

NOTES

TRANS FAT REGULATION: A LEGISLATIVE REMEDY FOR AMERICA'S HEARTACHE

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I. INTRODUCTION

Beginning in 2003, major food companies voluntarily undertook significant steps to remove *trans* fat as an ingredient in their food products.¹ *Trans* fatty acid, a substance present in forty percent of all processed foods,² has been prevalent in the American food supply and industrial food processing since the 1960s.³ For the past fifty years, *trans* fat has been enhancing the overall taste, texture, and quality of processed foods by keeping cakes moist, cookies crispy, chips crunchy, and breads soft.⁴ Yet, despite the longstanding use and commercial versatility of the substance, in recent years food companies have been actively exploring ways to squeeze *trans* fat out of their products.⁵

The trend was in part prompted by a new Food and Drug Administration (“FDA”) disclosure rule that required food manufacturers to list *trans* fat content on the Nutrition Facts Panel of their products.⁶

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¹ See PACKAGED FACTS, MARKET TRENDS: TRIMMING TRANS FAT – THE MOVE TOWARD “HEALTHY FATS,” 2004 at 32 [hereinafter TRIMMING TRANS FAT]. See also Unmesh Kher, *Target: Trans Fats*, TIME, Oct. 24, 2005, at 53, available at <http://www.time.com/time/magazine/article/0,9171,1118353,00.html>.

² Mary Carmichael, *The Skinny on Bad Fat*, NEWSWEEK, Dec. 1, 2003, at 66. See also Kim Severson, *Hidden Killer: It's Trans Fat. It's Dangerous. And Its In Food You Eat Every Day*, S.F. CHRON., Jan. 30, 2002, at FD1, available at <http://www.sfgate.com/cgi-bin/article.cgi?file=/c/a/2002/01/30/FD40307.DTL>.

³ Alberto Ascherio et al., *Trans Fatty Acids & Coronary Heart Disease*, 340 NEW ENG. J. MED. 25, 1994–98 (1999).

⁴ See generally Carmichael, *supra* note 2, at 66. Ctr. for Food Safety & Applied Nutrition, U.S. Food & Drug Admin., Questions & Answers About Trans Fat Nutrition Labeling (Update 2006) (2003), available at <http://www.cfsan.fda.gov/%7Edms/qatrans2.html#fn> [hereinafter FDA, Questions and Answers About Trans Fat].

⁵ See TRIMMING TRANS FAT, *supra* note 1, at 40.

⁶ See *id.* at 27. See also Kher, *supra* note 1, at 53.

General increased consumer awareness of *trans* fat health risks also pushed the anti-*trans* fat initiative in the food industry.⁷ By 2006, when the FDA's final *trans* fat labeling rule went into effect, major food companies were aggressively marketing hundreds of new and reformulated *trans* fat-free products.⁸ From cookies and frozen dinner packages at the grocery store to the menu panels of McDonald's and other major fast food chains,⁹ "*trans* fat-free" and "zero *trans* fat" labels were everywhere.¹⁰

In the past, the release of health information and dietary advice about saturated fats, whole grains, and other foods have similarly fueled food fads among consumers and food companies.¹¹ For example, in the 1990s, consumers and food companies responded to health warnings about saturated fats with a dramatic increase in the sale and introduction of fat-free products.¹² More recently, within eight weeks of the U.S. Department of Agriculture ("USDA") and Human Services ("DHHS") release of the 2005 Dietary Guidelines of Americans, the per capita purchase of whole-grain foods increased thirteen percent.¹³ So when the *trans* fat movement emerged, it resembled the rapid rise of popularity and heavy marketing scheme associated with many other health and food trends.¹⁴ However, the reach of *trans* fat fad soon transgressed beyond the realm of consumers and businesses. On December 5, 2006, New York City announced its own *trans* fat initiative.¹⁵ Citing to *trans* fat's alleged contribution to the high prevalence rate of heart disease, New York City implemented a strict restriction against the use of *trans* fat in the city's 20,000 food establishments.¹⁶

Prior to New York City's ban, the government and its agencies played a relatively minor and passive role in the *trans* fat fad. The government generally limited its participation to the publication of recommendations

⁷ See Kher, *supra* note 1, at 53.

⁸ See *id.*

⁹ John Schmeltzer, *Oil Makes Grade on Fries*, CHI. TRIB., Jan. 28, 2007.

¹⁰ See TRIMMING TRANS FAT, *supra* note 1, at 27. See also Kher, *supra* note 1, at 53. See, e.g., Louisville K.Y. Wire, *Taco Bell Switching to Trans-Fat-Free Cooking Oils*, L.A. TIMES, Nov. 17, 2006, at C3. See also, e.g., Alicia Chang, *Theme Parks Join Movement to Ban Trans Fat*, L.A. TIMES, Jan. 1, 2006, at C3; Press Release, J.M. Smucker Co., *Crisco Shortening Products Reformulated to Contain Zero Trans Fat Per Serving* (Jan. 24, 2007), available at http://www.crisco.com/Promotions_News/Press_Releases/2007/zero_grams_trans_fat.aspx.

¹¹ See, e.g., Econ. Res. Serv., U.S. Dep't of Agric., *Whole Grains*, 3 AMBER WAVES 3, available at <http://www.ers.usda.gov/AmberWaves/June05/pdf/FeatureWholeGrainJune05.pdf> [hereinafter ERS & USDA, *Whole Grains*]. See also, e.g., ERS, USDA, ECON. INFORMATION BULLETIN NO. 5, FOOD DYNAMICS & USDA'S NEW DIETARY GUIDELINES, available at <http://www.ers.usda.gov/AboutERS/Privacy.htm> [hereinafter ERS & USDA, FOOD DYNAMICS].

¹² See ERS & USDA, *Whole Grains*, *supra* note 11.

¹³ *Id.* ERS & USDA, FOOD DYNAMICS, *supra* note 11.

¹⁴ For a general discussion on the effect of food trends on consumer and industry behavior, see *Spreading Yourself Too Thin: The Atkins Diet and Other Fads*, KNOWLEDGE@WHARTON, Oct. 19, 2005, <http://knowledge.wharton.upenn.edu/createpdf.cfm?articleid=1295&CFID=3742332&CFTOKEN=52534156> [hereinafter *Spreading Yourself Too Thin*].

¹⁵ BD. OF HEALTH, N.Y. CITY DEP'T. OF HEALTH & MENTAL HYGIENE, NOTICE OF ADOPTION OF AN AMENDMENT (§ 81.08) TO ARTICLE 81 OF THE NEW YORK CITY HEALTH CODE, at 1, available at <http://home2.nyc.gov/html/doh/downloads/pdf/public/notice-adoption-hc-art81-08.pdf> [hereinafter N.Y. CITY DEP'T. OF HEALTH & MENTAL HYGIENE, NOTICE OF ADOPTION].

¹⁶ N.Y. CITY DEP'T. OF HEALTH & MENTAL HYGIENE, NOTICE OF ADOPTION, *supra* note 15, at 1.

and findings on *trans* fatty acid intake.¹⁷ However, ever since New York City passed its *trans* fat intervention, the government has become increasingly involved in the *trans* fat issue in a more politically coercive and proactive manner. Local and state legislatures throughout the U.S. have joined to launch a nationwide legal movement against *trans* fat as a mechanism to reduce heart disease in the population.¹⁸ Within a couple months of New York City, Philadelphia became the second major city to pass a city-wide restriction on the use of *trans* fat.¹⁹

Considering the high social and economic costs associated with the 700,000 annual heart disease related deaths in the United States, the government has a legitimate interest in reversing, or even containing, the heart disease epidemic.²⁰ However, while some have praised legislatures for their proactive governmental *trans* fat campaign to fight heart disease, others believe that government regulation of *trans* fat interferes in matters of personal taste and choice.²¹ Legal and non-legal remedies to the heart disease problems will be the central focus of this Note, appraising each of their individual abilities to facilitate healthier behavior and to limit heart disease related deaths, illnesses, and economic costs in the United States.

This Note assesses past, pending, and potential *trans* fat initiatives, both within the law and independent from the law, that can be implemented to counter the prevalence of heart disease in America and its associated public health problems. In doing so, this Note considers the growing trend within the food industry to remove *trans* fat from food products, the potential passage of pending *trans* fat regulation in various state and local governments, and the degree to which current FDA *trans* fat regulation can be legally expanded from a labeling requirement to an outright ban on *trans* fat. Throughout the discussion, this Note will support government regulation of *trans* fat as a necessary and efficient tool to reduce *trans* fat in the national food supply if current consumer and political pressures are insufficient to effect meaningful permanent changes in food industry *trans* fat practices.

Part II provides an overview of cardiovascular and heart disease in the United States. Part III explains the impact that *trans* fat specifically has on heart disease and mortality rates in the U.S., presenting the reasons why *trans* fat is relevant to America's heart disease epidemic and to what extent a reduction in *trans* fat intake can help limit the high social and economic costs associated with epidemic. Part IV describes the recent removal of *trans* fat from food products as a food trend, discussing its impact on

¹⁷ See, e.g., DEP'T OF HEALTH & HUMAN SERVS. & U.S. DEP'T OF AGRIC., DIETARY GUIDELINES FOR AMERICANS, 15 (2000), available at <http://www.health.gov/dietaryguidelines/dgac/pdf/2kdiet.pdf>.

¹⁸ See Janet Adamy, *New York Trans-Fat Ban Could Spread – Others Are Likely to Follow Health Department's Move to Outlaw Artery Clogger*, WALL ST. J. Dec. 6, 2006, at D8.

¹⁹ *Philadelphia Set to Ban Trans Fats*, CBSNEWS.COM, Feb. 9, 2006, available at http://www.cbsnews.com/stories/2007/02/09/health/main2453862.shtml?source=RSSattr=Business_2453862.

²⁰ Ctrs. for Disease Control & Prevention, Dep't of Health & Human Servs., *February is Heart Month*, available at http://www.cdc.gov/dhdsp/announcements/american_heart_month.htm [hereinafter CDC, *February is Heart Month*].

²¹ See The Becker-Posner Blog: The Trans Fat Ban, available at http://www.becker-posner-blog.com/archives/2006/12/the_trans_fats.html.

American *trans* fat consumption preferences and on the use of *trans* fat in the food industry. Part V provides an overview of the food regulation infrastructure in the United States. From an examination of previous *trans* fat lawsuits to a survey of the latest legislative *trans* fat initiative throughout various state and local governments, this part also assesses various legal strategies that have been implemented in efforts to reduce the use and consumption of *trans* fats in the American diet. Part VI examines the legislative history and rationale behind the FDA's final rule on *trans* fat labeling requirements. In a related discussion, Part VII evaluates the potential of expanding current labeling regulations to a future outright *trans* fat ban, discussing the FDA's scope of authority over *trans* fats and applying current FDA standards of regulation to *trans* fats. In its conclusion, this Note recommends nationwide regulation of *trans* fat as an efficient and appropriate legal remedy to the nation's heart disease crisis.

II. AMERICA'S HEARTACHE

A. HEART DISEASE IN THE U.S.

Heart disease,²² the most common form of cardiovascular disease ("CVD"),²³ is the single leading cause of death in the United States.²⁴ Associated with an increased risk of death or disability from arrhythmia, coronary heart disease ("CHD"), congestive heart failure, high blood pressure, and periphery artery disease,²⁵ heart disease kills more Americans in one year than cancer, accidents, Alzheimer's disease, and HIV/AIDS combined.²⁶ In fact, a National Center for Health Studies ("NCHS") study shows that, at birth, there is a forty-seven percent probability of eventually

²² Heart disease includes acute rheumatic fever/chronic rheumatic heart disease, hypertensive disease and hypertensive heart and renal disease, coronary heart disease, pulmonary heart disease and diseases of pulmonary circulation, heart failure, and other forms of heart disease. Wayne Rosamond et al., Am. Heart Ass'n, *Heart Disease and Stroke Statistics – 2007 Update: A Report From the American Heart Association Statistics Committee and Stroke Statistics Subcommittee*, 115 CIRCULATION e69, e168 (2007), available at <http://circ.ahajournals.org/cgi/content/full/115/5/e69>.

²³ Cardiovascular disease is not equivalent to heart disease. It is a broader category of diseases that includes rheumatic fever/rheumatic heart disease, hypertensive disease, ischemic (coronary) heart disease, pulmonary heart disease and diseases of pulmonary circulation, other forms of heart disease, cerebrovascular disease (stroke), atherosclerosis, other diseases of arteries, arterioles and capillaries, diseases of veins, lymphatics and lymph nodes not classified elsewhere, and other and unspecified disorders of the circulatory system. Rosamond et al., *supra* note 22, at e169–70.

²⁴ CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T OF HEALTH & HUMAN SERVS., DIVISION FOR HEART DISEASE & STROKE PREVENTION: ADDRESSING THE NATION'S LEADING KILLERS 2007 2, available at <http://0-www.cdc.gov.mill1.sjlibrary.org/nccdphp/publications/AAG/pdf/dhdsp.pdf> [hereinafter CDC, ADDRESSING THE NATION'S LEADING KILLERS 2007]. CDC, *February is Heart Month*, *supra* note 20. Rosamond et al., *supra* note 22, at 73.

²⁵ See CDC, *February is Heart Month*, *supra* note 20.

²⁶ AM. HEART ASS'N, HEART DISEASE & STROKE STATISTICS 2007 UPDATE AT-A-GLANCE 7, available at http://www.americanheart.org/downloadable/heart/1166712318459HS_StatsInsideText.pdf [hereinafter AHA, HEART DISEASE & STROKE STATISTICS 2007]. In 2004, cancer killed 550,270; accidents, 108,694; Alzheimer's diseases, 65,829; HIV/AIDS, 12,995 for a combined total of 727,688, whereas CVD caused 871,517 deaths. *Id.* See also Rosamond et al., *supra* note 22, at e78–79 (numbers derived from "NCHS compressed mortality file 1979–2003" with "[d]ata provided by personal communication with NHLBI.").

dying of CVD related causes.²⁷ However, despite its dangerous and deadly health implications, the prevalence of heart disease is alarmingly high and continues to be the deadliest underlying cause of death among American males and females for the last eighty years.²⁸

The Centers for Disease Control (“CDC”) report that more than seventy-nine million people currently have one or more types of CVD.²⁹ The American Heart Association (“AHA”) estimates a marginally higher number, approximating that the prevalence of heart disease is about 79,400,000, or one in every three men and women, in the United States.³⁰ Of the nearly eighty million people who reportedly have CVD, more than half of them are under the age of sixty-five.³¹

When looking at each individual type of cardiovascular diseases, CHD is the principal type of heart disease.³² More than 12.5 million Americans currently live with CHD.³³ This year alone, an estimated 1.2 million people will have a myocardial infarction or a heart attack—700,000 will be a new coronary attack and 500,000 will be a recurrent attack.³⁴ As for the prevalence of other cardiovascular diseases, the National Health and Nutrition Examination Survey (“NHNES”) of the U.S. population from 1999–2004 estimates that in 2004, 72,000,000 had high blood pressure,³⁵ 15,800,000 had CHD,³⁶ 5,200,000 had heart failure, 5,700,000 suffered a stroke, and 650,000–1,300,000 had congenital cardiovascular defects.³⁷

Among U.S. adults over the age of eighteen, the highest prevalence of heart disease is among the Native Hawaiian and other Pacific Islanders

²⁷ Rosamond et al., *supra* note 22, at e73 (citing ROBERT N. ANDERSON, NAT’L CTR. FOR HEALTH STATISTICS, ELIMINATING CERTAIN CAUSES OF DEATH, U.S. DECENNIAL LIFE TABLES FOR 1989–91 5–6 (Volume 1, No. 4 1999)).

