IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Center for Science in the Public Interest	)	
Plaintiff,	)	Civil Action No. 1:07-cv-01092 (RJL)
v.	)	
Burger King Corporation	)	Judge Richard J. Leon
Defendant.	)	

DECLARATION OF ERICH O. GROSZ

I, ERICH O. GROSZ, hereby declare as follows:

1. I am a member of the Bar of the State of New York and an attorney with Debevoise & Plimpton LLP, counsel for Burger King Corporation

2. I submit this declaration pursuant to 28 U.S.C. § 1746, in support of Burger King Corporation's Motion to Dismiss.

3. In support of this Motion, I attach the following exhibits:

No.	Exhibit
1.	A true and correct copy of Dietary Guidelines for Americans 2005, Ch. 6 published by the U.S. Department of Health and Human Services
2.	A true and correct copy of Guidelines: Aim for Fitness published by the U.S. Department of Health and Human Services

No.	Exhibit
3.	A true and correct copy of HHS Unveils FDA Strategy to Help Reduce Obesity (March 12, 2004) published by the U.S. Department of Health and Human Services
4.	A true and correct copy of Questions and Answers about Trans Fat Nutrition Labeling (updated January 1, 2006) published by the U.S. Food and Drug Administration
5.	A true and correct copy of FDA News: FDA Receives Keystone Forum Report on Away-From-Home Foods (June 2, 2006) published by the U.S. Food and Drug Administration
6.	A true and correct copy of Letter Report on Dietary Reference Intakes for Trans Fatty Acids (2002) published by the National Academy of Sciences / Institute of Medicine
7.	A true and correct copy of Summary Minutes of Nutrition Subcommittee, April 27 & 28, 2004 of the U.S. Food and Drug Administration, Nutrition Subcommittee of the Food Advisory Committee
8.	A true and correct copy of Petition for Rulemaking to Revoke the Authority for Industry to Use Partially Hydrogenated Vegetable Oils in Foods submitted to U.S. Food and Drug Administration on May 18, 2004 by the Center for Science in the Public Interest
9.	A true and correct copy of the Nutritional Information Poster available in Burger King Restaurants
10.	A true and correct copy of Nutritional Information posted on Burger King's Website, available at http://www.bk.com/Nutrition/PDFs/brochure.pdf
11.	A true and correct copy of the Burger King Press Release dated July 6, 2007, available at http://www.bk.com/companyinfo/content/news/detail.aspx?id=908

I declare under penalty of perjury that the foregoing is true and correct.

Dated: July 20, 2007
New York, New York

/s/ Erich O. Grosz
Erich O. Grosz

Declaration of Erich O. Grosz

Exhibit 1

Case No. 1:07-CV-01092 (RJL)

Dietary Guidelines for Americans 2005

USDA

Chapter 6 Fats

OVERVIEW

Fats and oils are part of a healthful diet, but the type of fat makes a difference to heart health, and the total amount of fat consumed is also important. High intake of saturated fats, *trans* fats, and cholesterol increases the risk of unhealthy blood lipid levels, which, in turn, may increase the risk of coronary heart disease. A high intake of fat (greater than 35 percent of calories) generally increases saturated fat intake and makes it more difficult to avoid consuming excess calories. A low intake of fats and oils (less than 20 percent of calories) increases the risk of inadequate intakes of vitamin E and of essential fatty acids and may contribute to unfavorable changes in high-density lipoprotein (HDL) blood cholesterol and triglycerides.

KEY RECOMMENDATIONS

- Consume less than 10 percent of calories from saturated fatty acids and less than 300 mg/day of cholesterol, and keep *trans* fatty acid consumption as low as possible.
- Keep total fat intake between 20 to 35 percent of calories, with most fats coming from sources of polyunsaturated and monounsaturated fatty acids, such as fish, nuts, and vegetable oils.
- When selecting and preparing meat, poultry, dry beans, and milk or milk products, make choices that are lean, low-fat, or fat-free.
- Limit intake of fats and oils high in saturated and/or *trans* fatty acids, and choose products low in such fats and oils.

Key Recommendations for Specific Population Groups

- *Children and adolescents.* Keep total fat intake between 30 to 35 percent of calories for children 2 to 3 years of age and between 25 to 35 percent of calories for children and adolescents 4 to 18 years of age, with most fats coming from sources of polyunsaturated and monounsaturated fatty acids, such as fish, nuts, and vegetable oils.

DISCUSSION

Fats supply energy and essential fatty acids and serve as a carrier for the absorption of the fat-soluble vitamins A, D, E, and K and carotenoids. Fats serve as building blocks of membranes and play a key regulatory role in numerous biological functions. Dietary fat is found in foods derived from both plants and animals. The recommended total fat intake is between 20 and 35 percent of calories for adults. A fat intake of 30 to 35 percent of calories is recommended for children 2 to 3 years of age and 25 to 35 percent of calories for children and adolescents 4 to 18 years of age. Few Americans consume less than 20 percent of

calories from fat. Fat intakes that exceed 35 percent of calories are associated with both total increased saturated fat and calorie intakes.

To decrease their risk of elevated low-density lipoprotein (LDL) cholesterol in the blood, most Americans need to decrease their intakes of saturated fat and *trans* fats, and many need to decrease their dietary intake of cholesterol. Because men tend to have higher intakes of dietary cholesterol, it is especially important for them to meet this recommendation. Population-based studies of American diets show that intake of saturated fat is more excessive than intake of *trans* fats and cholesterol. Therefore, it is most important for Americans to decrease their intake of saturated fat. However, intake of all three should be decreased to meet recommendations. Table 8 shows, for selected calorie levels, the maximum gram amounts of saturated fat to consume to keep saturated fat intake below 10 percent of total calorie intake. This table may be useful when combined with label-reading guidance. Table 9 gives a few practical examples of the differences in the saturated fat content of different forms of commonly consumed foods. Table 10 provides the major dietary sources of saturated fats in the U.S. diet listed in decreasing order. Diets can be planned to meet nutrient recommendations for linoleic acid and α-linolenic acid while providing very low amounts of saturated fatty acids.

Based on 1994-1996 data, the estimated average daily intake of *trans* fats in the United States was about 2.6 percent of total energy intake. Processed foods and oils provide approximately 80 percent of *trans* fats in the diet, compared to 20 percent that occur naturally in food from animal sources. Table 11 provides the major dietary sources of *trans* fats listed in decreasing order. *Trans* fat content of certain processed foods has changed and is likely to continue to change as the industry reformulates products. Because the *trans* fatty acids produced in the partial hydrogenation of vegetable oils account for more than 80 percent of total intake, the food industry has an important role in decreasing *trans* fatty acid content of the food supply. Limited consumption of foods made with processed sources of *trans* fats provides the most effective means of reducing intake of *trans* fats. By looking at the food label, consumers can select products that are lowest in saturated fat, *trans* fats,[13] and cholesterol.

