

**DESPITE WHAT YOU’VE BEEN SOLD—UNWRAPPING THE
FALSITIES SURROUNDING FOOD LABELS**

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I. INTRODUCTION

Have you ever bought a food product based on a health claim on the label? For instance, have you ever bought Dannon’s “Activia” or “DanActive” because the label claimed the product would “strengthen immune systems” and “regulate digestion?” If so, you are eligible to claim damages under the \$45

million class action settlement awarded to the consumers of Dannon for inherently deceptive advertising surrounding their yogurt products.¹ Dannon sold these yogurt products at a 30% premium over other brands based on the “clinically proven” marketing ploy.² The “[d]eceptive advertising [] enabled Dannon to sell hundreds of millions of dollars worth of ordinary yogurt at inflated prices to responsible, health-conscious consumers.”³

Until recently, food manufacturers have dictated what foods are “healthy” through unregulated front-of-packaging (“FOP”) food labels without consumer backlash. In the past, social stigmas reinforced the notion that obese people were overindulging, lethargic individuals who should be personally accountable for solving their own health issues.⁴ Yet today, we face an industry of harmful additives and overly processed foods in which manufacturers have arguably overcome individual willpower.⁵

Accordingly, more than one-third (34.9%) of the United States’s adult population is obese⁶ and 35.7% of West Virginia’s adults are obese.⁷ Comparatively, the United States has the highest obesity rate *in the world*,⁸ while West Virginia has the second highest adult obesity rate *in the nation*.⁹ As one commentator has stated, this “tsunami of obesity threaten[s] to cripple health care systems, burden economies and damage productivity.”¹⁰ From 1990 to 2013, obesity related health issues in the United States have steadily increased each year and today the global economic impact of non-communicable diseases related to obesity could total \$47 trillion over the next 20 years.¹¹

¹ Troy McMullen, *Dannon to Pay \$45M to Settle Yogurt Lawsuit*, ABC NEWS (Feb 26, 2010), <http://abcnews.go.com/Business/dannon-settles-lawsuit/story?id=9950269>.

² *Id.*

³ *Id.* (quoting Timothy Blood, Plaintiff’s attorney).

⁴ See Mark Hyman, *Four Ways Other Countries Are Successfully Tackling Obesity. Take Note, America*, THE WORLD POST (Sept. 30, 2014, 12:34 PM), http://www.huffingtonpost.com/dr-mark-hyman/four-ways-countries-obesity_b_5845336.html.

⁵ *See id.*

⁶ *Adult Obesity Facts*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/obesity/data/adult.html> (last visited Mar. 31, 2016).

⁷ *The State of Obesity in West Virginia*, THE STATE OF OBESITY, <http://stateofobesity.org/states/wv/> (last visited Mar. 31, 2016).

⁸ *International Comparisons*, PUB. HEALTH ENG., http://www.noo.org.uk/NOO_about_obesity/adult_obesity/international (last visited Mar. 31, 2016).

⁹ THE STATE OF OBESITY, *supra* note 7.

¹⁰ Hyman, *supra* note 4.

¹¹ Anthon Muchoki, *Non-Communicable Diseases to Cost \$47 Trillion by 2030, New Study Released*, PAMOMA (Sept. 20, 2011, 6:48 PM), <http://www.pamoma.com/stream/180-non-communicable-diseases-to-cost-47-trillion-by-2030-new-study-released/> (indicating that the global economic impact of the top non-communicable diseases, including cardiovascular disease (CVD), chronic respiratory disease, cancer, diabetes, and mental ill-health, could amount to \$47 trillion by 2030).

Further, obesity reduces one's lifespan by an estimated 5 to 20 years.¹² Obesity's negative effect on the life expectancy of the general population is critically important.¹³ The current generation's children may not only have a shorter lifespan, but also a lessened quality of life compared to their parents.¹⁴ Specifically, obesity-related health conditions are the leading causes of preventable death: heart disease, stroke, type II diabetes, and an increased risk of certain types of cancer.¹⁵ Shockingly, obesity reduces life expectancy by a larger percentage than all accidental deaths combined.¹⁶

Additionally, people who are obese pay an average of \$1,429 (42%) more in health care costs per year than individuals of normal weight.¹⁷ Analysis on the Medical Expenditure Panel Surveys has shown an undeniable link between increased Medicaid spending and growth of obesity.¹⁸ Pharmaceuticals and non-inpatient services, two major drivers of Medicare spending, were more than \$600 per year higher for obese beneficiaries than for those of a normal weight.¹⁹ In aggregate, the annual medical burden of obesity has increased.²⁰ It is estimated that if obesity had remained at 1998 levels, private and public spending would have been \$39 billion dollars less.²¹

Consequently, the public has overwhelmingly shifted its interest toward healthier food product selection and consumer awareness to mitigate the "obesity tsunami." The public strategy centers on a balanced daily diet and the reduction of high calorie, low nutritive value food products. As food companies market toward the "health conscious consumer," manufacturer's informative health claims—or lack thereof—on food product's labels became a hot topic in the fight against the obesity epidemic and have earned a spotlight in the legal

¹² S. Jay Olshansky et al., *A Potential Decline in Life Expectancy in the United States in the 21st Century*, 352 NEW ENG. J. MED. 1138, 1140 (2005), http://www.sjayolshansky.com/sjo/Background_files/NEJM2005final.pdf.

¹³ *Id.*

¹⁴ *Id.* at 1141.

¹⁵ *Adult Obesity Facts*, *supra* note 6.

¹⁶ Olshansky et al., *supra* note 12, at 1141 ("This reduction in life expectancy is not trivial—it is larger than the negative effect of all accidental deaths combined (e.g. accidents, homicide, and suicide).").

¹⁷ Eric A. Finkelstein et al., *Annual Medical Spending Attributable to Obesity: Payer- and Service-Specific Estimates*, 28 HEALTH AFF. 822, 825 (2009), <http://content.healthaffairs.org/content/28/5/w822.full.pdf+html> (\$1,429).

¹⁸ *See id.* at 823.

¹⁹ *Id.* at 828.

²⁰ *Id.*

²¹ *Id.* ("Across all payers, we estimate that had obesity prevalence remained at 1998 levels, spending attributable to obesity would have been \$47 billion in 2006 rather than \$86 billion (based on MEPS spending data).").

field similar to tobacco litigation.²² In support of higher understanding of labels, Michael Jacobson of the Center for Science in the Public Interest said it best, “When you look at the label, there are roughly two dozen numbers of substances that people aren’t intuitively familiar with.”²³

This Note argues that the United States Food and Drug Administration (“FDA”) should implement mandatory FOP disclosure labels to provide consumers with accurate information relating to the regularity of added sugar, *trans* fat, and sodium in their daily diet. The recommended FOP disclosures hold manufacturers accountable for these harmful additives, which will incentivize the production of healthier foods. Ideally, these disclosures will change not only how consumers select their daily food products but how food products—as a whole—are manufactured.

First, Part II of this Note focuses on three main nutritional culprits vital in informing consumers of a food product’s potential adverse health risks. Part III then describes the establishment of the regulatory system and the supervisory agency broadly controlling food labels. Next, Part IV analyzes the historical evolution of nutritional labeling on food products. Specifically, Part IV provides an overview of the regulations surrounding FOP disclosures and unwraps the shortfalls of the lax disclosure requirements. Lastly, Part V recommends the use of a mandatory FOP disclosure on manufactured products when nutrition guidelines indicate problematic levels of added sugar, *trans* fats, and sodium. More specifically, Part V sets out the technical and visual framework for the recommended FOP label “High in ____.” For example, a mandatory FOP label will directly indicate “High in *Trans* Fat.”

Ultimately, the Government cannot prevent the industry from imaginative labeling. However, mandatory FOP disclosure labels raise a symbolic red flag to consumers to beware of the product’s nutritive value. Together with continued consumer education initiatives, these disclosures achieve a low tolerance environment for illusory labeling and heighten expectations for nutritious food products.

II. THREE MAIN NUTRITIONAL CULPRITS CONTRIBUTING TO OBESITY

Within the American diet, there are certain nutrients that have been criticized greatly as contributing to an unhealthy lifestyle. Targeted by various pieces of legislation and diet campaigns, added sugar, sodium, and *trans* fat exemplify the core additives accelerating the obesity epidemic. These culprits are used in food products not for nutritional value, but by manufacturers to

²² See Barbara L. Atwell, *Is Sugar the New Tobacco? How to Regulate Toxic Foods*, 22 ANNALS HEALTH L. 138, 140 (2013) (suggesting that tobacco regulation, “including educational initiatives, warning labels, advertising restrictions, age limitations, and taxes,” should be used as a model for sugar regulation).

²³ Mary Clare Jalonick, *FDA to Revise Nutrition Facts Label*, USA TODAY (Jan. 23, 2014, 2:13 PM), <http://www.usatoday.com/story/money/business/2014/01/23/fda-to-revise-nutrition-facts-label/4799911/>.

extend shelf-life,²⁴ serve as a bulking agent,²⁵ make foods more appetizing by covering up less desirable flavors,²⁶ retain moisture,²⁷ and enhance colors.²⁸ Although these additives are ever-present in our daily food products, the nutritional guidelines and regulatory food labeling requirements have yet to adapt accordingly.²⁹ Moreover, consumers lack information on suggested daily intakes and adverse health conditions in choosing less healthy products.

This part highlights three nutritional culprits: added sugar, *trans* fat, and sodium. While an analysis of each and every harmful food additive is outside the scope of this Note, these select culprits are chosen because of their elevated presence and lack of necessity in food products. Furthermore, consumers need to be informed of these culprits' presence because they are the largest contributors to the consumption of high calorie, low nutritive value food products. The following sections examine each culprit's use, health impacts, suggested intake, and statutory display requirements on food labels.

A. Added Sugar

Added sugar contributes extra calories to an individual's diet, but provides little nutritional value.³⁰ Most clinical trials and dietary associations conclude that individuals who consume higher amounts of added sugar tend to gain more weight and have a higher risk of obesity along with obesity-related health concerns, especially cardiovascular disease ("CVD").³¹ In a study performed by the American Medical Association ("AMA"), analysts suggested

²⁴ *Trans Fat is Double Trouble for your Heart Health*, MAYO CLINIC (June 19, 2015), <http://www.mayoclinic.org/diseases-conditions/high-blood-cholesterol/in-depth/trans-fat/ART-20046114?> [hereinafter *Trans Fat*].

²⁵ *Added Sugar: Don't Get Sabotaged by Sweeteners*, MAYO CLINIC (Jan. 24, 2016), <http://www.mayoclinic.org/healthy-living/nutrition-and-healthy-eating/in-depth/added-sugar/art-20045328> [hereinafter *Don't Get Sabotaged by Sweeteners*].