²⁸ See Jonathan Neyer et al., Ctrs. for Disease Control & Prevention, *Prevalence of Heart Disease - United States, 2005*, MORBIDITY AND MORTALITY WKLY. REP., Feb. 16, 2007, at 113, available at <http://www.cdc.gov/mmwr/PDF/wk/mm5606.pdf>. See also CDC, ADDRESSING THE NATION’S LEADING KILLERS 2007, *supra* note 24, at 2; CDC, *February is Heart Month*, *supra* note 20.

²⁹ See also CDC, ADDRESSING THE NATION’S LEADING KILLERS 2007, *supra* note 24, at 2.

³⁰ AHA, HEART DISEASE & STROKE STATISTICS 2007, *supra* note 26, at 6 (citing NAT’L CTR. FOR HEALTH STATISTICS, NAT’L HEALTH & NUTRITION EXAMINATION SURVEY (1999–2004), available at <http://www.cdc.gov/nchs/nhanes.htm> [hereinafter NHANES 1999–2004]).

³¹ AHA, HEART DISEASE & STROKE STATISTICS 2007, *supra* note 26, at 6.

³² Ctrs. for Disease Control & Prevention, Heart Disease Facts & Statistics, http://aaps.nccd.cdc.gov/emailform/print_table.asp [hereinafter CDC, Heart Disease Facts & Statistics] (citing KENNETH D. KOCHANEK ET AL., NAT’L CTR. FOR HEALTH STATISTICS, DEATHS: FINAL DATA FOR 2002, NAT’L VITAL STAT REP. (Volume 53, No. 5 2004), available at http://www.cdc.gov/nchs/data/nvsr/nvsr53/nvsr53_05acc.pdf).

³³ CTR. FOR FOOD SAFETY & APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., TRANS FAT NOW LISTED WITH SATURATED FAT & CHOLESTEROL ON THE NUTRITION FACTS LABEL (Updated 2006) (2004), available at <http://www.cfsan.fda.gov/~dms/transfat.html#unhide> [hereinafter FDA, TRANS FAT NOW LISTED]. See also Rosamond et al., *supra* note 22, at e89.

³⁴ See Rosamond et al., *supra* note 22, at e89 (citing Lori L. Boland et al., *Occurrence of Unrecognized Myocardial Infarction in Subjects Aged 45 to 65 Years (the ARIC study)*, 90 AMER. J. CARDIOL. 927, 927–31 (2002)).

³⁵ AHA, HEART DISEASE & STROKE STATISTICS 2007, *supra* note 26, at 6 (defining high blood pressure “as systolic pressure of 140 mm Hg or greater and/or diastolic pressure of 90 mm Hg or greater, taking antihypertensive medication or being told at least twice by a physician or other health professionals that you have high blood pressure.”).

³⁶ Among the 15,800,000, 7,900,000 suffered from a myocardial infarction (MI or heart attack) and 8,900,000 had angina pectoris (AP or chest pain). AHA, HEART DISEASE & STROKE STATISTICS 2007, *supra* note 26, at 6.

³⁷ AHA, HEART DISEASE & STROKE STATISTICS 2007, *supra* note 26, at 6 (citing NHANES 1999–2004, *supra* note 30).

population at 13.8%; and from there, the descending order of prevalence is Caucasians at 11.9%, American Indians or Alaska Natives at 11.6%, African Americans at 9.6%, Hispanic or Latinos at 9.2%, and Asians at 6.7%.³⁸

B. MORTALITY RATES

Every thirty-six seconds, one American dies from CVD.³⁹ Each day, about 2400 people die from CVD in the United States.⁴⁰ In 2004, there were a total of over 870,000 CVD related deaths in the United States.⁴¹ In terms of ratio, that equated to one of every 2.8 deaths or 36.3% of all deaths that year.⁴²

Within the total CVD mortality rate, there is a wide disparity in the specific mortality rate of the various types of cardiovascular diseases.⁴³ CHD, the most common type of CVD, has the highest mortality rate by far.⁴⁴ About fifty-two percent of all the 870,000 CVD fatalities in 2004 were attributed to CHD.⁴⁵ In fact, CHD is considered the “*single largest killer*” of American males and females.⁴⁶ Moreover, mortality data shows CHD was the cause of death in twenty percent of all deaths in the United States in 2004.⁴⁷ Coming in a distant second, with a mortality rate of seventeen percent, stroke was the next leading underlying cause of CVD deaths.⁴⁸ The other types of CVD—heart failure, high blood pressure, diseases of the arteries, congenital cardiovascular defects, rheumatic fever/rheumatic heart disease, and other cardiovascular diseases—collectively caused the remaining thirty-one percent of deaths.⁴⁹

Whether in the form of CHD, stroke, heart failure or any other type of CVD, CVD affects all groups within the U.S. population. While the specific prevalence data for heart disease fatalities vary by gender, ethnicity, race, and state,⁵⁰ it is not to imply that one group has low CVD mortality rates. The mortality rates are devastating all around, even among the groups that have the least CVD related fatalities. For instance, by

³⁸ AHA, HEART DISEASE & STROKE STATISTICS 2007, *supra* note 26, at 6 (citing Margaret Lethbridge-Cejku et al., *Summary Health Statistics for U.S. Adults: National Health Interview Survey, 2004*, 10(228) VITAL HEALTH STAT. 1, 17 (2006), available at http://www.cdc.gov/nchs/data/series/sr_10/sr10_228.pdf).

³⁹ AHA, HEART DISEASE & STROKE STATISTICS 2007, *supra* note 26, at 7 (citing ARIALDI M. MININO ET AL., *Deaths: Preliminary Data for 2004*, 54(19) NAT'L VITAL STAT. REP. 1 (2006), available at http://www.cdc.gov/nchs/data/nvsr/nvsr54/nvsr54_19.pdf).

⁴⁰ AHA, HEART DISEASE & STROKE STATISTICS 2007, *supra* note 26, at 7 (citing MININO ET AL., *supra* note 39).

⁴¹ *See id.* (citing MININO ET AL., *supra* note 39).

⁴² *Id.* at 6 (citing MININO ET AL., *supra* note 39).

⁴³ *See* Rosamond et al., *supra* note 22, at e81 (citing NAT'L CTR. FOR HEALTH STATISTICS, HEALTH, UNITED STATES, 2005 WITH CHARTBOOK ON TRENDS IN THE HEALTH OF AMERICANS (2005), available at <http://www.cdc.gov/nchs/data/hus/05.pdf> [hereinafter NCHS, HEALTH, UNITED STATES, 2005]).

⁴⁴ *See id.*

⁴⁵ *Id.*

⁴⁶ *Id.* at e89. *See also* CDC, *February is Heart Month*, *supra* note 20.

⁴⁷ AHA, HEART DISEASE & STROKE STATISTICS 2007, *supra* note 26, at 9–10.

⁴⁸ Rosamond et al., *supra* note 22, at e81 (citing NCHS, HEALTH, UNITED STATES, 2005, *supra* note 43).

⁴⁹ *See id.*

⁵⁰ *See* Neyer et al., *supra* note 28. *See generally* CDC, *Heart Disease Facts & Statistics*, *supra* note 32.

gender, more men die from the disease than women,⁵¹ yet among females, CVD still causes one death every minute.⁵² In terms of race or ethnicity, heart disease is the leading cause for four of the five largest racial/ethnic groups in the U.S: American Indians and Alaska Natives, African-Americans, Hispanics, and Caucasians.⁵³ For the last group of Asians and Pacific Islanders, heart disease comes in a close second to cancer, which caused a meager 0.1% more deaths than heart disease.⁵⁴ By state, in 2003, the death rate per 100,000 was the highest in Mississippi at 405.9 and the lowest in Minnesota at 221.2.⁵⁵ These rates reflect an increase from the 2002 rates, which were estimated at 327 and 165 respectively.⁵⁶

However, even more disturbing than the high mortality rate is the premature nature of CVD fatalities. Today, the average life expectancy is about 77.9 years.⁵⁷ On the average, a heart attack reduces the number of years of life by fifteen years.⁵⁸ Since there will be a projected 1.2 million heart attacks this year, the reduction of life associated with heart attack will undoubtedly impact the life span of the American population. According to the AHA, “[m]ore than 147,000 Americans killed by CVD in 2004 were under age 65. In 2004, 32% of deaths from CVD occurred prematurely. . . .”⁵⁹ Given that the current average life expectancy is close to eighty years, CVD shortens the lives of many Americans by more than a decade. In fact, the NCHS claims that “if all forms of CVD were eliminated, life expectancy would rise by almost 7 years” in the United States as a whole.⁶⁰

C. CAUSES

Heart disease is largely preventable.⁶¹ The risk of CVD susceptibility and fatality is a function of several major risk factors, the majority of which can be dramatically reduced by controlling or preventing them.⁶² While there are some risk factors such as age, gender and heredity that can not be controlled, most major risk factors can be “modified, treated and controlled” by adopting certain lifestyle and dietary changes.⁶³ Such controllable risk factors include: high blood pressure, tobacco smoke,

⁵¹ In 2004, the mortality rate was 341.8 for males and 246.3 for females per every 100,000. Rosamond et al., *supra* note 22, at e73 (citing to “NCHS, unpublished mortality tables, 2004; personal communication with NHLBI.”).

⁵² *Id.*

⁵³ See CDC, Heart Disease Facts & Statistics, *supra* note 32 (citing ROBERT N. ANDERSON & BETTY L. SMITH, CTRES. FOR DISEASE CONTROL AND PREVENTION, LEADING CAUSES FOR 2002, 53(7) NAT’L VITAL STATS REPS 1 (2005), available at http://www.cdc.gov/nchs/data/nvsr/nvsr53/nvsr53_17.pdf).

⁵⁴ Cancer accounted for 26.1 percent of all deaths, whereas heart disease accounted for 26 percent of all deaths. CDC, Heart Disease Facts & Statistics, *supra* note 32.

⁵⁵ Rosamond et al., *supra* note 22, at e78.

⁵⁶ CDC, Heart Disease Facts & Statistics, *supra* note 32 (citing KOCHANNEK ET AL., *supra* note 32).

⁵⁷ In 2004, the average life expectancy was 77.9 years. Rosamond et al., *supra* note 22, at e73 (citing MININO ET AL., *supra* note 39).

⁵⁸ AHA, HEART DISEASE AND STROKE STATISTICS 2007, *supra* note 26, at 11.

⁵⁹ Rosamond et al., *supra* note 22, at e73 (citing MININO ET AL., *supra* note 39).

⁶⁰ Rosamond et al., *supra* note 22, at e73 (citing ANDERSON, *supra* note 27).

⁶¹ See AM. HEART ASS’N, *Risk Factors for Heart Disease* in Heart and Stroke Facts 36, 36–43 (2003), available at <http://www.americanheart.org/downloadable/heart/1056719919740HSFacts2003text.pdf> [hereinafter AHA, Heart and Stroke Facts].

⁶² *See id.*

⁶³ *See id.* at 36.

elevated low-density lipoprotein (“LDL”) cholesterol, lowered high-density lipoprotein (“HDL”) cholesterol, physical inactivity, and obesity.⁶⁴ CDC surveys have revealed that from 1999–2002 in Americans aged twenty years and over, about 30.2% had high blood pressure; 17.3% had high blood cholesterol; 6.5% were diagnosed with diabetes; and 30.5% were obese.⁶⁵ A 2003 CDC survey found that in Americans aged eighteen years and older, 21.6% were smokers and 37.6% did not exercise.⁶⁶ Even more disturbing, the prevalence of those people who have two or more risk factors has increased over the years despite the fact that most of these risk factors are controllable.⁶⁷

While each risk factor independently influences the chances of developing and dying from heart disease, the CDC has singled out high blood pressure and high blood cholesterol as the two risk factors that must be addressed by the nation.⁶⁸ Studies on people with heart disease have shown that “lowering high blood cholesterol and high blood pressure can reduce the risk of dying of heart disease, having a nonfatal heart attack and needing heart bypass surgery or angioplasty.”⁶⁹ In a related study of people without heart disease, it has been shown that lowering blood cholesterol and high blood pressure can even reduce the occurrence of heart disease.⁷⁰ The CDC points out that “a 12- to 13- point reduction in blood pressure can reduce heart attacks by 21%, strokes by 37%, and all death from CVD by 25%”⁷¹ and that “a 10% decrease in blood cholesterol levels may reduce the incidence of CHD by an estimated 30%.”⁷²

D. HIGH ECONOMIC IMPLICATIONS OF HEART DISEASE

Personal choices about diet, exercise, and lifestyle primarily impact the individual. As such, CVD imposes substantial social and economic consequences for people with the disease. For instance, those who have heart disease are more likely to face higher medical expenses (including cost for hospital and nursing home services, physician and other professionals, drugs, home health care, other medical durables), lost productivity, and death.⁷³ But when individuals neglect to address the controllable and preventable risk factors for heart disease, their personal choices will inevitably lead to a rampant heart disease epidemic that

⁶⁴ See *id.* at 36–43.

⁶⁵ CDC, Heart Disease Facts & Statistics, *supra* note 32.

⁶⁶ *Id.*

⁶⁷ Rosamond et al., *supra* note 22, at e74.

⁶⁸ See CDC, ADDRESSING THE NATION’S LEADING KILLERS 2007, *supra* note 24, at 2.

⁶⁹ CDC, Heart Disease Facts & Statistics, *supra* note 32.

⁷⁰ *Id.*

⁷¹ CTNS. FOR DISEASE CONTROL AND PREVENTION, U.S. DEP’T OF HEALTH AND HUMAN SERVS., DIVISION FOR HEART DISEASE AND STROKE PREVENTION: PREVENTION WORKS: CDC STRATEGIES FOR A HEART-HEALTHY AND STROKE-FREE AMERICA (2006), available at http://www.cdc.gov/DHDSP/library/prevention_works/ [hereinafter CDC, PREVENTION WORKS].