To meet the total fat recommendation of 20 to 35 percent of calories, most dietary fats should come from sources of polyunsaturated and monounsaturated fatty acids. Sources of omega-6 polyunsaturated fatty acids are liquid vegetable oils, including soybean oil, corn oil, and safflower oil. Plant sources of omega-3 polyunsaturated fatty acids (α-linolenic acid) include soybean oil, canola oil, walnuts, and flaxseed. Eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) are omega-3 fatty acids that are contained in fish and shellfish. Fish that naturally contain more oil (e.g., salmon, trout, herring) are higher in EPA and DHA than are lean fish (e.g., cod, haddock, catfish). Limited evidence suggests an association between consumption of fatty acids in fish and reduced risks of mortality from cardiovascular disease for the general population. Other sources of EPA and DHA may provide similar benefits; however, more research is needed. Plant sources that are rich in monounsaturated fatty acids include vegetable oils (e.g., canola, olive, high oleic safflower, and sunflower oils) that are liquid at room temperature and nuts.

Considerations for Specific Population Groups

Evidence suggests that consuming approximately two servings of fish per week (approximately 8 ounces total) may reduce the risk of mortality from coronary heart disease

and that consuming EPA and DHA may reduce the risk of mortality from cardiovascular disease in people who have already experienced a cardiac event.

Federal and State advisories provide current information about lowering exposure to environmental contaminants in fish. For example, methylmercury is a heavy metal toxin found in varying levels in nearly all fish and shellfish. For most people, the risk from mercury by eating fish and shellfish is not a health concern. However, some fish contain higher levels of mercury that may harm an unborn baby or young child's developing nervous system. The risks from mercury in fish and shellfish depend on the amount of fish eaten and the levels of mercury in the fish. Therefore, the Food and Drug Administration (FDA) and the Environmental Protection Agency are advising women of childbearing age who may become pregnant, pregnant women, nursing mothers, and young children to avoid some types of fish and shellfish and eat fish and shellfish that are lower in mercury. For more information, call FDA's food information line toll-free at 1-888-SAFEFOOD or visit http://www.cfsan.fda.gov/~dms/admehg3.html.

Lower intakes (less than 7 percent of calories from saturated fat and less than 200 mg/day of cholesterol) are recommended as part of a therapeutic diet for adults with elevated LDL blood cholesterol (i.e., above their LDL blood cholesterol goal [see table 12]). People with an elevated LDL blood cholesterol level should be under the care of a healthcare provider.

TABLE 8. Maximum Daily Amounts of Saturated Fat To Keep Saturated Fat Below 10 Percent of Total Calorie Intake

The maximum gram amounts of saturated fat that can be consumed to keep saturated fat intake below 10 percent of total calorie intake for selected calorie levels. A 2,000-calorie example is included for consistency with the food label. This table may be useful when combined with label-reading guidance.

Total Calorie Intake	Limit on Saturated Fat Intake
1,600	18 g or less
2,000[a]	20 g or less
2,200	24 g or less
2,500[a]	25 g or less
2,800	31 g or less

[a] Percent Daily Values on the Nutrition Facts Panel of food labels are based on a 2,000-calorie diet. Values for 2,000 and 2,500 calories are rounded to the nearest 5 grams to be consistent with the Nutrition Facts Panel.

TABLE 9. Differences in Saturated Fat and Calorie Content of Commonly Consumed Foods

This table shows a few practical examples of the differences in the saturated fat content of different forms of commonly consumed foods. Comparisons are made between foods in the same food group (e.g., regular cheddar cheese and low-fat cheddar cheese), illustrating that lower saturated fat choices can be made within the same food group.

Note: Table updated to reflect 2005 DASH Eating Plan.

Food Category	Portion	Saturated Fat Content (grams)	Calories
Cheese			
• Regular cheddar cheese	1 oz	6.0	114
• Low-fat cheddar cheese	1 oz	1.2	49
Ground beef			
• Regular ground beef (25% fat)	3 oz (cooked)	6.1	236
• Extra lean ground beef (5% fat)	3 oz (cooked)	2.6	148
Milk			
• Whole milk (3.25%)	1 cup	4.6	146
• Low-fat (1%) milk	1 cup	1.5	102
Breads			
• Croissant (med)	1 medium	6.6	231
• Bagel, oat bran (4")	1 medium	0.2	227
Frozen desserts			
• Regular ice cream	1/2 cup	4.9	145
• Frozen yogurt, low-fat	1/2 cup	2.0	110
Table spreads			
• Butter	1 tsp	2.4	34
• Soft margarine with zero *trans* fats	1 tsp	0.7	25
Chicken			
• Fried chicken (leg with skin)	3 oz (cooked)	3.3	212
• Roasted chicken (breast no skin)	3 oz (cooked)	0.9	140
Fish			
• Fried fish	3 oz	2.8	195
• Baked fish	3 oz	1.5	129

Source: ARS Nutrient Database for Standard Reference, Release 17.

TABLE 10. Contribution of Various Foods to Saturated Fat Intake in the American Diet (Mean Intake = 25.5 g)

The major dietary sources of saturated fats in the U.S. diet listed in decreasing order.

Food Group	Contribution (percent of total sat fat consumed)
Cheese	13.1
Beef	11.7
Milk[a]	7.8
Oils	4.9
Ice cream/sherbet/frozen yogurt	4.7

Cakes/cookies/quick breads/doughnuts	4.7
Butter	4.6
Other fats [b]	4.4
Salad dressings/mayonnaise	3.7
Poultry	3.6
Margarine	3.2
Sausage	3.1
Potato chips/corn chips/popcorn	2.9
Yeast bread	2.6
Eggs	2.3

[a] The milk category includes all milk, including whole milk, low-fat milk, and fat-free milk.
[b] Shortening and animal fats

Source: Adapted from Cotton PA, Subar AF, Friday JE, Cook A, Dietary Sources of Nutrients among U.S. Adults, 1994-1996. *JADA* 104:921-931, 2004.

TABLE 11. Contribution of Various Foods to *Trans* Fat Intake in the American Diet (Mean Intake = 5.84 g)

The major dietary sources of *trans* fats listed in decreasing order. Processed foods and oils provide approximately 80 percent of *trans* fats in the diet, compared to 20 percent that occur naturally in food from animal sources. *Trans* fats content of certain processed foods has changed and is likely to continue to change as the industry reformulates products.

Food Group	**Contribution (percent of total *trans* fats consumed)**
Cakes, cookies, crackers, pies, bread, etc.	40
Animal products	21
Margarine	17
Fried potatoes	8
Potato chips, corn chips, popcorn	5
Household shortening	4
Other [a]	5

[a] Includes breakfast cereal and candy. USDA analysis reported 0 grams of *trans* fats in salad dressing.

Source: Adapted from *Federal Register* notice. *Food Labeling; Trans Fatty Acids in Nutrition Labeling; Consumer Research To Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements; Final Rule and Proposed Rule.* Vol. 68, No. 133, p. 41433-41506, July 11, 2003. Data collected 1994-1996.

TABLE 12. Relationship Between LDL Blood Cholesterol Goal and the Level of Coronary Heart Disease Risk

Information for adults with elevated LDL blood cholesterol. LDL blood cholesterol goals for these individuals are related to the level of coronary heart disease risk. People with an elevated LDL blood cholesterol value should make therapeutic lifestyle changes (diet, physical activity, weight control) under the care of a healthcare provider to lower LDL blood cholesterol.