²⁶ See U.S. FOOD & DRUG ADMIN., FOOD FACTS: SODIUM IN YOUR DIET: USE THE NUTRITION FACTS LABEL AND REDUCE YOUR INTAKE (2016), <http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/UCM315471.pdf> ("As a food ingredient, sodium has multiple uses, such as curing meat, baking, thickening, retaining moisture, enhancing flavor (including the flavor of other ingredients), and as a preservative.").

²⁷ *Id.*

²⁸ *Why Processed Foods Contain So Much Sodium*, FITDAY, <http://www.fitday.com/fitness-articles/nutrition/healthy-eating/why-processed-foods-contain-so-much-sodium.html> (last visited Mar. 31, 2016).

²⁹ See U.S. DEP'T OF AGRICULTURE: FOOD AND NUTRITION SERVICE, *TRANS FAT ON NUTRITION FACTS LABEL* (2015), http://portal.nysed.gov/portal/page/portal/CNKC/Nutrition_Page_pp/TransFatFactSheet.pdf (*Trans fat must be listed on the Nutrition Fact label; however no one "[has] recommended an amount of trans fat that FDA could use to establish a Daily Value (DV)"*).

³⁰ *Don't Get Sabotaged by Sweeteners*, *supra* note 25.

³¹ Quanhe Yang et al., *Added Sugar Intake and Cardiovascular Diseases Mortality Among US Adults*, 174 JAMA 523 (Apr. 2014) ("A higher percentage of calories from added sugar is associated with significantly increased risk of CVD mortality.").

“that participants who consumed greater than or equal to 10% but less than 25% of calories from added sugar . . . had a 30% higher risk of CVD mortality.”³² Moreover, the relative risk of CVD mortality nearly tripled for “those who consumed 25% or more calories from added sugar.”³³ The intake of excessive added sugar can lead to the development of hypertension, increased blood pressure, decreased high-density lipoprotein cholesterol levels, and increased genetic effects of obesity.³⁴ It is shown that “the number of people adversely impacted by sugar exceeds the number adversely impacted by tobacco.”³⁵

Currently, the United States FDA does not distinguish between added sugar and natural sugar present on nutrition labeling: “Sugars shall be defined as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose).”³⁶ The labels must contain the number of grams of sugars per serving, but if the product contains less than one gram of sugar per serving then the declaration of sugars content is not required.³⁷ Sugar content must be indented and expressed to the nearest gram.³⁸ However, there is a key difference between natural and added sugars: “Added sugars include all artificial sugars used in processed or prepared foods,” such as ready-to-eat cereals, dairy desserts, “but not naturally occurring sugar, such as in fruits.”³⁹ Even with this apparent difference, current labeling requirements do not allow consumers to distinguish between added sugar and naturally occurring sugar.

State legislatures and public interest groups have begun to single out sugary beverages as a leading cause of obesity due to added sugar.⁴⁰

³² *Id.* at 522.

³³ *Id.*

³⁴ *Id.*

³⁵ Atwell, *supra* note 22, at 140.

³⁶ Nutrition Labeling of Food, 21 C.F.R. § 101.9(c)(6)(ii) (2015).

³⁷ *Id.* (“[L]abel declaration of sugars content is not required for products that contain less than 1 gram of sugars in a serving if no claims are made about sweeteners, sugars, or sugar alcohol content.”).

³⁸ *Id.*

³⁹ Yang et al., *supra* note 31, at 517.

⁴⁰ For a discussion of when the New York City Department of Health and Mental Hygiene proposed amending Article 81 of the Health Code to reduce increased sugar consumption by limiting the maximum size of sugary drinks and beverage cups sold at food service establishments (“FSEs”), see N.Y.C. DEP’T OF HEALTH & MENTAL HYGIENE, NOTICE OF PUBLIC HEARING (June 5, 2012), <http://www.nyc.gov/html/doh/downloads/pdf/notice/2012/amend-food-establishments.pdf>. Sugary drinks are shown to be the largest contributor of added sugar in the average American’s diet, comprising nearly 43% of added sugar intake, and the proposal was intended to control added sugar in the everyday diets of New York City adults and reduce the rising percentage (58%) currently overweight. *Id.* at 2. The rationale being that “[w]hen people are given larger portions they unknowingly consume more and do not experience an increased sense of satiety.” *Id.* at 3. Proportionally, with every additional sugary beverage consumed, the odds of becoming obese increase by 60%. *Id.* at 2. The stringent amendment was said to be

Internationally, various countries are taking a different strategy by implementing additional taxes to deter consumers from buying foods high in added sugar.⁴¹ In 2013, Mexico taxed one additional peso per liter of soda and other high sugar beverages⁴² and an eight percent tax on “junk food.”⁴³ Hungary taxed select “manufactured foods high in sugar, salt or caffeine,” Finland taxed confectionery products (except biscuits, buns and pastries), and France taxed soft drinks.⁴⁴ These taxes aim to create a monetary incentive not to purchase food products high in added sugar while promoting less expensive, more nutritious food products. These countries implement such remedies to keep their citizens from being washed away by the obesity tsunami. Similarly, the United States Government has recently placed great emphasis on controlling *trans* fat intake to reduce obesity.

B. *Trans Fat*

Trans fat is considered by many medical professionals to be the worst type of fat because it increases the likelihood of CVD, decreases “good” cholesterol, raises “bad” cholesterol, and contributes to preventable deaths.⁴⁵ The Dietary Guidelines for Americans 2010⁴⁶ and the Institute of Medicine⁴⁷ recognize the need to keep *trans* fat consumption as low as possible for individual health.⁴⁸ *Trans* fat appears to have no known health benefit.⁴⁹ Artificial *trans* fat is created by hydrogenation—adding hydrogen to liquid

“taking an important step in reducing sugary drink consumption and combating obesity and its resulting morbidity and mortality.” *Id.* at 3.

⁴¹ Franco Sassi, *How U.S. Obesity Compares with Other Countries*, INST. FOR AM.’S HEALTH (April 12, 2013, 10:54 AM), <http://www.healthy-america.org/how-u-s-obesity-compares-with-other-countries/> (“Other countries, other schemes: Hungary introduced a tax on selected manufactured foods high in sugar, salt or caffeine. . . . And for the past year, France has been taxing soft drinks.”).

⁴² Larry Cohen, *New Soda Tax Makes Mexico a Leading Guardian of Public Health*, THE WORLD POST (Nov. 22, 2013, 6:33 PM), http://www.huffingtonpost.com/larry/new-soda-tax-makes-mexico_b_4325724.html.

⁴³ *Id.*

⁴⁴ Sassi, *supra* note 41.

⁴⁵ *Trans Fat*, *supra* note 24.

⁴⁶ U.S. DEP’T OF AGRIC. & U.S. DEP’T OF HEALTH & HUMAN SERVS., DIETARY GUIDELINES FOR AMERICANS 2010, at 25–26 (2010).

⁴⁷ INST. OF MED. OF THE NAT’L ACADS., DIETARY REFERENCE INTAKES FOR ENERGY, CARBOHYDRATE, FIBER, FAT, FATTY ACIDS, CHOLESTEROL, PROTEIN, AND AMINO ACIDS 836 (2005), <http://www.nap.edu/openbook.php?isbn=0309085373>.

⁴⁸ *Trans Fat: The Facts*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/nutrition/downloads/trans_fat_final.pdf (last visited Mar. 31, 2016) [hereinafter *CDC Trans Fat Facts*].

⁴⁹ *Trans Fat*, *supra* note 24.

hydrogenated oil turning it into solid fat—to form an inexpensive additive to stabilize the food and elongate its shelf-life.⁵⁰

The Centers for Disease Control and Prevention (“CDC”) suggests consumers choose food product with 0 grams of *trans* fat or food products with five percent of the Daily Reference Value (“DRV”) or less.⁵¹ In 2006, nutrition labels began to require “[a] statement of the number of grams of *trans* fat in a serving, defined as the sum of all unsaturated fatty acids.”⁵² However, a label may state 0 grams of *trans* fat if the food product “contain[s] less than 0.5 gram of total fat in a serving” and it does not include any assertions about fat, fatty acid or cholesterol content.⁵³ Thus, the CDC advises that food labels can conceal the presence of artificial *trans* fat because products containing less than 0.5 grams of *trans* fat per serving can be labeled as having 0 grams *trans* fat.⁵⁴

More recently, the FDA tentatively declared that partially hydrogenated oils, the primary dietary source of artificial *trans* fat in processed foods, are no longer “generally recognized as safe” for use in food.⁵⁵ However, this decision does not eliminate *trans* fat in processed foods, since “any interested party may seek food additive approval for one or more specific uses of [partially hydrogenated oils] with data demonstrating a reasonable certainty of no harm of the proposed use(s).”⁵⁶ While the amount and type of *trans* fat intake is still in debate, sodium has long been established as a nutritional culprit causing the obesity tsunami to swell.

C. Sodium

Although sodium is an essential nutrient, very little of it is needed in a daily diet.⁵⁷ Sodium attracts water and high-sodium diets may draw water into the bloodstream, increasing the volume of blood and eventually raising blood

⁵⁰ *Id.*

⁵¹ CDC *Trans Fat Facts*, *supra* note 48 (DRV for total fat is 65 g).

⁵² Final Rule and Proposed Rule: Food Labeling; *Trans Fatty Acids in Nutrition Labels*, 68 FR 41434–41506 (July 11, 2003) (“This rule is effective January 1, 2006.”).

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ Notice: Final Determination Regarding Partially Hydrogenated Oils, 80 Fed. Reg. 34650 (June 17, 2015), <https://federalregister.gov/a/2015-14883>. This notice will have a comment period until June 18, 2018. (“The tentative determination was based on evidence including results from a number of controlled feeding studies on *trans* fatty acid consumption in humans, findings from long-term prospective epidemiological studies, and the opinions of expert panels.”).

⁵⁶ *Id.*

⁵⁷ *Processed Foods: Where is All the Salt Coming From?*, AM. HEART ASS’N (Dec. 8, 2015), http://www.heart.org/HEARTORG/GettingHealthy/NutritionCenter/HealthyEating/Processed-Foods-Where-is-all-that-salt-coming-from_UCM_426950_Article.jsp (estimating that “the body needs less than 500 mg of sodium a day to perform its functions”) [hereinafter *Processed Foods*].

pressure.⁵⁸ In fact, the FDA noted that evidence from clinical trials strongly supports that this relationship exists.⁵⁹ High blood pressure, also known as hypertension, increases the risk of heart disease, kidney disease, and stroke.⁶⁰ One in three adults are affected by hypertension—approximately 75 million people—and an additional 78 million adults suffer from elevated blood pressure.⁶¹

Additionally, high-salt diets may cause damage to the kidneys and heart without necessarily resulting in high blood pressure.⁶² According to a long-term study published by the Harvard School of Public Health in 2009, “higher salt intake was linked to a 23% increase in stroke and a 14% increase in heart disease.”⁶³ Also, the World Cancer Research Fund and American Institute for Cancer Research concluded that high-salt diets are a “probable cause of stomach cancer.”⁶⁴ Consuming excess sodium may result in weakened bones because the calcium is flushed out of your body through urine.⁶⁵

About 90% of Americans eat too much sodium, with an average excess of 1,000 milligrams daily.⁶⁶ While most Americans believe that table salt is a leading cause of sodium intake, “[s]odium shows up in . . . products that don’t immediately come to mind when we think of ‘salty’ foods, such as pasta, bread and cereals.”⁶⁷ Typically, over 77% of dietary sodium comes from eating packaged and processed foods.⁶⁸ The Mayo Clinic suggests that products with more than 200 milligrams of sodium per serving should be avoided.⁶⁹ Although

⁵⁸ U.S. FOOD & DRUG ADMIN., *supra* note 26.