⁷² CDC, ADDRESSING THE NATION’S LEADING KILLERS 2007, *supra* note 24, at 2. See also Ctrs. for Disease Control & Prevention, *State-Specific Cholesterol Screening Trends – United States, 1991–1999*, MORBIDITY AND MORTALITY WKLY. REP., Aug. 25, 2000, at 750, available at <http://www.cdc.gov/mmwr/PDF/wk/mm4933.pdf>.

⁷³ See Rosamond et al., *supra* note 22, at e92.

implicates staggeringly high economic consequences for the American society.

The national economic costs associated with CVD are substantial. In 2006, the total annual estimated economic cost of CVD was \$403 billion.⁷⁴ In 2007, the estimate is even higher and will cost an estimated \$431.8 billion⁷⁵ in direct and indirect cost:⁷⁶ \$151.5 billion from CHD, \$66.4 billion from hypertensive disease, \$62.7 billion from stroke, and \$33.2 billion from heart failure.⁷⁷ In terms of lost productivity, CHD is also the leading cause of premature, permanent disability in the workforce.⁷⁸ These costs will be felt directly by taxpayers, even those who do not have a heart condition. In 2001, the government financed \$23.9 billion of CVD cost using taxpayer dollars.⁷⁹ Through Medicare and Medicaid programs, even the most health-conscious Americans are paying the price for heart disease.⁸⁰

Moreover, considering that the major risk factors for CVD are preventable, the billions of dollars associated with its high occurrence and mortality rate is nothing more than a needless and wasteful cost. Studies have revealed that if the occurrence of heart attack is reduced 0.1 to 0.05 percent annually from current rates,⁸¹ Americans would save between \$900 million to \$1.8 billion dollars per year in medical costs, lost productivity, and pain and suffering.⁸² Thus, given the preventable nature of CVD and the unreasonably high social and economic costs associated with CVD, the widespread prevalence of CVD is a legitimate and important national health issue that can not be ignored and must be contained. If these trends continue unaddressed by the American people themselves, it is a part of the government's duty to shield the national public from such high costs and risks associated with heart disease.

III. ALL ABOUT TRANS FAT

A. WHAT IS TRANS FAT?

Trans fat is a particular form of fat.⁸³ All fats are comprised of a group of chemical compounds that contain fatty acids.⁸⁴ There are four main types

⁷⁴ CDC, PREVENTION WORKS, *supra* note 71.

⁷⁵ AHA, HEART DISEASE & STROKE STATISTICS 2007, *supra* note 26, at 9.

⁷⁶ Direct costs include health care expenditures whereas indirect costs consist of lost productivity from death and disability. AHA, HEART DISEASE & STROKE STATISTICS 2007, *supra* note 26, at 9, 26.

⁷⁷ Rosamond et al., *supra* note 22, at e162–3. *See also* Neyer et al., *supra* note 28.

⁷⁸ Rosamond et al., *supra* note 22, at e162–3.

⁷⁹ Michael A. McCann, *Economic Efficiency and Consumer Choice Theory in Nutritional Labeling*, 2004 WIS. L. REV. 1161, 1168 (2004). *See also* Lawrence O. Gostin, *Law as a Tool to Facilitate Healthier Lifestyles and Prevent Obesity*, 297 J. AM. MED. ASS'N 87, 87 (2007).

⁸⁰ Karen Tumulty, *The Politics of Fat*, TIME, Mar. 19, 2006, available at <http://www.time.com/time/magazine/article/0,9171,1174679,00.html?promoid=googlep>.

⁸¹ An estimated 1.2 million people will have a myocardial infarction or heart attack in 2007. *See discussion supra* Part I.A., B.

⁸² FDA, Questions and Answers About *Trans* Fat, *supra* note 4.

⁸³ *See* Dariush Mozaffarian et al., *Trans Fatty Acids and Cardiovascular Disease*, 354 NEW ENG. J. MED. 1601, 1601 (2006), available at

<http://content.nejm.org/cgi/content/full/354/15/1601?ijkey=Ulbtkh3itKkQ&keytype=ref&siteid=nejm> (for a discussion of the chemical composition of *trans* fatty acids). *See also* FDA, Questions and

of fatty acids: *trans* fat, saturated fat, monounsaturated fat, and polyunsaturated fat.⁸⁵ *Trans* fats are specific types of fat formed by “unsaturated fatty acids that contain one or more isolated double bonds in a *trans* configuration.”⁸⁶

Trans fats are derived from two main sources: natural and artificial.⁸⁷ The distinctive *trans* fat configuration naturally occurs in the stomach of ruminant animals.⁸⁸ Such natural *trans* fats are consumed in very small amounts (about 0.5 percent of total energy intake),⁸⁹ primarily in the form of dairy and meat products from cows, lambs, sheep, and other ruminant animals.⁹⁰ *Trans* fat is also industrially produced during a chemical process called hydrogenation, where hydrogen atoms are added to either vegetable or fish oils.⁹¹ *Trans* fat in the U.S. diet are sourced from both natural and artificial foods; however, most dietary *trans* fat is artificial.⁹²

Most dietary *trans* fat is found in partially hydrogenated vegetable oil (“PHVO”).⁹³ PHVO was originally formulated in the 19th Century to lengthen the shelf life of foods.⁹⁴ The chemically added hydrogen in the vegetable oil also provides many other qualities advantageous for food processing: it modifies the liquid oil to a solid form, makes frying oil last longer, increases flavor stability, maintains texture, and acts as a preservative.⁹⁵ Given its commercial versatility, PHVO is used in forty percent of all industrialized foods.⁹⁶ Consequently, artificial *trans* fat has become a prevalent ingredient among a widespread range of foods in the average American diet. Major dietary sources of *trans* fatty acids include: cakes, cookies, crackers, pies, bread, breakfast cereal, candy, salad dressing, pre mixed hot chocolate and pancake mix, taco shells, fried chicken, pizza dough, and hamburger buns.⁹⁷

Answers About *Trans* Fat, *supra* note 4; Am. Heart Ass’n., *Trans* Fatty Acids, <http://www.americanheart.org/presenter.jhtml?identifier=3030450> [hereinafter AHA, *Trans* Fatty Acids].

⁸⁴ FDA, Questions and Answers About *Trans* Fat, *supra* note 4.

⁸⁵ *Id.*

⁸⁶ *Trans* Fatty Acids in Nutrition Labeling, 68 Fed. Reg. 41461 (July 11, 2003) (codified in 21 C.F.R. pt. 101) [hereinafter *Trans* Fatty Acids in Nutrition Labeling].

⁸⁷ See Mozaffarian et al., *supra* note 83, at 1608–09. See also FDA, Questions and Answers About *Trans* Fat, *supra* note 4.

⁸⁸ FDA, Questions and Answers About *Trans* Fat, *supra* note 4. See also Mozaffarian et al., *supra* note 83, at 1608.

⁸⁹ *Trans* fats occurring in products of ruminant origin (e.g., cow’s milk) are found in amounts less than 0.5 grams and would be considered *trans* fat-free according to the FDA’s *trans* fat labeling regulations. See *Trans* Fatty Acids in Nutrition Labeling, *supra* note 86, at 41461. See also Mozaffarian et al., *supra* note 83, at 1608–09.

⁹⁰ Mozaffarian et al., *supra* note 83, at 1608.

⁹¹ See Alice H. Lichtenstein, *Trans* Fatty Acids, *Plasma Lipid Levels, and Risk of Developing Cardiovascular Disease*, 95 CIRCULATION 2588, 2588–90 (1997), available at <http://www.americanheart.org/presenter.jhtml?identifier=1728>.

⁹² See Mozaffarian et al., *supra* note 83, at 1608. See also FDA, Questions and Answers About *Trans* Fat, *supra* note 4. See also U.S. Food & Drug Admin., *Revealing Trans Fats*, FDA CONSUMER, Oct. 2003, available at http://www.fda.gov/food/features/2003/503_fats.html [hereinafter FDA, *Revealing Trans Fats*] (containing revisions made in Sept. 2005).

⁹³ See Mozaffarian et al., *supra* note 83, at 1608.

⁹⁴ See Ascherio et al., *supra* note 3, at 2.

⁹⁵ See *id.* See also FDA, Questions and Answers About *Trans* Fat, *supra* note 4.

⁹⁶ Carmichael, *supra* note 2, at 66. See also Severson, *supra* note 2, at 1.

⁹⁷ See FDA, *Revealing Trans Fats*, *supra* note 92. See also N.Y. CITY DEP’T. OF HEALTH & MENTAL HYGIENE, NOTICE OF ADOPTION, *supra* note 15, at 2.

B. TRANS FAT IN THE U.S. DIET

As of 2006, the estimated daily average consumption of *trans* fat in the United States among adults twenty years or older was 5.8 grams of *trans* fat, about 2.6% of total caloric intake.⁹⁸ While this estimate reflects a combined total of both natural and artificial *trans* fat, the individual contributions of natural and artificial *trans* fat to the overall consumption of *trans* fat is drastically disproportionate.

Only about twenty-one percent of dietary *trans* fat consumed by Americans is from products of ruminant animal origin; the remaining seventy-nine percent of dietary *trans* fat is from processed food products that are either prepared using PHVO or contain PHVO as an ingredient.⁹⁹ As such, the food industry—including both manufacturers and food service establishments—is directly and predominately responsible for the *trans* fatty acid content of the national food supply and consumer intake of the substance.

Table 1. Contribution of Various Foods to *Trans* Fat Intake in the American Diet¹⁰⁰

Food Group		Contribution (percent of total <i>trans</i> fat consumed)
Animal Products	Natural	21%
Cakes, cookies, crackers, pies, bread, etc.	Artificial	40%
Margarine		17%
Fried Potatoes		8%
Potato chips, corn chips, popcorn		5%
Household shortening		4%
Others: including breakfast cereal, candy, salad dressing		5%

In food manufacturing, as discussed above, the industrial advantages of PHVO have made it a very commonly used food additive and ingredient in processed foods. The prevalence of the chemically modified oil in food processing practices has directly contributed to the presence of *trans* fat in

⁹⁸ The FDA's estimate, based on different types of studies for the U.S. population, including estimates from food disappearance data and a national food consumption survey, is considered to be an underestimate. See *Trans Fatty Acids in Nutrition Labeling*, *supra* note 86, at 41446.

⁹⁹ FDA, *Revealing Trans Fats*, *supra* note 92.

¹⁰⁰ FDA, *Revealing Trans Fats*, *supra* note 92. See also N.Y. CITY DEP'T. OF HEALTH & MENTAL HYGIENE, NOTICE OF ADOPTION, *supra* note 15, at 2.

approximately forty percent of all manufactured food products in grocery stores.¹⁰¹

As for foods prepared by restaurants and other retail food outlets, studies have indicated high levels of *trans* fats in popular fast foods.¹⁰² For instance, the cooking oil used for french fries in McDonald's restaurants contains twenty-three percent *trans* fatty acids¹⁰³—one large order of fries contains eight grams of *trans* fats.¹⁰⁴ Before Kentucky Fried Chicken ("KFC") made its switch to a *trans* fat-free oil, one three-piece Extra Crispy combo meal had 15 grams of *trans* fat.¹⁰⁵ The high *trans* fatty acid content in fast food is especially relevant to U.S. *trans* fat consumption trends since national surveys indicate that Americans are eating out much more frequently, consuming more foods prepared outside the home by food establishments.¹⁰⁶ In fact, Americans spend nearly half their food money (47%) on foods prepared outside the home and "an estimated one third of daily caloric intake comes from food purchased in restaurants."¹⁰⁷ In Los Angeles County, one in four children has eaten fast food in the past day.¹⁰⁸ In reference to the correlation between the American restaurant/fast food habit and *trans* fat consumption, one study notes that "it is possible [for the average person] to consume 10 to 25 g of these *trans* fatty acids in one day and for habitual consumers of large amounts of [fast] food to have an average daily intake far above 5 g."¹⁰⁹

Even if McDonald's and KFC are not directly representative of all food establishments, PHVO is a commonly used substance in restaurants throughout the country. If McDonald's fries fried in PHVO have eight grams of *trans* fat and KFC's chicken fried in PHVO has fifteen grams, it would only be reasonable to assume that fries, chicken, and other foods from establishments that use PHVO would also contain comparably high amounts of *trans* fat. As indicated in Table 2, many popular foods in the United States prepared using PHVO have a high amount of *trans* fat per serving, some with higher *trans* fat content in one serving than the average daily consumption of *trans* fat.

¹⁰¹ See also Severson, *supra* note 2.

¹⁰² See generally *High Levels of Industrially Produced Trans Fat in Popular Fast Food*, 354 NEW ENG. J. MED. 1650, 1650–52 (2006) [hereinafter *Trans Fat in Popular Fast Food*].

¹⁰³ *Trans Fat in Popular Fast Food*, *supra* note 102, at 1652.

¹⁰⁴ McDonald's USA Nutrition Facts for Popular Menu Items, available at http://www.mcdonalds.com/app_controller.nutrition.index1.html#1 (last visited Feb. 5, 2008).

¹⁰⁵ *KFC Sued for Fattening Menu*, ABCNEWS.COM, Health Section, June 13, 2006, available at <http://abcnews.go.com/Health/story?id=2070417&page=1>.

¹⁰⁶ See *Trans Fat in Popular Fast Food*, *supra* note 102, at 1650–52. See also Jonathan E. Fielding, COUNTY OF LOS ANGELES DEP'T OF PUB. HEALTH, TRANS FAT REGULATION AND CALORIE LABELING ATTACHMENT, 1–2 [hereinafter Fielding, TRANS FAT REGULATION AND CALORIE LABELING ATTACHMENT] ("Nationally, the percentage of food dollars spent on foods prepared outside the home increased from 26% in 1970 to 47% in 2002.").

¹⁰⁷ N.Y. CITY DEP'T. OF HEALTH & MENTAL HYGIENE, NOTICE OF ADOPTION, *supra* note 15, at 1.

¹⁰⁸ Fielding, TRANS FAT REGULATION AND CALORIE LABELING ATTACHMENT, *supra* note 106, at 1.

¹⁰⁹ See *Trans Fat in Popular Fast Food*, *supra* note 102, at 1652.