If Someone Has:	LDL Blood Cholesterol Goal Is:
CHD or CHD risk equivalent [a]	Less than 100 mg/dL
Two or more risk factors other than elevated LDL blood cholesterol [b]	Less than 130 mg/dL
Zero or one risk factor other than elevated LDL blood cholesterol [b]	Less than 160 mg/dL

[a] CHD (coronary heart disease) risk equivalent = presence of clinical atherosclerotic disease that confers high risk for CHD events:

- Clinical CHD
- Symptomatic carotid artery disease
- Peripheral arterial disease
- Abdominal aortic aneurysm
- Diabetes
- Two or more risk factors with >20% risk for CHD (or myocardial infarction or CHD death) within 10 years

[b] Major risk factors that affect your LDL goal:

- Cigarette smoking
- High blood pressure (140/90 mmHg or higher or on blood pressure medication)
- Low HDL blood cholesterol (less than 40 mg/dL)
- Family history of early heart disease (heart disease in father or brother before age 55; heart disease in mother or sister before age 65)
- Age (men 45 years or older; women 55 years or older)

Source: NIH Publication No. 01-3290, U.S. Department of Health and Human Services, National Institutes of Health, National Heart, Lung, and Blood Institute, National Cholesterol Education Program Brochure, High Blood Cholesterol What You Need to Know, May 2001.
www.nhlbi.nih.gov/health/public/heart/chol/hbc_what.htm.

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[13] Including the amount of *trans* fats on the Nutrition Facts Panel is voluntary until January 2006.

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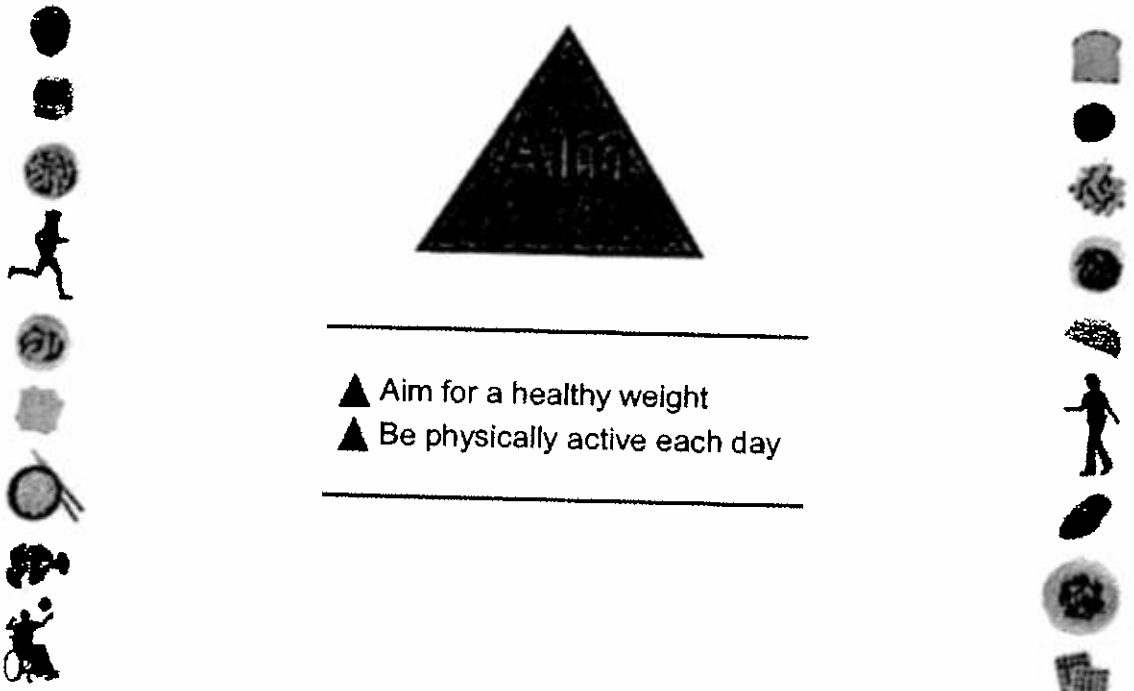
Updated Tuesday, June 13, 2006 by ODPHP Web Support

Declaration of Erich O. Grosz

Exhibit 2

Case No. 1:07-CV-01092 (RJL)



- Aim for a healthy weight
- Be physically active each day

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Aim for a healthy weight

Choose a lifestyle that combines sensible eating with regular physical activity. To be at their best, adults need to avoid gaining weight, and many need to lose weight. Being overweight or obese increases your risk for high blood pressure, high blood cholesterol, heart disease, stroke, diabetes, certain types of cancer, arthritis, and breathing problems. A healthy weight is key to a long, healthy life.

Evaluate your body weight

For adults and children, different methods are used to find out if weight is about right for height. If you have concerns about your child's body size, talk with your health care provider. Also see the section *Encourage healthy weight in children.*

If you are an adult, follow the directions in box 1 to evaluate your weight in relation to your height, or Body Mass Index (BMI). Not all adults who have a BMI in the range labeled "healthy" are at their most healthy weight. For example, some may have lots of fat and little muscle. A BMI above the healthy range is less healthy for most people; but it may be fine if you have lots of muscle and little fat. The further your BMI is above the healthy range, the higher your weight-related risk (see figure 1). If your BMI is above the healthy range, you may benefit from weight loss, especially if you have other health risk factors (see box 2).

BMI's slightly below the healthy range may still be healthy unless they result from illness. If your BMI is below the healthy range, you may have increased risk of menstrual irregularity, infertility, and osteoporosis. If you lose weight suddenly or for unknown reasons, see a health care provider. Unexplained weight loss may be an early clue to a health problem.

Keep track of your weight and your waist measurement, and take action if either of them increases. If your BMI is greater than 25, or even if it is in the "healthy" range, at least try to avoid further weight gain. If your waist measurement increases, you are probably gaining fat. If so, take steps to eat fewer calories and become more active.

Box 1

HOW TO EVALUATE YOUR WEIGHT (ADULTS)

1. Weigh yourself and have your height measured.

   Find your BMI category in figure 1. The higher your BMI category, the greater the risk for health problems.

2. Measure around your waist, just above your hip bones, while standing. Health risks increase as waist measurement increases, particularly if waist is greater than 35 inches for women or 40 inches for men. Excess abdominal fat may place you at greater risk of health problems, even if your BMI is about right.

