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**Retooling Food Standards of Identity
To Address Diet-Related Chronic Disease**

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Abstract

Chronic disease rates have increased dramatically in the United States over the past several decades, and scientists believe that many such diseases, including heart disease and Type II diabetes, are partly attributable to dietary factors. This paper explores various ways in which the U.S. Food and Drug Administration could wield its existing statutory authority to reduce the rates of such diseases, including through enforcement of food adulteration provisions, expansion of nutritional labeling requirements, and reformulation of food standards of identity. It posits that, because they provide significant regulatory flexibility, food standards of identity are a promising means of regulating the nutrient content of foods. The paper then describes the history and structure of food standards and discusses ways in which food standards could be altered and expanded to meet nutritional goals. The FDA could promulgate standards for more foods, especially processed foods, but could make them less recipe-like in nature than most standards are currently. Such

an approach would allow food manufacturers to create a wide variety of unique recipes but would allow the FDA to set forth maximum quantities of certain macronutrients or specific ingredients that are deleterious to health. Broadening the range of food standards in this way would require more stringent enforcement at the boundaries to be an effective strategy, and costs to consumers would likely increase at least marginally, but the benefits of disease reduction might outweigh those costs to both government and consumers.

Introduction

A high school sophomore walks into a convenience store after school looking for a snack to eat before band practice. Wanting something more wholesome than chips or candy, she picks up a product in a foil wrapper marked with the (slightly confusing) verbiage “Kellogg’s Nutri-Grain Cereal Bars Yogurt Bars. Strawberry. Low fat, with natural and artificial flavors.” Cereal, yogurt, and fruit, she thinks—sounds healthy. The health instructor who taught her class about the USDA food pyramid would be delighted.

The “yogurt bar” might not be the health food the student imagines it to be, however, as a close examination of the ingredients list would reveal. First ingredient: “filling,” which contains “high fructose corn syrup, glycerin, water, fructose, modified corn starch, partially hydrogenated cottonseed and soybean oil, nonfat yogurt powder, strawberries,” and a few other starches, flavors, and colors. Second and third ingredients by weight: enriched wheat flour, whole oats. And then: sugar, partially hydrogenated soybean and/or

cottonseed oil, high fructose corn syrup, honey, and a few other ingredients, including calcium carbonate, iron, and B vitamins.

Is this “yogurt bar” better than a candy bar or potato chips? Almost certainly; it contains some whole grains, after all, which seem to account for the bar’s one gram of fiber. (The equivalent weight of Cheerios would contain more than three times as much fiber, however.)¹ The bar is fairly low-sodium (110 milligrams), fairly low fat (3 grams, of which only half a gram is saturated). And it contains twenty percent of the Recommended Daily Intake (RDI) of calcium² and significant RDI percentages of other nutrients.

What the healthy-sounding bar also contains, however, are ingredients that have been implicated in heart disease, obesity, and diabetes—ingredients that may not need to be present to create a “yogurt bar” or “cereal bar” of substantially similar flavor and micronutrient value. Partially hydrogenated oils, for example, contain trans fats, which many medical researchers believe contribute significantly to heart disease³ and even to Type II diabetes.⁴ The U.S. Food and Drug Administration (FDA) promulgates food standards of identity that have traditionally been characterized as a way of preventing consumers from “being defrauded by the sale of cheapened products masquerading as traditional staples of the basic American diet”;⁵ why should it

¹The 37 gram “cereal bar” contains one gram of fiber, whereas 37 grams of Cheerios contain approximately 3.3 grams of fiber (9 g per 100 g sample, according to USDA data).

²Prepared Foods magazine notes that calcium carbonate is the main calcium fortifier in the bars, not the yogurt powder or dry milk that the bars contain. Claudia D. O’Donnell, *Ingredients in Use: Calcium*, PREPARED FOODS, October 2002, http://www.preparedfoods.com/archives/2002/2002_10/1002calcium.htm.

³See Alberto Ascherio et al., Harvard Sch. Pub. Health, *Trans Fatty Acids and Coronary Heart Disease* (Background and Scientific Review) (1999) (“[T]he adverse impact of trans fat is stronger than that of saturated fat. By our most conservative estimate, replacement of partially hydrogenated fat in the U.S. diet with natural unhydrogenated vegetable oils would prevent approximately 30,000 premature coronary deaths each year, and epidemiologic evidence suggests this number is closer to 100,000 premature deaths annually.”), www.hsph.harvard.edu/reviews/transfats.html.

⁴See *Trans Fats Defined*, WASH. POST, Dec. 10, 2003, at F4 (“[S]ome short-term studies show that trans fat increases insulin resistance, the underlying mechanism for type 2 diabetes.”) (citing Walter Willett, Chairman, Dep’t of Nutrition, Harvard School of Public Health), <http://www.washingtonpost.com/wp-dyn/articles/A48799-2003Dec9.html>.

⁵Richard A. Merrill & Earl M. Collier, Jr., “*Like Mother Used To Make*”: *An Analysis of FDA Food Standards of Identity*, 74 COLUM. L. REV. 561, 561 (1974). Merrill and Collier’s article is considered to be “the seminal legal analysis regarding food standards.” Frederick H. Degnan, *What Is in a Name? The Legal Effect of Food Standards*, 45 FOOD DRUG COSM. L.J. 263 n.4 (1990).

not consider creating food standards that force producers to conform to consumers' expectations about the healthfulness of foods?

I. The Nutritional Landscape

Chronic diet-related diseases, including heart disease, obesity, and diabetes, are on the rise in the United States and throughout the world—even in the developing world, where chronic diseases now rival communicable diseases and malnutrition as leading causes of death.⁶ In the United States, the Centers for Disease Control estimate that five diseases—heart disease, cancer, stroke, diabetes, and chronic obstructive pulmonary diseases—account for fully two-thirds of deaths.⁷ Of these five diseases, at least four are suspected of having a significant dietary component.⁸ It is hardly an overstatement to call the drastic increase in such diseases over the past several decades an epidemic, one made all the more regrettable by the fact that a chronic disease such as diabetes often advances to the detriment of an individual's lifestyle for years before he or she succumbs—or indeed, degrades a person's quality of life (and consumes medical resources) even if he or she succumbs to another cause of death. Moreover, the public health situation only appears to be growing

⁶See WORLD HEALTH ORG., DIET, NUTRITION AND THE PREVENTION OF CHRONIC DISEASES sec. 2.1, at 3-5 (Technical Rep. Ser. 916, Advance Final Draft, March 3, 2002). In five out of the six regions covered by the WHO, chronic diseases are collectively the leading cause of death. *Id.* at 3.

⁷CENTERS FOR DISEASE CONTROL, NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION, THE BURDEN OF CHRONIC DISEASES AND THEIR RISK FACTORS: NATIONAL AND STATE PERSPECTIVES 2002, *available at* http://www.cdc.gov/nccdphp/burdenbook2002/01_tables.htm. Chronic obstructive pulmonary diseases include bronchitis, emphysema, asthma, and chronic airway obstruction. *Id.*

⁸These four are heart disease, cancer, stroke, and diabetes. Heart disease and Type II diabetes have long been well-known to have a dietary component. A less well-known fact is that the impact of diet on cancer risk is not limited to the effects of carcinogens: "Evidence suggests that one third of the 550,000 cancer deaths that occur in the United States each year are due to unhealthy diet and insufficient physical activity." Dr. Tim Byers and Colleen Doyle, MS, RD, Am. Cancer Soc'y, Diet, Physical Activity, and Cancer... What's the Connection?, CANCER.ORG, at http://www.cancer.org/docroot/PED/content/PED_3_1x_Link_Between_Lifestyle_and_CancerMarch03.asp (last visited Dec. 21, 2003). And high blood pressure, a diet- and lifestyle-related condition, is one of the leading causes of stroke. Nat'l Stroke Ass'n, Stroke & High Blood Pressure Fact Sheet, at <http://209.107.44.93/NationalStroke/HavingAStroke/default.htm> (last visited Dec. 21, 2003).

worse: obesity rates in children have skyrocketed in the past few decades,⁹ and because obese children tend to become obese adults,¹⁰ these findings may be a harbinger of higher chronic disease rates to come.