⁵⁹ 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. 58, 2302, 58, 2308 (Jan. 6, 1993) (codified at 21 C.F.R. pts. 5, 101) (“The agency notes that the evidence from clinical trials supports that high sodium intake is related to high blood pressure.”).

⁶⁰ U.S. FOOD & DRUG ADMIN., *supra* note 26.

⁶¹ *Id.*

⁶² Linda H. Lamb, *High Sodium Effects on Health*, LIVESTRONG (July 7, 2015), <http://www.livestrong.com/article/371494-high-sodium-effects-on-health/>.

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ U.S. FOOD & DRUG ADMIN., *supra* note 26.

⁶⁷ *Processed Foods*, *supra* note 57 (quoting Rachel Johnson, Ph.D., R.D., a professor of nutrition at the University of Vermont and a volunteer for the American Heart Association).

⁶⁸ U.S. FOOD & DRUG ADMIN., *supra* note 26 (“In fact, over 75% of dietary sodium comes from eating packaged and restaurant foods, whereas only a small portion (11%) comes from salt added to food when cooking.”).

⁶⁹ *Nutrition and Healthy Eating: Tips for Cutting Back on Sodium*, MAYO CLINIC, <http://www.mayoclinic.org/healthy-living/nutrition-and-healthy-eating/in-depth/sodium/art-20045479?pg=2> (last visited Mar. 31, 2016).

intake suggestions vary, the FDA concluded “that sodium reduction is likely to benefit a significant portion of the general population.”⁷⁰

Within the regulatory system, all food products shall contain “a statement of the number of milligrams of sodium in a specified serving of food expressed as zero when the serving contains less than 5 milligrams of sodium, to the nearest 5–milligrams increment when the serving contains 5 to 140 milligrams of sodium, and to the nearest 10–milligrams increment when the serving contains greater than 140 milligrams.”⁷¹ Similar to sugar and *trans* fat, a food product can be labeled as having 0 milligrams sodium while still containing sodium. Thus, the statement of contents per serving can hide small amounts of sodium, sugar, and *trans* fat without consumer awareness.

Food labels, however, have not historically been so descriptive or informative. The labels on food products have come a long way in terms of information presented and the quality of that presentation. Today, consumers are a lot more privy to serving sizes, nutritional component intake levels, ingredient lists, and the dietary structure through the establishment of statutory requirements. Further, these requirements set mandatory display requirements to ensure all products had similarly situated information available directly on their label.

III. THE ESTABLISHMENT OF A STATUTORY SYSTEM FOR FOOD LABELING

As food has advanced through science, an entirely new and more sophisticated vision of nutrition developed. From the discovery of essential vitamins to the newest fad of “gluten-free” products, nutrition has become a highly competitive field of manufacturing and advertising.⁷² Part III is a historical snapshot of the complex statutory system controlling food products’ advertising and labeling requirements affecting consumer knowledge of food’s nutritional content. Sections A and B thoroughly examine the establishment and rationalizations of the food industry’s initial regulations. Section C discusses the delegation of implementation power to the FDA.

⁷⁰ 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. 58, 2302, 58, 2308 (Jan. 6, 1993) (codified at 21 C.F.R. pts. 5, 101).

⁷¹ 21 C.F.R. § 101.9(c)(4) (2015). Additionally, beware of products labeled “reduced sodium” or “light in sodium” because such products still may contain high sodium levels, for example “chicken noodle soup that claims to have 25 percent less sodium still has . . . 524 mg in 1 cup. . . . compared with regular chicken noodle soup, which has more than 790 mg of sodium in a cup.” *Nutrition and Healthy Eating*, *supra* note 69.

⁷² See generally FOOD LAW INST. SERIES, FEDERAL FOOD, DRUG, AND COSMETIC LAW ADMINISTRATIVE REPORTS 1907–1949 (1951).

A. History

In 1906, “reacting to widely publicized examples of filth and deception,” the federal government proclaimed authority over the quality and safety of food products.⁷³ Congress enacted the Federal Food and Drug Act of 1906 (“1906 Act”), which provided that any food containing an “added poisonous or other added deleterious ingredient which may render such article injurious to health” would be deemed adulterated by federal enforcement officials.⁷⁴ The Act’s language demonstrates the high standard set to classify a food product as adulterated. Additionally, the 1906 Act prohibited “false or misleading” statements on a food or drug label.⁷⁵ A label was considered “any statement, design, or device regarding the ingredients of the substances contained” within the product.⁷⁶ While the 1906 Act terms seemed to be plain and definite, the Bureau of Chemistry received numerous complaints regarding the scope and application of the 1906 Act.⁷⁷ Five years later, Congress created The Food, Drug, and Cosmetic Act (“FDCA”), more fully discussed in the following section, to replace and improve the 1906 Act’s shortcomings.⁷⁸

B. Food, Drug, and Cosmetic Act

Aiming to broaden the jurisdictional implications and administer stricter requirements, Congress replaced the original 1906 Act with the FDCA in 1938.⁷⁹ The FDCA “keeps interstate channels free from misbranded articles of specified types” to protect and advance consumer health “from inferior foods

⁷³ Lars Noah & Richard A. Merrill, *Starting from Scratch?: Reinventing the Food Additive Approval Process*, 78 B.U. L. REV. 329, 331 (1998) (discussing the history of safety in novel foods and food ingredients); see also Federal Food and Drugs Act, Pub. L. No. 59-384, 34 Stat. 768 (1906) (codified as 21 U.S.C. §§ 1–15 (1934)) (repealed 1938) (the origination of food labeling laws).

⁷⁴ Federal Food and Drugs Act, Pub. L. No. 59-384, 34 Stat. 768 (1906) (codified at 21 U.S.C. § 6 (1934)) (repealed 1938). The Act defines “food” as “all articles used for food, drink, confectionery, or condiment by man or other animals, whether simple, mixed, or compound.” *Id.* § 7.

⁷⁵ *Id.* § 8; Peter Barton Hutt, *Government Regulation of Health Claims in Food Labeling and Advertising*, 41 FOOD DRUG COSM. L.J. 3, 5 (1986).

⁷⁶ Federal Food and Drugs Act, Pub. L. No. 59-384, 34 Stat. 768 (1906) (codified at 21 U.S.C. § 6 (1934)) (repealed 1938).

⁷⁷ *Id.* (citing Bureau of Chemistry, USDA, Service and Regulatory No. 15, SRA No. 142, (Nov. 4, 1915) at 21).

⁷⁸ *The 1938 Food, Drug and Cosmetic Act*, U.S. FOOD & DRUG ADMIN. (Sept. 24, 2012), <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054826.htm>.

⁷⁹ See *id.* (“[T]he bill that would replace the 1906 was ultimately enhanced and passed in the wake of a therapeutic disaster in 1937. . . . The public outcry not only reshaped the drug provisions of the new law to prevent such an event from happening again, it propelled the bill itself through Congress.”); see also Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399f (2012) (a full discussion of which is beyond the scope of this article).

resembling standard products but marketed under distinctive names,” including misrepresentations and material omissions.⁸⁰ The FDCA was enacted to enable consumers to make intelligent choices and misbranding was one of the chief issues Congress sought to end.⁸¹

To widen the scope, the FDCA’s provision enlarged the classification of what is to be considered a “label.”⁸² The FDCA broadly defines the term “label” as “a display of written, printed, or graphic matter upon the immediate container of any article,” and labeling is defined as “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.”⁸³ The labels of food containers must specify nutrition information, including the total number of calories derived from any source and derived from total fat, the amount of specified nutrients, vitamins, and minerals.⁸⁴

Additionally, the prominence of information of the label must be “in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.”⁸⁵ Thus, the FDCA’s prohibition of misbranding covers affirmative misrepresentations and material omissions on labels.⁸⁶ A food shall be held as misbranded if its “labeling is false or misleading” or “its advertising is false or misleading in a material respect.”⁸⁷ In determining if an article was misbranded, the question is whether the ultimate purchaser *could* be misled, while intention of the designer of the label to deceive is of no consequence.⁸⁸ Thus, with the subjective standards, Congress created the FDA to oversee and properly implement the Act’s provisions.

⁸⁰ 35A AM. JUR. 2D *Food* § 24, Westlaw (database updated Feb. 2016); see *United States v. An Article of Food*, 678 F.2d 735, 736 (7th Cir. 1982); *Carnohan v. United States*, 616 F.2d 1120, 1121 (9th Cir. 1980).

⁸¹ *United States v. Watkins*, 278 F.3d 961, 964 (9th Cir. 2002).

⁸² 21 U.S.C. § 321(k) (2012) (“The term ‘label’ means a display of written, printed, or graphic matter upon the immediate container of any article.”).

⁸³ *Id.* (defining the term “label”); *id.* § 321(m) (defining the term “labeling”).

⁸⁴ *Id.* § 343(q).

⁸⁵ *Id.* § 343(f).

⁸⁶ *United States v. Hanafy*, 302 F.3d 485, 489 (5th Cir. 2002) (“[T]he Federal Food, Drug, and Cosmetic Act covers not only affirmative representations but material omissions as well.”).

⁸⁷ 21 U.S.C. § 343(a).

⁸⁸ *United States v. Thirty-Six Bottles of London Dry Gin*, 210 F. 271, 272 (3d Cir. 1914) (“This the label, and the label alone, must determine. The intention of the user to deceive is of no consequence.”); *United States v. 267 Boxes of Macaroni*, 225 F. 79, 81 (W.D. Pa. 1915) (“The purpose of the act is to protect the people from deception by selling him one thing when the purchaser desires to purchase another. The intention of the maker is therefore not an element in the case.”).