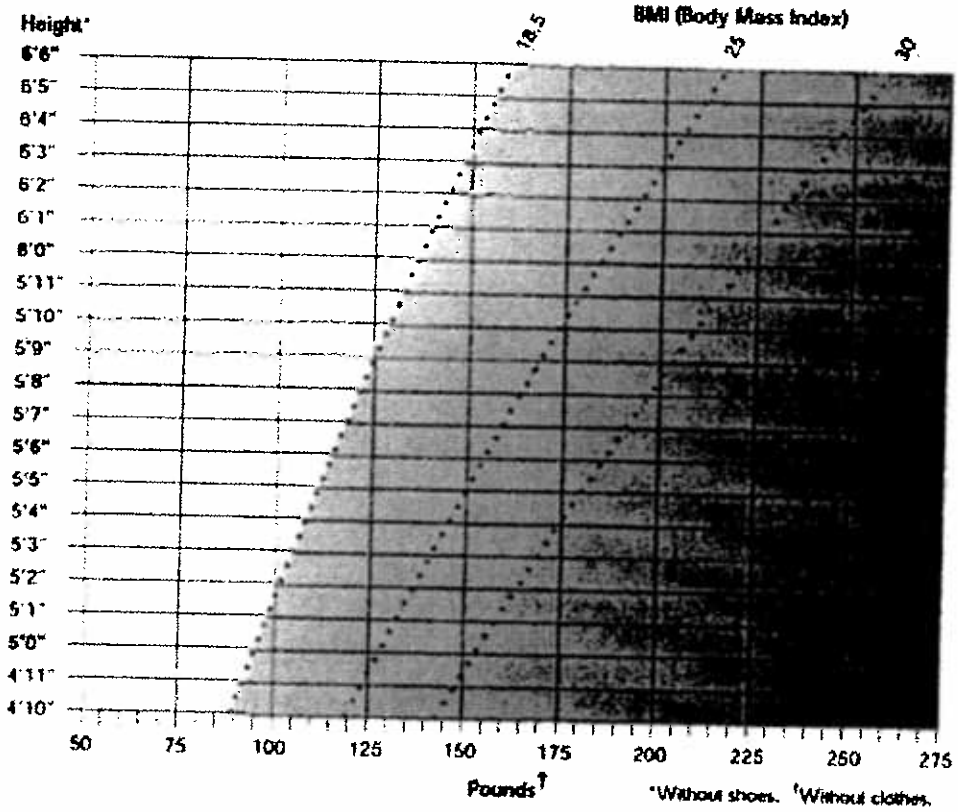
3. Use box 2 to find out how many other risk factors you have.

The higher your BMI and waist measurement, and the more risk factors you have from box 2, the more you are likely to benefit from weight loss.

NOTE: Weight loss is usually not advisable for pregnant women.

Figure 1

ARE YOU AT A HEALTHY WEIGHT?



BMI measures weight in relation to height. The BMI ranges shown above are for adults. They are not exact ranges of healthy and unhealthy weights. However, they show that health risk increases at higher levels of overweight and obesity. Even within the healthy BMI range, weight gains can carry health risks for adults.

Directions: Find your weight on the bottom of the graph. Go straight up from that point until you come to the line that matches your height. Then look to find your weight group.

Healthy Weight BMI from 18.5 up to 25 refers to a healthy weight.

Overweight BMI from 25 up to 30 refers to overweight.

Obese BMI 30 or higher refers to obesity. Obese persons are also overweight.

Source: *Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans*, 2000, page 3.

Box 2

FIND OUT YOUR OTHER RISK FACTORS FOR CHRONIC DISEASE

The more of these risk factors you have, the more you are likely to benefit from weight loss if you are overweight or obese.

- Do you have a personal or family history of heart disease?
- Are you a male older than 45 years or a postmenopausal female?
- Do you smoke cigarettes?
- Do you have a sedentary lifestyle?
- Has your doctor told you that you have
  - high blood pressure?
  - abnormal blood lipids (high LDL cholesterol, low HDL cholesterol, high triglycerides)?
  - diabetes?

Manage your weight

Our genes affect our tendency to gain weight. A tendency to gain weight is increased when food is plentiful and when we use equipment and vehicles to save time and energy. However, it is possible to manage your weight through balancing the calories you eat with your physical activity choices.

To make It easier to manage your weight, make long-term changes in your eating behavior and physical activity. To do this, build a healthy base and make sensible choices. Choose a healthful assortment of foods that includes vegetables, fruits, grains (especially whole grains), skim milk, and fish, lean meat, poultry, or beans. Choose foods that are low in fat and added sugars most of the time (see section *Choose Sensibly*). Whatever the food, eat a sensible portion size (see box 3).

Try to be more active throughout the day. The physical activity guideline (see section *Be Physically Active Each Day*) recommends that all adults get at least 30 minutes of moderate physical activity most or preferably all days of the week. To maintain a healthy weight after weight loss, adults will likely need to do more than 30 minutes of moderate physical activity daily. Over time, even a small decrease in calories eaten and a small increase in physical activity can keep you from gaining weight or help you lose weight.

Box 3

CHOOSE SENSIBLE PORTION SIZES

Control portion size. See guideline "Let the Pyramid guide your food choices" for sensible sizes and numbers of servings.

- If you're eating out, choose small portion sizes, share an entree with a friend, or take part of the food home (if you can chill it right away).
- Check product labels to learn how much food is considered to be a serving, and how many calories, grams of fat, and so forth are in the food. Many items sold as single portions actually provide 2 servings or more. Examples include a 20-ounce container of soft drink, a 12-ounce steak, a 3-ounce bag of chips, and a large bagel.
- Be especially careful to limit portion size of foods high in calories, such as cookies, cakes, other sweets, French fries, and fats, oils, and spreads.

The carbohydrates, fats, and proteins in food supply energy, which is measured in calories. High-fat foods contain more calories than the same amount of other foods, so they can make it difficult for you to avoid excess calories. However, *low fat* doesn't always mean low calorie. Sometimes extra sugars are added to low-fat muffins or desserts, for example, and they may be just as high in calories.

Your pattern of eating may be important. Snacks and meals eaten away from home provide a large part of daily calories for many people. Choose them wisely. Try fruits, vegetables, whole grain foods, or a cup of low-fat milk or yogurt for a snack. When eating out, choose small portions of foods. If you choose fish, poultry, or lean meat, ask that it be grilled rather than fried.

Like younger adults, overweight and obese older adults may improve their health by losing weight. The guidance of a health care provider is recommended, especially for obese children and older adults. Since older people tend to lose muscle mass, regular physical activity is a valuable part of a weight-loss plan. Building or maintaining muscle helps keep older adults active and reduces their risk of falls and fractures. Staying active throughout your adult years helps maintain muscle mass and bone strength for your later years.

If you need to lose weight, do so gradually

If you are overweight, loss of 5 to 15 percent of your body weight may improve your health, ability to function, and quality of life. Aim to lose about 10 percent of your weight over about 6 months. This would be 20 pounds of weight loss for someone who weighs 200 pounds. Loss of 1/2 to 2 pounds per week is usually safe. Even if

you have regained weight in the past, it's worthwhile to try again.

Encourage healthy weight in children

Children need enough food for proper growth, but too many calories and too little physical activity lead to overweight. The number of overweight U.S. children has risen dramatically in recent years. Encourage healthy weight by offering children grain products; vegetables and fruits; low-fat dairy products; and beans, lean meat, poultry, fish, or nuts—and let them see you enjoy eating the same foods. Let the child decide how much of these foods to eat. Offer only small amounts of food high in fat or added sugars. Encourage children to take part in vigorous activities (and join them whenever possible). Limit the time they spend in sedentary activities like watching television or playing computer or video games.

Help children to develop healthy eating habits. Make small changes. For example, serve low-fat milk rather than whole milk and offer one cookie instead of two. Since children still need to grow, weight loss is not recommended unless guided by a health care provider.

Serious eating disorders

Frequent binge eating, with or without periods of food restriction, may be a sign of a serious eating disorder. Other signs of eating disorders include preoccupation with body weight or food (or both—regardless of body weight), dramatic weight loss, excessive exercise, self-induced vomiting, and the abuse of laxatives. Seek help from a health care provider if any of these apply to you, a family member, or a friend.

