious consumers. FDA announced on March 12, 2004 that, in response to the petitions, it would “initiate rulemaking proceedings for nutrient content claims for carbohydrate [and] provide guidance to food manufacturers on the use of the term ‘net’ in relation to the carbohydrate content of food.”<sup>93</sup> Two years later, FDA has not

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<sup>91</sup>See Kraft Petition, *supra* note 13.

<sup>92</sup>See Letter from Nancy R. Green, Vice President, Nutrition Technology, and Mark L. McGowan, Chief Counsel, Foods Division, Pepsico, to Robert E. Brackett, Director of Food Safety and Security Staff, CFSAN, FDA (Dec. 19, 2003) (No. 2004P-0105) [hereinafter Pepsico Letter].

<sup>93</sup>See FDA, Fact Sheet, Carbohydrates (Mar. 12, 2004), <http://www.fda.gov/oc/initiatives/obesity/factsheet.html> [hereinafter FDA Fact Sheet].

yet taken any regulatory action on these petitions. In fact, in recent letters to CFSAN, petitioners agreed to an extension of the decision date on the carbohydrate petitions to April 30, 2007.<sup>94</sup> Notwithstanding the agreement to an extension to 2007, FDA has suggested more imminent changes may be coming. In a recent speech before the GMA Annual Meeting, Dr. Scott Gottlieb, FDA's Deputy Commissioner for Medical and Scientific Affairs, noted that FDA has "drafted a proposed rule that would define nutrient content claims to describe the carbohydrate content of foods, and an advanced notice of proposed rulemaking to solicit public comments on available data and information relative to carbohydrate-related label claims and consumer understanding and behaviors related to such claims," going on to say that FDA hopes "these will be published this fiscal year."<sup>95</sup>

This is not to say that at the height of the low-carbohydrate trend FDA did not enforce existing law against the worst offenders. Indeed, FDA has imposed its existing regulations, including the prohibition on explicit nutrient content claims, through a warning letter process. For example, in a 2003 letter to PureDe-lite Products, Inc., FDA warned that the company's Chocolate Bar was misbranded under section 403(r)(1)(A) of the FDCA because it used the unauthorized "low carb" claim.<sup>96</sup> Furthermore, Carbolite Foods, Inc. endured an extensive two-year saga of FDA enforcement, ending in an unsuccessful attempt to call its products "Carbolite" because the name implied a prohibited "lite" ("light") carbohydrate claim.<sup>97</sup>

But these enforcement efforts elucidate the problem rather than reflecting a long-term solution. The activ-

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<sup>94</sup>See, e.g., Letter from Bruce Silverglade, Director of Legal Affairs, CSPI, to Shellee A. Anderson, Regulations and Review Team, CFSAN, FDA 1 (Dec. 12, 2005) (No. 2004P-0297).

<sup>95</sup>Scott Gottlieb, Deputy Commissioner for Medical and Scientific Affairs, FDA, Address to GMA Annual Meeting (Nov. 30, 2005), <http://www.fda.gov/oc/speeches/2005/gma1130.html>.

<sup>96</sup>Warning Letter from Felicia B. Satchell, Director, Division of Food Labeling and Standards, CFSAN, FDA, to Kurtis D. Nielson, President, PureDe-lite Products, Inc. (Apr. 25, 2003), [http://www.fda.gov/foi/warning\\_letters/g4030d.htm](http://www.fda.gov/foi/warning_letters/g4030d.htm).

<sup>97</sup>See Petition of Carbolite Foods, Inc. for Reconsideration and Stay of Action (Feb. 13, 2003) (No. 02P-0462), <http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/021403/80050b73.pdf>. It is interesting to note that the successor product to Carbolite is called "Carborite", an acceptable name under current rules but implying no less the low-carbohydrate nature of the product than Carbolite. See Part III.E below for a discussion of these implied nutrient content claims.

ities characterized above indicate that FDA has worked exclusively to ensure that food companies do not make carbohydrate claims that require FDA definitions. Thus, rather than being provided with consistent definitions by FDA, consumers have been left with a hodge-podge of implied low-carbohydrate claims and inconsistent net carbohydrate definitions, as food companies skirt around the prohibition on explicit “low” labels. Moreover, ad hoc enforcement likely is more expensive for a resource-constrained agency than a blanket definition.<sup>98</sup> Comprehensive regulatory oversight is needed, in order to create a consistent definition for carbohydrate claims on which both food companies and consumers can come to rely. This is the promise of the elusive rules Dr. Gottleib alluded to in his recent speech. The remainder of Part III will explore one key question – what should these proposed rules *say* when they are released? This examination will proceed by examining the petitions submitted both by the food industry and consumer groups as well as the experience of other US regulators as well as their Canadian counterparts.

Before undertaking this examination, as a threshold issue it is important to understand why FDA did not previously authorize nutrient content claims for carbohydrates and why circumstances have changed such that action today is appropriate. In 1990, the NLEA amendments to the FDCA were signed into law, which prohibited foods from bearing claims about the level of a nutrient without the claims first being defined by federal regulations.<sup>99</sup> Final regulations on nutrient content claims were published on January 6, 1993<sup>100</sup> and carbohydrates were consciously excluded from the definitions.<sup>101</sup> On the high carbohydrate claims, the agency reasoned that “a nutrient content claim such as ‘high in carbohydrate,’ or ‘source of carbohydrate,’

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<sup>98</sup> See Kraft Petition, *supra* note 13, at 16 (“FDA-defined nutrient content claims for carbohydrates . . . could bring reasoned consistency to the marketplace without the considerable expenditure of FDA resources that would be required to do so through enforcement actions.”).

<sup>99</sup> See Federal Food, Drug, and Cosmetic Act § 403(r)(1)(A), (2)(A), 21 U.S.C. § 343(r)(1)(A), (2)(A) (2004).

<sup>100</sup> See Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302 (Jan. 6, 1993) (to be codified at 21 C.F.R. pts. 5, 101).

<sup>101</sup> See, *e.g.*, Nutrient Content Claims for “Good Source,” “High,” “More,” and “High Potency,” 21 C.F.R. § 101.54(a) (2005) (explicitly excluding carbohydrates from the high nutrient content claim definitions).

provides misleading dietary advice. At best, the claim is ambiguous in that it does not allow for the distinction between high levels of complex carbohydrates and high levels of sugars.”<sup>102</sup> FDA’s rationale for excluding carbohydrates from nutrient content claims also included a belief that “claims for specific amounts of carbohydrates . . . [cannot] be supported based on dietary recommendations in the major consensus reports because quantitative recommendations for carbohydrate consumption are not included.”<sup>103</sup>

However, since 1993, more definitive dietary recommendations on carbohydrates have emerged, and as importantly, the obesity epidemic that has developed in America has raised the stakes for taking actions that will help to mitigate the consequences. In 2002, the Institute of Medicine (“IOM”) published its *Macronutrient Report*, which sets a minimum Recommended Dietary Allowance (“RDA”) for carbohydrates for energy purposes at 130 grams per day as well as an acceptable macronutrient distribution range (“AMDR”) for carbohydrates of forty-five to sixty-five percent of daily calories.<sup>104</sup> The report also notes that not more than twenty-five percent of daily calories (within the forty-five to sixty-five percent figure) should come from “added sugars”.<sup>105</sup> Thus, recommendations, including those that distinguish sugars from other carbohydrates, are now on the table, allowing FDA to act. In addition, the findings of FDA’s Obesity Working Group – namely that obesity has reached epidemic proportions in America and “shows no signs of abating” – make changes to nutritional labeling practices that would support a variety of diet approaches very timely.<sup>106</sup>

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<sup>102</sup>Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60421, 60444 (proposed Nov. 27, 1991) (to be codified at 21 C.F.R. pts. 5, 101, 105).

<sup>103</sup>*Id.* at 60453. Notwithstanding the express rationales provided at the time of the NLEA regulations, Pepsico notes another likely explanation for the lack of carbohydrate claim definitions: “[o]wing, we suspect, to the lack of interest in carbohydrate content when the current rules were written in 1993, carbohydrate content claims have never been defined.” Pepsico Letter, *supra* note 92, at 1.

<sup>104</sup>*See* IOM, DIETARY REFERENCE INTAKES FOR ENERGY, CARBOHYDRATE, FIBER, FAT, FATTY ACIDS, CHOLESTEROL, PROTEIN, AND AMINO ACIDS 290, 769 (2002) [hereinafter *Macronutrient Report*]. As will be relevant when the various nutrient content claims are evaluated below, it should be noted that the IOM report concedes the safety and appropriateness of a low-carbohydrate approach, notwithstanding these RDA and AMDR recommendations. The report notes that “it should be recognized that the brain can still receive enough glucose from the metabolism of the glycerol component of fat and from the gluconeogenic amino acids in protein when a very low carbohydrate diet is consumed” and that “[t]he lower limit of dietary carbohydrate compatible with life apparently is zero, provided that adequate amounts of protein and fat are consumed. However, the amount of dietary carbohydrate that provides for optimal health in humans is unknown. There are traditional populations that ingested a high fat, high protein diet containing only a minimal amount of carbohydrate . . . for a lifetime after infancy (Alaska and Greenland Natives[])] . . . . There was no apparent effect on health or longevity.” *Id.* at 289, 275.

<sup>105</sup>*Id.* at 770.

<sup>106</sup>FDA OBESITY WORKING GROUP, *supra* note 9; *see also* Petition of Unilever to FDA, Nutrient Content Claims for the

Thus, what may have been premature in 1993 is ripe today. Carbohydrate nutrient content claims are now appropriate; the question is how they should be defined.

B.

#### The Easier Definitions: “Carbohydrate Free” and “Reduced Carbohydrate”

Before tackling the tough terrain of “low” and “net” claims, two other claims can first more easily be resolved: how to define “carbohydrate free” and “reduced carbohydrate”. Both have clear analogs in other areas of nutrition, making the establishment of a consistent claim fairly unobjectionable to food companies and consumer advocates alike. A “free” claim, like “fat free”, describes an absolute level of a nutrient, and a “reduced” claim, like “reduced fat”, is easy to set consistently at some percentage reduction from a reference point. Both types of claims have built-in consistency that makes their use a more black-and-white issue for food companies and consumers.