Table 2. Typical *Trans* Fatty Acid Content of Foods Produced or Prepared with Partially Hydrogenated Vegetable Oils in the United States¹¹⁰

Type of Food	<i>Trans</i> Fatty Acid Content	
	% of Total Fatty Acids	% of Daily Energy Intake for 2000 Calorie Diet (average daily intake: 2.6%)
Fast or Frozen		
French fries	28–36	2.1–2.7
Breaded fish burger	38	2.5
Breaded chicken nuggets	25	2.3
French fries, frozen	30	1.3
Enchilada	12	0.9
Burrito	12	0.5
Pizza	9	0.5
Packaged snacks		
Tortilla (corn) chips	22	0.7
Popcorn, microwave	11	0.5
Granola bar	18	0.5
Breakfast bar	15	0.3
Bakery products		
Pie	28	1.8
Danish or sweet roll	25	1.5
Doughnuts	25	1.2
Cookies	26	0.8
Cake	16	0.8
Brownie	21	0.5
Muffin	14	0.3
Other		
Vegetable shortening	19	1.2
Pancakes	21	1.4
Crackers	34	0.9
Tortillas	25	0.2
Chocolate bar	2	0.1
Peanut Butter	1	0.05

¹¹⁰ Mozaffarian et al., *supra* note 83, at 1604–05.

C. OPTIMAL DAILY INTAKE OF *TRANS* FAT

Trans fat consumption is unavoidable when maintaining a healthy and ordinary diet.¹¹¹ Given the natural occurrence of *trans* fatty acids in meat products and dairy, it is impossible to completely remove *trans* fat without making “extraordinary changes in patterns of dietary intake.”¹¹² Health experts, including those from the Institute of Medicine (“IOM”),¹¹³ Dietary Guideline Advisory Committee,¹¹⁴ and the FDA,¹¹⁵ do not recommend making such adjustments since they may lead to undesirable effects and unknown health risks.¹¹⁶ For instance, avoiding all *trans* fatty acids would require that all animal products naturally containing *trans* fats be eliminated from the diet. Adopting such dietary practices would not only involve avoiding many common dairy, meat, and poultry products, it would also result in insufficient intakes of protein and certain essential nutrients.

While health expert groups may not endorse the complete avoidance of *trans* fat,¹¹⁷ there is a consensus among such expert groups that U.S. consumers should keep *trans* fat consumption low or “as low as possible” while consuming a nutritionally adequate diet.¹¹⁸ For instance, the 2005 Dietary Guidelines for Americans recommends that people should “keep *trans* fatty acid consumption as low as possible.”¹¹⁹ Similarly, the AHA also recommends keeping *trans* fat intake “below one percent of total daily calories”¹²⁰ and that “naturally occurring unhydrogenated oil be used when possible and attempts made to substitute unhydrogenated oil for hydrogenated or saturated fat in processed foods.”¹²¹ The IOM study concluded that there is “no safe level” of artificial *trans* fat consumption,

¹¹¹ FOOD & NUTRITION BD., INST. OF MED., DIETARY REFERENCE INTAKES FOR ENERGY, CARBOHYDRATE, FIBER, FAT, FATTY ACIDS, CHOLESTEROL, PROTEIN, AND AMINO ACIDS 423–24 (2005) [hereinafter IOM, DIETARY REFERENCE INTAKES FOR ENERGY 2005]. See *Trans Fatty Acids in Nutrition Labeling*, *supra* note 86, at 41442–45 (citing Food & Nutrition Bd., Inst. of Med., Letter Report on Dietary Reference Intakes for *Trans* Fatty Acids (2002) [hereinafter IOM, Report on *Trans* Fatty Acids]. See also FDA, Questions and Answers About *Trans* Fat, *supra* note 4.

¹¹² *Trans Fatty Acids in Nutrition Labeling*, *supra* note 86, at 41445 (citing IOM, Report on *Trans* Fatty Acids, *supra* note 111).

¹¹³ See IOM, DIETARY REFERENCE INTAKES FOR ENERGY 2005, *supra* note 111, at 473–99. See generally IOM, Report on *Trans* Fatty Acids, *supra* note 111.

¹¹⁴ See generally DEP’T OF HEALTH & HUMAN SERV. & U.S. DEP’T OF AGRIC., DIETARY GUIDELINES FOR AMERICANS, 2005 (2005), available at <http://www.health.gov/dietaryguidelines> [hereinafter DHH & USDA, 2005 GUIDELINES].

¹¹⁵ See generally FDA, Questions and Answers About *Trans* Fat, *supra* note 4. See also FDA, *Revealing Trans Fats*, *supra* note 92.

¹¹⁶ *Trans Fatty Acids in Nutrition Labeling*, *supra* note 86, at 41442. See also IOM, DIETARY REFERENCE INTAKES FOR ENERGY 2005, *supra* note 111, at 423–24.

¹¹⁷ See, e.g., FDA, Questions and Answers About *Trans* Fat, *supra* note 4.

¹¹⁸ See, e.g., IOM, DIETARY REFERENCE INTAKES FOR ENERGY 2005, *supra* note 111, at 424. See also, e.g., Nat’l Cholesterol Educ. Program, *High Blood Cholesterol: What You Need to Know*, <http://www.nhlbi.nih.gov/health/public/heart/chol/wyntk.htm>; AHA, *Trans Fatty Acids*, *supra* note 83.

¹¹⁹ DHH & USDA, 2005 GUIDELINES, *supra* note 114, at 30.

¹²⁰ Am. Heart Ass’n., *Trans Fat Overview*, available at <http://www.americanheart.org/presenter.jhtml?identifier=3045792> [hereinafter AHA, *Trans Fat Overview*]. See also Alice H. Lichtenstein et al., *Diet and Lifestyle Recommendations Revision 2006: A Scientific Statement From the American Heart Association Nutrition Committee*, 114 CIRCULATION 82, 82–96 (2006), available at <http://circ.ahajournals.org/cgi/content/full/114/1/82>.

¹²¹ Lichtenstein, *supra* note 91.

unlike other dietary fats that are a natural part of a healthy diet when consumed in moderation.¹²²

Since natural *trans* fat is essential and unavoidable in a nutritionally adequate diet, the healthiest way to keep *trans* fat intake as low as possible would be to eliminate the consumption of artificial *trans* fats.¹²³ Unlike naturally occurring *trans* fats, industrially produced *trans* fat found in PHVO is avoidable without adverse health ramifications.¹²⁴ Moreover, to that effect, the 2005 Dietary Guidelines explicitly state that “limited consumption of foods made with processed sources of *trans* fats provides the most effective means of reducing intake of *trans* fats.”¹²⁵

In terms of economic feasibility, there are other healthy, inexpensive alternatives to *trans* fats. According to a surveillance study of Denmark’s national *trans* fat ban, the change “did not appreciably affect the quality, cost or availability of food,” strongly supporting the notion that *trans* fat can be replaced “without any noticeable effect for the consumers.”¹²⁶ As such, health experts have consequently focused their *trans* fat directive on reducing artificial *trans* fat consumption in particular. Emphasizing this point, a study published in *New England Journal of Medicine* plainly states:

[T]rans fats from partially hydrogenated oils have no intrinsic health value above their caloric value. Thus, from a nutritional standpoint, the consumption trans fatty acids results in considerable potential harm but no apparent benefit Thus, complete or near-complete avoidance of industrially produced trans fat—consumption of less than 0.5 percent of the total energy intake—may be necessary to avoid adverse effects and would be prudent to minimize health risks.¹²⁷

The findings of the Demark surveillance study are further strengthened by the recent *trans* fat trend in the United States. The recent elimination of *trans* fats from the products of many major food manufacturers, distributors, and establishments not only indicates the availability of an economically feasible substitute, but strengthens the notion that artificial *trans* fat can be completely eradicated from the U.S. food supply.¹²⁸

D. WHY TRANS FAT IS BAD: CORONARY HEART DISEASE

There are no health benefits derived from consuming *trans* fats.¹²⁹ Even worse, *trans* fat consumption has a direct correlation to increasing CHD risk factors.¹³⁰ *Trans* fatty acid increases two major preventable heart

¹²² N.Y. CITY DEP’T. OF HEALTH & MENTAL HYGIENE, NOTICE OF ADOPTION, *supra* note 15, at 4.

¹²³ See discussion, *supra* Part III.C.

¹²⁴ See Mozaffarian et al., *supra* note 83, at 1609–11. See also *Trans Fat in Popular Fast Food*, *supra* note 102, at 1652.

¹²⁵ DHH & USDA, 2005 GUIDELINES, *supra* note 114, at 31.

¹²⁶ Mozaffarian et al., *supra* note 83, at 1610. See also *Trans Fat in Popular Fast Food*, *supra* note 102, at 1652.

¹²⁷ See Mozaffarian et al., *supra* note 83, at 1609.

¹²⁸ See discussion, *infra* Part III.D.

¹²⁹ IOM, DIETARY REFERENCE INTAKES FOR ENERGY 2005, *supra* note 111, at 473.

¹³⁰ See Mozaffarian et al., *supra* note 83, at 1601. See also FDA, Questions and Answers About *Trans* Fat, *supra* note 4.

disease risk factors: raised LDL cholesterol and lowered HDL levels.¹³¹ According to *trans* fat studies conducted by various panels of independent and government health experts, a positive relationship between *trans* fat and bad cholesterol levels provides compelling evidence that foods containing *trans* fatty acids increase CHD risks. A wide range of scientific literature, produced in part by health experts from IOM,¹³² the Advisory Committee on Dietary Guidelines,¹³³ the DHHS,¹³⁴ USDA,¹³⁵ the AHA,¹³⁶ and New England Journal of Medicine,¹³⁷ provides a strongly accepted body of persuasive evidence that support an adverse *trans* fat-CHD relationship. Notwithstanding the difference among study designs, the levels of *trans* fat consumed by study subjects, and the source of *trans* fat studied, all the studies agree and consistently report *trans* fatty acid's negative impact on cholesterol levels.

For instance, the 2005 Dietary Guidelines for Americans Advisory Committee Report, a joint publication from the DHHS and USDA, concluded that “[t]he relationship between *trans* fatty acid intake and LDL cholesterol is direct and progressive, increasing the risk of CHD.”¹³⁸ The AHA similarly states, that consumption of “*trans* fats raise your bad (LDL) cholesterol levels and lowers your good (HDL) cholesterol levels, [which] increases your risk of developing heart disease and stroke.”¹³⁹ And, upon its own extensive evaluation of the available scientific literature, the FDA also proclaimed:

In summary, based on the consistent results across a number of the most persuasive types of study designs (i.e., intervention trails and prospective cohort studies) that were conducted using a range of test conditions and across different geographical regions and populations, the agency now agrees . . . that the available evidence for an adverse relationship between *trans* fat intakes and CHD risk is strong.¹⁴⁰

This is not to say that *trans* fat is the only indicator of cholesterol levels. To the contrary, scientific evidence shows that consumption of saturated fat and dietary cholesterol also induces the same effects on LDL levels.¹⁴¹ In fact, saturated fat consumption is the main dietary culprit that raises LDL.¹⁴² However, even while Americans may consume approximately four to five times more saturated fat than *trans* fat in their

¹³¹ IOM, DIETARY REFERENCE INTAKES FOR ENERGY 2005, *supra* note 111, at 494–96.

¹³² *See id.* at 423–99. *See also* IOM, Report on *Trans* Fatty Acids, *supra* note 111.

¹³³ *See* DHH & USDA, 2005 GUIDELINES, *supra* note 114.

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ *See* Lichtenstein, *supra* note 91; AHA, *Trans Fat Overview*, *supra* note 120.

¹³⁷ *See* Mozaffarian et al., *supra* note 83, at 1601–13.

¹³⁸ DEP'T OF HEALTH & HUMAN SERV. & U.S. DEP'T OF AGRIC. 2005 DIETARY GUIDELINES ADVISORY COMMITTEE REPORT SECTION 10 (2005), *available at* <http://www.health.gov/DietaryGuidelines/dga2005/report/default.htm>.

¹³⁹ AHA, *Trans Fat Overview*, *supra* note 120.

¹⁴⁰ *Trans Fatty Acids in Nutrition Labeling*, *supra* note 86, at 41442–45.

¹⁴¹ *See* IOM, DIETARY REFERENCE INTAKES FOR ENERGY 2005, *supra* note 111, at 422.

¹⁴² FDA, TRANS FAT NOW LISTED, *supra* note 33.

diet,¹⁴³ solely reducing *trans* fat intake could independently reduce CHD risk.¹⁴⁴

Moreover, some studies have indicated that *trans* fat may be even unhealthier than the saturated fats—the leading indicator of high cholesterol levels.¹⁴⁵ This observation is also derived from the impact that *trans* fatty acid intake has on good cholesterol levels or LDL levels. LDL/HDL ratio levels are relevant to CHD since a high level of LDL will protect against heart attack and, alternatively, a low level will increase its risk. In fact, a two percent increase in *trans* fat intake is associated with a twenty-three percent increase in the risk of CHD.¹⁴⁶ *Trans* fat intake lowers LDL levels, and is considered worse than saturated fats precisely because an increase in the consumption of *trans* fat is associated with double the effect on total cholesterol levels than saturated fat.¹⁴⁷ Studies have indicated that “the adverse effect of *trans* fatty acids is stronger than that of saturated fatty acids,” and that the decrease of *trans* fatty acid intake would translate to death reductions that are higher than what could be achieved with reductions in saturated fat intake.¹⁴⁸ By even the most conservative estimates, the study claims that a two percent reduction in *trans* fat intake with the “replacement of partially hydrogenated fat in the U.S. diet with natural unhydrogenated vegetable oils would prevent approximately 30,000 premature coronary deaths per year, and epidemiologic evidence suggests this number is closer to 100,000 premature deaths annually.”¹⁴⁹ In comparison, saturated fat consumption would need to be reduced by ten percent to have the same impact.¹⁵⁰

Furthermore, regulation of artificial *trans* fat is more favorable than that of saturated fats simply because it could be done with little or no impact or notice to consumers. Reducing saturated fats would entail the major alteration of the food supply that would be undeniably noticeable to the taste buds, throwing most of popular fried foods, fast foods, desserts, and junk food off of dinner plates and out of pantries. However, since *trans* fat is mostly used as an industrial ingredient that can be substituted for other food substances substitutes, *trans* fat regulation could be changed without imposing such major changes on the American diet and palate.

In either case, even the slightest increase in *trans* fat consumption can greatly increase the LDL levels and the prevalence of heart disease. An analysis of four large research studies found that a two percent increase daily in caloric intake from *trans* fat can increase the incidence of CHD by twenty-three percent.¹⁵¹ Moreover, not only does the scientific evidence strongly suggest a connection between *trans* fat consumption and increased CHD risk, other observational studies on U.S. dietary patterns suggests that

¹⁴³ AHA, *Trans Fat Overview*, *supra* note 120.

¹⁴⁴ See *Trans Fatty Acids in Nutrition Labeling*, *supra* note 86, at 41467.