ADVICE FOR TODAY

- Aim for a healthy weight. If you are at a healthy weight, aim to avoid weight gain. If you are already overweight, first aim to prevent further weight gain, and then lose weight to improve your health.
- Build a healthy base by eating vegetables, fruits, and grains (especially whole grains) with little added fat or sugar.
- Select sensible portion sizes.
- Get moving. Get regular physical activity to balance calories from the foods you eat.
- Set a good example for children by practicing healthy eating habits and enjoying regular physical activities together.

- Keep in mind that even though heredity and the environment are important influences, your behaviors help determine your body weight.

Be physically active each day

Being physically active and maintaining a healthy weight are both needed for good health, but they benefit health in different ways. Children, teens, adults, and the elderly—all can improve their health and well-being and have fun by including moderate amounts of physical activity in their daily lives. Physical activity involves moving the body. A moderate physical activity is any activity that requires about as much energy as walking 2 miles in 30 minutes.

Aim to accumulate at least 30 minutes (adults) or 60 minutes (children) of moderate physical activity most days of the week, preferably daily. If you already get 30 minutes of physical activity daily, you can gain even more health benefits by increasing the amount of time that you are physically active or by taking part in more vigorous activities. No matter what activity you choose, you can do it all at once, or spread it out over two or three times during the day.

Make physical activity a regular part of your routine

Choose activities that you enjoy and that you can do regularly (see box 4). Some people prefer activities that fit into their daily routine, like gardening or taking extra trips up and down stairs. Others prefer a regular exercise program, such as a physical activity program at their worksite. Some do both. The important thing is to be physically active every day.

Most adults do not need to see their health care provider before starting to become more physically active. However, if you are planning to start a vigorous activity plan and have one or more of the conditions below, consult your health care provider:

- Chronic health problem such as heart disease, hypertension, diabetes, osteoporosis, or obesity.
- High risk for heart disease (see box 2).
- Over age 40 for men or 50 for women.

Health benefits of physical activity

Compared with being very sedentary, being physically active for at least 30 minutes on most days of the week reduces the risk of developing or dying of heart disease. It has other health benefits as well (see box 5). No one is too young or too old to enjoy the benefits of regular physical activity.

Two types of physical activity are especially beneficial:

- *Aerobic activities.* These are activities that speed your heart rate and breathing. They help cardiovascular fitness.

- *Activities for strength and flexibility.* Developing strength may help build and maintain your bones. Carrying groceries and lifting weights are two strength-building activities. Gentle stretching, dancing, or yoga can increase flexibility.

To get these health benefits, adults need moderate physical activity for a total of at least 30 minutes most days of the week, preferably daily, and children need at least 60 minutes per day.

Box 4

EXAMPLES OF PHYSICAL ACTIVITIES FOR ADULTS

For at least 30 minutes most days of the week, preferably daily, do any one of the activities listed below—or combine activities. Look for additional opportunities among other activities that you enjoy.

As part of your routine activities:

- Walk, wheel, or bike ride more, drive less.
- Walk up stairs instead of taking an elevator.
- Get off the bus a few stops early and walk or wheel the remaining distance.
- Mow the lawn with a push mower.
- Rake leaves.
- Garden.
- Push a stroller.
- Clean the house.
- Do exercises or pedal a stationary bike while watching television.
- Play actively with children.
- Take a brisk 10-minute walk or wheel in the morning, at lunch, and after dinner.

As part of your exercise or recreational routine:

- Walk, wheel, or jog.
- Bicycle or use an arm pedal bicycle.
- Swim or do water aerobics.
- Play racket or wheelchair sports.
- Golf (pull cart or carry clubs).
- Canoe.
- Cross-country ski.
- Play basketball.
- Dance.
- Take part in an exercise program at work, home, school, or gym.

Box 5

HEALTH BENEFITS OF REGULAR PHYSICAL ACTIVITY

- Increases physical fitness.
- Helps build and maintain healthy bones, muscles, and joints.
- Builds endurance and muscular strength.
- Helps manage weight.
- Lowers risk factors for cardiovascular disease, colon cancer, and type 2 diabetes.
- Helps control blood pressure.
- Promotes psychological well-being and self-esteem.
- Reduces feelings of depression and anxiety.

Physical activity and nutrition

Physical activity and nutrition work together for better health. For example, physical

activity increases the amount of calories you use. For those who have intentionally lost weight, being active makes it easier to maintain the weight loss. However, 30 minutes of activity daily may not be enough to lose weight or maintain weight loss. Read the preceding guideline "Aim for a Healthy Weight," for more information about weight management.

Physical activity and nutrition work together in more ways than weight management. Increasing the calories you use allows you to eat more, which makes it easier to get the nutrients you need. Physical activity and nutrition work together for bone health, too. Calcium and other nutrients are needed to build and maintain strong bones, but physical activity is needed as well.

Help children be physically active

Children and adolescents benefit from physical activity in many ways. They need at least 60 minutes of physical activity daily (see box 6). Parents can help:

- Set a good example. For example, arrange active family events in which everyone takes part. Join your children in physical activities.
- Encourage your children to be physically active at home, at school, and with friends by jumping rope, playing tag, riding a bike.
- Limit television watching, computer games, and other inactive forms of play by alternating with periods of physical activity.

Box 6

PHYSICAL ACTIVITIES FOR CHILDREN AND TEENS

Aim for at least 60 minutes total per day:

- Be spontaneously active.
- Play tag.
- Jump rope.
- Ride a bicycle or tricycle.
- Walk, wheel, skip, or run.
- Play actively during school recess.
- Roller skate or in-line skate.

- Take part in physical education activity classes during school.
- Join after-school or community physical activity programs.
- Dance.

Older people need to be physically active too

Older persons also need to be physically active. Engage in moderate physical activity for at least 30 minutes most days of the week, preferably daily, and taking part in activities to strengthen muscles and to improve flexibility. Staying strong and flexible can reduce your risk of falling and breaking bones, preserve muscle, and improve your ability to live independently. Lifting small weights and carrying groceries are two ways to include strength building into your routine.

ADVICE FOR TODAY

▲ Engage in at least 30 minutes (adults) or 60 minutes (children) of moderate physical activity most, preferably all, days of the week.

▲ Become physically active if you are inactive.

▲ Maintain or increase physical activity if you are already active.

▲ Stay active throughout your life.

▲ Help children get at least 60 minutes of physical activity daily.

▲ Choose physical activities that fit in with your daily routine, or choose recreational or structured exercise programs, or both.

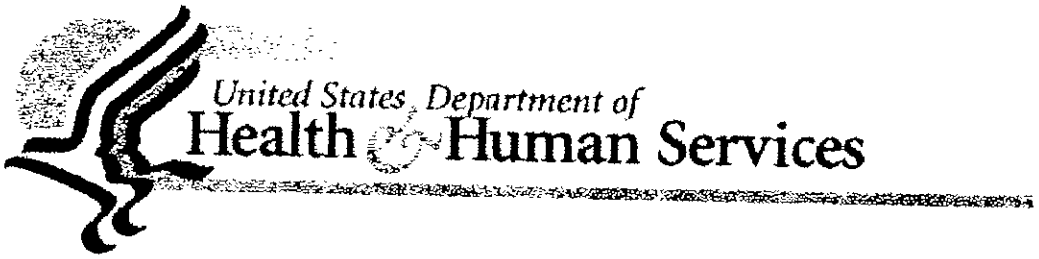
▲ Consult your health care provider before starting a new vigorous physical activity plan if you have a chronic health problem, or if you are over 40 (men) or 50 (women).