##### 1. The “Free” Claim

The petitions submitted on the “free” claim unanimously suggest a definition of “carbohydrate free” of less than 0.5 grams of total carbohydrates per serving, which is intended to approximate zero grams of carbohydrates. With other nutrients, FDA arrived at “free” claims by choosing “the level of a nutrient that is at the reliable limit of detection and that is dietetically trivial or physiologically inconsequential.”<sup>107</sup> The

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Carbohydrate Content of Food 7 (Apr. 16, 2004) (No. 2004P-0298) [hereinafter Unilever Petition] (“The recommendations in the report of FDA’s Obesity Working Group . . . provide a sound basis for . . . taking [steps] to help consumers improve their diets in order to reduce the incidence of overweight and obesity.”).

<sup>107</sup>Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2378 (Jan. 6, 1993) (to be codified at 21 C.F.R. pts. 5, 101).

food company petitioners thus propose to define “carbohydrate free” based on the amount of carbohydrates FDA has generally found to be nutritionally insignificant – less than 0.5 grams per serving.<sup>108</sup> CSPI supports this approach because it believes that “[i]t is critical that FDA limit claims to the same lexicon used for other nutrient content claims.”<sup>109</sup>

Though ultimately agreeing to the basic idea of a 0.5 grams definition for “free”, the petition submitted by Unilever reflects the first in a series of disagreements among food companies over the definitions FDA should adopt for carbohydrate claims. On the “free” claim as well as all the other claims discussed below, Unilever believes the defined term should “distinguish between carbohydrates that contribute significant levels of calories to the diet (such as sugars and starches) and those that do not (such as dietary fiber and sugar alcohols). With these claims, consumers will be better able to reduce intake of the former types of carbohydrates without inadvertently also reducing intake of the latter types.”<sup>110</sup> Unilever is correct that it may be important nutritionally to distinguish between these; however, if one of the goals of FDA defining carbohydrate claims is to create a consistent labeling scheme, allowing the exclusion of fiber and sugar alcohols from defined carbohydrate claims is not helpful, at least for the present time. Defining “free” and other claims allows FDA to provide consumers with a consistent scheme on which they can depend, whether they are trying to be conscientious about fats, sodium, carbohydrates, or some other nutrient. And it is important that this scheme refer back to the Nutrition Facts information, which currently centers on a “Total Carbohydrates” figure for carbohydrates.<sup>111</sup> Unilever has a valid concern that relying on total carbohydrates in

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<sup>108</sup>See Kraft Petition, *supra* note 13, at 6; Petition of GMA to FDA, Nutrient Descriptor Claims for the Carbohydrate Content of Food 11-12 (Feb. 2, 2004) (No. 2004P-0110) [hereinafter GMA Petition]; Letter from Lee Sanders, Vice President, Regulatory & Technical Services, and Paul C. Abenante, President & CEO, ABA, to Lester Crawford, Acting Commissioner, FDA and Robert E. Brackett, Director, CFSAN, FDA 2 (June 22, 2004) (No. 2004P-105) [hereinafter ABA Letter]. FDA’s regulation of Total Carbohydrates for purposes of the Nutrition Facts panel states that “if the serving contains less than 0.5 gram, the content may be expressed as zero.” Nutrition Labeling of Food, 21 C.F.R. § 101.9(c)(6) (2005).

<sup>109</sup>CSPI Petition, *supra* note 66, at 4-5.

<sup>110</sup>Unilever Petition, *supra* note 106, at 1.

<sup>111</sup>Unilever’s scheme would partially address this by providing a disclosure that a product is “[f]ree of carbohydrates that provide calories (which excludes fiber and some sugar alcohols).” *Id.* at 15.

the definitions of these claims may confuse consumers into reducing consumption of beneficial carbohydrates like fiber.<sup>112</sup> However, even greater confusion would be engendered by allowing claims on the front of a package that exclude fiber and sugar alcohols from the carbohydrate count and thus do not match up with the Nutrition Facts panel.<sup>113</sup> The Unilever concern would better be allayed in the short to medium term if food companies were to highlight the fiber content of fiber-rich foods and rely on a well-defined and clearly-labeled “net carbohydrate” claim, discussed below, which would stand apart from the standard claims like “free”, “reduced”, and “low” that apply consistently to various nutrients. Indeed, as Kretser noted, when GMA formulated its carbohydrate claim recommendations, the organization looked back to the methodology for fat claims at the time of the NLEA in order to maintain this consistency.<sup>114</sup> Using total carbohydrates as the reference point for defining nutrient content claims is the approach taken by all but one petitioner and should be FDA’s approach as well. While in the long-term it is possible that the Nutrition Facts panel should not reflect carbohydrates that do not impact blood sugar or contribute to calories, in the meantime consistency is necessary. This future possibility is discussed further in Part IV.B below.

There are two additional challenges involved with formulating a “carbohydrate free” definition, one that applies specifically to the “free” claim and one that also applies generally to all carbohydrate claims indicating some lower number of carbohydrates (i.e., “free”, “reduced”, and “low”). The “free”-specific problem is that 0.49 grams of carbohydrates per serving would qualify as “carbohydrate free” yet is technically not free of carbohydrates. In fact, if all of one’s daily servings of food included such products, one might consume a significant number of carbohydrates, despite a desire to strictly curtail one’s carbohydrate intake.<sup>115</sup> Though

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<sup>112</sup>See *id.* at 1-2.

<sup>113</sup>In its petition, Kraft addresses this issue by noting that “FDA may well decide to require that fiber and digestible carbohydrates be declared separately in nutrition labeling, which would clearly provide the necessary foundation for their disparate treatment in carbohydrate nutrient content claim criteria. In the meantime, however, it is imperative that FDA act to bring consistency to ‘low carbohydrate’ and other carbohydrate nutrient content claims in the marketplace.” Kraft Petition, *supra* note 13, at 12-13. CSPI affirms this view: “If the FDA determines that it is important for labels to distinguish between carbohydrates that are or are not absorbed, that information should appear on all Nutrition Facts panels, not just on foods that choose to make a carbohydrate claim.” CSPI Petition, *supra* note 66, at 8.

<sup>114</sup>Interview with Alison Kretser, *supra* note 30.

<sup>115</sup>*Cf.* Bob Meadows et al., *The Problem with Low-Fat Diets*, PEOPLE, Feb. 27, 2006, at 89 (noting the danger with foods

this is certainly a problem, in particular for foods with small serving sizes, the same issue comes up, for example, with “low sodium” foods that contain five milligrams of sodium. Furthermore, this problem actually already exists for carbohydrates, since the Nutrition Facts panel may list zero grams of Total Carbohydrates even when there are 0.49 grams. It is a problem that occurs only at the margins and those concerned about this issue can take some comfort in the fact that FDA has set “free” at a level it believes to be physiologically insignificant. Moreover, consumers focused on reducing carbohydrate consumption to extremely low levels (i.e., products with truly only 0.00 grams of carbohydrates) are likely also to refer to the product ingredients list, which would typically reveal a carbohydrate ingredient in a product with 0.49 grams of carbohydrates. The second concern is that labeling a product as “carbohydrate free” may lure consumers into a false sense of security that the product is healthy. Even though a product is free of carbohydrates does not mean it should be overconsumed (a double problem when a “carbohydrate free” product with 0.49 grams of carbohydrates is overconsumed) or is necessarily appropriate for weight control, since even with no carbohydrates, the product may very well be very high in calories or fat. This “Snackwell Syndrome”-type concern applies beyond “carbohydrate free” to all of the claims discussed herein that suggest the lower carbohydrate nature of the product. Thus, a key to providing consumers with balanced carbohydrate information, particularly in light of scientific uncertainty, is to mandate that when any such claim is made, there be a corresponding disclaimer. In its petition, CSPI suggests that “[t]o increase the likelihood that the public does not ignore or dismiss the calorie content of foods that make carbohydrate claims,” FDA should require a “not a low-calorie food” disclosure (assuming the food does not meet FDA’s criteria for the low-calorie claim), similar to the currently mandated disclosure for “no sugar added” claims.<sup>116</sup> CSPI hopes that “although the disclosure may not persuade all low-carbohydrate dieters that calories count, it will at least draw their attention to the

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labeled as “free” of trans fats that contain just under 0.5 grams of trans fats and commenting that “when people choose snack type foods that are easy to overconsume . . . this can lead to a sizable helping of trans fats”) (internal citations omitted).

<sup>116</sup>CSPI Petition, *supra* note 66, at 10.

calorie content of the food and may convince some to think twice before dismissing the food's calories.”<sup>117</sup> This solution allows food companies to make carbohydrate-related claims but ensures that such claims do not have the opportunity to mislead consumers.

## 2. The “Reduced” Claim

Like the claim that a product is “carbohydrate free,” defining a product as “reduced carbohydrate” should not be a major challenge for FDA or a cause for much consternation among food companies or consumer groups. The goal is to establish a meaningful percentage reduction in carbohydrates relative to a reference food. For calories, fat, sugar and other nutrients, FDA has authorized a “reduced” claim for a twenty-five percent reduction in the nutrient, determining that proportion to be nutritionally significant.<sup>118</sup> And as Kraft notes in its petition, “[t]he general principles relied upon in adopting existing definitions for ‘reduced’ and ‘less’ are equally applicable to carbohydrates.”<sup>119</sup> Reducing the carbohydrate content of a product by twenty-five percent from a reference food is not only meaningful for consumers trying to limit their carbohydrates, but also creates a consistent regime with other reduced claims on which consumers can rely. Thus, “reduced carbohydrate” should be defined as a twenty-five percent reduction in total carbohydrates.

The “reduced carbohydrate” claim is an integral part of the carbohydrate nutrient content claim regime. As opposed to “free” or “low” claims, this claim is most well suited to the creation of innovative product offerings that are not easily made to be extremely low in carbohydrates, but can more modestly have twenty-five percent removed without impacting palatability. A twenty-five percent reduction in carbohydrates via a diminished amount of sugar is a possibility for many products and thus such a claim has the potential to signal both to serious low-carbohydrate dieters as well as those interested in making more modest reductions in carbohydrates that a product has reduced carbohydrates. Kretser notes that no matter how an observer

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<sup>117</sup>*Id.*

<sup>118</sup>See Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2349 (Jan. 6, 1993) (to be codified at 21 C.F.R. pts. 5, 101) (setting a 25% reduction for “reduced” claims).