The fact that many chronic diseases are related to diet raises the question of what measures the FDA, the agency with the most comprehensive direct regulatory authority over the nutritional content of most foods, should take to reduce the prevalence of preventable diet-related chronic diseases. In the past, the FDA has addressed chronic disease issues largely through labeling requirements, but it has been loath to enact regulations imposing a general ban on a particular ingredient unless the ingredient either presents an imminent threat to safety or is carcinogenic. There are at least two possible reasons for the FDA's reluctance to directly regulate the general usage of food ingredients that have been implicated in chronic disease: the FDA may have judged that wielding its authority too broadly over the content of food would be unwise as a policy matter, or the agency may be skeptical that its statutory authority would extend to such measures. This paper considers what measures the FDA could feasibly consider taking to reduce the prevalence of food ingredients that cause chronic diet-related disease and concludes that food standards of identity are some of the most promising current tools that the agency can adapt to regulate chronic disease contributors. It then considers whether Congress has granted the FDA sufficient authority to use food standards in this manner. This is not a scientific paper and therefore does not evaluate the validity of specific claims about the contribution of particular food ingredients to disease; it does, however, use specific examples of suspected dietary disease contributors to avoid lingering too much within abstraction and to facilitate the use of real-world examples in the discussion.

⁹See Centers for Disease Control, Nat'l Center for Health Statistics, Prevalence of Overweight Among Children and Adolescents: United States, 1999-2000 (last updated Oct. 24, 2002), <http://www.cdc.gov/nchs/products/pubs/pubd/hestats/overwght99.htm>.

¹⁰See *id.*

There are two general categories of dietary disease contributors that the FDA might consider regulating. The first category is macronutrients that have been implicated in the development of disease; saturated fat and trans fats are examples of these. The second category, often a subset of the first, includes ingredients that have more deleterious health effects than other similar ingredients. An example of a second-category ingredient is high fructose corn syrup, which studies have suggested may be a culprit in obesity¹¹ and the early onset of Type II diabetes, a disease dramatically on the rise in the United States. Other examples are partially hydrogenated soybean oil and partially hydrogenated cottonseed oils, which are thought to be less healthful than other fats because they contain trans fats. The following Part explores ways for the FDA to regulate either or both of these categories of food ingredients.

II. A Brief Overview of FDA Regulatory Options

A. Banning or Limiting Ingredients Generally

The most direct manner in which the FDA is authorized to regulate the contents of food is by enforcing the food safety provisions of the Food, Drug, and Cosmetics Act of 1938 (FDCA).¹² One way in which

¹¹“Nothing else in the food supply” is as closely correlated to the jump in obesity rates of the past few decades as the growing use of high fructose corn syrup (HFCS) in foods and beverages. Patricia King, *Blaming It on Corn Syrup*, L.A. TIMES, Mar. 24, 2003 (quoting George A. Bray, obesity researcher and professor of medicine at Louisiana State University Medical Center), <http://www.latimes.com/la-he-fructose24mar24.htmlstory>. Fructose “appears to behave more like a fat [than a sugar] with respect to the hormones involved in body weight regulation.” Sally Squires, *Sweet but Not So Innocent? High-Fructose Corn Syrup May Act More Like Fat Than Sugar in the Body*, WASH. POST, Mar. 11, 2003, at HE01 (quoting Peter Havel, associate professor of nutrition at the University of California, Davis, who went on to note that “the studies have not been conducted”). Fructose consumption has also been linked to higher triglyceride levels in the blood, which are in turned linked to heart disease. *See id.* (citing a University of Minnesota study published in 2000 in the American Journal of Clinical Nutrition). Fructose may even affect the body’s magnesium balance, which could lead to bone loss. *See id.* (citing a USDA study published in 2000 in the Journal of the American College of Nutrition). Regardless of whether fructose poses a graver threat to health than other forms of sugar, it is clear that sugar consumption has risen dramatically in the United States and worldwide in the last few decades. The WHO recently recommended that people limit their free sugar consumption to ten percent of their daily calories, a measure that it suggested would help prevent obesity. *See id.*; *see also* WORLD HEALTH ORG., *supra* note 6, at 40.

American corn producers are concerned enough about suggestions that HFCS has unique adverse health consequences that the Corn Refiners Association has created a website, www.hfcsfacts.com, that attempts to counter the adverse claims.

¹²Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–397 (2000)).

the agency may directly exclude certain ingredients from the food supply is by eliminating them from its list of additives generally recognized as safe (GRAS). The GRAS list was created soon after the passage of the Food Additives Amendment of 1958 (FAA),¹³ which provided that new additives would be subjected to safety testing requirements. Ingredients that were “so well recognized as safe that they had become generally accepted constituents of the food supply,”¹⁴ however, were specifically excepted from the definition of “additive” in the FAA. The FDA maintains a list of GRAS ingredients that it has reviewed for safety, and it reevaluates its determinations if new evidence casts the safety of an ingredient into doubt. Concerns about dietary disease contributors could therefore conceivably motivate the agency to eliminate some ingredients from the list. Hydrogenated and partially hydrogenated oils that contain a significant amount of trans fat are currently considered GRAS, for example, but the agency might wish to revisit this designation: the National Academy of Sciences has concluded that there is actually no “safe” level of the trans fats these oils contain.¹⁵ Instead of removing an ingredient from the GRAS list altogether, the FDA may also impose “conditions of use” that limit the quantity of an ingredient that manufacturers may add to food or impose other restrictions.¹⁶ The imposition of conditions of use may be an option for regulating macronutrients such as sodium or saturated fat that it would be impossible to ban altogether.

The FDA may also regulate the use of food ingredients by invoking the food adulteration provisions of Sections 402(a) and 406 of the FDCA. Section 402(a)(1) provides that a food shall be deemed adulterated if it contains “any poisonous or deleterious substance which may render it injurious to health.”¹⁷ However, this provision is qualified by the language that “in case the substance is not an added substance such food shall not

¹³Pub. L. No. 85-929, 72 Stat. 1784 (1958) (codified at 21 U.S.C. § 348).

¹⁴Frederick H. Degnan, *Rethinking the Applicability and Usefulness of the GRAS Concept*, 46 FOOD DRUG COSM. L.J. 553, 553 (1991). This article includes a useful history of the GRAS concept.

¹⁵Andrew Martin, *FDA Imposes New Fat Labels on Food*, CHI. TRIB., July 10, 2003, <http://www.chicagotribune.com/business/chi-0307100373jul10,1,2519968.story>.

¹⁶See 21 C.F.R. 184.1(b)(1) (2003).

¹⁷21 U.S.C. § 342(a)(1).

be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health”¹⁸—language that may serve as a bar to the regulation of macronutrients that are only harmful if eaten in quantity over a long period of time. Section 406 provides that the FDA may set limits on poisonous or deleterious substances if their presence in a food is unavoidable—as indeed might be the case for some macronutrients—“to such extent as [the Administrator] finds necessary for the protection of public health.”¹⁹ It further provides that in setting those limits the agency “shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.”²⁰ This language seems to authorize the FDA to consider the cumulative effects of certain food ingredients and macronutrients in the diet in deciding whether to impose limits on certain ingredients.

If the FDA chose to regulate food ingredients through the food additives provisions or the food adulteration provisions of the FDCA, because the statutory provisions refer solely to substances’ effects on human health, the legal legitimacy of the agency’s determinations would rest entirely on the strength of the scientific evidence at hand.²¹ This presents a higher bar than the agency would have to clear to impose labeling requirements or food standards of identity.

¹⁸ *Id.*

¹⁹ *Id.* § 346.

²⁰ *Id.*

²¹ See Peter Barton Hutt, *Regulatory Implementation of Dietary Recommendations*, FOOD DRUG COSM. L. J., Feb. 1981, at 71 & n.30 (noting, in the GRAS list review context, an instance in which the a court nullified an FDA limitation on the amount of mercury that could be present in fish after finding the limitation unsupported).