Return to Table of Contents

Declaration of Erich O. Grosz

Exhibit 3

Case No. 1:07-CV-01092 (RJL)



Press Release

FOR IMMEDIATE RELEASE
Friday, March 12, 2004

FDA Press Office
301-827-6242

HHS UNVEILS FDA STRATEGY TO HELP REDUCE OBESITY
New "Calories Count" Approach Builds on HHS' Education, Research Efforts

HHS Secretary Tommy G. Thompson today released a new Food and Drug Administration (FDA) report outlining another element in HHS' comprehensive strategy for combating the epidemic of obesity that threatens the health of millions of Americans with a focus on the message, "calories count."

The report by FDA's Obesity Working Group includes recommendations to strengthen food labeling, to educate consumers about maintaining a healthy diet and weight and to encourage restaurants to provide calorie and nutrition information. It also recommends increasing enforcement to ensure food labels accurately portray serving size, revising and reissuing guidance on developing obesity drugs and strengthening coordinated scientific research to reduce obesity and to develop foods that are healthier and low in calories.

"Counting calories is critical for people trying to achieve and maintain a healthy weight," Secretary Thompson said. "This new report highlights FDA's overall strategy for getting consumers accurate, helpful information that allows them to make wise food choices at home, at supermarkets and in restaurants. Taking small steps to eat a more balanced diet and to stay physically active can go a long way to reversing the epidemic of obesity that harms far too many Americans."

The FDA report comes on the heels of a new study from HHS' Centers for Disease Control and Prevention (CDC) that shows poor diet and inactivity are poised to become the leading preventable cause of death among Americans -- causing an estimated 400,000 deaths in 2000. CDC estimates that 64 percent of all Americans are overweight, including more than 30 percent who are considered obese. About 15 percent of children and adolescents, aged 6 to 19, are overweight -- almost double the rate of two decades ago.

Secretary Thompson on Tuesday unveiled a new national education campaign to encourage Americans to take small steps to fight obesity and a new obesity research strategy at the National Institutes of Health. Today's report builds on those initiatives by highlighting actions that FDA, which regulates many foods and their labels, can take to enable consumers to make smart choices about their diet and maintain a healthy weight.

"Our report concludes that there is no substitute for the simple formula that 'calories in must equal calories out' in order to control weight," said FDA Deputy Commissioner Lester M. Crawford, D.V.M., Ph.D. "We're going back to basics, designing a comprehensive effort to

attack obesity through an aggressive, science-based, consumer-friendly program with the simple message that 'Calories Count.'"

The report's recommendations include:

- Evaluating how the "Nutrition Facts" panel on food labels can be revised to highlight the critical role calories play in consumers' diets -- such as increasing type size and adding a column to list quantitative amounts of calories as a Percent Daily Value for the entire package. The report recommends FDA issue an advance notice of proposed rulemaking to gain public input on approaches to effectively revise food labels.
- Considering the authorization of health claims on certain foods that meet FDA's definition of "reduced" or "low" calorie. An example of such a health claim might be: "Diets low in calories may reduce the risk of obesity, which is associated with type 2 diabetes, heart disease, and certain cancers." The report recommends an advance notice of proposed rulemaking to obtain public input on the approach.
- Encouraging manufacturers to use dietary guidance statements, such as, "To manage your weight, balance the calories you eat with your physical activity; have a carrot, not the carrot cake; or have cherry yogurt, not cherry pie."
- Defining such terms as "low," "reduced," or "free" carbohydrates, as well as providing guidance for the use of the term "net" in relation to carbohydrate content of food, in light of increasing consumer interest in low carbohydrate diets and in response to petitions asking FDA to define these terms.
- Focusing FDA's consumer education strategy on influencing behavior and promoting healthy eating choices with the basic message that "Calories Count." FDA will work with private and public sector partners, including youth-oriented organizations, to give consumers a better understanding of the food label and how to use it to make healthier food choices.
- Encouraging the restaurant industry to launch a national, voluntary effort to include nutritional information for consumers at the point of sale. Such information would help consumers make healthier and lower-calorie choices outside the home, where Americans now spend nearly half their total food budget. The report recommends that FDA seek restaurants to participate in a pilot program to study effective options for simple, voluntary, standardized nutritional information at the point of sale in restaurants.
- Increasing FDA's focus on enforcing accurate serving size declarations on food labels and advising manufacturers when the agency identifies apparent errors in declared serving sizes. FDA is issuing a letter to encourage the food industry to review its nutrition information and ensure that the serving size declared is appropriate for the food product in question.
- Revising and reissuing FDA's 1996 draft Guidance for the Clinical Evaluation of Weight-Control Drugs. This action item reflects the fact that some obese and extremely obese individuals are likely to need medical intervention to reduce weight and mitigate associated diseases and other adverse health effects. FDA would issue this revised guidance for public comment.
- Strengthening the coordination of research into obesity and the development of foods that are healthier and lower in calories with other HHS agencies, the U.S. Department of Agriculture, and other public and private sector partners. Specific target areas include research related to information to facilitate consumers' weight management decisions; the relationship between overweight and obesity and food consumption patterns; incentives for product reformulation; the potential for FDA-regulated products to contribute unintentionally to weight gain; and the extension of basic research findings to the regulatory environment.

The full report from the FDA's obesity working group is available at http://www.fda.gov/oc/initiatives/obesity/. More information about HHS' new anti-obesity campaign and NIH's obesity research agenda is available at http://www.hhs.gov/news/press/2004pres/20040309.html .

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Additional Information

Declaration of Erich O. Grosz

Exhibit 4

Case No. 1:07-CV-01092 (RJL)

CFSAN Office of Nutritional Products, Labeling and Dietary Supplements
July 9, 2003; Updated March 3, 2004, June 25, 2004, August 1, 2005, September 6, 2005, and January 1, 2006

Questions and Answers about *Trans* Fat Nutrition Labeling

Disclaimer

Section 1 - Fat, Trans Fatty Acid (Trans Fat), and Cholesterol

Section 2 - Foods that Contain Trans Fat, Saturated Fat, and Cholesterol

Section 3 - FDA's Regulation on Trans Fat Labeling

Section 1 - Fat, Trans Fatty Acid (Trans Fat), and Cholesterol

Q: What are fats and fatty acids?

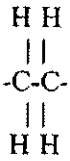
A: Fats are a group of chemical compounds that contain fatty acids. Energy is stored in the body mostly in the form of fat. Fat is also needed in the diet to supply essential fatty acids that are substances essential for growth but not produced by the body itself. The terms fat and fatty acids are frequently used interchangeably.

Q: What are the main types of fatty acids?

A: There are three main types of fatty acids: saturated, monounsaturated and polyunsaturated. All fatty acids are chains of carbon atoms with hydrogen atoms attached to the carbon atoms. A saturated fatty acid has the maximum possible number of hydrogen atoms attached to every carbon atom. It is therefore said to be "saturated" with hydrogen atoms, and all of the carbons are attached to each other with single bonds.