<sup>119</sup>Kraft Petition, *supra* note 13, at 13.

feels about low-carbohydrate dieting, one phenomenon the low-carbohydrate trend spurred is unassailable – companies innovated their products to make significant reductions in the sugar content.<sup>120</sup> And this kind of positive product innovation was precisely what FDA envisioned would result from its original reduced claim definitions: “The agency believes that the overall approach . . . will provide the best balance between encouraging manufacturers to produce foods with significant nutrient reductions by authorizing them to tell the public about the products’ attributes and protecting consumers from being misled by claims directing them to foods that are not meaningfully improved in nutrient content.”<sup>121</sup>

It should be noted that GMA believes further rulemaking is not even necessary in order for food companies to use a “reduced” claim with carbohydrates.<sup>122</sup> Indeed, 21 C.F.R. § 101.13, which provides “general principles” for nutrient content claims, permits a food to “bear a statement that compares the level of a nutrient in the food with the level of a nutrient in a reference food. These statements shall be known as ‘relative claims’ and include ‘light,’ ‘reduced,’ ‘less’ (or ‘fewer’), and ‘more’ claims.”<sup>123</sup> However, unlike for other nutrients, there is not a specific regulation, found in Subpart D of the regulations (“Specific Requirements for Nutrient Content Claims”) that applies to carbohydrates.<sup>124</sup> From this, some food companies conclude that “the absence of a regulation in Subpart D relating to carbohydrate . . . in no way limit[s] the applicability of Section 101.13(j) with respect to relative claims regarding carbohydrate content.”<sup>125</sup> As a result, GMA asks that FDA only “confirm” the application of section 101.13 to reduced carbohydrate claims and “expressly extend” the twenty-five percent reduction definition for other nutrients to carbohydrates.<sup>126</sup>

While GMA’s interpretation is plausible, FDA was quite explicit in its 1991 proposed regulations: “FDA

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<sup>120</sup>See Interview with Alison Kretser, *supra* note 30.

<sup>121</sup>Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. at 2348.

<sup>122</sup>See GMA Petition, *supra* note 108, at 29.

<sup>123</sup>Nutrient Content Claims – General Principles, 21 C.F.R. § 101.13(j) (2005).

<sup>124</sup>See, e.g., Nutrient Content Claims for the Sodium Content of Foods, 21 C.F.R. § 101.61(b)(6) (2005); Nutrient Content Claims for Fat, Fatty Acid, and Cholesterol Content of Foods, 21 C.F.R. § 101.62(b)(4) (2005).

<sup>125</sup>GMA Petition, *supra* note 108, at 29.

<sup>126</sup>*Id.* at 31.

is proposing to define ‘reduced’ for the following nutrients: total fat, saturated fat, cholesterol, sodium, and calories . . . . FDA tentatively concludes that reduced claims for nutrients other than these five are not appropriate because the reduction of other nutrients in the diet is not identified as being of public health importance.”<sup>127</sup> In addition, as GMA even concedes, FDA has challenged food companies who have used a reduced carbohydrate claim without such term being defined by regulation.<sup>128</sup> As a result, it appears that FDA regulations on the “reduced” claim belong on par with the other claims described herein as new rulemaking rather than simply confirming an existing rule. Ultimately, even if GMA is correct, including a twenty-five percent “reduced” claim – even in confirmatory language – will be a critical part of regulating carbohydrate nutrient content claims.

C.

#### The “Low Carbohydrate” Claim

While “free” and “reduced” can be defined by FDA comparably to other nutrients, given the absolute and relative meanings, respectively, of these claims, the “low carbohydrate” claim requires a different approach. FDA believes that the term “low” does not necessarily mean “that a nutrient is present in a food in an inconsequential amount, as with ‘free,’ but rather that the selection of a food bearing the term should assist consumers in assembling a prudent daily diet and in meeting overall dietary recommendations to limit the intake of certain nutrients.”<sup>129</sup> Thus, “low” claims should be based on dietary recommendations as they

<sup>127</sup>Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60421, 60447 (proposed Nov. 27, 1991) (to be codified at 21 C.F.R. pts. 5, 101, 105).

<sup>128</sup>*See, e.g.*, Warning Letter from Felicia B. Satchell, Director, Division of Food Labeling and Standards, CFSAN, FDA, to Mickey Miller, President, Flowers Baking Co. of Thomasville, Inc. (July 27, 2003), [http://www.fda.gov/foi/warning\\_letters/g4263d.htm](http://www.fda.gov/foi/warning_letters/g4263d.htm) (finding claims made by “Nature’s Own Reduced Carbohydrate Premium Wheat bread” to violate section 403(r)(1)(A) of the FDCA).

<sup>129</sup>Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2334 (Jan. 6, 1993) (to be codified at 21 C.F.R. pts. 5, 101).

apply to a given nutrient. Kraft notes in its petition that FDA’s approach to “low” claims has been to “tak[e] into account the unique circumstances surrounding each nutrient for which ‘low’ has been defined.”<sup>130</sup> As will be discussed below, the circumstances for carbohydrates are particularly “unique” and make coming up with a uniform “low” definition challenging, as reflected in the lack of consensus among the food industry petitioners. Indeed, divergent petitions were submitted by GMA and several food companies on the issue of the “low” definition. Kretser notes that GMA does not typically submit a petition without the consensus of its membership, but given the urgent need for regulation at the height of the low-carbohydrate trend, GMA submitted its unprecedented petition with just a majority.<sup>131</sup> Nestle was the most vociferous dissenter from GMA’s petition, noting in a letter commenting on the GMA and Kraft petitions that “[t]he agency should be aware of the struggles that industry faced in trying to recommend meaningful and responsible criteria” for carbohydrate-related definitions.<sup>132</sup> Ultimately, the dissent focused on the industry’s ambivalence over where on the spectrum the “low carbohydrate” claim should fall as between what Kretser calls “Atkins low carb”<sup>133</sup> – that is, a severe carbohydrate reduction – and a carbohydrate reduction consistent with current mainstream “dietary recommendations” that call for carbohydrates to be a very significant source of calories. Where numerically a given petition came out on the “low” definition reflected where it stood in this range. Moreover, Nestle explains that what “makes carbohydrate claims so confounding is that it would be the only nutrient for which there would be both high and low claims. The result is a potentially confusing message to consumers: [s]hould they consume less carbohydrate or more? Are carbohydrates good for us or bad for us?”<sup>134</sup> The disparity was also inevitably colored by a given company’s capacity to remove carbohydrates from its existing products and maintain their palatability. In the end, petitions called for “low” definitions

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<sup>130</sup>Kraft Petition, *supra* note 13, at 7.

<sup>131</sup>Interview with Alison Kretser, *supra* note 30.

<sup>132</sup>Letter from Kenneth Mercurio, Director, Regulatory and Nutrition, Nestle, to Laura Tarantino, CFSAN, FDA 1 (Apr. 23, 2004) (No. 2004P-0105) [hereinafter Nestle Letter].

<sup>133</sup>Interview with Alison Kretser, *supra* note 30.

<sup>134</sup>Nestle Letter, *supra* note 132.

ranging from six grams per serving to fifteen grams per serving.<sup>135</sup> It is critical to determine where FDA should come out on this divisive issue.

While each petition cites nutritional science to back-up its view on the definition of “low”, each merely manipulates existing dietary recommendations in order to bolster its position. Therefore, common sense may ultimately prove more helpful than delving deeply into the science. The ultimate goal of defining “low carbohydrate” is to choose a level low enough to be meaningful for those attempting to limit their carbohydrate intake, while ensuring that consumers get sufficient nutritional balance in their diets consistent with dietary recommendations. As a low-carbohydrate dieter myself, as a rule of thumb I would try not to consume any product that has more than five or six grams of carbohydrates per serving (assuming it had no sugar alcohol or fiber to subtract).<sup>136</sup> A number in the five to six gram range provides a reasonable signal for those seriously dedicated to limiting their carbohydrate intake, particularly since they will likely also look at “net” figures, either through a labeling claim or by subtracting fiber and sugar alcohols from the Nutrition Facts panel, and often end up at an even lower carbohydrate count.

But would such a number also satisfy those who want to remain conscious of carbohydrates but still heed general current dietary recommendations about carbohydrates? The Kraft and Unilever petitions demonstrate that six grams is consistent with dietary recommendations. “Low” claims have typically started with what FDA calls a “rough and simplistic ‘rule of thumb’” of the level of a nutrient that FDA has defined as nutritionally measurable, which is two percent of the daily reference value (“DRV”) for the nutrient.<sup>137</sup>

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<sup>135</sup>See CSPI Petition, *supra* note 66, at 4 (recommending a “low” claim of six grams); Kraft Petition, *supra* note 13, at 9 (six grams); Unilever Petition, *supra* note 106, at 16 (six grams, though excluding fiber and sugar alcohol); GMA Petition, *supra* note 108, at 12 (nine grams); Nestle Letter, *supra* note 132, at 2 (fifteen grams).

<sup>136</sup>Atkins suggests that at the lifetime maintenance phase of his diet, one could consume up to ninety or more grams of carbohydrates per day without gaining weight back. See ATKINS, NEW DIET REVOLUTION, *supra* note 3, at 209. Assuming a standard of sixteen to twenty servings of food per day, consuming only products with five to six grams of carbohydrates per serving would yield daily carbohydrate consumption in the range of 100 grams. Since for a low-carbohydrate dieter some of those servings would likely be even lower in counted carbohydrates (through fiber, sugar alcohol, etc.), such a rule of thumb for “low” products makes Atkins lifetime maintenance achievable.

<sup>137</sup>Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60421, 60440

Assuming sixteen to twenty servings of food per day, a person would thus be consuming in the range of thirty to forty percent of the DRV for the nutrient. FDA has typically made adjustments to the percentage based on the ubiquity of the nutrient in the food supply, to ensure that consumers can select a variety of foods, including some that are “low” in the nutrient and some that are higher but still meet dietary recommendations.<sup>138</sup> Both Kraft and Unilever maintain that carbohydrates are ubiquitous in the food supply based on an evaluation of the categories into which USDA has divided foods.<sup>139</sup> Moreover, Kraft confirms this ubiquity by noting that for the median person, carbohydrate intake represents half of energy intake, with fat representing approximately one-third and proteins the remaining fifteen percent.<sup>140</sup> From this, Kraft concludes that “a large proportion of energy is obtained from carbohydrate-containing foods,” indicating carbohydrates’ ubiquity.<sup>141</sup> Thus, a calculation of two percent of the DRV seems appropriate, and given the DRV for carbohydrates of approximately 275 grams, the calculation yields a “low” value of 5.5 grams per serving, which we can appropriately round up to six grams per serving.<sup>142</sup> Such a definition for “low carbohydrate” would achieve a meaningful reduction in carbohydrates for consumers restricting carbohydrates, but would not diminish carbohydrate intake so starkly as to be far below the RDA for carbohydrates – a minimum target of digestible carbohydrates for the body’s energy needs – set by the IOM’s macronutrient report at 130 grams per day.<sup>143</sup> Not only would a consumer eat in the range of 96 grams to 120 grams of carbohydrates per day if only consuming low-carbohydrate defined products,<sup>144</sup> but as Kraft notes “it

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(proposed Nov. 27, 1991) (to be codified at 21 C.F.R. pts. 5, 101, 105).