B. Labeling Requirements

Food labels are where the FDA has so far taken its most active role in pursuing the public health goals of reducing chronic diet-related diseases. Since 1973, the FDA has interpreted Sections 403(a)(1)²² and 201(n)²³ of the FDCA to require manufacturers to affirmatively disclose nutritional information if a food contained added nutrients or a label made a nutrition-related claim,²⁴ but Congress gave the agency a much broader mandate to require nutrition labeling of foods with the Nutrition Labeling and Education Act of 1990 (NLEA).²⁵ The NLEA provided that virtually all food labels, including those for standardized foods,²⁶ must include such information as portion sizes, total calories, calories from fat, and amounts of fat, saturated fat, cholesterol, carbohydrates, sugars, and proteins.²⁷ The FDA immediately promulgated new regulations in accordance with the NLEA and created the now-familiar “Nutrition Facts” labels that adorn most food packages today. The labels are now by all accounts clearer and much more informative than before, but the extent of their impact on consumer behavior is still unclear.²⁸

The NLEA contained a number of new provisions about health claims as well.²⁹ The Act allows the FDA to issue regulations allowing manufacturers to make specific claims regarding the relationship between food and disease “if the Secretary determines, based on the totality of publicly available scientific evidence that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate

²²21 U.S.C. § 343(a)(1) (2003) (prohibiting labeling that is “false or misleading”).

²³*Id.* § 321(n) (In determining whether labeling or advertising is misleading, “there shall be taken into account...not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates....”).

²⁴*See* Hutt, *supra* note 21, at 74.

²⁵Pub. L. No. 101-535, 104 Stat. 2353 (codified in 21 U.S.C. § 343(q) and other scattered sections of 21 U.S.C.).

²⁶*See infra* section II.C.

²⁷*See* 21 U.S.C. § 343(q). The extraordinarily detailed regulation that sets forth precise labeling requirements can be found at 21 C.F.R. § 101.9.

²⁸*See* David A Kessler, Jerold R. Mande et al., *Developing the “Nutrition Facts” Food Label*, 4 HARV. HEALTH POLICY REV., Fall 2003, at 13, 23 (noting promising early studies, but bemoaning the lack of recent and definitive data on the subject).

²⁹*See* 21 U.S.C. § 343(r).

such claims, that the claim is supported by such evidence.”³⁰ (As of Fall 2003, the FDA had authorized eight such claims, including claims about the relationship between saturated fat and heart disease and between fat and cancer.³¹) In 1997, Congress passed legislation allowing labels to carry disease-related claims if “a scientific body of the United States Government” or the National Academy of Sciences “has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers.”³² The FDA is currently also considering allowing for “qualified health claims” in instances where the evidence does not meet the NLEA “significant scientific agreement” standard. Labels including such claims would have to qualify them with the information that the FDA has not yet found the evidence supporting the claim to be conclusive.³³

Overall, disease-related health claims may be more prone to cause consumer overreaction or confusion than simple nutritional breakdowns on food labels, but such health claims may also be more directly informative. Detailed nutrition labels, on the other hand, empower already informed (or at least motivated) consumers to choose more healthful foods; in addition, they may cause some food producers to preemptively remove “bad” ingredients from their products. In July 2003, for example, the FDA announced a final rule that will require manufacturers to list the amount of trans fats a product contains on the same portion of the label that breaks out the amount of saturated fat.³⁴ Manufacturers are now reportedly accelerating their attempts

³⁰*Id.* § (r)(3)(B)(i). The NLEA also bars certain claims or requires manufacturers to qualify them if the food contains other ingredients that increase the risk of disease—for example, a label may not state that a food is high in fiber “unless the food is low in total fat... or the label or labeling discloses the level of total fat in the food in immediate proximity to such statement and with appropriate prominence.” 21 U.S.C. § 343(a)(2)(v). In the same vein, the general FDA regulation on health claims disqualifies a manufacturer from labeling a product with health claims if certain macronutrient levels—such as cholesterol, sodium, and saturated fat—are exceeded. *See id.* § 101.14(a)(4).

³¹*See* Kessler, *supra* note 28, at 22.

³²21 U.S.C. § 343(r)(3)(C)(i).

³³Kessler, *supra* note 28, at 22.

³⁴Food Labeling; Trans Fatty Acids in Nutrition Labeling... Final Rule and Proposed Rule, 68 Fed. Reg. 41433 (July 11, 2003) (to be codified at 21 C.F.R. pt. 101). For a brief description of the new rule, see FDA Backgrounder, FDA Acts to Provide Better Information to Consumers on Trans Fats (July 9, 2003), <http://www.fda.gov/oc/initiatives/transfat/backgrounder.html>.

to reformulate products to reduce or eliminate trans fats.³⁵

In a world of fully informed, perfectly rational consumers, adequate nutritional labeling would suffice to accomplish public health goals to reduce the occurrence of diet-related chronic diseases. Unfortunately, consumers may not be aware of the gravity of some health threats, may not be entirely rational in their purchasing decisions, or may be inclined to take the nutritional path of least resistance.³⁶ In addition, at least one study of has found that older, less educated, and less healthy consumers are the least likely to be able to process the information on food labels to their advantage,³⁷ even though these groups may be among those who could most benefit from dietary improvements.

C. Food Standards of Identity

The FDCA provides that the FDA shall “promulgate regulations fixing and establishing for any food, under its common or usual names so far as practicable, a reasonable definition and standard of identity” if doing so will “promote honesty and fair dealing in the interest of customers.”³⁸ The FDA has used standards of identity since the beginning to improve the nutritional content of foods by adding fortification with micronutrients to some standards,³⁹ so the standards’ use as a health policy tool, rather than merely as

³⁵See Lorene Yue, *Trans-Fat Rules Spur Race for New Foods*, CHI. TRIB. July 10, 2003, <http://www.chicagotribune.com/business/chi-0307100287jul10,1,4289444.story?coll=chi-business-hed>.

³⁶See Judith Weinraub, *The Blame Game: Is It Our Fault We Like Bad Fats?*, WASH. POST, Dec. 10, 2003, at F1 (“If the environment provides reasonable access to a variety of healthy foods, we adjust and maintain good health. We choose. But when the environment becomes toxic, with heavy promotions, and good-tasting, high-calorie inexpensive foods, the body can’t adjust, except in few cases where people exert extraordinary control.”) (quoting Kelly Brownell, Director, Yale Center for Eating and Weight Disorders), <http://www.washingtonpost.com/wp-dyn/articles/A48809-2003Dec9.html>.

³⁷This particular study was entirely of women because women are the primary food purchasers in many households. See Lisa Alferi et al., *Assessing the Performance of Women on Nutrition Labeling Tasks*, AM. J. HEALTH STUDIES, Summer 2000.

³⁸21 U.S.C. § 341 (2000).

³⁹See Hutt, *supra* note 21, at 71 (“Some of the first standards of identity promulgated by FDA in the 1940s included

a mechanism for preventing the sale of economically adulterated products, has precedent. Standards of identity may be a promising means of regulation of dietary disease contributors for several reasons.

First, under the current FDA enforcement regime, using standards of identity to accomplish policy goals is arguably less heavy-handed than across-the-board regulation; the macronutrients or ingredients in question are not banned outright, but rather would be excluded from formulations bearing the name of the standard (or limited to a specified percentage). Using standards of identity to address the problem of dietary disease contributors would therefore be particularly useful if the contributor in question were an ingredient that would be impossible or undesirable—as either a health matter or a political matter—for the FDA to exclude from all foods by, for example, removing it from its list of GRAS additives. There are several reasons why it might be undesirable to ban a specific ingredient outright. Unlike carcinogens, most dietary disease contributors are fine in moderate amounts. Consuming too much sodium has been linked to hypertension, for example, but few doctors would argue that judicious consumption of added salt is not safe for most people. In addition, it may be a perfectly justifiable policy decision to hold different kinds of foods to different overall standards of healthfulness; consumers already know that they should limit their consumption of cookies and chocolate if they are concerned about their health, but they may be unlikely to realize that their breakfast cereal or fruit juice could contain ingredients that may be harmful to them in the long run.