¹⁴⁵ See Mozaffarian et al., *supra* note 83, at 1613.

¹⁴⁶ Mozaffarian et al., *supra* note 83, at 1613.

¹⁴⁷ *Id.*

¹⁴⁸ Ascherio et al., *supra* note 3, at 3.

¹⁴⁹ *Id.* See also Mozaffarian et al., *supra* note 83, at 1613–14.

¹⁵⁰ See *id.*

¹⁵¹ Fielding, TRANS FAT REGULATION AND CALORIE LABELING ATTACHMENT, *supra* note 106, at 1.

current *trans* fat consumption levels are a cause for concern for American health. According to the AHA, “[o]n the whole, Americans should reduce the amount of . . . *trans* fat . . . in their diet.”¹⁵² Studies conducted on the relationship between CHD and *trans* fat show “10 to 19 percent of CHD events in the United States could be averted by reducing the intake of *trans* fat.”¹⁵³

The benefits of reducing *trans* fat in the diet will largely be a function of what replaces the *trans* fats. However, even a smallest decrease in *trans* fat consumption will correlate to a large CHD risk reduction, simply because of the pervasive frequency of the disease among the U.S. population. Of course, the most optimal results will be achieved if it is replaced with a heart healthy alternative. Considering the high prevalence of CHD in the United States, even the slightest reduction in the rate of CHD will correspond to a significant reduction of deaths in the United States. As of 2007 estimates, the disease kills nearly 700,000 people in the U.S. and CHD kills seven million people worldwide on an annual basis.¹⁵⁴ In other words, when the FDA passed down its final rule on *trans* fat labeling in 2003, the agency stated:

CHD is a common disease in the general U.S. population, with about 1.1 million hearts attacks annually, 40 percent of them fatal. Therefore, a small decrease in risk corresponds to a large number of attacks and death prevented. Thus. . . reducing *trans* fat intake by about 0.04 percent of energy (projected to decrease CHD risk by 0.05 percent), prevents approximately 600 heart attacks per year, including 200 fatal heart attacks.¹⁵⁵

While there is a lot of scientific literature on the overall negative health impact of *trans* fat, other studies have indicated that the risks may only be associated with the consumption of artificially produced *trans* fats. According to a comprehensive survey of *trans* fat studies published in the New England Journal of Medicine:

Of four prospective studies evaluating the relation between the intake of *trans* fatty acids from ruminants and the risk of CHD, none identified a significant positive association, whereas three identified nonsignificant trends toward an inverse association. . . . [T]he sum of the current evidence suggests that the public health implications of consuming *trans* fats from ruminant products are relatively limited.¹⁵⁶

Together, the studies on the *trans* fat-LDL link, the impact of current dietary practices on the level of CHD risk, the potential advantages to minimizing *trans* fat consumption, and the consequences attributed to increased consumption provides strong confirmation that *trans* fat in the U.S. diet should be reduced. Additionally, given that the evidence of health risks is especially strong for artificial *trans* fat, efforts in reducing *trans* fat should be directed at artificial *trans* fat in particular. Unless Americans

¹⁵² AHA, Heart and Stroke Facts, *supra* note 61, at 39.

¹⁵³ See Mozaffarian et al., *supra* note 83, at 1611.

¹⁵⁴ CDC, February is Heart Month, *supra* note 20.

¹⁵⁵ Trans Fatty Acids in Nutrition Labeling, *supra* note 86, at 41467.

¹⁵⁶ See Mozaffarian et al., *supra* note 83, at 1608–09.

reduce the level of *trans* fat in their daily caloric intake, the U.S. population will continue to needlessly expose itself to a major, preventable, CHD risk factor. Therefore, steps must be taken to reduce the mean intake of 5.8 grams of *trans* fat per day by the average American as a preventative measure against heart-related disease and death.

IV. THE FOOD INDUSTRY AND *TRANS* FAT

A. FOOD TRENDS AND MARKET REGULATION

In the United States, food consumption preferences are heavily influenced by the rise and fall in popularity of food and diet fads.¹⁵⁷ Diet and nutrition fads are generally marked by a rapid rise in popularity among consumers.¹⁵⁸ Businesses also frequently succumb to fads.¹⁵⁹ When a food craze hits, food companies often concentrate their marketing strategies to capitalize on the increased consumer demand, fueling food fads with advertisements, new product development, reformulation of current products, and packaging strategies.¹⁶⁰ As a result, whenever a hot new health fad emerges, the market becomes instantly saturated with an influx of foods specifically designed by the food companies to appeal to the latest fad.¹⁶¹ Today, thousands of foods are marketed as sugar-free, low-carbohydrate, high protein, whole grain, fat-free, and organic.¹⁶² While health fads may lead to marketing schemes and odd products like low-carbohydrate beer, vitamin water, or high-protein breakfast cookies, their impact on American food demand is straightforward and clear.

The *trans* fat trend started to gain momentum in 2003.¹⁶³ New FDA labeling regulations and a lawsuit involving *trans* fats led to increased consumer awareness of the negative health impacts of *trans* fat. Since then, consumer pressure has resulted in changes to the industry's use of *trans* fats.¹⁶⁴ Since 2003, major food manufacturers and restaurants alike started to remove *trans* fats from their foods: McDonald's, Burger King, Kraft Foods, Disneyland, Starbucks, Frito-Lay (Doritos, Tostitos, and Cheetos), Unilever Bestfoods (I Can't Believe It's Not Butter!), etc. U.S. consumers have responded with a twelve percent increase (\$6.4 billion) in the national sale of *trans* fat-free products between 2003 and 2004.¹⁶⁵

¹⁵⁷ See generally BARBARA CHARLET & SHIDA R. HENNEBERY, OKLA. ST. UNIV., OKLAHOMA COOPERATIVE EXTENSION FACT SHEET: A PROFILE OF FOOD CONSUMPTION TRENDS AND CHANGING MARKET INSTITUTIONS; *Spreading Yourself Too Thin*, *supra* note 14.

¹⁵⁸ *Spreading Yourself Too Thin*, *supra* note 14.

¹⁵⁹ *Id.* at 4 (discussing why businesses succumb to fads).

¹⁶⁰ *Id.* See also CHARLET & HENNEBERY, *supra* note 157.

¹⁶¹ For instance, at the height of the Atkins Diet in 2003, food manufacturers introduced more than 3000 new low-carbohydrate products in a single year. *Spreading Yourself Too Thin*, *supra* note 14, at 4.

¹⁶² See Denise Webb, *Naughty and Nice: The Best and the Worst Food Fads of 2005*, SHAPE, Dec. 1, 2005.

¹⁶³ TRIMMING TRANS FAT, *supra* note 1, at 27.

¹⁶⁴ See TRIMMING TRANS FAT, *supra* note 1, at 23–27. See also Anthony Fletcher, *Trans-fat Deadline Pushes Healthy Oil Innovations*, FOODNAVIGATOR, July 6, 2005, available at <http://www.foodnavigator-usa.com/news/ng.asp?n=61125-transfat-oil-soy>.

¹⁶⁵ Fletcher, *supra* note 164.

**Table 3. A Select Look at Companies Removing *Trans* Fats
2003/2004¹⁶⁶**

Marketer/Food Company	Product
Kraft/Nabisco	Three varieties of Oreo cookies Wheat Thin crackers Chips Ahoy! Cookies Cheese Nips crackers Triscuit crackers
Voortman	All cookie products
Pepperidge Farm (Campbell)	90% of Goldfish line products
Quaker Oats (PepsiCo.)	Q-Smart snack bars
Frito Lay (PepsiCo.)	More than 150 snack products total
Wild Oats	Removed all products with hydrogenated oils from grocery shelves
Tyson	Removed trans fat from fully cooked meat/chicken products
Crisco/J.M. Smucker	Crisco 0 Gram Trans Fat Shortening

However, as the dramatic rise of food fads is often accompanied by an equally fast decline, the lasting impact of the anti-*trans* fat trend remains uncertain.¹⁶⁷ Though the food industry and consumer taste may be *trans* fat adverse now, consumer attention spans are generally temporary when it comes to food preferences and typically only regulates consumer behavior for a fixed amount of time. According to Wharton Business School marketing professor Stephen Hoch, “[t]here is a great deal of media hype about food trends, but if you look at U.S. Department of Agriculture data, it’s amazing how slowly food preferences actually change.”¹⁶⁸

Take for example the drastic transition of consumer attention from fats to carbohydrates. During the non-fat craze of the 1990s, consumers became keenly aware of the fat content of their foods and food manufacturers scrambled to introduce low-fat products.¹⁶⁹ Despite the general increase in public awareness of the health risks associated with saturated fat and the borderline obsessive fear of fats that spread among millions of Americans during the 1990s, the same fat-averse population later succumbed to a low-carbohydrate trend that promoted the animal-fat filled, protein-centered

¹⁶⁶ TRIMMING TRANS FAT, *supra* note 1, at 6.

¹⁶⁷ See *Spreading Yourself Too Thin*, *supra* note 14, at 1.

¹⁶⁸ *Id.* at 3.

¹⁶⁹ TRIMMING TRANS FAT, *supra* note 1, at 57.

diets like Atkins.¹⁷⁰ For a while, Americans abandoned their commitment to the low-fat diet, fully committing themselves to the promises of the latest low-carb trend. In fact, the low-carb craze caused “rebirth to sales of fat-laden products such as meat, butter, and dairy.”¹⁷¹ According to the National Cattlemen’s Beef Association, U.S. sales of red meat were at their highest levels in years, and cheese sales rose 3.4% to \$8.4 billion in 2005.¹⁷²

It is duly noted that the anti-*trans* fat movement is not necessarily a “diet” trend in the strict sense like a low-carb or low-fat diet since it does not actually involve weight loss, but rather heart health. However, it is still comparable to “diet” trends since it impacts health. Even more convincingly, a consumer marketing study shows that consumers would not perceive a difference:

Although the public has been relatively well-informed about the general need to cut back on fat, the distinction between “good” cholesterol and “bad” cholesterol remains somewhat unclear for many people. Further complicating the picture is the fact that during the past 20 years, when low-fat diets and products were at their peak, overweight and obesity have nevertheless grown at epidemic rates. . . . And again, many people miss the point that reducing fat intake, while it may provide a number of cardiovascular and other health benefits, will not necessarily lead to a loss of body fat unless caloric intake is also decreased and/or physical activity increased.¹⁷³

The public has become increasingly aware and educated on the risks associated with *trans* fat consumption, like risks associated with saturated fats; however, studies on consumer food choices have corroborated that “just knowing that trans fats can be harmful isn’t enough to get most people to change their habits.”¹⁷⁴ And, while some have argued that market pressures will be enough to regulate *trans* fat, claiming that “[t]he industry is moving away from trans fat regardless of what happens,”¹⁷⁵ previous market trends in the industry suggest that consumers’ interest and concerns regarding *trans* fat could eventually wane as it did in the case of carbohydrates. Once the *trans* fat hype subsides and consumer pressures disappear, without statutory restrictions the food industry will be able to regress back its prior uses of *trans* fat.

The current *trans* fat trend in the food industry has to be effective at reducing the presence of the substance in the food supply. As long as the industry finds it advantageous to not use PHVO even after the *trans* fat hype has subsided, the industry could regulate its own use of *trans* fat making governmental intervention unnecessary. However, there are no

¹⁷⁰ US URGED TO INCREASE FIBER INTAKE, FOODNAVIGATOR, May 19, 2004, <http://www.nationalfiberCouncil.org/PDF/foodnavigator.pdf>.

¹⁷¹ TRIMMING TRANS FAT, *supra* note 1, at 9.

¹⁷² *Id.*

¹⁷³ *Id.* at 74.

¹⁷⁴ *Id.* at 1.

¹⁷⁵ Tony Barboza, *Restaurant Group Agrees to Phase Out Trans Fat in L.A.-area Eateries*, L.A. TIMES, Jan. 31, 2007, at B6 (quoting Andrew Casana, the director of local government affairs for the California Restaurant Association).

guarantees that restaurants and food manufacturers will not revert back to their old habits, especially since PHVO is still a cheaper commodity than its alternatives and has many advantages that made its use so prevalent in the industry since it was first introduced decades ago. In that case, the market will only offer a limited impact on the industry's use of *trans* fats and a temporary remedy to the related health issue.

V. LEGAL REMEDIES

A. FOOD REGULATION INFRASTRUCTURE

All three branches of federal government and the state and local governments share complimentary roles to ensure the safety of the national food supply: the legislative branch enacts statutes and oversees federal agencies; the executive branch and its agencies implement the statutes; and the judicial branch enforces and settles any arising disputes. State and local governments also enact regulations for foods that fall under their respective jurisdictions.

The primary foundation for modern federal food regulation is embedded in the Federal Food, Drug, and Cosmetic Act (FD & C Act).¹⁷⁶ Originally passed by Congress in 1938, and amended several times thereafter, the FD & C Act established fundamental food safety policies and the groundwork for a federal governmental infrastructure to enforce and administer Congress's statutory mandates. The federal food regulatory system in the United States has since evolved into a comprehensive body of statutory law and case law derived from over thirty-five additional federal statutes.¹⁷⁷

In addition to setting general food policies and guidelines, federal food statutes also authorize governmental agencies to implement and enforce their regulations. Directed by the principles and objectives of Congress, federal agencies generally have the benefit of broad statutory authority to integrate strong regulatory measures into their food safety programs and impose additional legal responsibilities on the food industry.¹⁷⁸ For

¹⁷⁶ Fed. Food, Drug, & Cosmetic Act, 21 U.S.C. §§ 301–99 (2004); NAT'L CTR. FOR AGRIC. LAW RES. & INFO. & NAT'L ASS'N OF ST. DEP'T OF AGRIC., FOOD SAFETY: STATE AND FEDERAL STANDARDS & REGULATIONS 4, <http://www.nasda-hq.org/nasda/nasda/Foundation/foodsafety/fed-state.pdf> [hereinafter NASDA, STATE AND FEDERAL].

¹⁷⁷ Other statutes authorizing food safety agencies are: the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), the Egg Products Inspection Act (EPIA), the Food Quality Protection Act (FQPA), and the Public Health Service Act. 21 U.S.C. §§ 301–99. NASDA, STATE AND FEDERAL, *supra* note 176, at 2 (explaining that “[t]he USDA and the FDA bear the major responsibility for food safety programs at the federal level. However, federal food safety responsibilities are shared by at least a dozen separate agencies whose authority is derived from over 35 separate statutes.”).