C. *United States Food and Drug Administration's Authority*

According to Section 337 of the FDCA, “all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.”⁸⁹ Pursuant to the Act, the FDA is charged with protecting the public health by ensuring that, among other things, “foods are safe, wholesome, sanitary, and properly labeled.”⁹⁰ Additionally, “the agency serves as the initial information broker—it mandates what labels must disclose to consumers and how that disclosure takes place, as well as prohibits certain disclosures or claims.”⁹¹ The FDA has authority to regulate the safety and labeling of packaged foods under the FDCA.⁹² Courts have expanded a product’s “label” to all “accompanying” materials on or in its package and “all literature used in the sale of food” to maximize the FDA’s authority.⁹³ As such, the FDA may prohibit all advertisements or commercial messages related to the sale of food to “appear in such a form, or include additional information, warnings, and disclaimers, as are necessary to prevent its being deceptive.”⁹⁴

IV. THE EVOLUTION OF FOOD LABELING REQUIREMENTS

Before industrialization, food was thought to be mostly unaltered, and food labels contained very little information to identify the nutrient content of the food.⁹⁵ However, when processed foods became more prevalent in the industry, consumers requested more information about the products they purchased.⁹⁶ After the establishment of the FDA, regulations were placed on various health claims and consumers became more informed. However, this willingness to accept the accuracy on food labels soon became detrimental to consumers when manufacturers adapted creative health-orientated slogans, buzzwords, and marketing schemes to yield higher sales and profit margins.⁹⁷

⁸⁹ 21 U.S.C. § 337(a) (as amended by the NLEA in 1990).

⁹⁰ *Id.* § 393(b)(2)(A).

⁹¹ Margaret Sova McCabe, *Loco Labels and Marketing Madness: Improving How Consumers Interpret Information in the American Food Economy*, 17 J.L. & POL’Y 493, 496 (2009).

⁹² 21 U.S.C. § 393(b)(2)(A).

⁹³ *V.E. Irons, Inc. v. United States*, 244 F.2d 34, 39 (1st Cir. 1957).

⁹⁴ *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 n.24 (1976).

⁹⁵ See ELLEN A. WARTELLA ET AL., EXAMINATION OF FRONT-OF-PACKAGE NUTRITION RATING SYSTEMS AND SYMBOLS: PHASE I REPORT 19 (2010).

⁹⁶ *Id.*

⁹⁷ Chelsea M. Childs, Note, *Federal Regulation of the “Smart Choice Program”: Subjecting Front-of-Package Nutrition Labeling Schemes to Concurrent Regulation by the FDA and the FTC*, 90 B.U. L. REV. 2403, 2404 (Dec. 2010) (“Most notably, the Smart Choices Program displays a green checkmark next to a food product’s relevant calorie and serving information on the front of the package. Other front-of-package nutrition labeling campaigns include Kraft

In this part, Section A delves into the development of food labels. Next, Section B describes how the Nutrition Labeling and Education Act, an amendment to the FDCA, changed the labeling landscape greatly for nutrient health claims. Beyond these mandated labeling requirements, the industry began incorporating front-of-package (“FOP”) labels as covered in Section C. More specifically, Section C shows the recent efforts taken by the Government and manufacturers to improve the FOP labels’ effectiveness.

A. *Creation of Health and Nutrient Content on Food Labels*

At the 1969 White House Conference of Food, Nutrition, and Health (“1969 Conference”), President Richard Nixon stated: “Our private food industry has made great advances in food processing and packaging, and has served the great majority of us very well. But these advances have placed great burdens . . . [on] making nutritious foods widely available in popular forms.”⁹⁸ The 1969 Conference was called to develop a national policy aimed to eliminate malnutrition and to improve the nutritional health of all Americans.⁹⁹ After the 1969 Conference, the White House requested that the FDA develop a system for identifying nutritional qualities of food, and manufacturers were encouraged to reveal truthful dietary information about their products.¹⁰⁰ President Nixon at the opening plenary session of the Conference solidified that “[t]he task of [the] Government is not to make decisions for you or for anyone. The task of [the] Government is to enable you to make decisions for yourselves. . . . Our job is to get resources to people in need and then to let them run their own lives.”¹⁰¹

After the FDA finalized regulations in 1973, nutrition labels must identify “the number of calories; the grams of protein, carbohydrates, and fat; and the percent of the United States Recommended Daily Allowance (“RDA”)¹⁰² of protein, vitamins A and C, thiamin, riboflavin, niacin, calcium,

Foods’ ‘Sensible Solution’—a green flag with a yellow sun and white lettering—and PepsiCo’s ‘Smart Spot’—a white checkmark inside a green circle with the phrase ‘Smart Choices Made Easy.’”).

⁹⁸ WHITE HOUSE CONFERENCE ON FOOD, NUTRITION AND HEALTH, FINAL REPORT 1 (1969), <http://hdl.handle.net/2027/umn.31951d02987449r?urlappend=%3Bseq=2>.

⁹⁹ *Id.* at 5.

¹⁰⁰ WARTELLA ET AL., *supra* note 95, at 19.

¹⁰¹ WHITE HOUSE CONFERENCE ON FOOD, NUTRITION AND HEALTH, *supra* note 98, at 9.

¹⁰² In 1941, the National Research Council issued its first set of Recommended Dietary Allowances for vitamins, minerals, protein, and energy. Developed initially by the forerunner of the Food and Nutrition Board of the Institute of Medicine, the recommendations were intended to serve as a guide for good nutrition and as a “yardstick” by which to measure progress toward that goal. INST. OF MED., DIETARY REFERENCE INTAKES: THE ESSENTIAL GUIDE TO NUTRIENT REQUIREMENTS 5–7 (2006), <http://www.nap.edu/read/11537/chapter/4>.

and iron.”¹⁰³ The values selected for the RDAs were set at the highest value for each nutrient given because of the need for uniformity throughout the national labeling system.¹⁰⁴ As progress of the food industry continued, the need for reformation of labeling requirements expanded.

B. Nutrition Labeling and Education Act

Accordingly, Congress amended the FDCA with the Nutritional Labeling and Education Act of 1990 (“NLEA”).¹⁰⁵ In furtherance of “creat[ing] uniform national standards regarding the labeling of foods,”¹⁰⁶ the amendment broadened the scope to include packaged foods that are meaningful sources of nutrients and revised the conditions under which nutrients could be included in nutrition labeling.¹⁰⁷ The NLEA aimed “to clarify and . . . strengthen the Food and Drug Administration’s legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about nutrients in foods.”¹⁰⁸

As a result, the FDA was charged with setting forth general principles for nutrient content claims and health claims.¹⁰⁹ As defined under the NLEA, a health claim is “any claim made on the label or in labeling of a food . . . that expressly or by implication . . . characterizes the relationship of any substance to a disease or health-related condition.”¹¹⁰ Health claims may be either express or implied.¹¹¹ Implied health claims include “those statements, symbols,

¹⁰³ WARTELLA ET AL., *supra* note 95, at 20. FDA regulated foods do not include meat and poultry, but the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (“USDA”) “provided for nutrition labeling of meat and poultry products in a similar manner through policy memoranda.” *Id.*

¹⁰⁴ *Id.* at 20.

¹⁰⁵ National Labeling and Education Act, Pub. L. No. 101-535, 104 Stat. 2353 (1990).

¹⁰⁶ *In re Farm Raised Salmon Cases*, 175 P.3d 1170, 1175 (2008) (citing Remarks of Rep. Waxman, 136 Cong. Rec. 5840 (daily ed. July 30, 1990) (debate on H.R. No. 3562, 101st Cong. (1990))).

¹⁰⁷ WARTELLA ET AL., *supra* note 95, at 22 (“FDA acknowledged that there was some question as to whether the agency had the legal authority under the FD&C Act to mandate nutrition labeling on all foods that were meaningful sources of calories or nutrients, so comments were requested on that issue as well as on the proposed nutrient requirements.”); *see also* Food Labeling; Mandatory Status of Nutritional Labeling and Nutrient Content Revision, 55 Fed. Reg. 29487 (1990) (codified at 21 C.F.R. pts. 101, 105) (“[A]pproximately 60 percent of the processed and packaged foods regulated by FDA carry nutrition labeling.”).

¹⁰⁸ *Food Fight: FDA Preemption And Food Labeling Claims*, LAW360 (Jan. 27, 2011, 2:14 PM), <http://www.law360.com/articles/221444/food-fight-fda-preemption-and-food-labeling-claims> (citing H.R. Rep. No. 101-538, at 7 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3337).

¹⁰⁹ 21 U.S.C. § 343 (2012) (discussing the ways in which an item could be considered misbranded under the Act).

¹¹⁰ 21 C.F.R. § 101.14(a)(1) (2015).

¹¹¹ *Id.*

vignettes, or other forms of communication” that denote “a relationship exists between the presence or level of a substance in the food and a disease or health-related condition.”¹¹² The cornerstone of the NLEA is the requirement that packaged foods bear information on serving size, calories, and nutrient content within the Nutritional Facts panel.¹¹³ Below is an example of the Nutritional Facts panel. All information required must fall within the panel.¹¹⁴

Nutrition Facts	
Serving Size 1 egg (50g)	
Serving per Container 12	
Amount Per Serving	
Calories 70	Calories from Fat 45
	% Daily Value*
Total Fat 5g	8%
Saturated Fat 1.5g	8%
Polyunsaturated Fat 1g	
Monounsaturated Fat 2g	
Trans Fat 0g	
Cholesterol 185mg	60%
Sodium 70mg	3%
Potassium 70mg	2%
Total Carbohydrate 0g	0%
Protein 6g	13%
Vitamin A 6% • Vitamin C 0%	
Vitamin D 10% • Calcium 2%	
Iron 4% • Thiamin 0%	
Riboflavin 10% • Vitamin B-6 4%	
Folate 6% • Vitamin B-12 8%	
Phosphorus 10% • Zinc 4%	

The FDA fully implemented the NLEA on January 6, 1993, by mandating nutrition labeling in the form of a Nutrition Facts Panel on most packaged foods.¹¹⁵ Moreover, NLEA established first reference values, known as daily reference value (“DRVs”), to report values of total fat, saturated fatty acids, cholesterol, sodium, total carbohydrate, dietary fiber, sugar, and protein.¹¹⁶ The DRVs were appraised on a scientific basis to achieve “both a healthier diet and to reduce the risk factors for chronic disease” and accordingly, set the caloric diet requirements at 2,000 calories.¹¹⁷ Dietary concerns grew throughout the passage of the NLEA.¹¹⁸ As a result,

¹¹² *Id.*

¹¹³ See Front-of-Pack and Shelf Tag Nutrition Symbols; Establishment of Docket; Request for Comments and Information, 75 Fed. Reg. 22602 (April 29, 2010).

¹¹⁴ 21 U.S.C. § 343.