In addition, limiting the amount of a certain ingredient consumed by the population, which the FDA could accomplish either through limiting the permissible percentage of such an ingredient in most identity standards or excluding it altogether from the identity standards for certain staple items, might be a more carefully

requirements for enrichment with vitamins and minerals.”); Sanford A. Miller & Karen Skinner, *The Nose of the Camel: The Paradox of Food Standards*, 39 FOOD DRUG COSM. L.J. 99, 105 (1984) (“The establishment of a fortification policy for flour and bread represented one of the earliest and most important health uses of food standards.... [T]hus bread was used as a vehicle for improving public health.”). *But see id.* (stating that “[i]n general, however, standards have *not* been used to address nutritional problems” and that “nutritional considerations have not been among the primary determinants of the components of standards”). Some fortification standards are still in force today. *See, e.g.*, 21 C.F.R. § 137.165(a) (2003) (specifying that “enriched flour” must contain “in each pound 2.9 milligrams of thiamin, 1.8 milligrams of riboflavin, 24 milligrams of niacin, 0.7 milligrams of folic acid, and 20 milligrams of iron.”).

calibrated response to scientific uncertainty than an outright ban on the ingredient. As Peter Barton Hutt acknowledged in a 1981 article, the FDA “could... target future food standards for those categories of products for which control of the macronutrient content could potentially have the greatest public health impact.”⁴⁰ Imagine, for example, that credible scientific evidence points increasingly, but not definitively, to the conclusion that high-fructose corn syrup is metabolized differently than other sugars and is disproportionately a culprit in rising obesity levels in youth. The FDA could respond by eliminating high-fructose corn syrup from its identity standards for fruit juices and not for soft drinks, or vice versa, depending on which measure it judged would most reduce children’s consumption of the ingredient until its danger—or its safety—was more conclusively established. Such an approach could strive to adjust the overall use of an ingredient in inverse proportion to the known risk the ingredient poses to public health. It could also allow the FDA to err on the side of caution when a product tends to be marketed to or consumed by a particularly vulnerable segment of the population—most often, children.

III.

Food Standards of Identity: History and Structure

Providing the FDA with the authority to promulgate food standards of identity was one of the main aims driving the passage the FDCA in 1938;⁴¹ the Pure Food and Drug Act of 1906,⁴² which preceded the FDCA, did not provide such administrative authority. With no standards of identity to consider, courts had only a vague baseline for determining whether a product had been economically adulterated.⁴³ Courts thwarted

⁴⁰Hutt, *supra* note 21, at 72.

⁴¹See Merrill & Collier, *supra* note 5, at 566–67.

⁴²Ch. 3915, 34 Stat. 768 (repealed 1938).

⁴³See Merrill & Collier, *supra* note 4, at 565.

the federal government's repeated attempts in the late 1920s and early 1930s to stop a manufacturer from selling a jamlike product that contained little fruit, for example, because there was no legal standard setting forth what the fruit content of jam (or a product that looked and tasted like jam) should be.⁴⁴

According to Merrill and Collier, "Congress authorized the adoption of food standards to ensure that manufacturers would not frustrate consumer expectations respecting particular foods by exploiting their ignorance or indolence."⁴⁵ In addition to preventing consumers from being in some manner fooled, standards of identity also empowered the FDA to prevent potential health catastrophes by excluding untested chemical additives from the rundown of acceptable ingredients for each food.⁴⁶ (The Food Additives Amendment,⁴⁷ which now serves this function, was not passed until two decades after the FDCA.)

A standard of identity sets forth a list of mandatory and optional ingredients in a product; it may also specify the amount of each ingredient the food must contain or prescribe a specific method of production. A regulation setting forth a standard of identity has traditionally resembled a recipe for the food in question,⁴⁸ in fact, standards of identity were originally crafted to resemble "time-honored standards employed by housewives and reputable manufacturers"⁴⁹ so that food would meet consumers' expectations. When the standards for jams and jellies were being established soon after the passage of the FDCA, for example, the FDA "accepted evidence from cookbooks and family recipes dating back at least 200 years."⁵⁰

⁴⁴See *id.* at 565 n.20 (describing the famous "Bred Spred" line of cases).

⁴⁵See *id.* at 594.

⁴⁶See Miller & Skinner, *supra* note 39, at 101 ("[B]ecause the 1938 Act gave the agency only limited powers to control unsafe food additives prior to their use, FDA turned to standards as one way of limiting introduction into food of new chemical substances that had not undergone exhaustive testing.")

⁴⁷Pub. L. No. 85-929, 72 Stat. 1784 (1958) (codified at 21 U.S.C. § 348).

⁴⁸See *id.* at 563.

⁴⁹Merrill & Collier, *supra* note 5, at 567 (quoting H.R. REP. NO. 2139 at 5, 75th Cong., 3d Sess. (1938)).

⁵⁰Suzanne White Junod, The Rise and Fall of Federal Food Standards in the United States: The Case of the Peanut Butter and Jelly Sandwich (Apr. 9, 1999), <http://www.fda.gov/oc/history/slideshow/default.htm>.

After Congress passed the Food Additives Amendment of 1958,⁵¹ which provided for a general prescreening of all new ingredients to ensure they were “safe and suitable,” and the Color Additives Amendment of 1960,⁵² the FDA moved toward less restrictive and less recipe-like food standards.⁵³ The 1965 standard for frozen raw breaded shrimp, for example, was hailed as an innovation⁵⁴ because, while it specified the requisite quantity of shrimp by weight, it left the breading content wide open.⁵⁵

Though promulgated under the rubric of consumer protection, standards of identity were also significant boon to established manufacturers⁵⁶ and to many primary food producers, such as fruit growers and dairy farmers.⁵⁷ By specifying base percentages of primary ingredients in many foods, the standards prevented food producers from marketing products such as nearly fruitless jam and “filled milk,” the vegetable-oil-fortified milk product that formed the controversy in *Carolene Products Co. v. United States*.⁵⁸ Not coincidentally, proposals for new standards of identity and amendments to existing standards are often initiated by food industry trade groups. To convince the FDA to amend or promulgate a standard, however, food producers must establish that the regulation will benefit consumers. (A good recent example of this emphasis can be found in the National Yogurt Association’s request that the FDA add active culture requirements to the standard of identity for their product because “yogurt has been characterized for centuries by its live and active cultures, and thus a minimum content of live and active cultures is crucial to the yogurt standard of

⁵¹Pub. L. No. 85-929, 72 Stat. 1784 (1958) (codified at 21 U.S.C. § 348 (2000)).

⁵²Pub. L. No. 86-618, 74 Stat. 397 (1960) (codified at 21 U.S.C. § 376 (2000)).

⁵³See Junod, *supra* note 50.

⁵⁴See Chen, *supra* note 56, at 202; Merrill & Collier, *supra* note 5, at 611–612.

⁵⁵21 C.F.R. § 161.175 (2003) (frozen raw breaded shrimp).

⁵⁶Some commentators have pointed out that standards of identity increase entry barriers for new food producers because they effectively impose a minimum cost for the manufacture of standardized foods. See, e.g., Christopher Chen, *Food and Drug Administration Standards of Identity: Consumer Protection Through the Regulation of Product Information*, 47 Food & Drug L.J. 185, 197 (1992) (“For example, assuming that peanuts are the most expensive ingredient in peanut butter, the peanut butter standards sets a minimum price for peanut butter.”). If new manufacturers lack the opportunity to distinguish themselves through lower prices, established brand names will enjoy an even greater advantage than usual.

⁵⁷See *id.* at 198 (noting that the dairy industry resisted the relaxation of the standard for ice cream, and observing that “the peanut growers of America, for example, naturally have a vested interest in the creation of a peanut butter standard that would have the highest possible percentage of peanuts”).