In some fatty acids, a pair of hydrogen atoms in the middle of a chain is missing, creating a gap that leaves two carbon atoms connected by a double bond rather than a single bond. Because the chain has fewer hydrogen atoms, it is said to be "unsaturated." A fatty acid with one double bond is called "monounsaturated" because it has one gap. Fatty acids having more than one gap are called "polyunsaturated."

The fat in foods contains a mixture of saturated, monounsaturated and polyunsaturated fatty acids. In foods of animal origin, a large proportion of fatty acids are saturated. In contrast, in foods of plant origin and some seafood, a large proportion of the fatty acids are monounsaturated and polyunsaturated. The structure of saturated and unsaturated chemical bonds looks like the diagram below.

Saturated Fat (i.e., saturated fatty acid)	**Unsaturated Fat (i.e., unsaturated fatty acid)**
	
Carbon-Carbon Single Bond	**Carbon-Carbon Double Bond**

Q: What is *trans* fat?

A: *Trans* fat (also known as *trans* fatty acids) is a specific type of fat formed when liquid oils are made into solid fats like shortening and hard margarine. However, a small amount of *trans* fat is found naturally, primarily in some animal-based foods.

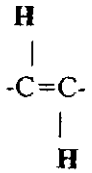
Trans fat behaves like saturated fat by raising low-density lipoprotein (LDL or "bad") cholesterol that increases your risk of coronary heart disease (CHD). *Trans* fat can be found in some of the same foods as saturated fat, such as vegetable shortenings, some margarines, crackers, candies, cookies, snack foods, fried foods, baked goods, and other processed foods made with partially hydrogenated vegetable oils.

Where will I find *trans* fat?

Vegetable shortenings, some margarines, crackers cookies, snack foods, and other foods made with or fried in partially hydrogenated oils.

Trans fat is made when hydrogen is added to vegetable oil -- a process called hydrogenation. Hydrogenation increases the shelf life and flavor stability of foods containing these fats. Usually the hydrogen atoms at a double bond are positioned on the same side of the carbon chain. However, partial hydrogenation reconfigures some double bonds and the hydrogen atoms end up on different sides of the chain. This type of configuration is called "*trans*" (means "across" in Latin). The structure of a *trans* unsaturated chemical bond looks like the diagram below.

***Trans* Fat**
(i.e., *trans* fatty acids)



Hydrogen atoms are on opposite sides of the chain of carbon atoms at the carbon-carbon double bond.

As stated in FDA's labeling regulations, if a fat or oil ingredient is completely hydrogenated, the name in the ingredient list will include the term "hydrogenated." Or, if partially hydrogenated, the name in the ingredient list will include the term "partially hydrogenated." As stated above, oil that is partially hydrogenated is a source of *trans* fat.

Q: What is the role of fat in the diet?

A: Fat is a major source of energy for the body and aids in the absorption of vitamins A, D, E, and K, and carotenoids. Both animal and plant-derived food products contain fat, and when eaten in moderation, fat is important for proper growth, development, and maintenance of good health. As a food ingredient, fat provides taste, consistency, and stability and helps us feel full. In addition, parents should be aware that fats are an especially important source of calories and nutrients for infants and toddlers (up to 2 years of age), who have the highest energy needs per unit of body weight of any age group.

Q: Are all fats the same?

A: Simply put: no. While **un**saturated fats (monounsaturated and polyunsaturated) are beneficial when consumed in moderation, saturated fat and *trans* fat are not. Saturated fat and *trans* fat raise LDL ("bad") cholesterol. Therefore, it is advisable to choose foods low in both saturated and *trans* fats as part of a healthful diet.

Q: What about cholesterol?

A: Cholesterol is a waxy substance that occurs naturally in the tissues of all animals. The human body needs cholesterol to function properly, such as producing vitamin D, bile acids to digest fat, and many hormones. Given the capability of all tissues to synthesize sufficient amounts of cholesterol for their needs, there is no evidence for a biologic requirement for dietary cholesterol. Scientific evidence indicates a positive linear trend between cholesterol intake and LDL-cholesterol levels, and therefore, an increased risk of CHD.

Section 2 - Foods that Contain Trans Fat, Saturated Fat, and Cholesterol

Q: What is the daily *trans* fat intake of Americans?

A: FDA estimates that the average daily intake of *trans* fat in the U.S. population is about 5.8 grams or 2.6% of calories per day for individuals 20 years of age and older. On average, Americans consume approximately 4 to 5 times as much saturated fat as *trans* fat in their diet.

Trans fat can be found in vegetable shortenings, some margarines, crackers, candies, cookies, snack foods, fried foods, baked goods, and other processed foods made with partially hydrogenated vegetable oils. Small amounts of naturally occurring *trans* fat can be found in

some animal products, such as butter, milk products, cheese, beef, and lamb.

Estimates of the average trans fat intake of U.S. adults from food groups (e.g., cakes, cookies, shortening, etc.) are described in the economic analysis for FDA's final trans fatty acid labeling rule, *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims published July 11, 2003 (68 FR 41434 at 41468-41470). FDA based its estimates on USDA's 1994-96 Continuing Survey of Food Intakes by Individuals and on the special 1995 USDA database of *trans* fat content of selected foods.

Q: What foods contain saturated fat, *trans* fat, and cholesterol?

A: Saturated and *trans* fats can be found in some of the same foods, such as vegetable shortenings, some margarines (especially margarines that are harder), crackers, candies, cookies, snack foods, fried foods, baked goods, and other processed foods made with partially hydrogenated vegetable oils. High amounts of saturated fat are found in animal products, such as beef and pork, chicken skin, butter, whole milk, and cheese. Foods high in cholesterol include liver, other organs meats, egg yolks, and dairy fats.

It is important to choose foods with the lower combined amount of saturated fat and *trans* fat and the lower amount of cholesterol.

Q: Should *trans* fat be eliminated from the diet?

A: No. According to experts, eliminating *trans* fat completely from the diet would require such extraordinary dietary changes (e.g., elimination of foods, such as dairy products and meats that contain *trans* fatty acids) that eliminating *trans* fat could cause an inadequate intake of some nutrients and create health risks.

Q: What actions can consumers take to lower their intake of saturated fat, *trans* fat, and cholesterol?

A: Here are some actions you can take every day to keep your consumption of both saturated and *trans* fats and cholesterol low while consuming a nutritionally adequate diet.

- Check the Nutrition Facts panel to compare foods because the serving sizes are generally consistent in similar types of foods. Choose foods lower in saturated fat, *trans* fat, and cholesterol. For saturated fat and cholesterol, use the Quick Guide to %DV: 5%DV or less is low and 20%DV or more is high. (Remember, there is no %DV for *trans* fat.)

- Choose Alternative Fats. Replace saturated and *trans* fats in your diet with mono- and polyunsaturated fats. These fats do not raise LDL (or "bad") cholesterol levels and have health benefits when eaten in moderation. Sources of monounsaturated fats include olive and canola oils. Sources of polyunsaturated fats include soybean, corn, sunflower oils, and foods like nuts.

- Choose vegetable oils (except coconut and palm kernel oils) and soft margarines (liquid, tub, or spray) more often because the combined amount of saturated and *trans* fats is lower than the amount in solid shortenings, hard margarines, and animal fats, including

butter.