¹¹⁵ Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label, 58 Fed. Reg. 2079, 2079 (Jan. 6, 1993) [hereinafter Format for Nutrition Label] (codified as 21 C.F.R. pts. 1, 101); Nutrition Labeling of Meat and Poultry Products, 58 Fed. Reg. 632, 632 (July 6, 1993) (codified as 9 C.F.R. pts. 317, 320, 381) (emphasizing that, even though meat and poultry product labels fall under the authority of FSIS in the USDA, “FSIS’s nutrition labeling final regulations will parallel to the extent possible, as authorized by the Federal Meat Inspection Act and the Poultry Products Inspection Act, FDA’s nutrition labeling regulations promulgated under the Nutrition Labeling and Education Act (NLEA)”). Alcoholic beverage product labels fall under the authority of the Alcohol and Tobacco Tax and Trade Bureau of the Department of the Treasury.

¹¹⁶ Format for Nutrition Label, *supra* note 115.

¹¹⁷ Food Labeling; Reference Daily Intakes and Daily Reference Values, 58 Fed. Reg. 2206, 2217 (Jan. 6, 1993) (codified as 21 C.F.R. pts. 1, 101).

¹¹⁸ *Id.* at 2217.

manufacturers began more vividly displaying nutritional information on the front of the labels to entice the consumers' seemingly "healthier appetite."

C. Front-of-Package Food Labels

Over the last several years, numerous manufacturers began incorporating nutrition symbols and representations on food packages, particularly symbols and terms intended to denote nutritional quality of a food, selective nutrient disclosures, and content claims.¹¹⁹ Separate from the specific requirements of the Nutrition Facts Panel, these symbols are typically displayed on the principal display panels ("PDPs") of food packages and are commonly referred to as front-of-package ("FOP") labeling.¹²⁰ Below are examples of popular FOP labels.



FOP labels better inform consumers to identify and comprehend nutritional attributes of food products.¹²¹ An FOP label study found that consumers were more likely to correctly answer content-based questions when the information was on the FOP label.¹²² Overall, 86% of the study's participants reported reading products' labels regularly, or occasionally when purchasing a product for the first time.¹²³ The most significant finding was the FOP labels aided those with high school level or lower education, closing the education gap in selecting healthful food products.¹²⁴ Yet, regardless of education level, all participants strongly agreed that the FOP labels do not include enough important information.¹²⁵

¹¹⁹ Front-of-Pack and Shelf Tag Nutrition Symbols; Establishment of Docket; Request for Comments and Information, 75 Fed. Reg. 22602-3 (April 29, 2010).

¹²⁰ *Id.*

¹²¹ Jenni Spinner, *Front-of-Pack Labels Nourish Food Consumers*, FOODPRODUCTIONDAILY.COM (Apr. 17, 2014), <http://www.foodproductiondaily.com/Packaging/Front-of-pack-labels-nourish-food-consumers>.

¹²² Marianne Smith Edge et al., *The Impact of Variations in a Fact-Based Front-of-Package Nutrition Labeling System on Consumer Comprehension*, 114 J. ACAD. NUTRITION & DIETETICS 843 (2014) (showing that consumers looked at four versions of the label, including one with no front-facing nutrition information, one with only calories, one with calories and nutrients to limit, and one with calories and nutrients to limit or encourage; all had access to the full Nutrition Facts Panel with results indicating that more information given on the package front, the better consumers did at identifying and comprehending nutritional attributes for the food).

¹²³ *Id.* at 845.

¹²⁴ *Id.*

¹²⁵ *Id.* at 849.

Because of increasing proliferation of FOP labels and concerns about consumer misperceptions, the FDA and the USDA's Food Safety and Inspection Service sent a joint letter in 2009 to a general manager of one of the FOP labeling systems.¹²⁶ The letter expressed the agencies' concern that if the FOP labeling systems "were not stringent enough to protect consumers against misleading claims; were inconsistent with the Dietary Guidelines for Americans; or had the effect of encouraging consumers to choose highly processed foods and refined grains instead of fruits, vegetables, and whole grains."¹²⁷ Another strong supporter of the FOP labeling as a means to offer consumers an "understandable summary" of information concerning nutrition attributes of food products is the Center for Science in the Public Interest.¹²⁸ The Center petitioned the FDA to develop "a simple, uniform science-based system . . . [that would] help consumers choose more healthful diets."¹²⁹

As highlighted in subsections 1 through 3 below, the FDA has taken an active role by assessing consumer response to FOP labeling systems and requesting public comments of FOP labeling systems. As a result, Congress directed the Institute of Medicine and the Centers for Disease Control and Prevention to develop FOP labeling guideline reports as covered in Subsection 4. Additionally, as discussed in Subsection 5, the manufacturers recognized the need for reform and consolidated their efforts into one scheme, "Facts Up Front," of FOP labeling.

1. FOP Food Label's Defined Terms

The FDA specified that the level of nutrients and other health claims listed on FOP labels must use terms defined in the NLEA and its regulations.¹³⁰ The NLEA specifically required definitions for the terms "free," "low," "light," "reduced," and "less" in relation to nutrients required to be listed in the Nutrition Facts Panel.¹³¹ Further, FDA defined "high" as 20% or more of the appropriate Reference Daily Intake ("RDI") or DRV per serving.¹³² Likewise, "good source" claims, defined as 10% to 19% of the DRV, were intended to emphasize the presence of a nutrient at a mid-range of nutrient content,

¹²⁶ WARTELLA ET AL., *supra* note 95.

¹²⁷ *Id.*

¹²⁸ Timothy D. Lytton, *Signs of Change or Clash of Symbols? FDA Regulation of Nutrient Profile Labeling*, 20 HEALTH MATRIX 93, 109–10 (2010) (petition available at http://www.cspinet.org/new/pdf/healthy_symbol_petition.pdf).

¹²⁹ *Id.*

¹³⁰ Nutritional Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990).

¹³¹ *Id.*

¹³² 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) (codified at 21 C.F.R. pts. 5, 101).

drawing consumers' attention to foods that contain a significant amount of a nutrient and that are likely to help meet dietary recommendations.¹³³ The FDA and USDA also defined the terms "more," "fewer," "lean," and "extra lean" and provided for the use of synonyms for many of the terms.¹³⁴

Similarly, sugar content claims have a separate detailed subsection of use.¹³⁵ The terms "no sugar added" or "without added sugar" may be used on foods that contain "less than 0.5 g of sugars per reference amount customarily consumed."¹³⁶ Because consumers reasonably expect these terms to also indicate a food containing low calories, the terms may be used only if "[i]t is labeled 'low calorie' or 'reduced calories'"¹³⁷ or "[t]he product bears a statement that the food is not 'low calorie' or 'calorie reduced' and that directs consumers' attention to the nutrition panel for further information on sugar and calorie content."¹³⁸ Terms such as "reduced sugar," "less sugar," or "lower in sugar" may be used on food labels that "contain[] at least 25% less sugar per reference amount . . . than an appropriate reference food."¹³⁹ Reference foods vary depending on the term indicated.¹⁴⁰ However, typically a reference food must be a similar food, such as "potato chips as a reference for potato chips."¹⁴¹

2. FOP Food Label's Disclosure Statements

Additionally, if a food contains more than a pre-determined amount of fat, saturated fat, cholesterol, or sodium per reference amount, the food must contain a disclosure statement.¹⁴² The disclosure levels must be applied to individual foods, but the basis of their derivations take into account the

¹³³ Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60421 (Nov. 27, 1991) (codified at 21 C.F.R. pts. 5, 101, 105).

¹³⁴ *Id.*; Nutrition Labeling of Meat and Poultry Products, 58 Fed. Reg. 632 (Jan. 6, 1994) (codified at 21 C.F.R. pts. 317, 320, 381).

¹³⁵ 21 C.F.R. § 101.60(c)(1)(i) (2015).

¹³⁶ *Id.*

¹³⁷ *Id.* § 101.60(c)(1)(iii)(A)

¹³⁸ *Id.* § 101.60(c)(2)(v).

¹³⁹ *Id.* § 101.60(c)(5)(i).

¹⁴⁰ *Id.* § 101.13(j)(1).

¹⁴¹ *Id.* § 101.13(j)(1)(i)(B).

¹⁴² *Id.* § 101.13(h)(1) ("[E]xcept a meal product as defined in § 101.13(l), a main dish product as defined in § 101.13(m), or food intended specifically for use by infants and children less than 2 years of age, contains more than 13.0 g of fat, 4.0 g of saturated fat, 60 milligrams (milligram) of cholesterol, or 480 milligrams of sodium per reference amount customarily consumed, per labeled serving, or, for a food with a reference amount customarily consumed of 30 g or less or 2 tablespoons or less, per 50 g.").

significance of the food in the total daily diet.¹⁴³ The FDA's disclosures utilized the DRVs and recognized the "difficulty in maintaining healthy dietary practice that is created if these nutrients are consumed in particular foods at levels that exceed those established suggested amounts."¹⁴⁴

The disclosure statement must read "See nutrition information for ___ content."¹⁴⁵ The blank is replaced "with the identity of the nutrient exceeding the specified level," such as fat, saturated fat, or sodium.¹⁴⁶ The disclosure statement shall "be easily legible boldface print or type, in distinct contrast to other printed or graphic matter," and in a size no less than other similarly placed nutrient claims.¹⁴⁷ Also, the disclosure statement shall have no intervening symbol or overlapping print and must be immediately adjacent to all nutrient claims on each label panel.¹⁴⁸

Disclosure requirements fill in the gaps between the defined terms to bring attention to the negative attributes of food products not typically advertised on FOP labels by manufacturers. Beyond these specific disclosures and defined terms requirements, manufacturers capitalize on generally recognized terms that are undefined, such as "all natural," to advertise their seemingly healthy food products.¹⁴⁹ The FDA recognized this widespread misrepresentation issue and held a public hearing to gather information relating to the use and effectiveness of FOP labels.

3. FDA's Docket & Hearing on FOP Labeling

On July 20, 2007, the FDA issued a notice of public hearing entitled "Use of Symbols to Communicate Nutrition Information, Consideration of Consumer Studies and Nutritional Criteria."¹⁵⁰ Overall, the FDA's goal was to solicit interested persons and organizations about the use of symbols to communicate nutrient requirements to consumers.¹⁵¹ The public hearing

¹⁴³ 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) (codified at 21 C.F.R. pts. 5, 101).

¹⁴⁴ *Id.*

¹⁴⁵ 21 C.F.R. § 101.13(h)(1)(2015).

¹⁴⁶ *Id.* (for example, "See nutrition information for fat content").

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

¹⁴⁹ Mike Adams, "All Natural" Claim on Food Labels is Often Deceptive; Foods Harbor Hidden MSG and Other Unknown Ingredients, NAT. NEWS, <http://www.naturalnews.com/005778.html>.

¹⁵⁰ Memorandum from the Dep't of Health & Human Servs. to the Div. of Dockets Mgmt. (Apr. 21, 2009).