⁵⁸304 U.S. 144 (1938). *Carolene Products* was being prosecuted for violating the Filled Milk Act of 1923. Footnote four of the opinion yielded the famous “discrete and insular minorities” justification for heightened equal protection scrutiny. *Id.* at 153 n.4.

identity to promote honesty and fair dealing in the interest of consumers.”⁵⁹) Although some commentators have pointed out that food standards provide ample opportunities for political rent-seeking,⁶⁰ the standards may also help prevent a ‘race to the bottom’ in which manufacturers compete to the extent the market will allow by selling foods that are less wholesome and therefore cheaper to produce.⁶¹ Assuming that the assurance that many staple foods meet a minimum standard of quality and healthfulness should be balanced against the need to keep food prices down, the interests of consumers and established food producers are certainly not always at odds.

More than forty percent of existing food standards of identity are for dairy products⁶²—milk and cream,⁶³ cheeses,⁶⁴ ice cream,⁶⁵ and yogurt⁶⁶ among them. Other major categories of food for which standards

⁵⁹Milk and Cream Products and Yogurt Products; Petition to Revoke Standards for Lowfat Yogurt and Nonfat Yogurt and To Amend Standards for Yogurt and Cultured Milk, 68 Fed. Reg. 39,873, 39,874 (July 3, 2003). Citing both self-interest and consumer protection, the dairy lobby immediately objected to a portion of the proposed standard that would allow yogurt producers to add dairy protein concentrates to their products. See Letter of Robert D. Byrne, Vice President of Regulatory Affairs, National Milk Producers Federation, to Division of Dockets Management (HFA-305), Food & Drug Administration, Re: Notice of Proposed Rulemaking (September 29, 2003) (“Many of [the National Yogurt Association’s proposed changes] appear to be merely seeking an allowance to potentially use cheaper ingredients in the manufacture of yogurt. NMPF believes such actions will have a negative impact on the use of milk in yogurt making and will also negatively impact dairy producers across the U.S. Of equal importance is the fact that the potential for confusing labeling inconsistencies and for inferior quality products will not promote honesty and fair dealing in the interest of consumers.”), <http://nmpf.org/files/Yogurt.Comments.doc>.

⁶⁰See Chen, *supra* note 56, at 197–98.

⁶¹Similarly, Merrill and Collier describe a couple of different ways in which “disreputable” manufacturers could theoretically swindle hapless customers. A food producer could market a low-quality, low-priced product that customers would be unlikely to purchase again, but it could change the brand name frequently to keep luring purchasers. Merrill & Collier, *supra* note 5, at 595–96. Alternatively, a producer could introduce a quality product, cultivate loyal buyers, and then “vary its composition in ways that would reduce his costs but elude detection by consumers.” *Id.* at 596. In this era of mandatory ingredient labeling, of course, food producers would be less likely than past manufacturers to succeed with such tactics, but the FDA does not require information about the precise proportions of ingredients to be listed on the labels of most foods, and consumers may not scrutinize labels carefully in any event. See Chen, *supra* note 57, at 186 (“In a world of imperfect product information, a world in which mandatory label disclosures are often of limited value, government-enforced food standardization increases the information value of product names [and] reduces consumer search costs....”)

⁶²Letter from Greg Frazier, Senior Vice President, Int’l & Regulatory Affairs, Int’l Dairy Foods Ass’n, to Dockets Management Branch, Food & Drug Admin., Re: Docket No. 98N-0359—Program Priorities in the Center for Food Safety and Applied Nutrition; Request for Comments—Fiscal Year 2002-2003 (Aug. 19, 2002), <http://www.idfa.org/news/stories/2002/08/foodsafefcfm>.

⁶³See, e.g., 21 C.F.R. § 131.110 (milk); *id.* § 131.130 (evaporated milk); *id.* § 131.160 (sour cream); *id.* § 131.170 (eggnog).

⁶⁴See, e.g., *id.* § 133.133 (cream cheese); *id.* § 133.149 (gruyere cheese); *id.* § 133.171 (pasteurized process pimento cheese).

⁶⁵*Id.* § 135.110.

⁶⁶*Id.* § 131.200 (yogurt); *id.* § 131.203 (lowfat yogurt); *id.* § 131.206 (nonfat yogurt).

remain in force are fish and shellfish,⁶⁷ cereal flours,⁶⁸ macaroni and noodle products,⁶⁹ canned fruits and vegetables,⁷⁰ fruit jellies and jams,⁷¹ margarine,⁷² nut products,⁷³ cacao products,⁷⁴ and sweeteners and syrups.⁷⁵ A brand-new and fairly typical food standard is that for white chocolate, which becomes effective on January 1, 2004. (Incidentally, this standard was the first entirely new one promulgated by the FDA in some twenty years.) It begins with a brief description of the food: “White chocolate is the solid or semiplastic food prepared by intimately mixing and grinding cacao fat with one or more of the optional dairy ingredients... and one or more optional nutritive carbohydrate sweeteners....”⁷⁶ The standard then specifies mandatory amounts of key ingredients by weight;⁷⁷ lists optional ingredients such as butter, buttermilk, malted milk, spices, emulsifying agents, and even ground coffee;⁷⁸ and sets forth acceptable labeling nomenclature.⁷⁹

Something nearing two hundred standards of identity still exist. Although most now allow producers to add unspecified “safe and suitable” ingredients, the standards are usually crafted with a specificity that might stun the layman. Vice President Al Gore’s shock at learning that the FDA set forth precise standards for the shapes in which canned green beans could be sold evidently spurred a 1995 advance notice of proposed rulemaking to solicit comments on the ongoing viability of the food standards regime.⁸⁰ As one commentator

⁶⁷See, e.g., *id.* § 161.145 (canned oysters); *id.* § 161.190 (canned tuna).

⁶⁸See, e.g., *id.* § 137.185 (enriched self-rising flour); *id.* § 137.250 (white corn meal); *id.* § 137.350 (enriched rice).

⁶⁹See, e.g., *id.* § 139.115 (enriched macaroni products); *id.* § 139.155 (enriched noodle products).

⁷⁰See, e.g., *id.* § 145.110 (canned applesauce); *id.* § 145.131 (artificially sweetened canned figs); *id.* § 155.170 (canned peas); *id.* § 155.191 (tomato concentrates).

⁷¹See, e.g., *id.* 150.141 (artificially sweetened fruit jelly); *id.* § 150.160 (fruit preserves and jams).

⁷²*Id.* § 166.110.

⁷³See, e.g., *id.* § 164.110 (mixed nuts); *id.* § 164.150 (peanut butter).

⁷⁴See, e.g., *id.* § 163.112 (breakfast cocoa); *id.* § 163.130 (milk chocolate).

⁷⁵See, e.g., *id.* § 168.120 (glucose sirup); *id.* § 168.140 (maple sirup).

⁷⁶*Id.* § 163.124(a)(1).

⁷⁷*Id.* § 163.124(a)(2) (“White chocolate contains not less than 20 percent by weight of cacao fat as calculated by subtracting from the weight of the total fat the weight of the milkfat, dividing the result by the weight of the finished white chocolate, and multiplying the quotient by 100. The finished white chocolate contains not less than 3.5 percent by weight of milkfat... and not more than 55 percent by weight nutritive carbohydrate sweeteners.”)

⁷⁸*Id.* § 163.124(b).

⁷⁹*Id.* § 163.124(c) (“The name of the food is “white chocolate” or “white chocolate coating.” When one or more of the spices, flavorings, or seasonings specified... are used, the label shall bear an appropriate statement....”).

⁸⁰Stuart M. Pape, *Food Standards—Are They Obsolete?*, PREPARED FOODS, June 1996, at 33, <http://www.preparedfoods.com/archives/1997/1274>.

quipped at the time, “[b]y their very nature, food standards lend themselves to ridicule.”⁸¹ But if some of the standards appear ridiculous, it might be because they have been crafted to serve increasingly obsolete goals. There is probably no great need to protect consumers from the indignity of purchasing canned green-bean morsels cut to less than thirteen millimeters in length.⁸² But is beyond the pale to believe that consumers need to be protected from the partially hydrogenated oils and 900 milligrams of sodium in a single serving of cream of mushroom soup? We might be able to dismiss this sentiment as overly paternalistic were it not for the fact that current public health measures do not seem to be stemming the tide of chronic diet-related diseases.