<sup>138</sup> *Id.*

<sup>139</sup> *See, e.g.,* Unilever Petition, *supra* note 106, at 16 (“[O]f 23 food categories identified in the USDA’s Nutrient Database for Standard Reference, carbohydrates can reasonably be expected to be found in significant quantities in approximately 17 categories.”).

<sup>140</sup> Kraft Petition, *supra* note 13, at 9.

<sup>141</sup> *Id.*

<sup>142</sup> The figure of 275 grams for the DRV is derived by using the midpoint of IOM’s AMDR of forty-five to sixty-five percent of daily calories coming from carbohydrates (fifty-five percent) and calculating the DRV based on a 2,000 calorie diet (fifty-five percent of 2,000 calories is 1,100 calories; at four calories per gram of carbohydrates, the DRV is 275 grams). *See* Unilever Petition, *supra* note 106, at 10.

<sup>143</sup> *See* Kraft Petition, *supra* note 13, at 2, 10.

<sup>144</sup> Note that this number falls to seventy-one to ninety-five grams of carbohydrates assuming twenty-five grams of these daily carbohydrates come from dietary fiber, which does not count toward the energy need.

is unlikely that a person would consume only ‘low’ carbohydrate foods on a sustained basis” and “[i]n the unusual instances in which the RDA would not be met, alternative sources of glucose for the brain are available from dietary protein and fat.”<sup>145</sup> Thus, a definition of “low carbohydrate” at six grams per serving should be adopted by FDA.<sup>146</sup>

How, then, do GMA and Nestle’s petitions end up at higher figures for defining low carbohydrate? GMA’s analysis starts with the proposition that carbohydrates are not ubiquitous in the food supply and thus a higher percentage of the DRV is necessary to calculate the “low” definition; the petition finds carbohydrates in only fifteen of twenty-three categories, rather than the seventeen of twenty-three found by Unilever.<sup>147</sup> Yet, Kraft’s analysis is particularly compelling – for the purposes of confirming carbohydrates’ ubiquity in the food supply, Kraft collapses all six meat/protein categories, assuming they are “interchangeable” when accounting for “realistic eating patterns” (the list, after all, does come from USDA, which has regulatory oversight over those categories of foods), thus putting carbohydrates in thirteen of seventeen categories.<sup>148</sup>

Even if Kraft is as guilty of conveniently bending the numbers as any other petition, ultimately common sense dictates that carbohydrates are a very common nutrient in the food supply and realistically consumers

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<sup>145</sup>Kraft Petition, *supra* note 13, at 11. It is indeed these alternative energy sources that Atkins adherents rely upon in strictly limiting carbohydrate intake.

<sup>146</sup>This six-gram limit should apply not only to products that explicitly state they are low in carbohydrates, but also those that use “low carbohydrate lifestyle” and similar marketing terms. Products, such as those noted in Part II.A, that suggest they are for a “low carbohydrate lifestyle” are no different than those explicitly declaring the product “low carbohydrate.” See CSPI Petition, *supra* note 66, at 5. Unilever claims such a term might not be considered a nutrient content claim because it merely identifies that the product is “for special dietary use,” that is, as part of a low-carbohydrate diet. See Implied Nutrient Content Claims and Related Label Statements, 21 C.F.R. § 101.65(b)(6) (2005); Unilever Petition, *supra* note 106, at 22. However, noting that a product accords with a “low carbohydrate lifestyle” falls moreso into the category of implying the product is “low carbohydrate” – an *implicit* nutrient content claim governed by the nutrient content claims rules – rather than being a “special dietary use” claim. FDA thus should reconsider its current position that “there may be ways for a product to bear a low carbohydrate lifestyle claim . . . without the claim being considered a nutrient content claim.” Unilever Petition, *supra* note 106, at 24 (quoting FDA letter to Florida Department of Agriculture, July 18, 2002). On the other hand, while not an ideal distinction to draw, under currently codified law a product that bears the Atkins or South Beach seal of approval might have to be designated a food for “special dietary use”, exempt from the nutrient content claims definition. For FDA guidance on diet brands, see Food Labeling: Label Statements on Foods for Special Dietary Use, 58 Fed. Reg. 2427, 2429 cmt. 3 (Jan. 6, 1993) (to be codified at 21 C.F.R. pt. 105) (permitting use of “Weight Watchers” name on products when it appears without any other suggestion of nutrient levels). The applicability of the “low carbohydrate” definition to product names such as “Carb Clever” will be discussed in Part III.E below.

<sup>147</sup>See GMA Petition, *supra* note 108, at 15.

<sup>148</sup>See Kraft Petition, *supra* note 13, at 9.

will have more trouble staying away from them on a low-carbohydrate diet than finding them in food companies' offerings.

Moreover, both GMA and Nestle claim that setting "low" at six grams is "inconsistent with FDA's commitment to promoting a healthful diet" because this definition does not comport with the minimum dietary recommendations for carbohydrate consumption.<sup>149</sup> As stated above, it should not concern food companies that a six gram definition does not ensure carbohydrate intake consistent with dietary recommendations; it is unlikely consumers will consume a diet entirely of low-carbohydrate products, and even if they do (such as Atkins dieters might), the body has alternative energy sources available coming from the calories substituted for carbohydrate calories. Indeed, the Dietary Guidelines Advisory Committee, in its 2005 report, notes that these other energy sources will be tapped if the body lacks carbohydrates, and suggests that the IOM's AMDR recommendation that forty-five to sixty-five percent of daily calories come from carbohydrates – part of the recommendations that GMA and Nestle embrace as critical – may be flawed.<sup>150</sup> The report indicates that "at the high end of the [AMDR] range overconsumption of carbohydrates may result in high blood triglyceride values" and that the "primary beneficial physiological effect of sugars and starches . . . is the contribution of glucose as an energy source for the brain. However, the amount of glucose needed by the brain is lower than" IOM's forty-five to sixty-five percent figure.<sup>151</sup> Ultimately, a six-gram definition allows the significant reduction in carbohydrates (as much as a two-thirds reduction from the DRV) that consumers demand while still inviting a reasonably healthy balance of nutrients to be eaten by the average consumer. Nestle raises two additional avenues for challenging a lower definition for "low carbohydrate". First, the company's letter worries that by providing a definition for "low carbohydrate" but also "good source" and "excellent source" claims for carbohydrates, consumers will receive a mixed message about whether carbo-

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<sup>149</sup>GMA Petition, *supra* note 108, at 19.

<sup>150</sup>See Dietary Guidelines Advisory Committee, Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2005 pt. D § 5 (Aug. 19, 2004), [http://www.health.gov/dietaryguidelines/dga2005/report/HTML/D5\\_Carbs.htm](http://www.health.gov/dietaryguidelines/dga2005/report/HTML/D5_Carbs.htm).

<sup>151</sup>*Id.*

hydrates are good or bad.<sup>152</sup> As a result, Nestle pegs its “low” figure at fifteen grams, believing this will keep consumers away from what it believes are diets unhealthily low in carbohydrates. Nestle is making a *judgment* about low-carbohydrate diets and seems to be using the fifteen gram figure somewhat disingenuously. Realistically, there are consumers who want to follow a low-carbohydrate regime, and if they are told a product is “low carbohydrate” yet it has fifteen grams of carbohydrates per serving, that would be a statement fairly characterized as misleading. Because Nestle focuses its business on high carbohydrate foods and embraces high “good source” and “excellent source” claim definitions does not mean that consumers’ abilities to choose low carbohydrate-designated products should be limited by FDA. The way to appropriately reduce consumer confusion over the dual nature of carbohydrate claims is to set the “low” figure sufficiently low such that a clear-cut spectrum from low to high carbohydrate products is created and consumers can clearly differentiate. The mixed message of carbohydrates is a fact of life in a niche-marketed industry and scientific knowledge is mixed on what nutrients should be reduced or increased for weight control and health; FDA’s goal should thus be to help consumers make well-informed decisions in light of this uncertainty. Nestle’s perspective only engenders further confusion.

Nestle’s second tack, revealing even further that its products do not stack up under a lower definition of “low”, is to suggest that a fifteen gram definition “more realistically allows for product innovation to meet this claim.”<sup>153</sup> Nestle’s true colors come out with this statement. Yet, it does not seem to be the purpose of a “low” claim to make sure that every possible food item is available in a low-carbohydrate version; instead, “low” should be reserved for foods that are *meaningfully* low in carbohydrates. As stated above, in Part III.B.2, the “reduced” claim is more appropriate for Nestle to achieve its goals. Fifteen grams of carbohydrates is not “low”; in fact, sixteen to twenty servings of such “low carbohydrate” food per day would put a consumer at 240 to 300 grams per day, which is the full DRV for carbohydrates. If Nestle wants to make

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<sup>152</sup> See Nestle Letter, *supra* note 132, at 1.

<sup>153</sup> *Id.* at 2.

products with fifteen grams of carbohydrates, and that reduction is a major innovation for a given product (i.e., constitutes a 25% reduction), the company can put a “reduced” claim on the label. Some products will never be “low carbohydrate” and FDA should not simply adjust the definition of “low” upward to meet the products Nestle envisions (such as breads and candy<sup>154</sup>) as making some reduction in carbohydrates. Just as butter may never be low in fat, a traditional New York bagel may never be low in carbohydrates. To say otherwise is to mislead consumers. A six-gram limit on the “low” definition more appropriately provides consumers with a claim that helps them to reduce carbohydrate intake while not foregoing the nutritional requirements that carbohydrates provide.

D.