¹⁷⁸ See U.S. FOOD & DRUG ADMIN., FOOD SAFETY: A TEAM APPROACH (1998), available at <http://www.cfsan.fda.gov/~lrd/foodteam.html> [hereinafter FDA, FOOD SAFETY]. Principal federal regulatory organizations responsible for providing consumer protection are the Department of Health and Human Services' (DHHS) Food and Drug Administration (FDA), the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) and Animal and Plant Health Inspection Service (APHIS), and the Environmental Protection Agency (EPA). The Department of Treasury's Customs Service assists the regulatory authorities by checking and occasionally detaining imports based on guidance provided. Many agencies and offices have food safety missions within their research, education, prevention, surveillance, standard-setting, and/or outbreak response activities.

instance, under the FD & C Act, the FDA, a federal agency of the DHHS, has the responsibility of establishing the legal “standards for composition, quality, and safety of foods and food additives as well as economic standards to assure consumer confidence in labeling.”¹⁷⁹ Even more broadly, the Act also mandates the FDA’s legal authority to develop any related food safety regulation to effectuate its “efficient enforcement,”¹⁸⁰ giving any FDA regulation promulgated under the authority of the FD & C Act the same color of force and effect as the Congressional statute.¹⁸¹

The courts are also an inherent and integral part of the national legal food regulatory system. By way of the general liability system developed by the Congressional statutes and federal agency regulations, the requirements of food law can be enforced through court action. For example, Section 301 of the FD & C Act enumerates a list of prohibited acts and related provisions that can be used to impose criminal penalties and civil sanctions to anyone who does not adhere to the restrictions.¹⁸²

Since the FD & C Act does not have a preemption provision related to states, the federal, state, and local governments cooperate together to implement food safety programs.¹⁸³ The FDA delegates major food safety enforcement activities and responsibilities to the states, and in turn, the states also rely on the assistance of local governments. In fact, the FD & C Act authorizes a state to bring “in its own name and within its own jurisdiction, proceedings for the civil enforcement, or to restrain violations” of provisions under the Act if the food is “located in the State.”¹⁸⁴ Most notably, state and local regulation includes foods prepared by restaurants, retail food establishments, and nonprofit food establishments.¹⁸⁵ Thus, even where the jurisdiction of the federal law ends, state and local government regulation add an additional layer of consumer protection to create an extensive national food safety network administered and enforced by public officials at the federal and state level.

B. TRANS FAT SUITS

Within the legal food safety system, the law lends many possible tools that can be used to facilitate the reduction of *trans* fat in the American diet. In terms of modern legal interventions, lawsuits against the food industry

including DHHS’s Ctrs. for Disease Control and Prevention (CDC) and National Institutes of Health (NIH); USDA’s Agricultural Research Service (ARS); Cooperative State Research, Education, and Extension Service (CSREES); Agricultural Marketing Service (AMS); Economic Research Service (ERS); Grain Inspection, Packers and Stockyard Administration (GIPSA); and the U.S. Codex office; and the Department of Commerce’s National Marine Fisheries Service (NMFS). *Id.*

¹⁷⁹ NASDA, STATE AND FEDERAL, *supra* note 176, at 20.

¹⁸⁰ Generally, § 371 of the FD & C Act vests authority in the Secretary “to promulgate regulations for the efficient enforcement” of the prohibited acts; more specifically as to food, § 341 states that the Secretary “shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container.” 12 U.S.C. § 371.

¹⁸¹ See U.S. FOOD & DRUG ADMIN. & U.S. DEP’T OF AGRIC., U.S. FOOD SAFETY COUNTRY REPORT (2002), available at <http://www.foodsafety.gov/~fsg/fssyst2.html>.

¹⁸² 21 U.S.C. §§ 331 et seq.

¹⁸³ *Id.*

¹⁸⁴ § 337.

¹⁸⁵ § 350d(b).

have generally been relatively unpopular and ineffective at advancing legitimate public policy concerns.¹⁸⁶ In a majority of recent food cases, plaintiffs have faced significant legal hurdles in carrying their case through the course of litigation.¹⁸⁷ *Trans* fat lawsuits are not an exception; three major *trans* fat law suits filed against Kraft, McDonald's,¹⁸⁸ and KFC¹⁸⁹ over their use of *trans* fatty acids were eventually settled out of court.¹⁹⁰

Nevertheless, while *trans* fat cases have not directly translated into a court judgment for the plaintiffs, the wide publicity generated by them has been successful at bringing attention to public health concerns in the United States and effectuating some change in food company practices.¹⁹¹

The first major *trans* fat lawsuit was filed on May 1, 2003.¹⁹² In a very controversial effort to address the use of *trans* fat by the food industry, Stephen Joseph, a public interest lawyer and founder of BanTransFats.com, took the Oreo cookie to court. The suit was filed against Nabisco and its parent company, Kraft.¹⁹³ The suit asked for an injunction ordering the company "to cease and desist from marketing and selling Oreo Cookies to children in the State of California, until such cookies contain no partially hydrogenated oil or any other fat."¹⁹⁴ However, the widely publicized case was short-lived, and Joseph formally dropped the suit within a week of his filing. Nabisco announced it would "actively explor[e] ways to reduce *trans* fats in Oreo cookies while still maintaining the high quality standards consumers expect. . . ."¹⁹⁵ In a press release regarding the case, Joseph stated:

The factual and legal basis for the lawsuit when it was filed was that the American people did not know about trans fat. At best, perhaps 10 to 15% knew. The food manufacturers were keeping the American people in the dark. The word 'trans fat' is not even on food labels. That was then. This is now. . . . After three days of incredible national publicity, everyone in

¹⁸⁶ See Gostin, *supra* note 79, at 87–88.

¹⁸⁷ See, e.g., Pelman v. McDonald's Corp., 237 F. Supp. 2d 512, 516 (S.D.N.Y. 2003). See also Complaint, *Barber v. McDonald's* (N.Y. Sup. Ct. July 24, 2002), available at news.findlaw.com/hdocs/docs/mcdonalds/barbermcds72302cmp.pdf.

¹⁸⁸ See *Fettke v. McDonald's Corp.*, Case No. 044109 (Cal. Sup. Ct. 2003). See also *BanTransFat.com v. McDonald's Corp.*, Case No. 034828 (Cal. Sup. Ct. 2003).

¹⁸⁹ Complaint, *Hoyte v. Yum Brands*, No. 06-1127 (D.C. Sup. Ct., Sept. 12, 2006), available at http://www.cspinet.org/new/pdf/final_complaint.pdf. See also Press Release, Press Conference Announcing Lawsuits Against KFC, Ctr. for Science in the Public Interest (June 13, 2006), available at http://cspinet.org/new/pdf/mfj_kfc_statement.pdf.

¹⁹⁰ The Oreo Case, BanTransFats.com, <http://www.bantransfat.com/theoreocase.html>; Press Release, BanTransFats.com, Plaintiffs' Press Release on Settlement of McDonald's Trans Fat Litigation (Feb. 11, 2005), <http://www.bantransfat.com/images/Trans%20Fat%20Litigation%20Plaintiffs%27%20Press%20Release.pdf> [hereinafter Press Release, BanTransFats.com, Settlement of McDonald's Trans Fat]; Press Release, Ctr. for Science in the Public Interest, CSPI Withdraws from Lawsuit After KFC Cuts Trans Fat (June 13, 2006), available at <http://www.cspinet.org/new/200610301.html> [hereinafter Press Release, CSPI, CSPI Withdraws from Lawsuit].

¹⁹¹ For instance, fast food companies started offering healthier choices on the menu following the lawsuits against McDonald's. See Theodore H. Frank, *A Taxonomy of Obesity Litigation*, U. ARK. LITTLE ROCK L. REV., 427, 428–31 (2006).

¹⁹² *Oreo Cookies Lawsuit Crumbles: Lawyer Drops Suit, Saying Trans Fat Danger Has Been Publicized*, CBSNEWS.COM, Feb. 15, 2003, available at <http://www.cbsnews.com/stories/2003/05/13/health/main553619.shtml>.

¹⁹³ *Id.*

¹⁹⁴ The Oreo Case, *supra* note 190.

¹⁹⁵ TRIMMING TRANS FAT, *supra* note 1, at 8, 23.

America knows about *trans* fats. . . . [t]he factual and legal basis for the lawsuit has totally disappeared.¹⁹⁶

Also in 2003, Joseph represented Plaintiff Katherine Fettke and BanTransFats.com in a class action suit against McDonald's.¹⁹⁷ As in the Oreo case, Joseph sought injunctive relief against McDonald's, claiming that the popular fast food chain failed to adequately notify the public after not abiding by statements it had made about switching to cooking oil with less *trans* fat.¹⁹⁸ The goal of the lawsuit was for "McDonald's to give effective notice to the public that the oil was not changed."¹⁹⁹ McDonald's eventually settled out of court, agreeing to donate seven million dollars to the AHA, spend up to \$1.5 million on publishing public notices about its *trans* fat initiative, and pay the legal fees plus \$7500 to Joseph's non-public organization and Fettke.²⁰⁰

In a more recent case against the fast food industry, the nonprofit Center for Science in the Public Interest (CSPI) sued KFC.²⁰¹ The lawsuit, filed on June 12, 2006, sought economic damages and an injunction against KFC's "continued use of *trans* fat or in the alternative ordering [KFC] to take all necessary actions to insure that D.C. consumers are warned so that they may know, immediately prior to purchasing any food prepared using *trans* fat, that the food is prepared with *trans* fat products."²⁰² According to the CSPI, the primary objective behind the suit was to "[force] the chain to stop using *trans*-fat-laden partially hydrogenated oils for deep-frying."²⁰³ Within five months, KFC announced that the company planned to switch to a new soybean oil without *trans* fat.²⁰⁴ As in the Oreo case, as soon as the defendant company adopted a *trans* fat-free initiative, the nonprofit organization immediately dropped the lawsuit against KFC.²⁰⁵

KFC's timely *trans* fat initiative was announced the same day that New York health officials held a public hearing on *trans* fat, on the heels of the FDA *trans* fat labeling regulation. The two factors put tremendous pressure on other food companies to do the same, especially larger establishments like McDonald's.²⁰⁶ Upon KFC's declaration, McDonald's was particularly criticized and scrutinized for moving slower than its smaller competitors

¹⁹⁶ TRIMMING TRANS FAT, *supra* note 1, at 24 (quoting Stephen Joseph).

¹⁹⁷ See *Fettke v. McDonald's Corp.*, Case No. 044109 (Cal. Sup. Ct. 2003). See also *BanTransFat.com v. McDonald's Corp.*, Case No. 034828 (Cal. Sup. Ct. 2003).

¹⁹⁸ The McDonald's Settlement, BanTransFats.com, <http://www.bantransfat.com/mcdonalds.html>.

¹⁹⁹ Press Release, BanTransFats.com, Settlement of McDonald's Trans Fat, *supra* note 190.

²⁰⁰ See Press Release, BanTransFats.com, Settlement of McDonald's Trans Fat, *supra* note 190.

²⁰¹ See Press Release, Ctr. for Science in the Public Interest, KFC Sued for Foullying Chicken with Partially Hydrogenated Oil, June 6, 2006, <http://cspinet.org/new/200606121.html>. CSPI has been an active participant in the anti-*trans* fat movement. For more information on the non-profit organization, see CSPI's Home Page, <http://www.cspi.org>.

²⁰² Complaint, *Hoyte v. Yum Brands*, No. 06-1127 at 13 (D.C. Sup. Ct., Sept. 12, 2006), available at http://www.cspinet.org/new/pdf/final_complaint.pdf.

²⁰³ Press Release, CSPI, CSPI Withdraws from Lawsuit, *supra* note 190.

²⁰⁴ See Bruce Horovitz, *KFC Plans 'Important' Trans Fat 'Milestone'*, USA TODAY, Oct. 30, 2006, available at http://www.usatoday.com/money/industries/food/2006-10-29-kfc-transfat-usat_x.htm. See also Press Release, CSPI, CSPI Withdraws from Lawsuit, *supra* note 190.

²⁰⁵ See Press Release, CSPI, CSPI Withdraws from Lawsuit, *supra* note 190.

²⁰⁶ See Horovitz, *supra* note 204. See also Press Release, CSPI, CSPI Withdraws from Lawsuit, *supra* note 190.

and renegeing on its earlier promises to start using a reduced *trans* fat oil.²⁰⁷ Finally, on January 30, 2007, nearly five years after its initial announcement and four years after Joseph's lawsuit, McDonald's announced that the company had found new oil without *trans* fat that it would use in all of its restaurant chains.²⁰⁸ Since then, many more companies have also followed suit, including: Burger King, Starbucks, Wendy's, Subway, Red Lobster, Olive Garden, and Johnny Rockets.²⁰⁹

At the very least, litigation has helped reduce *trans* fat in the American food supply by directing nationwide media and consumer attention to the dangers of *trans* fat and also by applying considerable public pressure on at least three major food companies—Kraft, McDonald's, and KFC—to alter their use of *trans* fats in their products. The terms of the resulting settlements were directly aimed at promoting a *trans* fat reduction agenda, and to that effect they have been successful at positively influencing the disclosure practices and *trans* fat usage of the defendant food corporations. However, the McDonald's case stands to show the limitations of food litigation; even though litigation can be used as a strategy to promote publicity and apply pressure on food companies, the companies' reactions can vary and can be delayed at times. McDonald's took four years to actually implement the changes in its *trans* fat usage. Furthermore, considering that the switch to zero-*trans* fat came only a few months before a mandatory deadline imposed by the New York City ban, it is not entirely clear how much longer McDonald's would have taken if the only pressure to make the switch was the publicity from the *trans* fat litigation.

While litigation has helped motivate food companies to adopt changes in their use of *trans* fats, leaving local courts to regulate *trans* fats is also an unnecessarily arduous and inefficient way to regulate the use of *trans* fat. Solely relying on litigation to effectuate change would entail enjoining every last food establishment, including local independently owned "mom and pop" shops, to ensure that all restaurants comply with *trans* fat reductions. Although some major food companies may have implemented a voluntary *trans* fat reduction program as a result of the highly publicized *trans* fat lawsuits, there is less incentive for non-chain restaurants to conform to the trend and be affected by litigation since local establishments are not subject to the same public scrutiny as large national food companies.²¹⁰ In fact, an investigation by the Los Angeles County Public

²⁰⁷ *McDonald's Finally Picks Trans-Fat-Free Oil*, MSNBC.COM, Jan. 30, 2007, available at <http://www.msnbc.msn.com/id/16873869/>.