IV. Adapting Standards of Identity To Regulate Dietary Disease Contributors

Ironically, food standards of identity have been widely (and justly) criticized in the past for inhibiting rather than fostering the production of more healthful products, particularly in the case of dairy products.⁸³ For varieties of cheese, for example, the standards of identity often specify a minimum milk fat content; lower fat versions of those cheeses technically used to violate the applicable standards of identity. (The agency has since passed a regulation setting forth general requirements for standardized foods modified with a nutrient-content claim such as “lowfat.”⁸⁴) The FDA has in some instances even prosecuted food producers who have

⁸¹*Id.* Pape concluded, however, that “amidst all the ridicule, [food standards] are serious issues of food policy with enormous implications for both domestic and international trade in foodstuffs.” *Id.*

⁸²See 21 C.F.R. § 155.120(b)(1)(i).

⁸³NAT’L RESEARCH COUNCIL, BD. ON AGRIC., DESIGNING FOODS: ANIMAL PRODUCT OPTIONS IN THE MARKETPLACE, COMMITTEE ON TECHNICAL OPTIONS TO IMPROVE THE NUTRITIONAL ATTRIBUTES OF ANIMAL PRODUCTS 105 (1988) (“Standards of identity specifications for some animal products are so restrictive that replacing the high-fat or high-cholesterol components of foods with nonfat or low-fat ingredients is impossible.”), *quoted in* John Agar, *Generally Recognized as Sour Cream: Treating Standards of Food Identity as a Success*, 44 FOOD DRUG COSM. L.J. 237, 238 (1989).

⁸⁴See 21 C.F.R. § 130.10 (2003).

formulated products that were *more*, not less,⁸⁵ nutritional than the applicable standard prescribes, though the agency has since largely discontinued its policy of objecting to added nutrients,⁸⁶ so long as the product in question is clearly labeled.

The FDA could certainly adapt food standards of identity to support a wider range of health goals.⁸⁷ To make a real impact, however, it might need to significantly broaden the categories of food to which standards apply—specifically, to cover more foods that could be characterized as ‘highly processed’ or ‘convenience’ foods. In addition, the agency may need to alter existing enforcement strategies somewhat to prevent manufacturers from circumventing new, broader standards. Whether or not the FDA should choose to pursue this course is more a matter of policy than legal authority, as there appears to be “no legal basis”⁸⁸ for distinguishing between the FDA’s longstanding tradition of regulating the vitamin and mineral content of food and the regulation of macronutrients or specific ingredients implicated in diet-related diseases. However, this paper discusses specific criteria that relate to the propagation and enforcement of healthfulness-related food standards in Part V.

⁸⁵In the *Federal Security Administrator v. Quaker Oats Co.* case, one of the few Supreme Court cases dealing directly with food standards, the FDA had chosen to prosecute Quaker for adding Vitamin D to its wheat farina. 318 U.S. 218, 224 (1943). The FDA believed that adding “Enriched with Vitamin D” to the product’s label might confuse consumers into believing that the product met the identity standard for “enriched farina,” which included other nutrients such as iron, rather than the standard for simple “farina,” however, *see id.* at 226, so this enforcement measure was understandable. In another case, however, the FDA used its enforcement power to prevent a brand of spaghetti from formulating its product with twenty percent protein rather than the prescribed thirteen percent. *See United States v. 20 Cases, More or Less, Containing Buitoni 20% Protein Spaghetti*, 130 F. Supp. 715, 716 (D. Del. 1954), *aff’d*, 228 F.2d 912 (3d Cir. 1956); *see also* U.S. v. 856 Cases, More or Less, Labeled “Demi,” 254 F. Supp. 57, 62 (N.D.N.Y. 1966) (refusing to uphold an FDA order banning the sale of an “imitation margarine” with “half the calories of margarine” that contained 38% fat rather than the prescribed 80%).

⁸⁶*See* Degnan, *supra* note 5, at 269 (stating that, since the 1973 principles, “[t]he use of the name of a standardized food in the name of a substitute food is less troublesome to the FDA when the substitute food is merely the standardized food with added ingredients”).

⁸⁷Miller and Skinner briefly suggested such an approach in their 1984 article when they stated that new standards should perhaps “be based in large measure on nutritional considerations and the ability of products to satisfy nutritional needs rather than solely on the sensory qualities of food.” Miller & Skinner, *supra* note 39, at 105.

⁸⁸Hutt, *supra* note 21, at 72.

A. Creating Healthful Standards of Identity

The healthfulness of some foods could be improved by relatively minor changes to existing standards of identity. The detailed standard for tomato juice, for example, already prescribes a method of production, a certain “strength and redness of color,” the acceptable number of “defects”—meaning black specks, seeds, and bits of peel—per 500 milliliters, and fill-of-container standards.⁸⁹ It also specifies that the juice may be “seasoned with salt.”⁹⁰ Supposedly healthful vegetable juices often contain surprisingly large amounts of sodium, however. An eight-ounce serving of a popular brand of tomato juice from concentrate, for instance, contains thirty percent of the RDI of sodium. (My favorite brand of corn chips contains roughly the same amount of sodium in an entire eight-serving bag.) The FDA could consider setting a limit on the amount of sodium that producers could add to tomato juice and similar products.

Similarly, the current standard for bread⁹¹ could include an upper limit on the amount of sugar producers could include, or it could exclude certain types of sugars. (High fructose corn syrup, for example, is now an ingredient in a significant portion of national-brand breads on supermarket shelves.) The food standard for margarine⁹² could limit the amount of trans fats a product could contain. The standard for yogurt⁹³ could omit high-fructose corn syrup as an acceptable sweetener, if the FDA concluded that such a measure was prudent—and such a step might be particularly important for a product like yogurt that consumers consider generally healthful and even a “health food.” The imagination does not have to stretch far to locate examples of food standards that the FDA could retool in this way, provided that the regulations promoted “honesty and fair dealing in the interest of consumers.”⁹⁴

⁸⁹21 C.F.R. §§ 156.145, § 156.3 (2003).

⁹⁰*Id.* § 156.145(a).

⁹¹*Id.* § 136.110 (bread, rolls, and buns); *id.* § 136.115 (enriched bread, rolls, and buns).

⁹²*Id.* § 166.110.

⁹³*Id.* § 131.200 (yogurt); *id.* § 131.203 (lowfat yogurt); *id.* § 131.206 (nonfat yogurt).

⁹⁴21 U.S.C. § 341 (2000). For more on the implications of the statutory standard, see *infra* Part V.

B. Widening the Range of Standards

Over the past several decades, food manufacturers have introduced an often baffling number of new highly processed or “convenience” foods. Such processed foods tend to be high in sodium, low in fiber, and loaded with trans fats and added sugar. They also are generally not covered by food standards of identity. Part of the reason for this is probably logistical: such products are a boon for manufacturers precisely because there are millions of possible recipes for “cereal bars,” “fitness bars,” “snack crackers,” “sports beverages,” and the like (and there are certainly no “time-honored standards employed by housewives and reputable manufacturers”⁹⁵ to be consulted). Moreover, meaningful enforcement would be a problem: the success of such products is generally not dependent on consumers’ identifying them by an established name—unlike products such as “yogurt,” “cheddar cheese,” or “canned green beans.” The variety and novelty of processed food products need not prevent the FDA from imposing standards, however; the agency may just need to make particular standards very broad and to enforce them strictly around the edges.