#### Net Carbohydrates

Not only must FDA act to provide definitions for “free”, “reduced”, and “low” nutrient content claims for carbohydrates, but the agency must address the many “net” carbohydrate claims that currently exist in the marketplace. While the three defined terms discussed above help to provide a consistent basis for comparing the carbohydrate levels of foods as well as other nutrients with defined “free”, “reduced”, and “low” claims, rules – or at least guidance for the industry<sup>155</sup> – are also necessary for establishing a consistent basis of comparison for “net” claims. Indeed, the agency stated in its March, 12 2004 *Fact Sheet* that it plans to “provide guidance to food manufacturers on the use of the term ‘net’ in relation to the carbohydrate content of

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<sup>154</sup>*Id.*

<sup>155</sup>It is possible that there are First Amendment limits on FDA’s ability to set broad mandates for “net carbohydrates” and for other carbohydrate-related labeling that is neither false nor misleading and falls outside of the defined nutrient content claims. *See Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 564 (1980) (holding that if commercial speech “is neither misleading nor related to unlawful activity, the government’s power is more circumscribed. The State must assert a substantial interest to be achieved by restrictions on commercial speech. Moreover, the regulatory technique must be in proportion to that interest.”). Unilever’s petition emphasizes this point, noting that FDA regulation of carbohydrate labeling generally “must not be so extensive as to ban truthful and non-misleading claims about carbohydrates that may assist consumers in building a healthful diet.” Unilever Petition, *supra* note 106, at 25.

food.”<sup>156</sup> As stated in Part III.B.1, it is preferable not to take the Unilever approach to carbohydrate labeling and base the carbohydrate nutrient content claims themselves on a net-type figure. At least for the time being, until FDA can think further about the representation of digestible and non-digestible carbohydrates on the Nutrition Facts panel, it is important that the carbohydrate nutrient content claims match up with the Nutrition Facts and thus also with the content claims made for other nutrients.<sup>157</sup> At the same time, net carbohydrate labeling signals to consumers focused on reducing their intake of carbohydrates that products not only are low in carbohydrates, but that a consumer may reasonably subtract additional carbohydrates such as fiber and sugar alcohols, if that is the focus of their diet regime. Thus, net carbohydrate information should stand on its own, apart from the FDA defined terms; the key is to ensure that products utilize the “net” distinction consistently and in a way that will not be misleading for consumers.

There are two problems, noted above, with current net carbohydrate claims, based on my observations at Shaw’s. First, different products calculate the net term differently. FDA has previously indicated that as long as the definition is clearly explained and the explanation is not false or misleading, the agency will not object.<sup>158</sup> This is an appropriate approach; however, it is incumbent upon FDA to provide further guidance because the inconsistency of the definitions currently in use makes some of them, in effect, false and misleading. Indeed, Unilever identifies three different versions of net carbohydrate claims currently in use in the marketplace: (1) “[c]arbohydrates that provide significant levels of calories;” (2) “[c]arbohydrates that are readily digestible;” and, (3) “[c]arbohydrates that have significant effects on blood sugar levels.”<sup>159</sup> Unilever suggests that FDA adopt a definition of net carbohydrates that focuses on those carbohydrates that provide significant calories because, for consumers focused on net carbohydrates and presumably weight control,

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<sup>156</sup>FDA Fact Sheet, *supra* note 93.

<sup>157</sup>See Kraft Petition, *supra* note 13, at 12-13.

<sup>158</sup>See FDA Letter to NCL, *supra* note 55.

<sup>159</sup>Letter from Nancy L. Schnell, Deputy General Counsel – Marketing and Regulatory, Unilever, to Office of Nutritional Products, Labeling and Dietary Supplements, CFSAN, FDA 2 (June 29, 2004) (No. 2004P-0298).

“the most relevant definition – and the one that has the broadest scientific support – is that which refers to caloric levels.”<sup>160</sup> Such a focus would be prudent, particularly in light of the uncertainty surrounding nutritional approaches focused on maintaining low blood sugar. Scientific data shows that the glycemic index and the blood sugar response to carbohydrates is of uncertain usefulness for nutritional purposes<sup>161</sup> and as Kretser notes, reliance on blood sugar information is unreliable since consumers typically eat foods in combination.<sup>162</sup> Thus, FDA guidance should establish as a definition that is not false or misleading one that focuses on carbohydrates providing calories, thereby excluding dietary fiber and the non-caloric portion of sugar alcohols.

FDA guidance on net carbohydrates should also suggest that such calculations be clearly explained on food labels. An explanation will help consumers to match up net carbohydrate claims to the Nutrition Facts panel and may help consumers avoid cutting down on fiber and its attendant benefits as part of an uninformed reduction in carbohydrate intake. Such an explanation is also critical because the inclusion of sugar alcohols on the Nutrition Facts panel is voluntary for food companies;<sup>163</sup> explaining in a footnote that net carbohydrates equals X grams of total carbohydrates minus Y grams of dietary fiber and Z grams of sugar alcohols may be the only place on the label a consumer can note the Z grams of sugar alcohols. Such an explanation allows consumers to get a full picture of carbohydrate content, including sugar alcohols.

There is a second challenge posed by current net carbohydrate labeling practices, however. As some food companies have struggled with the most precise definitions for net carbohydrates, they have moved, in the

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

<sup>161</sup>*See, e.g.,* Dietary Guidelines Advisory Committee, *supra* note 150 (noting that “[c]urrent evidence suggests that the glycemic index and/or glycemic load are of little utility for providing dietary guidance for Americans” and that “[c]urrent evidence suggests that there is no relationship between total carbohydrate intake (minus fiber) and the incidence of either type 1 or type 2 diabetes”).

<sup>162</sup>Interview with Alison Kretser, *supra* note 30.

<sup>163</sup>*See* Nutrition Labeling of Food, 21 C.F.R. § 101.9(c)(6)(iii) (2005) (noting that “[a] statement of the number of grams of sugar alcohols in a serving may be declared voluntarily on the label, except that when a claim is made on the label or in labeling about sugar alcohol or sugars when sugar alcohols are present in the food, sugar alcohol content shall be declared”). Incidentally, it is interesting to consider that a net carbohydrate claim may actually invoke the requirement in the “except” clause of the regulation since a net carbohydrate claim, in effect, makes a labeling claim about sugar alcohols.

name of accuracy, to net carbohydrate labeling on the basis of independent clinical testing.<sup>164</sup> This effort appropriately recognizes that it may be misleading to suggest that the carbohydrates excluded from a traditional net number (i.e., sugar alcohols and dietary fiber) do not contribute any calories or impact blood sugar at all; however, the substitution of a black-box methodology that consumers cannot reconcile to the Nutrition Facts panel or any explanatory disclosure is equally unhelpful. As noted above in Part II.B, Atkins Nutritionals' old label for its Morning Start breakfast bars had a net carbohydrate figure and explained its calculation whereas the current product's "Net Atkins Count" figure does not match up to any number or explanation on the label. Unilever chides Atkins for its "effort to define and regulate its own, proprietary nutrient definition using a black-box scientific methodology[, which] undermines FDA's use of consistent nutrient definitions on which food labeling claims are based."<sup>165</sup> Unilever suggests that "the proprietary nature of the Atkins claim causes it to be *inherently* misleading because it cannot be made non-misleading by a disclaimer or other qualifying language."<sup>166</sup> FDA guidance on net carbohydrate claims should make clear that black-box claims, such as those made by Atkins and Dreamfields, are misleading to consumers and need to accord with a definition of net carbohydrates based on caloric contribution as well as provide a proper calculation. Until further scientific understanding of the glycemic index and the impact of carbohydrates on blood sugar emerges, this is the approach FDA should adopt.

E.

#### Implied Low-Carbohydrate Claims

FDA rules for carbohydrate nutrient content claims must emphasize that the definitions apply equally to

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<sup>164</sup> See *infra* Appendix B (stating that "Atkins has developed a breakthrough method to directly measure the low-glycemic impact of Atkins products and confirm the accuracy of Atkins net carb labeling claims").

<sup>165</sup> Unilever Letter to Michael M. Landa, *supra* note 60.

<sup>166</sup> *Id.* (emphasis in original).

*implied* nutrient content claims. As observations at the supermarket indicate, many food companies are using names like “Carb Options” and “Carb Clever” for their products in order to carefully avoid FDA-defined terms such as “low carbohydrate”. The use of such names violates both the spirit and the letter of FDA regulations on nutrient content claims. As CSPI notes, implied claims “are no different than claims such as ‘Low Carbohydrate.’”<sup>167</sup> And, these claims appear to fall within the definition of an implied nutrient content claim in 21 C.F.R. § 101.65(c)(1), which states that “[c]laims about the food or an ingredient therein that suggest that a nutrient or an ingredient is absent or present in a certain amount . . . are implied nutrient content claims.”<sup>168</sup> Suggesting that a version of Skippy peanut butter is a “Carb Options” variety unequivocally implies that carbohydrates are “absent or present in a certain amount,” particularly where the label also provides a prominent net carbohydrate count.<sup>169</sup> Since such product names are implied nutrient content claims, FDA nutrient content claim regulations must apply to them as well.

Such names do not escape via the “special dietary use” exemption of 21 C.F.R. § 101.65(b)(6), as Unilever’s petition might suggest (notably, “Carb Options” peanut butter is a Unilever product).<sup>170</sup> The names “Carb Options” and “Carb Clever” cannot reasonably be considered a suggestion that the peanut butter or pears are suitable to help achieve the weight loss benefits of a low carbohydrate diet, but that the peanut butter and pears are *themselves* low in carbohydrates. To propose otherwise is to defeat the purpose of FDA’s defined nutrient content claims. And, at the least, some existing products even violate the “special dietary use” exemption, which requires that the claim identify “the special diet of which the food is intended to be a part.”<sup>171</sup> While “Carb Options” Skippy does note “For Use as Part of a Low Carb Diet!”<sup>172</sup>, Carb

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<sup>167</sup> CSPI Petition, *supra* note 66, at 5.

<sup>168</sup> Implied Nutrient Content Claims and Related Label Statements, 21 C.F.R. § 101.65(c)(1) (2005).

<sup>169</sup> *See infra* Appendix D.

<sup>170</sup> *See* Unilever Petition, *supra* note 106, at 22.

<sup>171</sup> 21 C.F.R. § 101.65(b)(6).

<sup>172</sup> *See infra* Appendix D.

Clever pears make no such notation.<sup>173</sup> While this requirement would be the bare minimum, FDA should go one step further and declare that such implied claims must meet the requirements of its definition for “low carbohydrate”.

F.

#### “Excellent Source” and “Good Source” Claims

One major underlying challenge of defining nutrient content claims as they relate to the reduction of carbohydrates in foods is that there is another side to the coin – carbohydrates are central to human nutrition as a primary source of energy.<sup>174</sup> As a result, while some consumers limit carbohydrates in order to achieve weight loss, others are interested in increasing consumption of carbohydrates in order to enhance their energy levels. Thus, consumers generally would also benefit from the information provided by defined FDA terms for “excellent source of carbohydrates” and “good source of carbohydrates.” Indeed, many of the carbohydrate-related petitions submitted request FDA definitions for “excellent source” and “good source” claims.<sup>175</sup> However, there are two hurdles in arriving at effective definitions for “excellent source” and “good source”. First, FDA’s methodology for establishing “excellent source” and “good source” claims for other nutrients will not work with carbohydrates, since the methodology would put “excellent source” at sixty grams of carbohydrates per serving.<sup>176</sup> Such a figure would make the use of “excellent source” illusory, since virtually no foods have sixty grams of carbohydrates per serving (or even have a sixty gram serving size), not even products like PowerBar, which Nestle points out “has always been regarded by athletes as a ‘high

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<sup>173</sup> See *infra* Appendix C.