¹⁵¹ *Id.* at Part I.

outlined three main issues concerning: (1) Nutrition Issues; (2) Consumer Issues; and (3) Economic Issues.¹⁵²

First, during the Nutrition Issues portion, commenters discussed the types of foods that bear nutrition symbols and nutrient requirements for those symbols.¹⁵³ Public comments suggested that manufacturers use “specific formulas or criteria for eligibility [that] are specific to each program and are mostly proprietary.”¹⁵⁴ Comments further noted that the nutrition symbols on products are intended to market a particular food as healthier than comparable products without the symbol.¹⁵⁵ Other interested parties raised several objections to new government regulation of nutrient profile labeling.¹⁵⁶ For example, a representative for the Grocery Manufacturers Association (“GMA”) objected that new government restrictions on nutrient profile labeling would be redundant. She asserted that the FDCA already prohibits false or misleading claims on food labels and that FDA regulations impose extensive disclosure requirements on claims regarding the nutrient content of food items.¹⁵⁷ The FDA responsive remarks identified that it is clear “that the nutrition symbols used on food labels are very broad and diverse in their messages, presentation, and nutritional basis.”¹⁵⁸ Further, the FDA stressed that the diverse nature of the nutritional claims on labels muffled the consumers’ ability to make informed decisions and comparisons based on their desired dietary needs.¹⁵⁹

Second, the Consumer Issues portion of the hearing centered on consumer awareness and use of nutrition symbols. It revealed that consumers are generally willing to accept the credibility of symbols for identification of healthier products.¹⁶⁰ Although comments were split on importance of visual design (words and colors), most comments indicated that nutrition symbols are an influencing factor in product selection.¹⁶¹ On the other hand, some comments raised the possibility that nutrition symbols have no significant role in actual purchase selection.¹⁶² Accordingly, the FDA’s remarks stressed the need for further consumer information using quantitative and qualitative techniques to grasp a better understanding of the role that nutrition information symbols play in consumers’ dietary decisions.¹⁶³

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ *Id.* at Part I.A.

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

¹⁶⁰ *Id.* at Part I.B.

¹⁶¹ *Id.*

¹⁶² *Id.*

¹⁶³ *Id.*

Lastly, the FDA requested economic information on costs associated with product development/reformulation and inclusion of symbols on packages.¹⁶⁴ This Economic Issue portion of the hearing produced little information on the impact on manufacturing. However, some comments suggested “that costs associated with product reformulation or development of products bearing a symbol are just part of standard development costs . . . [and] are included in typical labeling costs.”¹⁶⁵ Comments showed that FOP labels are included in usual marketing costs and do not result in increased product costs for companies.¹⁶⁶ Thus, even though some comments indicate that the cost of implementing a nutrition symbol program depends on the manufacturer, many may not notice any increase in costs associated with the program compared to typical costs of product development.¹⁶⁷

Despite the fact that the information received was not conclusive, the hearings helped the FDA recognize faults in the preexisting nutrition-based symbol programs and their dietary ramifications.¹⁶⁸ Concluding, the FDA stated that “[b]ecause of the diverse nature of the nutritional claims and criteria in the numerous nutrition symbol systems, the ability of consumers to use these symbols to make nutritional comparisons between products or to determine how a food fits into a diet is uncertain.”¹⁶⁹ As a result, Congress commissioned labeling reports, Reports I & II, to develop a program to repair the current problems present in the industry.

4. Institute of Medicine Food Labeling Reports I & II

Congress directed the CDC to undertake the study on FOP nutrition labeling and related symbols with the Institute of Medicine (“IOM”).¹⁷⁰ The study, also supported by the FDA, recognized the need for a centralized FOP rating scheme because the dissimilarity of private manufacturers’ FOP labels results in consumers misconstruing critical nutrition information.¹⁷¹

The IOM completed Phase I of the task in October 2010.¹⁷² It entailed reviews of the current systems and “examine[d] the strength and weaknesses of the nutrition science . . . underlying them and reache[d] conclusions based on

¹⁶⁴ *Id.* at Part I.C.

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

¹⁶⁸ *Id.*

¹⁶⁹ *Id.*

¹⁷⁰ INST. OF MED., EXAMINATION OF FRONT-OF-PACKAGE NUTRITION RATING SYSTEMS AND SYMBOLS: PHASE I REPORT, at 1 (2010) <https://iom.nationalacademies.org/~media/Files/Report%20Files/2010/Examination-of-Front-of-Package-Nutrition-Rating-Systems-and-Symbols-Phase-1-Report/Front%20of%20Package%202010%20Report%20Brief.pdf>.

¹⁷¹ *Id.* at 1.

¹⁷² *Id.*

nutrition perspective.”¹⁷³ The Phase I report concluded that the goal of “FOP label[s] is to help consumers identify and select foods based on nutrients most strongly linked to public health concerns for Americans.”¹⁷⁴ Accordingly, the committee held that the largest areas of concern in the American diet are the overconsumption of calories, saturated fats, *trans* fats, added sugars, and too much sodium.¹⁷⁵ The committee concluded that “FOP systems may have the greatest benefit if nutrients are limited to those most closely related to prominent health conditions.”¹⁷⁶

Later in October 2011, a Phase II report outlined a simple food guidance system that best promotes health and would be useful to consumers in instantly recognizing healthier options.¹⁷⁷ The rating system envisioned by the committee awards a series of points to a food or beverage—the more points awarded the healthier the food product.¹⁷⁸ Points would be graphically displayed on packaging as an icon to be determined by the FDA, such as a checkmark or star.¹⁷⁹ A product could earn up to three points based on the amounts of nutrients of concern, saturated and *trans* fats, sodium, and added sugars, that are at or below threshold eligibility levels.¹⁸⁰ However, if a product exceeds any one of the eligibility criteria for the nutrients of concern, it would not be able to display any points.¹⁸¹ In other words, the system only awards points to food products that are at or below levels considered acceptable in *all* fields of concerns.¹⁸² The report also suggested that because of the nutritive difference, food and beverages should pass a separate set of eligibility criteria to determine point value.¹⁸³

¹⁷³ *Id.*

¹⁷⁴ *Id.* at 2.

¹⁷⁵ *Id.* at 3 (“Reducing saturated and *trans* fat intake may reduce the risk of coronary heart disease, and reducing sodium intake can reduce blood pressure, which, in turn, can reduce an individual’s risk of stroke and cardiovascular disease.”).

¹⁷⁶ *Id.* at 3.

¹⁷⁷ Press Release, Inst. of Med., Front-Of-Package Symbols and Systems: IOM Phase 2 Report (Oct. 18, 2011), <http://www.iom.edu/Activities/Nutrition/NutritionSymbols/Media-Advise-ory.aspx>.

¹⁷⁸ *IOM Releases Phase II Report on Front-of-Pack Nutrition Labeling*, INST. OF FOOD TECH. (Oct 21, 2011), <http://www.ift.org/Food-Technology/Daily-News/2011/October/21/IOM-releases-Phase-II-report-on-front-of-pack-nutrition-labeling.aspx>.

¹⁷⁹ *Id.*

¹⁸⁰ *Id.*

¹⁸¹ *Id.* (“For example, a sugar-sweetened soda could not earn points for having low sodium and no saturated or *trans* fats because its added sugar content is too high.”).

¹⁸² *Id.*

¹⁸³ *Id.*

5. “Facts Up Front” Food Labeling Program

Earlier in October 2011, the GMA and Food Marketing Institute (“FMI”) announced their Facts Up Front program, just weeks before the IOM released its recommendations for a new FOP nutrition-labeling program.¹⁸⁴ Facts Up Front combines four standardized basic icons—for calories, saturated fat, sodium, and total sugars.¹⁸⁵ Below is an example of the Facts Up Front program display.¹⁸⁶



The GMA stated that the most effective programs are those that consumers embrace and improve consumers’ own judgments rather than pushing governmental concerns of their diet.¹⁸⁷ In response to IOM’s Phase II report, GMA responded that the “report adds a perspective to the national dialogue about front-of-pack nutrition labeling. . . . In the meantime, food and beverage companies have developed a real-world program that delivers real value to real consumers in real time.”¹⁸⁸ Its voluntary nature means that the industry may choose which food products receive the icons and may add additional icons of other “informative” nutrients.¹⁸⁹ To promote their voluntary program, in March 2014, the organizations poured \$50 million into the campaign.¹⁹⁰

The FDA’s deputy commissioner for food, Michael Taylor, stated that the label standardization “would alleviate some of the FDA’s concerns regarding the potential for product labeling to mislead consumers by presenting only good news about nutrient content.”¹⁹¹ On the other hand, the Center of

¹⁸⁴ Carolina Scott-Thomas, *FDA Offers Support in Industry Roll-out of Facts up Front Labeling*, FOOD NAVIGATOR-USA.COM (Feb. 24 2012), <http://www.foodnavigator-usa.com/Regulation/FDA-offers-support-in-industry-roll-out-of-Facts-Up-Front-labeling>.

¹⁸⁵ *Id.*

¹⁸⁶ Marion Nestle, *Food Industry Puts \$50 Million into Another End Run Around the FDA*, FOOD POLITICS (Mar. 4, 2014), <http://www.foodpolitics.com/2014/03/food-industry-puts-50-million-into-another-end-run-around-the-fda/> [hereinafter Nestle, *Food Industry*].

¹⁸⁷ News Release, Grocery Mfr. Ass’n, Response to the Inst. of Med.’s Comm. on Examination of Front-of-Package Nutrition Rating Sys. & Symbols Report (Oct. 20, 2011), <http://www.gmaonline.org/news-events/newsroom/gma-statement-in-response-to-the-iom-front-of-package-nutrition-rating-syst/>.

¹⁸⁸ *Id.*

¹⁸⁹ *Id.*

¹⁹⁰ Nestle, *Food Industry*, *supra* note 186.

¹⁹¹ *Id.*

Science in the Public Interest executive director, Michael F. Jacobsen, explained that the IOM was called on by the FDA to design a simple labeling system easily understood by even less-educated consumers; instead, Jacobsen pointedly stated, “Facts Up Front is a joke that should be roundly ignored by the FDA and Administration.”¹⁹² He claims that the program was launched as an attempt to preempt FDA’s labeling initiatives and produce a more industry-friendly label without “successfully highlight[ing] the food’s unhealthfulness.”¹⁹³ The program’s icons display messages already present on the Nutrition Facts label and shrink the percent Daily Values until practically invisible.¹⁹⁴ Another critic, Congresswoman Rosa DeLauro, stated:

The industry’s unveiling today of its front-of-package labeling system is troubling and confirms that this effort should not circumvent or influence FDA’s effort to develop strong guidelines for FOP labels. . . . Given that negative and positive nutrients will not be differentiated on the package, there is significant risk that these labels will be ignored. An adequate labeling system must clearly alert consumers about potentially unhealthy foods, and should not mislead them into believing that some foods are healthy when they clearly are not.¹⁹⁵

While self-regulation can provide results in a quicker manner, the pivotal issue with self-regulation is that manufacturers’ and retailers’ bottom lines are the driving force, not public health.¹⁹⁶ Thus, there is no sufficient motivation for them to reformulate existing products nor manufacture new nutritious products when they can more lucratively redisplay the same product as “healthier.”¹⁹⁷ Likewise, manufacturers have moved toward over-processed, high-additive food products without consumer awareness by rebranding food products. For that reason, the FDA needs to take action and implement cohesive mandatory FOP disclosure statements to place nutrition back in the hands—and mouths—of consumers.