There is currently no standard of identity for “breakfast cereal,” for instance (or for specific forms of breakfast cereal such as corn flakes, raisin bran, or granola). It is not difficult to understand why; due to the great variety among the products currently marketed as breakfast cereal, it would be hard to create a recipe-like standard. Common offerings range from high-fiber flakes to puffed rice to granola (often high in fat) to Froot Loops and other “kids” cereals (in which sugar tends to be the most plentiful ingredient by weight). If food standards were reconceived to function partially as health policy tools, however, the FDA could conceivably

⁹⁵Merrill & Collier, *supra* note 5, at 567 (quoting H.R. REP. NO. 2139 at 5, 75th Cong., 3d Sess. (1938)).

promulgate a “breakfast cereal” standard (or set of standards) that merely specifies a certain percentage of grain and perhaps a minimum amount of dietary fiber and that limits sugar content, fat content, and/or the use of certain fats. Such a standard would resemble celebrate “frozen breaded shrimp” standard described above in its non-recipe-like nature but would encompass a much broader range of food products. Similar standards could exist for familiar categories of snack foods such as potato chips, corn or tortilla chips, granola bars, various categories of snack crackers, and so on—again, limited only by the statutory language of Section 401.⁹⁶

This “broad standards” approach could apply equally well to popular categories of beverages. Although there is a recent standard that sets forth detailed requirements for bottled water,⁹⁷ there is no such standard for cola⁹⁸ (except for the physical, microbiological, and chemical quality of the water that goes into it⁹⁹), even though Americans consume 56 gallons of soft drinks per person per year¹⁰⁰ and standards that raised the bar of healthfulness for these beverages (say, by limiting what sweeteners could be added) would therefore have a significant impact on the average diet. There is also no standard for products marketed as sports beverages, even though athletes who use them to replenish after vigorous exercise could conceivably be harmed if adequate carbohydrates, nutrients, and electrolytes were not in fact included in a formulation.

⁹⁶21 U.S.C. § 341 (2000); *see supra* Part V.

⁹⁷21 C.F.R. § 165.110.

⁹⁸There was apparently a food standard for cola in effect at one time. Beverage makers lobbied for one so they would not have to disclose the presence of caffeine on the product label. *See* Merrill & Collier, *supra* note 5, at 577 n.87 (citing J. TURNER, THE CHEMICAL FEAST 52 (1970)). (It was not until recently that all ingredients of standardized products were required to be listed on labels.)

⁹⁹*See id.* § 165.110(b).

¹⁰⁰Meg Jones, *Milk Vying with Soda for Pupils’ Attention*, MILWAUKEE J.-SENTINEL ONLINE, September 30, 2001, <http://www.jsonline.com/alive/nutrition/sep01/milk01093001.asp?format=print>.

If the FDA were to promulgate broader standards to cover a greater variety of processed foods, the necessary corollary would be to make enforcement stricter in some respects. After all, creating more health-centered food standards of identity and broadening the range of promulgated standards would be a futile exercise if food producers could evade standards by altering a label to give the food a slightly different name. The next Part will consider the scope of FDA authority to promulgate broad, health-based standards of identity and to prevent the circumvention of those standards.

V. The Scope of Regulatory Authority To Use Standards of Identity as a Means of Limiting Dietary Disease Contributors

A. FDA Discretion Under Section 401

As discussed in section II.C, the FDA creates food standards of identity pursuant to the statutory authority of Section 401 of the FDCA.¹⁰¹ The most direct Supreme Court authority on this provision consists of a 1943 case, *Federal Security Administrator v. Quaker Oats Co.*,¹⁰² in which the Court ruled that the FDA could create (and enforce) a standard of identity if “substantial evidence”¹⁰³ showed that its decision to do so was justified under the statutory standard of “promot[ing] honesty and fair dealing in the interest of customers.”¹⁰⁴ According to Merrill and Collier, the decision “confirmed that the FDA’s authority to establish standards of identity included the broad power to forbid the marketing of long-established, truthfully labeled, wholesome foods when in its judgment, such action was necessary to prevent consumer deception.”¹⁰⁵

¹⁰¹21 U.S.C. § 341 (2000).

¹⁰²318 U.S. 218 (1943). For a description of the holding of this case, see *supra* note 85.

¹⁰³*Id.* at 228.

¹⁰⁴21 U.S.C. § 341.

¹⁰⁵Merrill & Collier, *supra* note 5, at 570.

Guaranteeing the healthfulness of foods and preventing consumer deception have always gone hand in hand in the food standards arena. Congress was well aware when the statute was passed that economic fraud was often accompanied by nutritional inferiority.¹⁰⁶ In at least one case, however, *Cream Wipt Food Products Co. v. Federal Security Administrator*,¹⁰⁷ a circuit court struck down a standard of identity for salad dressing that the FDA justified in nutritional terms, voicing doubt as to whether customers actually chose salad dressing with a certain expectation of nutritional value.¹⁰⁸ Though that case is a half-century old, it may provide some indication of how courts will treat standards of identity premised on concerns over dietary disease contributors: the heart of the inquiry will likely be what consumers *expect* rather than what ingredients or macronutrient contents would objectively be the most healthful. That is, it seems clear that under the language of Section 401, the FDA must show that a standard of identity helps to ensure that a food will conform to consumer expectations. To promulgate a broad standard of identity for “breakfast cereal,” for example, the FDA would have to demonstrate that consumers expect breakfast cereal to be a healthful food.

An expectation of healthfulness would certainly be more difficult to establish for products that have traditionally been considered “junk food” than for those such as breakfast cereal that are considered dietary staples. The FDA could, however, present data suggesting that, while consumers know that consuming too many potato chips or cheese-flavored crackers could make them overweight, many do not realize that such foods could contribute to other specific diseases such as hypertension, heart disease, or even cancer. In any event, the agency would probably wish to choose its battles by formulating health-promoting standards first for those products that consumers are most likely to view as particularly healthful.

¹⁰⁶ See *Agar*, *supra* note 83, at 241 (“Protection of consumers’ pocketbooks indirectly also protected the public health, because the cost of ‘an economic cheat results in many instances in the undernourishment of children and resultant impairment of strength and loss of health.’” (quoting C.W. DUNN, FEDERAL FOOD, DRUG, AND COSMETIC ACT LEGISLATIVE RECORD 571 (1938))).

¹⁰⁷ 187 F.2d 789 (3d Cir. 1951).

¹⁰⁸ See *id.* at 791.

Though there is certainly a statutory threshold that the agency must meet, it seems certain that courts will take evolving consumer expectations as to healthfulness must be taken into account in determining whether a standard does indeed promote honesty and fair dealing in the interests of consumers. After noting that a primary purpose of standards of identity was to protect the consumer from economic adulteration, for example, a federal district court in Oklahoma expressed such a sentiment when it stated: “If the condemned article contains chemical preservatives and other optional ingredients in even minute amounts, such fact, in view of the increasing concern about chemical additives and preservatives in food, may reduce the value of the article in the eyes of the informed consumer.”¹⁰⁹ The same would likely hold true for food products with potentially dangerous levels of some macronutrients or specific ingredients that contribute to disease. Moreover, the FDA has traditionally been awarded a great deal of discretion in the food standards area. As the Second Circuit put it, “Striking a proper balance among the interests of sophisticated and unsophisticated consumers is for the agency, not for a reviewing court.”¹¹⁰

B. FDA Discretion Under Section 403

The FSA enforces standards of identity by invoking Section 403 of the FDCA, the Act’s misbranding provision. Section 403(g) provides that a product shall be considered misbranded if:

it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations. . . unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients... present in such food.¹¹¹

In addition, Section 403(b) deems a food to be misbranded “[i]f it is offered for sale under the name of

¹⁰⁹United States v. An Article of Food Consisting of 126 Cases, More or Less... Pure Raw Honey Packed For J.G. Samples, 550 F. Supp. 15, 19 (W.D. Okla. 1982).

¹¹⁰Nat’l Nutritional Foods Ass’n v. FDA, 504 F.2d 761, 782 (2d Cir. 1974).

another food,”¹¹² and Section 403(c) applies if the food “is an imitation of another food” without being clearly labeled as such.¹¹³ Misbranded products may not lawfully be sold.