<sup>174</sup> See Dietary Guidelines Advisory Committee, *supra* note 150.

<sup>175</sup> See, e.g., GMA Petition, *supra* note 108, at 24-28 (requesting “excellent source” and “good source” definitions).

<sup>176</sup> The methodology states that an “excellent source” claim can be made when the product “contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed.” Nutrient Content Claims for “Good Source,” “High,” “More,” and “High Potency,” 21 C.F.R. § 101.54(b)(1) (2005). At a 300 gram DRV for carbohydrates, twenty percent would put “excellent source” claims at sixty grams of carbohydrates per serving.

carbohydrate' food.”<sup>177</sup> Second and most notably, carbohydrates would be the first nutrient to have both high and low claims, a situation that might confuse consumers. Thus, “excellent source” and “good source” definitions need to be clearly distinguished from “low” and “reduced”.

What definitions for “excellent source” and “good source” make sense, given that it would be implausible to use an “excellent source” claim of sixty grams? For other nutrients, FDA has set “excellent source” at a level that “will permit a sufficient number of food items to bear a ‘high’ claim to allow consumers to use the claim in selecting a varied diet . . . and can readily be used by consumers to implement current dietary guidelines.”<sup>178</sup> Thus, for other nutrients “excellent source” was set at twenty percent of the DRV, in 21 C.F.R. § 101.54(b)(1).<sup>179</sup> However, the first criteria, that “sufficient” foods would be eligible for the claim, would not be met at sixty grams for carbohydrates. Even taking a low point of the DRV, based on the forty-five percent AMDR, yields a DRV of 225 grams, and a twenty percent “excellent” definition of forty-five grams. This figure is also unrealistically high. Thus, the value of consistency with other claims may have to be sacrificed in order to provide a definition that will allow consumers to have a reasonable variety of foods to choose from with “excellent source” claims. GMA, as well as Kraft, recommends cutting the factor in half, and using a figure of ten percent of the DRV for “excellent source” and five percent for “good source.”<sup>180</sup> This approach would set “excellent source” at thirty grams of carbohydrates per serving and “good source” at fifteen grams. While these figures are somewhat arbitrary, they are the most realistic way of ensuring that high claims for carbohydrates are provided on a reasonable variety of products. Moreover, such an approach accords with FDA’s second criteria, that the claim can be readily used to “implement current dietary guidelines.” In

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<sup>177</sup>Nestle Letter, *supra* note 132, at 4.

<sup>178</sup>Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2344 (Jan. 6, 1993) (to be codified at 21 C.F.R. pts. 5, 101).

<sup>179</sup>*See* 21 C.F.R. § 101.54.

<sup>180</sup>*See* GMA Petition, *supra* note 108, at 25-26.

fact, since the fundamental goal of high carbohydrate claims would be to identify foods with carbohydrates available as an energy source (e.g., for athletic competition), the most important dietary recommendation to focus on would be the 130 gram RDA, which sets an energy baseline for carbohydrates. And, in fact, thirty grams for “excellent source” and fifteen grams for “good source” approximate twenty percent and ten percent respectively of the 130-gram figure. Thus, some consistency with the approach for other nutrients is being maintained, though the twenty percent is being calculated on the RDA rather than the DRV. Kraft notes this correlation to the RDA figure in its petition.<sup>181</sup>

However, the thirty gram and fifteen gram criteria should be tied to an additional safeguard within the definition of “excellent source” and “good source” in order to ensure that foods meeting the high claims are not doing so merely by packing in added sugar. Indeed, part of the focus of high claims is to help consumers to meet “current dietary guidelines,” which include suggested limits on daily sugar intake.<sup>182</sup> Unilever concludes that “[i]t is appropriate for FDA to authorize the use of ‘good source’ and ‘excellent source’ claims for carbohydrates on the labeling of foods in which total carbohydrates . . . exclude significant levels of sugar.”<sup>183</sup> Offering consumers carbohydrate-loaded products with high levels of sugar is irresponsible. Thus, consistent with both the Unilever and Kraft petitions, FDA should limit the “excellent source” and “good source” claims to products from which no more than twenty-five percent of calories come from sugar.<sup>184</sup>

The second hurdle is to ensure that the “excellent source” and “good source” definitions do not send an irreconcilable message to consumers, in light of the “low carbohydrate” nutrient content claims also being proposed. First, as Nestle reasonably points out, “[w]e must accept that there will be examples of

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<sup>181</sup>See Kraft Petition, *supra* note 13, at 15.

<sup>182</sup>See Unilever Petition, *supra* note 106, at 20.

<sup>183</sup>*Id.*

<sup>184</sup>See *id.* (noting IOM’s recommendation that maximum intake from added sugar be limited to twenty-five percent of calories). Kraft takes a similar approach, though converts the twenty-five percent guidance into a limitation of six grams per serving of sugar. See Kraft Petition, *supra* note 13, at 16. On the other hand, Nestle would instead require only a disclosure of the sugar content because it believes “[a] sugars maximum does not necessarily make sense because sports nutrition products . . . rely on both complex carbohydrates and sugars to provide the energy delivery needed for athletes during performance.” Nestle Letter, *supra* note 132, at 6. Ultimately, though, since the opportunity has arisen to define the claim, FDA should do so in a way that takes into account nutritional recommendations on sugar intake, rather than relying on mere disclosure.

...dichotomies when dealing with carbohydrate claims.”<sup>185</sup> For example, there may be times when a product that qualifies for a “reduced carbohydrate” claim also qualifies as a “good source” of carbohydrates. However, this dilemma is unlikely to be as “confounding” as Nestle worries it could be since food companies are unlikely to consciously send any such mixed messages on any one single product – they are likely to choose to highlight a lower carbohydrate level or a higher one. Indeed it actually seems as if food companies generally prioritize low carbohydrate claims relative to high carbohydrate ones. In a letter agreeing to an extension for FDA to reply to its petition, Kraft notes that “[t]o help ensure that the agency’s resources are focused on the most important regulations, we are prepared to withdraw the part of our petition that seeks a rule governing ‘good source’ and ‘excellent source’ of carbohydrate claims, should it prove unrealistic to deal with the issues those claims present on the same schedule. Our key goal is to expedite the time when industry will be able to use the FDA defined [low carbohydrate] nutrient content claims . . . , as those are the claims in which consumers are most interested at this time.”<sup>186</sup>

And in the cases that these dichotomies become real problems, such as when low carbohydrate PowerBars are marketed side-by-side with high carbohydrate PowerBars, both with nutrient content claims, the solution will be to have a sufficiently large gap in required carbohydrate content in order to create a clear spectrum. Thus, if “good source” is going to be defined at fifteen grams, it would be inexplicable also to define “low carbohydrate” at fifteen grams as Nestle does, or even nine grams as GMA does; the need for a broader continuum thus reaffirms the appropriateness of a six gram “low carbohydrate” claim.<sup>187</sup> Such a gap will ensure that any consumer confusion over the conflicting claims is effectively mitigated.

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<sup>185</sup>Nestle Letter, *supra* note 132, at 6.

<sup>186</sup>Letter from Sheryl A. Marcouiller, Senior Food Law Counsel, Kraft, to Robert E. Brackett, Director, CFSAN, FDA 1 (July 26, 2004) (No. 2004P-0105).

<sup>187</sup>Though, admittedly, if “good source” were placed at twenty grams as the ABA suggests or 22.5 grams as Unilever suggests, a nine-gram “low carbohydrate” figure would not seem unreasonable in comparison. *See* ABA Letter, *supra* note 108, at 3; Unilever Petition, *supra* note 106, at 20. However, for the reasons stated above, and based on the general principle that the low claim is centered around weight control while the high claim is meant to encourage consumption, it is preferable to keep the low claim as low as possible but set the high claim at a low enough level that a reasonable number of foods will qualify. In addition, setting “good source” at twenty grams leads to setting “high source” at forty grams, which might be an unrealistically high level. Thus, a six-gram figure for “low” and a fifteen-gram figure for “good source” are appropriate.

G.

### Lessons from Other Regulatory Regimes

Unlike FDA, at least three other regulators – FSIS, TTF, and Canadian food regulators – have provided the food industry with rules for making carbohydrate nutrient content claims. Consideration of these existing rules will help us both to shed light on the rules FDA should enact and to raise the possibility that inconsistent regulatory regimes may coexist if FDA takes a different approach than other US regulators. And as will be discussed below in Part IV.A, the more responsive experience of these other regulators during the low-carbohydrate era can provide lessons for FDA in dealing with future trends in nutrition that are fast-moving and appear to be driven by fads.

#### 1. Other US Regulators

During the time period in late 2003 and early 2004 during which food companies were submitting the nutrient content claim petitions described above, both of FDA’s sister agencies, FSIS and TTF, were providing more definitive rules to companies they regulate, whom had been simultaneously clamoring for guidance on how to label low-carbohydrate foods. Though FSIS’s rules ultimately did not do more than FDA effectively allows at this point (e.g., prohibiting explicit “low” claims but allowing “net” claims), its *Statement of Interim Policy on Carbohydrate Labeling Statements* proactively provided food companies with a comprehensive directive on what was permissible and what was not.<sup>188</sup> TTF went further in its interim standards for the labeling of alcohol beverages with the terms “low carbohydrate”, “reduced carbohydrate”, and “net carbohydrate”,

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<sup>188</sup> See FSIS, *supra* note 31.

set in a ruling on April 7, 2004.<sup>189</sup> TTB's rules acknowledge that the agency has previously permitted, on a case-by-case basis, "low carbohydrate" claims on products ranging from three grams of carbohydrates per serving for some very low-carbohydrate beers to as high as fifteen grams per serving for a flavored malt beverage that had reduced the carbohydrate content versus its regular version of the product.<sup>190</sup> Realizing that such variation may mislead consumers, TTB's ruling distinguishes low-carbohydrate products from reduced-carbohydrate products, setting "low carbohydrate" at less than seven grams of carbohydrates per serving and allowing "reduced carbohydrate" for "[p]roducts that contain more than 7 grams of carbohydrates per serving, but that are lower in carbohydrates than the regular version of the comparable product."<sup>191</sup> TTB also decided to prohibit the use of the term "net carbohydrates" because it believes that "[w]ithout a scientific consensus as to the validity of these purported distinctions among carbohydrates . . . the use of these terms in the labeling or advertising of alcohol beverages would only tend to mislead consumers."<sup>192</sup>

The TTB position differs in several respects from the proposed nutrient content claims described above in Part III.B to III.F. First, the six grams of carbohydrates per serving recommended in Part III.C above for "low carbohydrate" claims is slightly lower than TTB's seven gram rule. While this is a distinction, TTB's logic in choosing seven grams is comparable to the rationale for the six gram figure recommended above for FDA rulemaking – a focus on "adopting a conservative standard for 'low carbohydrate,' to reduce the potential for consumer deception."<sup>193</sup> Moreover, in moving to final rulemaking on the topic, TTB is amenable to integrating "the benefit of FDA's decisionmaking process" on carbohydrate nutrient content claims, and acknowledges that its final figure "could be higher or lower after [its own] rulemaking."<sup>194</sup> Thus,

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<sup>189</sup> See TTB, *supra* note 31, at 8-9.