²⁰⁸ *Id.*

²⁰⁹ Fielding, TRANS FAT REGULATION AND CALORIE LABELING ATTACHMENT, *supra* note 106, at 2. See also *Burger King Testing Trans-Fat-Free Oils*, CHI. TRIB., Dec. 13, 2006, available at <http://www.chicagotribune.com/business/chi-0702010156feb01,1,2955679.story?coll=chi-news-hed>. See Nanci Hellmich & Bruce Horovitz, *NYC Proposes Ban on Trans Fats in Restaurant News*, USA TODAY (Sept. 27, 2006); Press Release, Darden Restaurants, Darden Restaurants Announces Red Lobster and Olive Garden Converting to Zero Trans Fat Frying Oils (Dec. 13, 2006), available at http://investor.dardenrestaurants.com/ir_ReleaseDetail.cfm?ReleaseID=222324; Johnny Rockets Jumps on No-Trans-Fat Bandwagon, CBS2.com, http://cbs2.com/topstories/local_story_024150202.html.

²¹⁰ Fielding, TRANS FAT REGULATION AND CALORIE LABELING ATTACHMENT, *supra* note 106, at 2 ("Recently, Wendy's, Kentucky Fried Chicken, Taco Bell, Olive Garden, Red Lobster, Arby's, Ruby Tuesday, Chili's, Loew's Hotels, Royal Caribbean International, Johnny Rockets and Starbucks have announced they will no longer use artificial trans fats or are phasing them out quickly.").

Health Department noted that “non-chain restaurants located in low-income communities would be more difficult to reach in educational campaigns and would be more resistant to change.”²¹¹

Thus, in the case of smaller establishments, absent a separate legal duty not to use *trans* fats in their foods, most individual local restaurants would actually need to be brought into the courtroom to be influenced by lawsuits. The mere threat of lawsuits or the publicity generated by them is insufficient. Furthermore, considering that none of the *trans* fat litigation was carried through the course of litigation and the shortcomings of food litigation generally, lawsuits would not necessarily create enough pressure on local establishments and companies to reach a settlement to reduce their usage of *trans* fats or conclude in a judgment for potential plaintiffs as in the McDonald’s and KFC cases. As such, solely relying on litigation as a tool to reduce *trans* fat would create an undoubtedly unnecessary and unproductive burden on the courts.

C. STATE AND LOCAL REGULATION OF *TRANS* FAT

On December 5, 2006, New York City, in perhaps the most direct and paternalistic form of government involvement, became the first major U.S. city to pass a legislative restriction against the use *trans* fat.²¹² The new amendment to the city health code prohibits New York City restaurants from frying foods in *trans* fats or serving food that contains more than 0.5 grams of artificial *trans* fat.²¹³ Effective July 1, 2007, New York City’s amended code allows for a phase-in period of six to eighteen months depending on the use of *trans* fat and type of food. The law also exempts food served in its original packages. The ban on *trans* fat, a very common ingredient in processed foods,²¹⁴ will radically impact the way food will be prepared in nearly all 20,000 of New York City restaurants. New York City’s ban set the national standard, prompting similar *trans* fat propositions to appear on state and local legislative agendas in more than half of the states throughout the country.²¹⁵

Invoking their constitutional authority to regulate foods that are not already occupied by federal regulation, other state and local legislatures throughout the nation have also proposed their own *trans* fat initiatives. Most proposals are similar to New York City’s, and contain four common provisions: 1) amending the current health code to limit or restrict the use of *artificial trans* fat in food service establishments; 2) an induction period allowing for businesses to phase-in necessary adjustments; 3) a 0.5 gram *trans* fat threshold; and 4) an exemption for food in its original packaging. At the state level, *trans* fat prohibition legislation is pending in: Arkansas;

²¹¹ Fielding, TRANS FAT REGULATION AND CALORIE LABELING ATTACHMENT, *supra* note 106, at 3.

²¹² Thomas J. Lueck and Kim Severson, *New York Bans Most Trans Fats in Restaurants*, N.Y. TIMES, Dec. 6, 2006, at A1.

²¹³ N.Y. CITY DEP’T. OF HEALTH & MENTAL HYGIENE, NOTICE OF ADOPTION, *supra* note 15.

²¹⁴ See discussion, *supra* Part II.

²¹⁵ For example, there is pending legislation in the state governments of Arkansas, California, Connecticut, Florida, Hawaii, Kentucky, Maryland, Michigan, New Hampshire, New Jersey, New York, Rhode Island, South Carolina, Tennessee, and Washington. Trans Fat Legislation: Pending Proposals – 2007, Nat’l Restaurant Ass’n, http://www.restaurant.org/government/state/nutrition/bills_trans_fat.cfm.

California; Connecticut; Florida; Hawaii; Kentucky; Maryland; Michigan; New Hampshire; New Jersey; New York; Rhode Island; South Carolina; Tennessee; and Washington. At the local level, city and county legislatures have proposals similar to New York City's ordinance in Oakland County, MI; Buffalo, NY; Baldwin Park, CA; Philadelphia, PA; Chicago, IL; Boston, MA; Seattle, WA; and Miami, FL.²¹⁶ On February 15, 2007, Philadelphia became the second city to ban *trans* fat when Mayor John Street signed the ordinance into law.²¹⁷ Most of the other proposals are awaiting hearings in the legislature.

In addition to *trans* fat bans, others legislatures have also proposed labeling and disclosure requirements that require restaurants and food establishments to provide warnings that indicate which foods contain artificial *trans* fats. *Trans* fat labeling laws have not been as popular as *trans* fat bans, and they have only been introduced in California, Florida, New Jersey, Rhode Island, and Tennessee.

Considering the social and economic benefits attributed to *trans* fat labeling,²¹⁸ legislative bans would certainly be an even more effective and rapid way to reduce the use of *trans* fat in the diets of Americans. And if passed into law, the proposals could potentially have a tremendous impact on *trans* fat consumption and substantially reduce rates of heart disease. For instance, McDonald's nationwide switch to a zero-*trans* fat menu probably had a lot to do with the impending New York City ban.²¹⁹

Nevertheless, legislative regulation of *trans* fat is not a feasible option for some local governments. For example, Los Angeles was poised to become the second city to ban *trans* fat after New York adopted its ban in December 2006. Within a week of New York City's ban, *trans* fat legislation was proposed in the city and county legislature and the Los Angeles County Director of Public Health immediately began a feasibility study on the implementation of a *trans* fat ban in Los Angeles. However, the study reported that attempts by Los Angeles City and County to regulate *trans* fat would "likely conflict with State law."²²⁰ Unlike New York City, the Los Angeles local government was preempted from regulating the restaurant's use of *trans* fats by the California State Constitution.²²¹ Regulatory law was not an available tool for Los Angeles, and *trans* fat reduction efforts were limited to a voluntary program.

Los Angeles's voluntary program *trans* fat initiative is a joint effort with the California Restaurant Association ("CRA").²²² The CRA has a membership of over 22,000 members and the self-proclaimed "definitive

²¹⁶ *Id.*

²¹⁷ *Id.*

²¹⁸ See discussion, *infra* Part V.B.

²¹⁹ See discussion, *supra* Part IV.C.

²²⁰ JONATHAN E. FIELDING, COUNTY OF LOS ANGELES DEP'T OF PUB. HEALTH, TRANS FAT REGULATION AND CALORIE LABELING at 1.

²²¹ Fielding, TRANS FAT REGULATION AND CALORIE LABELING ATTACHMENT, *supra* note 106, at 2.

²²² Press Release, Jose Huizar, Los Angeles City Council, City and County of Los Angeles and California Restaurants Announce Partnership to Voluntarily Phase Out Trans Fats: New Collaborations to Improve Public Health, *available at* http://www.lacity.org/council/cd14/press/cd14press255943006_01312007.pdf.

voice of California's restaurant industry."²²³ Using special zero-*trans* fat certification decals as the main incentive for cooperation, the program implements a voluntary phaseout of *trans* fat in foods sold in Los Angeles restaurants. According to the Los Angeles study, the voluntary approach coupled with an educational outreach program "would provide important information to consumers, allowing them to make an informed choice regarding *trans* fats in choosing a restaurant . . . [and] put pressure on restaurants to conform to a growing trend."²²⁴ However, CRA members only represent a few thousand restaurants out of more than 34,000 restaurants in Los Angeles.²²⁵ Furthermore, based on New York City's prior experience with its failed voluntary program, it is a likely possibility that the Los Angeles program will also produce "less than optimal" results.²²⁶

In cases like Los Angeles, where local governments are unable to enact their own *trans* fat regulation and are limited to voluntary programs, the federal regulation of *trans* fat would be especially appropriate. While there is a possibility that Los Angeles's program may achieve marginally better results since New York and Philadelphia programs have paved the road to establish an industry standard, as discussed earlier consumer pressure may not be sufficient to reach all local establishments.

VI. FEDERAL REGULATION OF TRANS FAT

A. THE ROAD TO TRANS FAT REGULATION: STATUTORY AUTHORITY AND LEGISLATIVE HISTORY

In 1990, the Congress passed the Nutrition Labeling and Education Act ("NLEA").²²⁷ The NLEA amended the FD & C Act to add, among other provisions, two subsections to section 403. The addition of 21 U.S.C. § 343(q) and (r) of the NLEA further strengthened and clarified the FDA's legal authority to require the nutritional labeling of foods. Twenty-one U.S.C. § 343(q) requires certain food components and nutrients to be included in nutrition labeling,²²⁸ whereas 21 U.S.C. § 343(r) regulates the proclamation of certain nutrition and health-related claims by food manufacturers.²²⁹

When the FDA finalized the NLEA amendments in 1993, the regulations required food manufacturers to declare total fat and saturated fat contents on the Nutrition Facts panel.²³⁰ However, the FDA did not require *trans* fat to be included in nutritional labeling. The agency

²²³ California Restaurant Ass'n Home Page, <http://www.calrest.com>.

²²⁴ Fielding, TRANS FAT REGULATION AND CALORIE LABELING ATTACHMENT, *supra* note 106, at 3.

²²⁵ Barboza, *supra* note 175.

²²⁶ Fielding, TRANS FAT REGULATION AND CALORIE LABELING ATTACHMENT, *supra* note 106, at 1–3 (In June 2005, the New York City Board of Health launched a year-long *trans* fat education campaign that called on all food service establishments in the city to voluntarily remove artificial *trans* fats from the foods they were serving. Unfortunately, despite an extensive educational outreach effort, follow-up surveys found no decrease in the use of *trans* fats among the city's food establishments.).

²²⁷ The Nutrition Labeling and Education Act of 1990, 21 USC § 343 (1990).

²²⁸ § 343(q).

²²⁹ § 343(r).

²³⁰ *Id.*

concluded that it was “premature” to require the declaration of *trans* fatty acids on the panel because the scientific evidence on the dietary implications of *trans* fat was still inconclusive at the time.²³¹

In 1994, CSPI filed a citizen petition with the FDA requesting that the agency modify its definition of saturated fats to include fatty acids and mandate the disclosure of *trans* fat information on nutrition labels.²³² CSPI amended its petition in July 1998, preserving the FDA’s definition of saturated fats, but maintaining its original request to provide information on *trans* fat content. In response to the 1998 CSPI petition, the FDA issued a proposed rule in the Federal Register on November 17, 1999. In the document, entitled “Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims,” the FDA proposed mandatory *trans* fat labeling.²³³

The 1999 proposal required food manufacturers to include the *trans* fat content of foods in the saturated fats amount on the nutrition label with a separate footnote indicating specific *trans* fat information. However, the footnote approach was received with a lot of criticism and was eventually abandoned. Four years later, the FDA implemented its current final rule on *trans* fat labeling.

B. THE FINAL RULE: CURRENT FDA *TRANS* FAT LABELING REQUIREMENTS

Relying on its statutory authority provided in 12 U.S.C. § 321(n), § 343(a)(1) and (q), and § 371(a) of the NLEA and new conclusive scientific evidence on the *trans* fat health risks, the FDA announced its final rule on *trans* fat labeling. This rule was the first significant change to the Nutrition Facts panel since implementing the final NLEA regulations in 1993.²³⁴

Published in the Federal Register²³⁵ on July 14, 2003 and later codified in 21 C.F.R. § 101.62,²³⁶ the final rule requires that all conventional foods

²³¹ *Trans Fatty Acids in Nutrition Labeling*, *supra* note 86, at 41434.

²³² The CSPI amended its petition on July 13, 1998. The original petition filed on February 14, 1994 requested that the FDA modify its definition of saturated fats to include fatty acids. The 1998 petition maintained the FDA’s original definition of saturated fats, but requested that *trans* fat information be disclosed in nutrition facts.

²³³ Press Release, U.S. Food & Drug Admin., FDA Proposes New Rules for *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims (Nov. 12, 1999), available at <http://www.fda.gov/bbs/topics/NEWS/NEW00698.html>.

²³⁴ FDA, Questions and Answers About *Trans* Fat, *supra* note 4. *Trans* Fatty Acids in Nutrition Labeling, *supra* note 86, at 41437; U.S. Food & Drug Admin., FDA Acts to Provide Better Information to Consumers on *Trans* Fats, <http://www.fda.gov/oc/initiatives/transfat>. Section 321(n) and § 343(a)(1) grant the FDA authority to require the adequate labeling of food with all truthful, non-misleading, and relevant material information. Section § 321(n) states:

Labeling of a food, drug, device, or cosmetic shall be deemed to be misleading if it fails to reveal facts that are: (1) Material in light of other representations made or suggested by statement, word, design, device or any combination thereof, or (2) Material with respect to consequences which may result from use of the article under: (i) The conditions prescribed in such labeling or (ii) such conditions of use as are customary or usual.

Section 343(q) provides the Secretary further statutory authority to add or delete nutrients included in the food label information if it is necessary “to assist consumers in maintaining healthy dietary practices.” Finally, section § 371(a) grants the FDA the necessary authority to ensure the efficient enforcement of the FD & C Act.

²³⁵ *Trans Fatty Acids in Nutrition Labeling*, *supra* note 86, at 41433–506.

and supplements disclose the amount of *trans* fatty acids on the Nutrition Facts panel, on a separate line, immediately under the declaration of saturated fats.²³⁷ The *Trans* fat amount is to be identified in increments of 0.5 grams when it is below five grams; but if the total *trans* fat content is less than 0.5 grams, it is considered to be *trans* fat-free and can be declared as having zero grams on its respective line.²³⁸ If the *trans* fat content is greater than five grams it is to be expressed in increments of one gram.²³⁹ The new label will not have a corresponding daily value for *trans* fat content.²⁴⁰ Even though scientific studies have produced very informative evidence on the health risks associated with *trans* fat, no study has recommended a daily intake value for *trans* fat.²⁴¹ Rather, recommendations regarding *trans* fat consumption suggest that consumption levels should be kept as low as possible.²⁴² As such, since the FDA did not have sufficient scientific evidence to establish a daily value, only the *trans* fat content would be listed on the panel.²⁴³

The FDA's primary motivation for *trans* fat regulation was to "provide consumers with information they need so that they may consider the amount of *trans* fat in products in their food purchasing decisions."²⁴⁴ The FDA believes that the increased awareness of "important health-related" information provided by the mandatory *trans* fat disclosure will reduce *trans* fat intake in the U.S. diet.²⁴⁵ Moreover, the agency predicts that the alteration of consumer purchasing practices will also provide an incentive for manufacturers to reduce their use of *trans* fat in food processing and production.²⁴⁶

Upon the announcement of the final rule, the FDA gave manufacturers two and a half years to phase-in the costs associated with the new label requirements.²⁴⁷ The final rule went into effect on January 1, 2006 and for the first time starting in 2006, consumers were able to determine material nutritional information and make conscious decisions regarding their daily intake of *trans* fat. While the food industry started to reformulate many of its products and offer more "*trans* fat-free" alternatives prior to 2006, for those foods that contained *trans* fat, consumers were left in the dark on exactly how much *trans* fat they were consuming.