The precise legal parameters of the “purports to be” language in Section 403(g) have long been somewhat of a mystery, as there is little case law on the provision.¹¹⁴ For the first several decades of the FDCA’s existence, the FDA was successful in bringing actions against manufacturers even when there seemed to be little risk that customers would mistake the claimed imposter for the standardized product. For example, in *Libby, McNeill & Libby v. United States*,¹¹⁵ the Second Circuit held that the FDA had the authority to ban the sale of a product labeled as “tomato catsup” because it contained a preservative not provided for in the standard, even though the label clearly indicated that the catsup contained the preservative and did not conform to the standard. In other cases, the product in question was not even labeled with the name of the standard, but the FDA nonetheless charged that it purported to be the standardized product. In several cases, the agency was successful in deeming “fruit spreads” and similarly designated products misbranded in violation of the standard of identity for fruit preserves.¹¹⁶ In another case, the Third Circuit held that an “orange beverage” might be misbranded because it violated the standard of identity for orange juice, though the FDA first had to establish that consumers confused the two products.¹¹⁷

In the early 1970s, however, the FDA softened its stance. For example, it redefined an “imitation” food as one which is used as a substitute for and which resembles a food for which a standard of identity exists,

¹¹²*Id.* § 343(b).

¹¹³*Id.* § 343(c).

¹¹⁴*See* Agar, *supra* note 83, at 244-46 (describing the early parameters of the FDA’s enforcement of food standards under Section 403(g)).

¹¹⁵148 F.2d 71 (2d Cir. 1945); *see also* *United States v. 20 Cases, More or Less, Containing Buitoni 20% Protein Spaghetti*, 130 F. Supp. 715, 716 (D. Del. 1954), *aff’d*, 228 F.2d 912 (3d Cir. 1956) (holding that pasta with a protein content higher than the standard of identity required was mislabeled); *Federal Security Administrator v. Quaker Oats*, 318 U.S. 218 (1943).

¹¹⁶*See, e.g.*, *United States v. Ninety-Nine Cases... Southland Fountain Fruit*, 89 F. Supp. 992 (E.D. Tenn. 1949); *United States v. 30 Cases... Leader Brand Strawberry Fruit Spread*, 93 F. Supp. 764 (S.D. Iowa 1950); *see also* Merrill & Collier, *supra* note 5, at 571-74 (describing the key early cases implicating the “purports to be” language).

¹¹⁷*See* *United States v. 88 Cases... Bireley’s Orange Beverage*, 182 F.2d 967, 974-74 (3d Cir. 1951).

but is “nutritionally inferior.”¹¹⁸ (Before, no such requirement of nutritional inferiority existed.) The FDA also promulgated “common or usual names” regulations that apply to some foods for which there are no standards of identity. Hutt has cited the fact that “there exists strong precedent authorizing the marketing of nonconforming products as nonstandardized versions with their own ‘common or usual name’”¹¹⁹ as an obstacle to the FDA’s regulating macronutrients through standards of identity—even if something looks a lot like jam or ketchup, the FDA will allow the product to be sold as long as it does not specifically claim to be the standardized product.

As stated above, addressing diet-related disease risks with a broadening of standards would also entail a stricter enforcement strategy around the edges. That is, although health-targeted standards themselves could be less recipe-like and more flexible, the FDA would have to take measures to assure that manufacturers could not circumvent such standards by using a slight alteration of a standardized product name. Preventing circumvention might mean that the agency would have to broaden its interpretation of the “purports to be” standard, as compared to its stance in recent years, to include even some products that could currently be marketed under another name—for instance, calling a food that looked like breakfast cereal and was marketed as such a “breakfast snack” would not pass muster. In shifting gears, however, the agency would only have to restrict the sale of products that are nutritionally inferior to the similar standardized products—a specification similar to the one the FDA used in its reinterpretation of the “imitation” food provision.

Such a strategy might also entail specific restrictions on the marketing of convenience forms of popular products. For example, the agency might consider restricting manufacturers’ practice of using the same general product names for snacks that they do for products held to more healthful standards. A Honey Nut Cheerios Milk ‘n Cereal Bar, for example, rides the marketing coattails of its relatively healthy breakfast-

¹¹⁸21 C.F.R. 101.3(e).

¹¹⁹Hutt, *supra* note 21, at 72.

cereal namesake but includes trans fats and forty-five percent more sugar than the original. Restricting such nomenclature would also help consumers in the position of our high school sophomore canvassing the convenience store for a healthy snack and coming upon a “cereal bar yogurt bar”: The FDA could promulgate a standard (or standards) of identity for breakfast cereal. Then it could either enforce its standards such that a “cereal” bar would have to bear a macronutritional resemblance to cereal (and, in addition, to require that a “yogurt bar” contain yogurt, or at least the same nutritional properties—macro and micro—as yogurt) or create separate (and similar) standards for cereal-based derivative products themselves. Doing so would help the food conform to her expectations and the expectations of most consumers.

Adopting a more rigorous enforcement strategy would naturally have its costs, both to taxpayers—because the FDA would have to expend significant resources in promulgating and enforcing retooled regulations—and to consumers, who would likely spend more for food of higher nutritional quality.¹²⁰ Consumers might also experience an additional food cost increase attributable to reductions in manufacturers’ profit margins, because food standards place constraints on innovation. Setting up a cost-benefit analytical framework to estimate the cost of standards of identity to government and (especially) to consumers was the primary goal of Merrill and Collier’s seminal 1974 article.¹²¹ The authors noted that food standards distort demand for standardized products, because the standards force some consumers to pay more than they otherwise would have if they had had the choice to buy what the FDA has deemed an inferior product (one that, for example, contains a lower percentage of a key ingredient than the standard requires). Such consumers will overpay if they insist on eating the standardized foods, which means that they may devote a greater proportion of their overall income to food.¹²²

¹²⁰Presumably, if more healthful ingredients were also less expensive, manufacturers would use them without any regulatory incentive (assuming that the more healthful ingredients created foods that were equally satisfying to consumers).

¹²¹See Merrill & Collier, *supra* note 5, at 591–610.

¹²²See *id.* at 604–07.

Such costs must be balanced against the benefits of such a strategy, however. Although the FDA should undoubtedly pursue any measure that would increase the price of food with great caution, it is worth noting that today's food prices are at a historical low as a percentage of the average household budget,¹²³ and that chronic diseases hastened by overconsumption of the wrong foods may currently be a far greater problem for the poor—whom food price increases would most affect—than is undernutrition. (One can be both obese and undernourished, of course, which seems to be a growing problem among the poor;¹²⁴ this fact suggests that measures that address both problems are not necessarily at odds.) Moreover, the burgeoning healthcare costs from the current epidemic of diet-related diseases fall—and will continue to fall—partly on taxpayers, a prospect which adds great weight to the pro-regulation, public health intervention side of the cost-benefit scale. Rather than dismissing as a reactionary strategy the broadening and rigorous enforcement of food standards of identity, the FDA should investigate the (quite realistic) possibility that such measures would leave both taxpayers and consumers better off on the whole.

Conclusion

In sum, the FDA should consider using food standards of identity as a means of regulating dietary disease contributors—that is, of both macronutrients and specific ingredients (apart from those left off the GRAS list altogether) that the scientific evidence indicates are particularly detrimental to human health. This strategy would be a reasonable way for the FDA to venture beyond labeling requirements, should it determine that

¹²³ See Remarks of Dr. Joseph Jen, Undersecretary for Research, Education, and Economics, U.S. Dep't of Agriculture, to Louisiana Food Producers' Conference (Oct. 2, 2002) ("Today we enjoy the highest quality and lowest cost food in the world... [T]he percentage of household income we spend on food has dropped from 20.5 percent in 1950 to 10.2 percent in 2000."), at http://www.reeusda.gov/ree/jen_presentations.htm.

¹²⁴ See generally CTR. ON HUNGER AND POVERTY, TUFTS UNIV., CHILDHOOD HUNGER, CHILDHOOD OBESITY: AN EXAMINATION OF THE PARADOX, http://nutrition.tufts.edu/pdf/publications/hunger/hunger_and_obesity.pdf.

labeling alone is not a sufficient means of protecting public health, because it would let the agency tailor the implementation of health standards to foods for which nutritional improvements would be most desirable and most feasible. Some might object that such a strategy is paternalistic as compared to labeling requirements, but a well-calibrated exercise of paternalism in the pursuit of public health goals may be no vice.