<sup>190</sup> See *id.* at 8.

<sup>191</sup> *Id.* at 9.

<sup>192</sup> *Id.*

<sup>193</sup> *Id.*

<sup>194</sup> *Id.* at 8-9.

the distinction between six grams and seven grams is easily reconcilable.

In addition, TTB takes a more general approach to “reduced carbohydrate” claims, rather than adopting a specific standard such as the twenty-five percent definition recommended in Part III.B.2 above. Setting a fixed percentage reduction is a more consistent approach and the one FDA should take. However, TTB’s logic in establishing the “reduced” claim reinforces the argument above that FDA-defined “reduced” claims are more appropriate for relatively high carbohydrate products that have made some respectable, but not large in absolute terms, reduction in carbohydrates, rather than bringing the definition for the “low” claim up into the teens to include these products. It is revealing that the fifteen grams Nestle recommends for “low carbohydrate” is the same definition TTB had previously approved for a malt liquor product, but now finds out of sync with providing a consistent, conservative rule for “low carbohydrate”.

The greatest divergence, however, between the various FDA proposals and TTB’s rules is that TTB bans all net carbohydrate claims, in light of scientific uncertainty. TTB notes that terms like “net carbohydrates” “are meant to refer to the carbohydrates that have a demonstrated effect on blood sugar levels; however, there is some controversy as to the validity of these concepts.”<sup>195</sup> While the uncertainty of relying on the impact of foods on blood sugar has also been noted in discussion of potential proposals for FDA to adopt, the “net carbohydrate” proposal that is recommended above would base the definition of “net carbohydrates” on the caloric contribution of various carbohydrates, which has a more sound scientific basis presently, rather than on their impact on blood sugar. In addition, such labels would be made not to be misleading to consumers by clearly defining the calculation of “net carbohydrates” on the product label.

2.

#### The Canadian Experience

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<sup>195</sup>*Id.* at 9.

Under amendments to Canada’s Food and Drug Regulations (“FDR”) published on January 1, 2003, companies selling food in Canada have to comply with a new set of nutrition labeling regulations, including new rules for carbohydrate-related nutrient content claims.<sup>196</sup> The previous regulations, in effect until December 2005, allowed a “carbohydrate reduced” claim when there was a fifty percent reduction in carbohydrates and a “low carbohydrate” claim when the product had less than two grams of carbohydrates per serving.<sup>197</sup> The new regulations take these fairly stringent rules a step further, prohibiting *all* carbohydrate-related nutrient content claims.<sup>198</sup> In an *Information Letter* published in August 2004, the Canadian Food Inspection Agency reminds that “[t]he new Regulations have restricted the list of nutrient content claims that may be made on foods. Carbohydrate claims, including ‘low carbohydrate’, ‘reduced carbohydrates’, [and] ‘source of carbohydrates’ are not included in the list under the regulations and are therefore *not permitted* . . . . [FDR] further prohibits other express or implied representations . . . . This means that other statements about the presence or absence of carbohydrates, including the use of brand names and trade-marks, are subject to these regulations.”<sup>199</sup> The new regulations not only ban all carbohydrate nutrient content claims, including presumably brands such as “Carb Clever”, but also prohibit the use of terms including “net”, “effective”, and “digestible” carbohydrates, “due to lack of scientific consensus on their definition and their potential to mislead consumers,” as well as statements about the glycemic index of foods.<sup>200</sup> Simply stated, no claims that insinuate a reduction in the carbohydrate level of food are permitted in Canada.

Instead of moving forward and defining nutrient content claims for carbohydrates, should the United States instead adopt the Canadian approach and keep all carbohydrate-related claims out of the market? Indeed this is – more or less – what FDA has done historically by not providing definitions for carbohydrate claims (though Canada has admittedly gone further in banning even net carbohydrate claims). However, FDA’s

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<sup>196</sup> See Canadian Food Inspection Agency, *supra* note 32.

<sup>197</sup> See *id.*

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

<sup>199</sup> *Id.* (emphasis in original).

<sup>200</sup> *Id.*

rationale for not previously defining carbohydrate claims was the lack of dietary recommendations for carbohydrates at the time of NLEA. As discussed in Part III.A above, such guidelines have now been bolstered and thus FDA definitions are timely. Canada has gone in the opposite direction – the new regulations *repeal* a regime that, though stringent, did permit such claims. The new Canadian regime is instead an absolute prohibition. The Canadian regulation’s simplicity certainly is an attractive feature in that it avoids confronting the “confounding” issues the food industry wrestled with in its petitions to FDA and that low-fat and low-carbohydrate advocates today battle over on supermarket shelves and in the media. It is undoubtedly a difficult issue: conventional science suggests glucose should provide basically all of the brain’s energy and a large proportion of calories, yet those advocating restricting carbohydrates have some science supporting an alternative metabolic pathway plus a general allure of reducing sugar intake. The Canadian approach simply shuts down the debate. Plus, as a matter of administrative law, it is an attractive alternative to our fragmented regulatory system. The *Information Letter* notes that “the labelling provisions . . . apply to all foods sold in Canada. This includes food, beverages, and alcoholic beverages, such as beer.”<sup>201</sup>

Yet, the Canadian approach is not responsive to a massive consumer desire for full information about food choices. Though the scientific debate over nutrition rages, consumer demand ultimately dictates the offerings of the marketplace. Even in the waning days of the low-carbohydrate fad, consumers still appear to be demanding products that are lower in carbohydrates. And while the FDA petitions reflect the “confounding” nature of the issue, their intransigence also indicates that food companies know consumer demand is out there and are merely jockeying to capture the largest possible market share. In this environment, the proper approach is not to shut down the system. Instead, the best we can do for consumers is given them accurate, full, and balanced information about food products on the packaging. FDA should allow food companies to signal that foods lower in carbohydrates are available to consumers, from which they may potentially

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<sup>201</sup> *Id.*

benefit. From a commonsense perspective, in light of this country’s incredible obesity epidemic, it cannot hurt to make alternatives to conventional dieting available to consumers. Moreover, in the American psyche, consumer choice and free speech – even for corporations – are important factors in the regulatory landscape. The role of regulators in this system is to make sure that the labeling regime is consistent and not false or misleading. To ensure that the provision of information to consumers is full and accurate, FDA should clearly and logically define carbohydrate claims along a spectrum, ensure that products disclaim that they are not necessarily for weight control, and mandate that net carbohydrate figures be clearly and consistently calculated. Through this approach, consumers are given safeguards, but are not denied information that will help them to make good nutritional choices. The Canadian approach, while safe, may do a disservice in the long-term to consumers, by stunting the emergence of a greater understanding of human nutrition through product experimentation and evolving consumer practices.

## **IV.**

### **Finding Larger Meaning in the Low-Carbohydrate Experience**

We now stand at the end of a food fad, though it is one that appears to have long-term staying power, both as a distinctive niche “diet” and as a broader component of healthy nutrition. FDA is on its way toward publishing regulations – presumably taking some of the approaches outlined in Part III above – that will allow food companies to make helpful claims about the carbohydrate content of their products. Yet the low-carbohydrate episode is more than a self-contained nutrient content claim issue. It also provides a pivotal opportunity to think more broadly about regulation and the future of nutrition. Indeed, regulators,

food companies, and consumers have a chance both to look *backward* at lessons from the handling of carbohydrates in order to determine the ideal general approach FDA should take in response to fast-evolving food trends as well as to look *forward* in order to anticipate the larger, long-term meaning of the low-carbohydrate experience.

A.

#### Slow Responses to Fast-Moving Trends

While providing definitions for carbohydrate nutrient content claims will be valuable in the long-term, their greatest worth might have come at the peak of consumer interest in low-carbohydrate foods, which has passed. First, such claims would have responded in a timely way to surging consumer and industry demand for helpful information about carbohydrates. As Pepsico puts it, “FDA leadership in taking interim measures . . . is central to the agency’s ability to maintain regulatory oversight in a marketplace that has witnessed an explosion of interest among consumers in carbohydrate content, and strong industry response.”<sup>202</sup> A second, though somewhat uncertain, point is that if food companies had the ability to make clearly defined and balanced claims, even on an interim basis – rather than revert to ambiguous implied claims or simply defy FDA and use inconsistent explicit claims in violation of the law – consumers might have reacted with a more positive long-term view to low-carbohydrate eating. With a consistent set of terms, the “wild west” entrepreneurs would have quickly dried up as mainstream companies had a responsible set of claims to employ.<sup>203</sup> Moreover, there is an argument that “FDA’s inaction is viewed by many consumers as . . . lending

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<sup>202</sup>Pepsico Letter, *supra* note 92, at 3.

<sup>203</sup>It should be noted that even some of the “wild west” low-carbohydrate start-ups waited patiently for FDA action and desired interim guidance. On a related topic of setting guidance for independent laboratories testing of foods’ carbohydrate content, a low-carbohydrate entrepreneur asked “if, during the interim period until FDA can establish and rule on a standardized test protocol, there is any possibility of the FDA providing a guideline . . . to assist . . . in testing low carb foods with some consistency.” E-mail from Heather Hines, Low Carb Creations, to CFSAN, FDA (Mar. 2, 2004) (No. 2004P-0105).

credence to misleading ‘low carb’ marketing messages.”<sup>204</sup> But the trend came and went without more out of FDA than some ad hoc responses permitting the use of net-carbohydrate labeling and admonishing the most defiantly rogue violators via an ineffectual warning letter process. Why was FDA not able to provide more guidance more quickly to consumers and food companies?