Unlike before, the new Nutrition Fact panel now includes information on all three dietary causes of bad cholesterol, a major controllable risk

²³⁶ Nutrient Content Claims for Fat, Fatty Acid, and Cholesterol Content of Foods, 21 C.F.R. § 101.62 (1998).

²³⁷ FDA, Questions and Answers About *Trans* Fat, *supra* note 4.

²³⁸ 21 C.F.R. § 101.62(c)(1).

²³⁹ *Trans* Fatty Acids in Nutrition Labeling, *supra* note 86, at 41457.

²⁴⁰ FDA, Questions and Answers About *Trans* Fat, *supra* note 4.

²⁴¹ *Trans* Fatty Acids in Nutrition Labeling, *supra* note 86, at 41436. *See also* FDA, Questions and Answers About *Trans* Fat, *supra* note 4.

²⁴² *Trans* Fatty Acids in Nutrition Labeling, *supra* note 86, at 41436 (citing, *e.g.*, IOM, DIETARY REFERENCE INTAKES FOR ENERGY 2005, *supra* note 111). *See also* FDA, Questions and Answers About *Trans* Fat, *supra* note 4.

²⁴³ *See* FDA, Questions and Answers About *Trans* Fat, *supra* note 4.

²⁴⁴ *Trans* Fatty Acids in Nutrition Labeling, *supra* note 86, at 41467.

²⁴⁵ *Id.*

²⁴⁶ *Id.* at 41457.

²⁴⁷ *Id.* at 41466.

factor for CHD. Consumers now have comprehensive information on how much saturated fat, cholesterol, and *trans* fat are in their food. This will allow the public to weigh each bad cholesterol variable and make conscious heart-healthy decisions, such as substituting *trans* fats for saturated fats, and vice-versa, or eliminating their intake altogether.

The NLEA regulation will primarily impact foods produced by food manufacturers, but its reach does not extend to the entire food industry. Many products, most importantly fast food products and foods with less than 0.5 grams of *trans* fat, are exempt from the final rule and do not have to be labeled as containing the substance. The rule, nonetheless, will effectuate great social and economic benefits for Americans and is a significant step in the right direction. The FDA estimates that the increased awareness from *trans* fat labeling will prevent approximately 600 to 1200 heart attacks and save 250 to 500 lives per year.²⁴⁸ Based on this estimate, this rule would reduce the total cost of CVD by \$900 million to \$1.8 billion per year in medical costs, lost productivity, and pain and suffering.²⁴⁹ Thus, in comparison to the benefits of the current labeling rule, a federal FDA regulation that extends to all foods and uses of *trans* fat—including foods prepared by food establishments and those with less than 0.5 grams of *trans* fat—would be even more effective at reducing the prevalence and consequences of heart disease in the United States.

VII. A FEDERAL *TRANS* FAT BAN

A. THE FDA'S AUTHORITY TO REGULATE THE USE OF *TRANS* FAT

As the source of modern food law, the FD & C Act authorizes the FDA's current *trans* fat labeling requirements and determines the FDA's ability to implement a *trans* fat ban.

The FD & C Act appoints the FDA as the agency primarily responsible for ensuring that foods are "safe, wholesome and sanitary" and that they are properly labeled.²⁵⁰ While the FD & C Act mandates the agency's broad authority to implement federal food safety programs regarding most foods, some foods and food products are regulated under the exclusive control of other federal agencies.²⁵¹ Under 21 U.S.C. § 350c(d), the FDA's statutory authority under the FD & C Act does not extend to foods that are "within the exclusive jurisdiction of the Secretary of Agriculture pursuant to the Federal Meat Inspection Act (21 U.S.C. § 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. § 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. § 1031 et seq.)."²⁵² Thus, depending on the origin of a food

²⁴⁸ FDA, Questions and Answers About *Trans* Fat, *supra* note 4.

²⁴⁹ *Id.*

²⁵⁰ U.S. Food & Drug Admin., What the FDA Regulates, <http://www.fda.gov/comments/regs.html>.

²⁵¹ NASDA, STATE AND FEDERAL, *supra* note 176, at 2 ("The USDA and the FDA bear the major responsibility for food safety programs at the federal level. However, federal food safety responsibilities are shared by at least a dozen separate agencies whose authority is derived from over 35 separate statutes. These wide ranging, and sometimes overlapping, responsibilities represent an impressive array of functions. Responsibility has been separated by food product or by food contaminants.").

²⁵² 21 U.S.C. § 350c(d).

product, the FDA may or may not have the statutory authority to regulate foods derived from certain sources like meat, poultry, and eggs.

First and foremost, the FDA's mandate to regulate *trans* fats in the national food supply relies on the source of *trans* fat. The source of artificial *trans* fatty acids, PHVO, an ingredient that is either added to foods or used during food processing, falls within the FDA's scope of authority under the FD & C Act. Natural *trans* fatty acids, on the other hand, are products of ruminant animals, which are regulated by the United States Department of Agriculture ("USDA") and not by the FDA.²⁵³ Therefore, the FDA would only have the statutory authority to implement rules on artificial *trans* fat and any FDA regulation on *trans* fats would have to distinguish between the two types.²⁵⁴

The FDA's authority to regulate PHVO under the FD & C Act includes complete legal power to eliminate artificial *trans* fat in the preparation, manufacturing, and processing of food products. Falling within the meaning of "food additive" of the FD & C Act, PHVO is subject to the FDA's scrutiny.²⁵⁵ As defined in Section 321, a food additive is "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food. . . ."²⁵⁶ Essentially, "food additive" is a very broad, all-inclusive term that includes nearly all natural and artificial substances that come into contact with processed foods. Generally the term includes "any substance used in the production, processing, treatment, packaging, transportation or storage of food."²⁵⁷ *Trans* fat does not itself fall under this category; however, PHVO, the source of artificial *trans* fat in foods, does fall under the meaning of a food additive and gives the FDA control over the presence of artificial *trans* fats in the food supply.

There are two main types of food additives: direct and indirect.²⁵⁸ Direct food additives are substances that are used in the production, processing, or treatment of food, and generally include any substance that is deliberately added to the food. Indirect food additives, on the other hand, are substances that become a part of the food as a result of packaging, transportation, or storage. PHVO is considered a direct food additive because it is added to processed foods as an ingredient or deliberately added to the food to enhance its quality.

The FDA's regulation of PHVO, as with any other direct food additive, primarily depends on whether it was in use before the implementation of

²⁵³ 21 U.S.C. § 350c (excluding foods that are "within the exclusive jurisdiction of the Secretary of Agriculture pursuant to the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.)" from the FDA's authority under the FD & C Act); 21 U.S.C. § 601 (giving the USDA exclusive authority over meat and meat products).

²⁵⁴ NASDA, STATE AND FEDERAL, *supra* note 176, at 2. *See also* FDA, FOOD SAFETY, *supra* note 178.

²⁵⁵ 21 U.S.C. § 321(s).

²⁵⁶ *Id.*

²⁵⁷ U.S. Food & Drug Admin. & Int'l Food Info. Council, FDA/IFIC Brochure: Food Additives 3 (1992), available at <http://www.cfsan.fda.gov/~lrd/foodaddi.html> [hereinafter FDA/IFIC, Food Additives].

²⁵⁸ For a discussion on food additives, *see generally* FDA/IFIC, Food Additives, *supra* note 257.

the 1958 Food Additive Amendment to the FD & C Act.²⁵⁹ The Food Additives Amendment requires FDA approval of food additives prior to their use in foods, unless the substance is “generally regarded as safe” (“GRAS”) or “prior sanctioned.”²⁶⁰ All substances that fall under either of the two legal categories are exempt from the food additive regulation process required by the amendment. The GRAS category is limited to substances that are generally recognized by experts as safe, based on their “proven track record of safety based either on a history of use before 1958 or published scientific evidence.”²⁶¹ Otherwise, prior sanctioned food additives, which are additives that were determined safe for use in specific foods by the FDA or USDA, are the only other substances that are declared exempt from FDA approval. Today, the use of *trans* fat as a food additive is approved for human consumption as a GRAS substance and thereby exempt from the Food Additives Amendment requirements.²⁶²

So long as PHVO is GRAS, the food industry has the full capacity to produce and process foods containing artificial *trans* fat without significant legal limitations. As such, the promulgation of a FDA *trans* fat ban that is consistent with the food additive provision of the FD & C Act necessitates the removal of PHVO’s GRAS label. PHVO would then come within the definition of “food additives” as contained in 21 U.S.C. § 321(s), and would have to meet FDA’s food additive safety requirements.

Using the risk analysis standard, a substance can be removed from the GRAS list “if new data suggests that a substance [already in use]. . . may be unsafe; the FDA may take action to remove the substance from food products or require the manufacturer to conduct studies to evaluate the newly raised concern.”²⁶³ Given the wealth of undisputed scientific evidence on the harmful effects of PHVO on the heart,²⁶⁴ and the FDA’s own concession that PHVO consumption is positively correlated with heart disease,²⁶⁵ the FDA should at least place a temporary ban on its use until the FDA can positively determine an appropriate daily value for the substance.

In fact, when the FDA reviews petitions for the approval of new food additives, sponsors must “make an affirmative showing of its safety; if this showing falls short, there is no approval even if there is no affirmative

²⁵⁹ 21 U.S.C. § 321(s).

²⁶⁰ *Id.*

²⁶¹ U.S. Food & Drug Admin., *GRAS: Time-Tested, and Trusted, Food Ingredients*, FDA CONSUMER, Apr. 2004, available at http://www.fda.gov/food/ingredientsandfood/2004/204_gras.html. See also OFFICE OF FOOD ADDITIVE SAFETY, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: FREQUENTLY ASKED QUESTIONS ABOUT GRAS (2004), available at <http://www.cfsan.fda.gov/~dms/grasguid.html> (“FDA has several lists of GRAS substances. Importantly, these lists are not all-inclusive. Because the use of a GRAS substance is not subject to premarket review and approval by FDA, it is impracticable to list all substances that are used in food on the basis of the GRAS provision.”).

²⁶² PHVO was in use before the passage of the Food Additive Amendment, therefore it qualifies as a GRAS substance. See Press Release, CSPI, CSPI Withdraws from Lawsuit, *supra* note 190.

²⁶³ FDA/IFIC, Food Additives, *supra* note 257, at 5.

²⁶⁴ See discussion, *supra* Part II.D.

²⁶⁵ Trans Fatty Acids in Nutrition Labeling, *supra* note 86, at 41442.

showing of risk.”²⁶⁶ In this case, there is an affirmative showing of a risk such that PHVO would fail to meet FDA current approval standards. Even if evidence of the harmful effects of *trans* fat is not sufficient to ban the additive as “unsafe”, there are additional considerations that support the FDA’s regulation of the substance.

PHVO should be banned as a food additive because it would be consistent with the cost-benefit standards currently used by the FDA to regulate other food and food products.²⁶⁷ Generally, under the Regulatory Flexibility Act, the FDA must apply a cost-benefit standard that incorporates an economic assessment of its food regulations.²⁶⁸ In the case of *trans* fat, the billions of dollars in economic costs associated with heart disease are undeniably much greater than any economic benefits realized by the food industry from using PHVO instead of other available substitutes. Given that numerous food companies have undergone that change without much notice or adverse economic impact realized by consumers, removing *trans* fat is clearly within the FDA’s regulatory standard.

Moreover, there will not necessarily be any “food foregone” because consumers are unable to distinguish between food products prepared with or without *trans* fats. Even if one were to argue that consumers should still have the freedom to consume *trans* fats if they choose, such an argument does not hold any weight because studies have shown that customers have been unable to taste the difference in foods reformulated without PHVO.

Once PHVO is declared unsafe and removed from the GRAS list, the FDA can classify the use of PHVO as a “prohibited act” under the FD & C Act.²⁶⁹ Among the enumerated prohibited acts, 21 U.S.C. § 331 outlaws the adulteration of foods and the introduction or sale of adulterated foods in interstate commerce.²⁷⁰ PHVO and artificial *trans* fat would thereby be illegal because a food is deemed “adulterated” within the meaning of the act if, in addition to other circumstances, it contains an “unsafe” food additive.²⁷¹

VIII. CONCLUSION

Although health and diet are considered primarily a function of personal choice and individual responsibility, the heart disease problem is one that can, and should, be alleviated by governmental intervention through *trans* fat regulation. CHD is a largely preventable disease. As such, the regulation of PHVO would help contain the negative effects of the heart disease epidemic.

²⁶⁶ See U.S. FOOD & DRUG ADMIN. & U.S. DEP’T OF AGRIC., PRECAUTION IN THE U.S. FOOD SAFETY DECISIONMAKING: ANNEX II TO THE UNITED STATES’ NAT’L FOOD SAFETY SYS. PAPER (2002), available at <http://www.foodsafety.gov/~fsg/fssystem4.html>.

²⁶⁷ *Id.*

²⁶⁸ *Id.*

²⁶⁹ 21 U.S.C. § 331.

²⁷⁰ § 331.

²⁷¹ § 342.

Implementing a federal or state restriction on the use of PHVO or *trans* fats is consistent with legal standards and policies. In addition to overwhelming scientific evidence supporting the existence of a direct relationship between artificial *trans* fats or PHVO consumption and America's heart disease crisis, other economic and legal considerations strongly suggest that governmental regulation of artificial *trans* fats through legislation is an appropriate remedy for the nation's heart disease epidemic. Not only is the substance indisputably detrimental to the public's health such that regulation would be beneficial, but the recent trend away from the use of *trans* fat clearly indicates that artificial *trans* fats can be substituted with an economically feasible substitute. Thus, depending on the lasting impact of the current trend to phase out *trans* fat within the food industry and consumer preference for *trans* fat-free products, the government should consider regulating the use of *trans* fat through state, local, or federal government legislation if economic pressures are insufficient to constitute lasting changes in the use of artificial *trans* fat in the national food supply.