¹⁹² Elaine Watson, *CSPI: “Facts Up Front Is a Joke That Should Be Roundly Ignored by The FDA,”* FOOD NAVIGATOR-USA.COM (Mar. 3, 2014), <http://www.foodnavigator-usa.com/Manufacturers/CSPI-Facts-Up-Front-is-a-joke-that-should-be-roundly-ignored-by-the-FDA>.

¹⁹³ *Id.*

¹⁹⁴ Scott-Thomas, *supra* note 184.

¹⁹⁵ Marion Nestle, “*Singing Kumbaya*,” *GMA/FMI Displays Preemptive Label Design*, FOOD POLITICS (Jan. 25, 2011), <http://www.foodpolitics.com/2011/01/singing-kumbaya-gmafmi-displays-preemptive-label-design/>.

¹⁹⁶ *Id.*; MARION NESTLE, *FOOD POLITICS: HOW THE INDUSTRY INFLUENCES NUTRITION AND HEALTH* 362, 391 (rev. ed. 2007) [hereinafter NESTLE, *FOOD POLITICS*].

¹⁹⁷ NESTLE, *FOOD POLITICS*, *supra* note 196, at 391.

V. THE FDA SHOULD IMPLEMENT MANDATORY FOP DISCLOSURE LABELS ON FOOD PRODUCTS

With approximately 34.9% of the United States adult population now obese,¹⁹⁸ health concerns relating to obesity are higher than ever. These health concerns are expected to cripple health care systems and limit life expectancy.¹⁹⁹ Apart from various overhaul initiatives of the FDA and large amendments to the FDCA, American consumers need a realistic plan that can be easily implemented to regulate the food industry's control over their daily diet. Theoretically, a diet of fresh foods would be ideal to maximize health. However, many consumers rely on processed foods for inexpensive and convenient alternatives to satisfy their dietary needs. Therefore, it is crucial to generate a coherent program to improve overall health. The program must include food products, from organic to highly-processed. As President Nixon once explained, our advancements in food manufacturing placed a burden "[to] mak[e] nutritious foods widely available in popular forms."²⁰⁰ Consumers deserve accurate FOP information, on all food products, that steers them to dietary options that are more nutritious. Thus, the FDA should implement mandatory FOP labeling disclosures to relay accurate information and hold manufacturers accountable.

This part explains the rationale and partial framework for the recommended mandatory requirements. First, Section A highlights that the FOP label disclosures requirements will enable consumers to more readily make informed food product selections. Section B then explains the easily implemented recommended FOP label disclosure requirements. More specifically, Section B sets out the technical and visual framework for the recommended FOP labels: "High in __," applied to sugar, *trans* fat, and sodium.²⁰¹ Lastly, Section C explores the overarching policy that FOP label disclosures will naturally endorse and incentivize manufacturers to produce health conscious food products—creating a healthier marketplace.

A. FOP Disclosure Labels Rebuild Consumer Choice

Today, most consumers lack time and knowledge to scrutinize the Nutrition Facts Panel and Ingredients Lists found on food products to choose healthy options. Consumers utilize and welcome nutrition claims placed on the FOP labels to guide their product selections.²⁰² Furthermore, FOP labels improve the likelihood of consumers identifying and comprehending nutritional

¹⁹⁸ THE STATE OF OBESITY, *supra* note 7.

¹⁹⁹ Olshansky et al., *supra* note 12.

²⁰⁰ WHITE HOUSE CONFERENCE ON FOOD, NUTRITION AND HEALTH, *supra* note 98.

²⁰¹ *E.g.*, "High in *trans* fat."

²⁰² Edge et al., *supra* note 122 and accompanying text.

attributes of food.²⁰³ However, with the heightened use of FOP labels, misleading and deceptive statements about a product's sustenance have increasingly become sales strategies for food manufacturers instead of informational tools. The original ideals of advancement in consumer health and well-informed decision-making have long been washed away by the "tsunami of obesity."²⁰⁴ As a result, FDA mandated FOP label requirements will ensure accurate information of food products and restore consumers' ability to choose their food products based on nutritional value.

Traditionally, labeling requirements were aimed at prohibiting "false or misleading" statements on food or drug labels.²⁰⁵ The FDCA aimed to enable consumers to engage in health conscious decision-making by removing misbranded food products from the marketplace shelves.²⁰⁶ The ultimate question used to determine misbranded articles is whether the purchaser *could* be misled.²⁰⁷ Yet today consumers have to be wary about the FOP labeling system that was originally developed for them because of the sporadic nature and presentation of the health claims marketed by individual manufacturers.

After the implementation of the NLEA, much to the delight to the food industry leaders, health claims separate from the Nutrition Facts Panel could appear on FOP labels.²⁰⁸ Health claims may be made by statements or by symbols, unintentionally opening the door for manufacturers' creative marketing ploys to attract consumers to buy their "better-for-you" products. While the NLEA defined specific terms characterizing certain levels of nutrients, the manufacturers quickly surpassed the NLEA-defined terms with new health claims not specifically controlled by the act.²⁰⁹ New fads of diets and resulting terms develop too quickly for the FDA to define all terms that would lead consumers to buy a certain product based of FOP labels.

Accordingly, the NLEA also defined disclosure statements to uniformly indicate excessive negative nutrient levels.²¹⁰ The disclosure statements seemingly solve the problem to inform consumers of adverse health consequences resulting from low nutritive value foods. However, the FOP label must say, "See nutrition information for [excessive nutrient] content."²¹¹ This type of disclosure statement does not explain why a consumer should see nutrition information nor does it advise that the product bearing the statement contains negative nutritional components. These current disclosure

²⁰³ *Id.*

²⁰⁴ Hyman, *supra* note 4.

²⁰⁵ U.S. FOOD & DRUG ADMIN., *supra* note 78.

²⁰⁶ *Id.*

²⁰⁷ United States v. Thirty-Six Bottles of London Dry Gin, 210 F. 271, 272 (3d Cir. 1914).

²⁰⁸ *See supra* Part IV.B.

²⁰⁹ *See supra* Part IV.C.1.

²¹⁰ *See supra* Part IV.C.2.

²¹¹ 21 C.F.R. § 101.13(h)(1) (2015).

requirements do not accurately distinguish food products high in harmful nutrients that are detrimental to consumers' health.

Similarly, the recently introduced Facts Up Front program purported to solve the FOP labeling issues and was said to have "alleviated some the FDA's concerns" for misrepresented food products.²¹² However, the program simply draws attention to information already present on the label and highlights supplementary health claims chosen by the manufacturers to boost their products' attractiveness.²¹³ The plan was promulgated by the GMA and FMI, both self-interested profit-seeking parties within the food industry, in order to preempt the IOM recommendations for new FOP nutrition labeling initiatives by the FDA.²¹⁴ While the plan immediately delivers "more information" on FOP labels, the Daily Value percentages are practically invisible and the facts displayed are chosen at the manufacturers' discretion.²¹⁵ Many critics expressed disdain for the program because the food industry is again generating a FOP program without accurately displaying the food's unhealthiness or differentiating the negative and positive nutrients.²¹⁶

Some critics may argue that the use of additional FOP labeling requirements is too redundant because requirements controlling false or misleading claims are already in place.²¹⁷ However, by mandating that FOP labels include negative nutritional components, the labels will symbolize "red flags" to consumers, which is distinct from the current "positive" health claims. Because consumers currently identify positive nutritional attributes of food products easier when displayed on FOP labels, consumers will also identify negative nutritional attributes more easily if displayed on FOP labels.²¹⁸ As a result, consumers will more readily make healthier choices.

Opponents may also claim that FOP labels have little influence over consumer purchasing.²¹⁹ On the contrary, manufacturers initially instituted creative FOP labeling for the purpose of influencing consumers' product decisions. Furthermore, the comments from the FDA's Food Labeling Hearing, although not definite, indicated that nutrition symbols are an influential factor for consumers in product selection.²²⁰ One of the main problems with current FOP labels is the unreliability of information displayed since it is largely chosen by the manufacturers.²²¹ If FOP labels are more cohesively portrayed

²¹² Scott-Thomas, *supra* note 184.

²¹³ See *supra* note 192 and accompanying text.

²¹⁴ See *supra* note 192 and accompanying text.

²¹⁵ News Release, *supra* note 187.

²¹⁶ Scott-Thomas, *supra* note 184 and accompanying text.

²¹⁷ Memorandum, *supra* note 150.

²¹⁸ Spinner, *supra* note 121.

²¹⁹ Memorandum, *supra* note 150.

²²⁰ Memorandum, *supra* note 150, at Part 1.B.

²²¹ News Release, *supra* note 187.

with positive and negative nutritional content claims, the consumers would likely rely more heavily on the FOP labels and thus choose products according to the displayed nutritional content. In sum, FDA mandated disclosure FOP label requirements would create healthier product selection through comprehensive and accurate nutritional information.

B. Mandatory FOP Disclosure Labels Requirements

Manufacturers are currently misleading consumers by using marketing ploys in FOP labeling, leading consumers vastly astray in the maze of marketplace aisles. Historically, food may be adulterated if found to contain “added deleterious ingredient[s].”²²² Today, manufacturers seem free to bolster food products with many harmful additives, yet still advertise the food products as “Fat Free” and “All-Natural.” Because manufacturers choose to cleverly use FOP labels to advance the positive qualities of their food products, they should be required to disclose harmful nutrients in a similar fashion. The recommended FOP disclosure labels ensure accurate information relating to the regularity of negative nutrients alongside the positive in consumers’ daily diets. Further, the requirements not only supplement the preexisting state of the law but hopefully stimulate the creation of new informative nutrient DRVs.

Subsection 1 describes the technical framework of the FOP mandatory disclosure labels for food products containing excessive amounts of added sugar, *trans* fat, and sodium. The FOP label disclosures indicate “High in _____;” for example, if a product is heavily saturated with *trans* fat, the FOP label should require the mandatory disclosure “High in *Trans* Fat.” This structure is almost parallel to the current disclosure requirement but much clearer in distinguishing the food by its negative attributes.²²³ Next, Subsection 2 analyzes numerous opposing viewpoints to demonstrate that the recommended FOP label disclosures strike a balance, for both public and market interests, between informative and attainable.