It is not implausible to expect quicker action from a regulator in response to an appeal for its leadership, at least in the form of interim guidance if formal rulemaking is not a possibility. Indeed, in response to interest in carbohydrate labeling and in recognition of the inconsistency of existing practices, TTB provided companies within its jurisdiction with timely and clear-cut nutrient content claim regulations for carbohydrates. While TTB “recognizes that the best way to develop a standard for the use of the term ‘low carbohydrate’ may be the notice and comment rulemaking process,” it nonetheless concludes that industry members “have the right to transmit truthful and accurate information about carbohydrate content on labels and in advertisements.”<sup>205</sup> Nonetheless, TTB issued the interim standards with a clear reminder that the rules “are subject to change pending rulemaking on these issues.”<sup>206</sup> Thus, the alcohol industry and its consumers had functioning regulations that would avoid the reversion to implied claims and/or the defiant use of illicit undefined terms, while still providing leeway for TTB to make appropriate modifications down the road in response to both its own rulemaking process as well as that of FDA.<sup>207</sup>

It may be argued that comparing FDA to TTB in the context of interim regulations is not a reasonable “apples-to-apples” comparison. TTB has a smaller, narrower group of regulated companies, among whom achieving consensus on the appropriate regulations might not be as difficult as with FDA-regulated compa-

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<sup>204</sup>Letter from Linda Golodner, President, NCL, to Lester M. Crawford, Acting Commissioner, FDA 3 (Oct. 7, 2004) (No. 2004P-0105).

<sup>205</sup>TTB, *supra* note 31, at 8.

<sup>206</sup>*Id.*

<sup>207</sup>*See id.*

nies.<sup>208</sup> Moreover, TTB's smaller constituency limits the ripple effect of the reliance problem that would result from changing an interim regulation at the final rulemaking stage. Plus, the interim rule provided by TTB is no panacea anyway. It is highly generalized, does not appear to derive too deeply from nutritional science, and critically, relies for final confirmation on whatever FDA decides to do on carbohydrate claims. But this reliance on FDA rulemaking can also be interpreted to underscore that TTB acted *in light of* FDA inaction, and thus FDA interim rules would have been the ideal first-step solution. This is also critical because in light of FDA silence on the issue, food companies made claims that violated existing FDA rules, which CSPI believes was "egged on, no doubt in part" by TTB and FSIS action on the issue.<sup>209</sup> TTB's success in issuing interim regulations should provide FDA with an important lesson from a more nimble agency.

The approach of TTB aside, FDA itself has a precedent of providing interim regulations when the need exists. Under section 403(r)(7) of the FDCA, Congress has granted FDA the authority to adopt interim final rules to ensure the agency can "review and act promptly" on petitions in order to "ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible."<sup>210</sup> Not only could FDA act under section 403(r)(7), but the agency could, as Kraft describes, issue guidance "indicating that enforcement discretion will be exercised to allow [defined carbohydrate nutrient content claims] on an interim basis as the rulemaking process evolves."<sup>211</sup> And not only does FDA have the power, but as Kraft points out, "[a]mple precedent supports the use of interim guidance when rapid evolution of the regulatory framework is in the best interests of consumers."<sup>212</sup> FDA issued such interim rules, for example, in the case of comparative

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<sup>208</sup>Yet, TTB-regulated companies may be as diverse as FDA's constituents on this issue. Compare the disparity among the brewer whose light beer has only three grams of carbohydrates to the spirit maker whose malt beverage has fifteen grams of carbohydrates. This is not too different from the disparity between a FDA-regulated company making cheese products versus one making chocolate candy.

<sup>209</sup>CSPI Petition, *supra* note 66, at 3.

<sup>210</sup>Federal Food, Drug, and Cosmetic Act § 403(r)(7)(A), (7)(A)(iii), 21 U.S.C. § 343(r)(7)(A), (7)(A)(iii) (2004).

<sup>211</sup>Letter from Sheryl A. Marcouiller, Senior Food Law Counsel, Kraft, to Division of Nutrition Programs and Labeling, CFSAN, FDA 2 (Dec. 1, 2003) (No. 2004P-0105).

<sup>212</sup>*Id.*

claims for sodium. In setting down rules for “less sodium than”-type claims, FDA noted that the “agency wishes to make it clear that it is not establishing any regulations governing these comparative claims, but it [sic] merely issuing this statement of policy to provide guidance to manufacturers on the appropriate use of these terms.”<sup>213</sup>

It has already been discussed as to why, in spite of this authority to act, FDA might not have moved more quickly in this case – limited resources, the “confounding” nature of carbohydrates and need for further understanding of the nutritional science and consumer perceptions, and the hope that the fad would simply fizzle out. Yet, given the continued interest of food companies and consumer groups alike in receiving this type of guidance, the decision of FDA to withhold interim policies on carbohydrates was likely incorrect. As food and drug law attorney Eric F. Greenberg wrote at the time, “[h]eck, any time an industry trade group and a consumer group are on the same side of an issue, FDA probably ought to take heed.”<sup>214</sup> However, even assuming hypothetically that FDA was correct in its decision to wait, the agency should nevertheless utilize the carbohydrate episode as an opportunity to refine its sense for *when* such interim guidance is appropriate. The authority to act exists and opportunities will continue to arise in our ever-evolving consumer society where, fast-and-furiously, nutritional information will emerge, and consumers and food companies will immediately respond. FDA must be well-prepared to act nimbly in this modern nutritional environment.

B.

#### Outlook for the Future

The carbohydrate experience may also lead to a major reshaping of the manner in which FDA responds to

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<sup>213</sup>Food Labeling; Declaration of Sodium Content of Foods and Label Claims for Foods on the Basis of Sodium Content, 47 Fed. Reg. 26580, 26586 (proposed June 18, 1982) (to be codified at 21 C.F.R. pts. 101, 105).

<sup>214</sup>Eric Greenberg, *Legal Impact: “Low Carb” Inspires Label Rules*, PACKAGING DIGEST, Mar. 2004, <http://www.packagingdigest.com/Legal/0304legal.php>.

nutrition more broadly. It cannot be ignored that part of FDA’s delay in addressing carbohydrate nutrient content claims was the “confounding” nature of the issue – food companies want to make both high and low carbohydrate claims and FDA is not certain how consumers react to either.<sup>215</sup> FDA may indeed be concerned not only about the mixed message of high and low claims but about whether we will learn down the road that one direction is definitively nutritionally correct and the other incorrect. In light of the obesity crisis and the corresponding increases in diabetes, there may very well be a key wisdom behind limiting intake of foods that lead to insulin resistance, even though severely limiting carbohydrates flies in the face of most conventional wisdom today. But whether the low-carbohydrate insight is valid or invalid, the link between carbohydrates and blood sugar focuses on a fundamental concept with which we must grapple in the future – foods are much more than just their chemical compositions as reflected on the Nutrition Facts panel, much more than just calories. Foods have different physiological effects on the body, which ultimately impact health and weight. It is to understand these insights better that must be a priority for FDA. CSPI’s petition lampoons the idea of FDA permitting declarations not only of net carbohydrates but “‘net fats’ (excluding fatty acids that do not raise blood cholesterol) or ‘net sodium’ (excluding sodium salts that do not raise blood pressure).”<sup>216</sup> Yet, these are the types of insights that may ultimately revolutionize human nutrition. The reconceptualization from chemical composition to physiological effect must be the priority, ultimately leading potentially to significant revision of NLEA and the Nutrition Facts panel.<sup>217</sup>

Thus, defining carbohydrate claims as outlined in Part III above is only a first, interim step. Consumers demand information today, and thus FDA should provide it, based on current nutritional science. However,

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<sup>215</sup>FDA’s uncertainty over consumer views of carbohydrates is reflected in its announcement of the consumer study, where it noted that “[t]he purpose of this proposed data collection is to help enhance FDA’s understanding of consumer response to carbohydrate content claims on food labels.” Notices, Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Carbohydrate Content Claims on Food Labels, 70 Fed. Reg. 18032, 18033 (Apr. 8, 2005).

<sup>216</sup>CSPI Petition, *supra* note 66, at 6.

<sup>217</sup>*See* Interview with Alison Kretser, *supra* note 30.

down the line, pure caloric bases for these claims and for the Nutrition Facts panel may not be appropriate. Employing a definition of “net carbohydrates” based on the caloric impact of various types of carbohydrates may be replaced with a definition of *total* carbohydrates that excludes these non-caloric carbohydrates altogether – the path down which Unilever’s petition leads – or at least with a “net carbohydrates” definition based on various carbohydrates’ impact on blood sugar. Further study may also suggest that the glycemic index is an appropriate area for IOM recommendations.<sup>218</sup> Developing these changes is a monumental challenge, particularly for an agency with limited resources and where the scientific understanding continues to develop, but progress is vital.

Most of all, as we move forward we need to be *open minded* toward diverse ideas about the future of nutrition if we are to solve the obesity epidemic. Woody Allen’s 1973 film *Sleeper* contains a memorable scene in which two doctors from two hundred years in the future puzzle over items sold in Allen’s character Miles Monroe’s 1970s health food store. Regarding items like wheat germ and organic honey, the doctors have the following exchange:

Dr. Aragon: Oh, yes. Those are the charmed substances that some years ago were thought to contain life-preserving properties.

Dr. Melik: You mean there was no deep fat? No steak or cream pies or . . . hot fudge?

Dr. Aragon: [chuckling] Those were thought to be unhealthy . . . precisely the opposite of what we now know to be true.

Dr. Melik: Incredible!<sup>219</sup>

What the future holds for human nutrition is very uncertain. While cream pies are not likely to ever be

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<sup>218</sup>IOM may be closer to this than it appears at first glance. In the *Macronutrient Report*, IOM writes that “[a]t a time when populations are increasingly obese, inactive, and prone to insulin resistance, there are theoretical reasons that dietary interventions that reduce insulin demand may have advantages. In this section of the population, it is likely that more slowly absorbed carbohydrate foods and low glycemic load diets will have the greatest advantage.” *Macronutrient Report*, *supra* note 104, at 322.

found to be healthy, scientific support for a low-carbohydrate, high-protein approach is developing support for the concept that steaks are healthy. Allen's satirical prophecy for the future in 1973 was not far off Atkins's serious one in 1972. As we move forward into uncharted nutritional territory, FDA must lead the way and those wed to a pure "calories count" approach must be open minded about alternative ideas, such as considering the physiological impacts of foods, so that we can overcome the obesity epidemic and definitively determine the "charmed" foods it took Allen's characters 200 years to develop.