1. FOP Disclosure Labels Technical Framework

Since obesity-related health conditions are among the leading non-communicable diseases in the world (heart disease, diabetes, cardiovascular disease, and cancer),²²⁴ the IOM reported that FOP claims narrowly defined to include high-risk nutrients would be the most successful.²²⁵ Further, the IOM concluded that the largest areas of concern are the overconsumption of calories,

²²² Federal Food and Drugs Act, Pub. L. No. 59-384, 34 Stat. 768 (1906) (codified at 21 U.S.C. § 6 (1934)) (repealed 1938).

²²³ See *supra* Part IV.C.2.

²²⁴ *Adult Obesity Facts*, *supra* note 6.

²²⁵ INST. OF MED., *supra* note 170 and accompanying text.

saturated fats, *trans* fats, added sugars, and sodium.²²⁶ While ingredients such as sodium, sugar, and *trans* fat can improve food taste, longevity, and consistency, prevalence of these additives is directly linked to public health problems.²²⁷ The FDA recognized the “difficulty in maintaining healthy dietary practice that is created if [] nutrients are consumed in particular foods at levels” that exceed those established disclosure amounts.²²⁸ Therefore, the mandatory disclosure requirements should focus on added sugar, *trans* fat, and sodium.

First, added sugar is currently not distinguished from natural sugar within the Nutritional Facts Panel.²²⁹ Thus, the amount of added sugar is implied within the grams of sugar indicated on the Panel. Further, the FDA has not established a DRV for sugar consumption apart from other carbohydrates. Because the FDA has yet to distinguish added sugar from sugar or define the DRV of sugar intake, the disclosure label shall be based off the total sugar value compared to total carbohydrates. A product receives the disclosure FOP label, “High in Sugar,” if it contains 20% or more of the appropriate Total Carbohydrate DRV per serving.²³⁰ For example, if the food products contained 51 grams Total Carbs (17% DRV) and 50 grams Sugars—typical sugar content of a soda pop—the product would receive “High in Sugar” because the food product contains 98% (more than 20%) of its carbohydrates from sugars. Once the FDA establishes an individual DRV for sugar and distinguishes added sugar, the requirements may be applied seamlessly to the newly established DRV. Added sugar is also a high source of added calories, thus consumers who consume food products high in added sugar tend to gain more weight than those consumers who come food products high in other nutrients. Largely, consumers’ weight and risk of cardiovascular disease, along with other obesity-related health concerns, will reduce drastically with decreased added sugar intake in their daily diet.

Second, *trans* fat recently was incorporated on the Nutritional Facts Panel but the DRV per serving for *trans* fat has not been established. Therefore, similar to sugar, the *trans* fat disclosure also adapts 20% or more of the appropriate Total Fat DRV per serving. A product will receive the disclosure FOP label, “High in *Trans* Fat,” if it contains 20% or more of the appropriate Total Fat DRV per serving. To illustrate, if a food product has 13 grams Total Fat (20% DRV) and 3 grams *Trans* Fat, the product would receive a label “High in *Trans* Fat” because the food product contains 23% (more than 20%) of its fat from *trans* fat. Thus, this food product would need 2.6 grams or less of

²²⁶ INST. OF MED., *supra* note 170.

²²⁷ *See supra* Part II.

²²⁸ *See supra* note 143 and accompanying text (the recommended disclosure labels should follow the current presentations requirements, discussed in Part IV(C)(2)).

²²⁹ *See* Nutrition Labeling of Food, 21 C.F.R. § 101.9(c)(6)(ii) (2015).

²³⁰ The term “high” is already defined by 21 C.F.R. § 101.54(b) (2015) as 20% or more of the appropriate DRV per serving. Thus, this program adapts existing terminology used by FDA and by manufacturers already for easily implementation.

trans fat to fall under the threshold disclosure requirement. Until the FDA establishes an individual DRV for *trans* fat or even possibly eliminates the use of the artificial additive altogether, the threshold will remain arguably low for “the worst type of fat” in food products.²³¹ But, any reduction in *trans* fat consumption decreases obesity and the likelihood of cardio vascular disease.²³²

Finally, sodium, unlike sugar and *trans* fat, was included in the NLEA’s disclosure requirements.²³³ The sodium disclosure threshold sits at “480 milligrams of sodium per reference amount customarily consumed, per labeled serving, or, for a food with a reference amount customarily consumed of 30 g or less or 2 tablespoons or less, per 50 gram.”²³⁴ Thus, this disclosure label will simply replace the previous disclosure statement with “High in Sodium.”²³⁵ With the current 90% of Americans indulging in too much sodium daily, a moderate reduction of high sodium foods within their diet may lower blood pressure, reduce the likelihood of stomach cancer, improve bone health, decrease the possibility of having a stroke, and reduce the development of heart disease.²³⁶ Each of these three FOP disclosure labels contribute to a reduction of the obesity tsunami, and resulting adverse health conditions, by directing consumers to look for “red flags” in the marketplace.

2. FOP Disclosure Labels Strike the Right Balance

FOP labels largely inform consumers to better identify and comprehend nutritional attributes of food.²³⁷ Likewise, 86% of the selected consumers who participated in a study reported that they read a products’ labels regularly when purchasing it for the first time.²³⁸ For these reasons, the FDA needs to take better advantage of FOP labels, as they are a powerful medium to relay information to consumers. Yet, the FDA has to tread lightly not to overburden consumers or manufacturers. This Note’s recommended FOP label requirements strike a balance between informative and attainable.

In opposition, some critics may argue that the use of additional FOP labeling requirements may increase manufacturing costs and thus increase the cost of goods. However, these disclosure recommendations are unobtrusive and easily applicable to products based on the information already calculated by the manufacturers. Labeling costs are a standard cost within development of

²³¹ *Trans Fat*, *supra* note 24.

²³² *Id.*

²³³ *See supra* Part IV.C.2.

²³⁴ 21 C.F.R. § 101.61 (this is roughly five percent of your recommended daily sodium intake per labeled serving based on DRVs).

²³⁵ *See supra* Part IV(C)(2); 21 C.F.R. § 101.13(h)(1) (2015).

²³⁶ *See supra* Part II .C.

²³⁷ Spinner, *supra* note 121.

²³⁸ Edge et al., *supra* note 122.

products and many manufacturers would likely not notice any increase in implementation with a disclosure-like program.²³⁹ For example, the industry is voluntarily including the Facts Up Front program on their labels without transmission of costs to consumers. Thus, the disclosures will not raise the cost of goods and will still successfully inform consumers of negative nutritional attributes in their daily diet.

Another possible counterargument is that additional FOP labels will not guarantee that Americans will more regularly choose a healthier diet. While this statement is arguably correct, it is not within the government's power to regulate food *so* strictly to force consumers into better purchase selections.²⁴⁰ The government's job is to present accurate information and transmit nutritional guidelines appropriately.²⁴¹ Representing the opposing market viewpoint, the GMA acknowledged that the most effective programs are those that improve consumers' own judgments rather than pushing governmental concerns of their diet.²⁴² Thus, balancing between public and market interests, these cohesive FOP label disclosures simply provide accurate information which allow consumers to choose for *themselves*.

Conversely, some critics may support a stricter symbol-based guidance system and argue that additional FOP content claims would only further confuse consumers. While the three disclosure requirements outlined above may not be as strict as some medical professionals advise, the applicability of the disclosures are manageable by the food industry and easily understood by consumers. Critics who propose large, more invasive measures are putting a higher burden on the food industry and on the governmental agencies to control consumers' health. Unlike many of the other proposed plans to restructure FOP labels by using third party experts, the FDA can exclusively implement the mandatory disclosures, allowing for a quicker and more cost effective remedy. These mandatory FOP disclosure recommendations are easily implemented while still bringing attention to three main nutrient components most closely linked to adverse health conditions. Moreover, if the manufacturers have to disclose to consumers the prevalence of these harmful additives then the prevalence will likely decrease in fear of backlash and reduced sales.

C. *High Manufacturer Culpability Leads to the Creation of a Healthier Marketplace*

Apart from the informative aspect of the mandatory disclosures, the overarching policy behind establishing mandatory disclosures is to incentivize the manufacturers to readily create more health-conscious products. Currently, manufacturers are not being held responsible by the government or by the

²³⁹ Memorandum, *supra* note 150.

²⁴⁰ WHITE HOUSE CONFERENCE ON FOOD, NUTRITION AND HEALTH, *supra* note 98.

²⁴¹ See *supra* Part III.

²⁴² News Release, *supra* note 187.

consumers for pumping processed foods with harmful additives. Likewise, neither the present FOP label programs nor the Nutritional Facts Panel adequately educate the consumers to beware of highly-processed food products—typically high in *trans* fat, sodium, and added sugar.

Since consumers have been shown to utilize FOP labels, consumers will purchase products that do not bear these “warning” or “red-flag” FOP labels. This food product selection will in turn reward manufacturers who produce health-conscious products by increasing sales. Naturally, through supply and demand, manufacturers will reengineer their food products to stay below the threshold requirements in order to avoid the required negative FOP labels. Thus, these FOP disclosures diminish manufacturers’ ability to add excessive amounts of toxic ingredients to food products to improve their bottom line. The FOP mandatory disclosure labels not only improve accuracy of information presented on FOP labels but improve how food products—as a whole—are being manufactured.

VI. CONCLUSION

Despite what you have been sold, food manufacturers dictate what is “healthy” by catchy, illusory FOP labels, not by the food product’s nutritional value. Today, consumers’ willpower to select healthy, nutritious food products is undermined by manufacturers’ bottom-lines. Manufacturers choose to use additives—such as added sugar, *trans* fat, and sodium—in food products as cost-effective bulking agents and to increase food products’ longevity. Yet, these same additives are contributing to one of the largest epidemics the world has ever seen—obesity. Obesity threatens to reduce our lifespan, to lessen the quality of living for the next generation, and is estimated to cost \$47 trillion over the next 20 years.

For these reasons, the FDA should implement mandatory FOP disclosure labels to provide consumers with accurate information relating to their dietary concerns. The FOP disclosure labels should dictate the excessive presence of harmful additives, like sugar, *trans* fat, and sodium, in food products. The FOP disclosure label should state “High in __,” with a nutrient culprit filling in the space. The FOP disclosure labels would hold manufacturers accountable—by the government and consumers—for their food products, which will incentivize the production of healthier foods.

Unlike the current FOP label systems, such as the Facts up Front lucrative rebranding of products as “healthier,” this informative set of mandatory disclosures will not allow manufacturers to hide behind self-regulation. The FDA, with minimal efforts, can create a marketplace that naturally endorses healthier products without the need for a structural overhaul. Ultimately, the government cannot prevent the industry from imaginative labeling, but mandatory FOP disclosure labels could raise a symbolic “red flag” for consumers enabling them to choose healthier products ultimately reducing the epidemic—obesity.

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