- Consider Fish. Most fish are lower in saturated fat than meat. Some fish, such as mackerel, sardines, and salmon, contain omega-3 fatty acids that are being studied to determine if they offer protection against heart disease.
- Limit foods high in cholesterol such as liver and other organ meats, egg yolks, and full-fat dairy products, like whole milk.
- Choose foods low in saturated fat such as fat free or 1% dairy products, lean meats, fish, skinless poultry, whole grain foods, and fruit and vegetables.

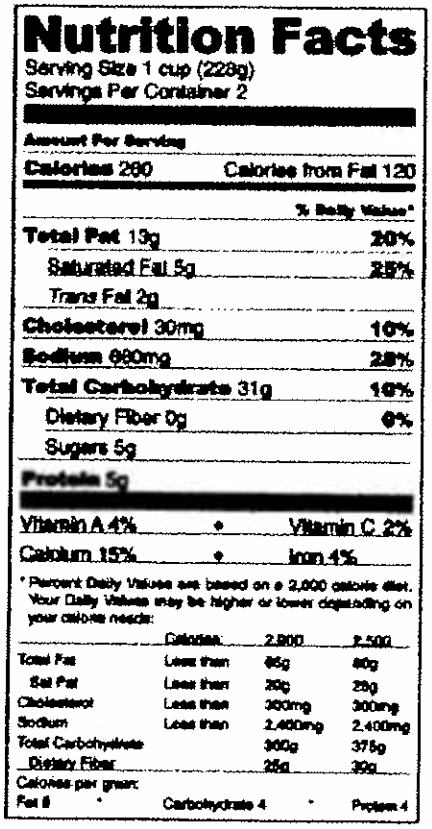
Q: Do dietary supplements contain *trans* fat?

A: Yes, some dietary supplements contain ingredients that also include partially hydrogenated vegetable oil or *trans* fat as well as saturated fat and cholesterol. As a result of FDA's new label requirement, if a dietary supplement contains a reportable amount of *trans* fat, which is 0.5 gram or more, dietary supplement manufacturers must list the amounts on the Supplement Facts panel. Examples of dietary supplements that may contain saturated fat, *trans* fat, and cholesterol include energy and nutrition bars.

Section 3 - FDA's Labeling of Trans Fatty Acids

Q: How will the nutrition label be different?

A: The FDA final rule on *trans* fatty acids (also called "*trans* fat") requires that the amount of *trans* fat in a serving be listed on a separate line under saturated fat on the Nutrition Facts panel (see figure). However, *trans* fat does not have to be listed if the **total** fat in a food is less than 0.5 gram (or 1/2 gram) per serving and no claims are made about fat, fatty acids or cholesterol content. If it is not listed, a footnote will be added stating that the food is "not a significant source of *trans* fat."



Nutrition Facts
Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving
Calories 260 Calories from Fat 120

% Daily Value*
Total Fat 13g 20%
Saturated Fat 5g 25%
Trans Fat 2g
Cholesterol 30mg 10%
Sodium 660mg 28%
Total Carbohydrate 31g 10%
Dietary Fiber 0g 0%
Sugars 5g
Protein 5g

Vitamin A 4% • Vitamin C 2%
Calcium 15% • Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Q: Why is there no %DV for *trans* fat?

A: Although the updated Nutrition Facts panel will now list the amount of *trans* fat in a product, be aware that it does not have a %Daily Value (%DV) for *trans* fat. While scientific reports have confirmed the relationship between *trans* fat and an increased risk of CHD, none has recommended an amount of *trans* fat that FDA could use to establish a Daily Value (DV). Without a DV, a %DV cannot be calculated. As a result, *trans* fat will be listed with only a gram amount.

But saturated fats do have a %DV. To choose foods low in saturated fat and cholesterol, use the Quick Guide to %DV - **5%DV or less is low and 20%DV or more is high.** You can also use the %DV to make dietary trade-offs with other foods throughout the day. You don't have to give up a favorite food to eat a healthy diet. When a food you like is high in any of these cholesterol-raising components, balance it with foods that are low in them at other times of the day.

The following graphic of the Nutrition Facts panel illustrates which nutrients experts recommend you limit and which they recommend you consume in adequate amounts.

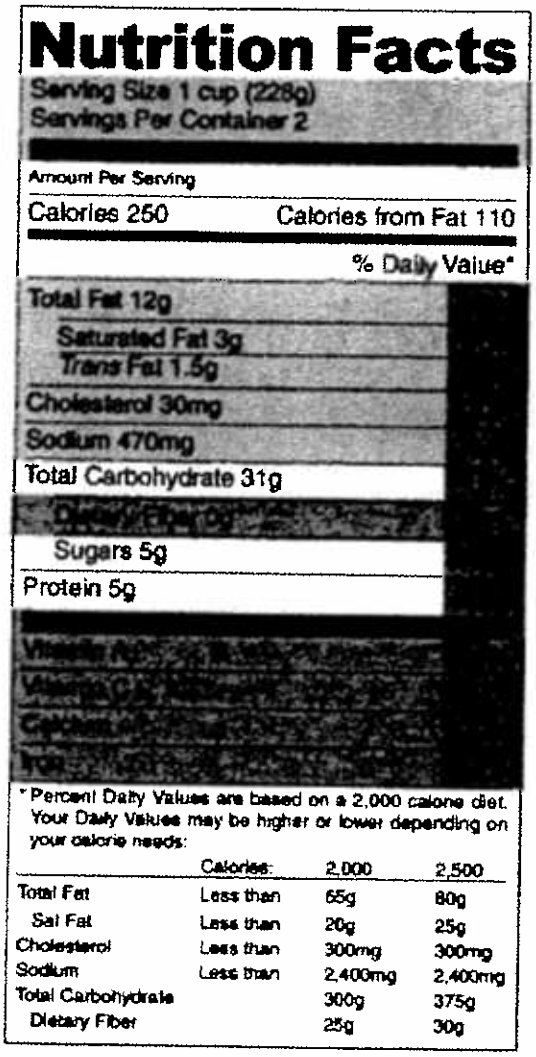
Sample Label for
Macaroni and Cheese

Start Here

Limit these Nutrients

Get Enough of these Nutrients

Footnote



Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving

Calories 250 Calories from Fat 110

% Daily Value*

Total Fat 12g
Saturated Fat 3g
Trans Fat 1.5g
Cholesterol 30mg
Sodium 470mg
Total Carbohydrate 31g
Dietary Fiber 0g
Sugars 5g
Protein 5g

Vitamin A
Vitamin C
Calcium
Iron

* Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Quick Guide to % DV

5% or less is low
20% or more is high

Q: Is it possible for a food product to list the amount of *trans* fat as 0 g on the Nutrition Facts panel if the ingredient list indicates that it contains "partially hydrogenated vegetable oil?"

A: Yes. Food manufacturers are allowed to list amounts of *trans* fat with less than 0.5 gram (1/2 g) as 0 (zero) on the Nutrition Facts panel. As a result, consumers may see a few products that list 0 gram *trans* fat on the label, while the ingredient list will have "shortening" or "partially hydrogenated vegetable oil" on it. This means the food contains very small amounts (less than 0.5 g) of *trans* fat per serving.

Q: What about nutrient content claims for *trans* fat?

A: Nutrient content claims are statements that are made on the food label package that indicate that the product contains a range from low to high of the amount of a specific nutrient. Examples: "Low Fat" and "High in Fiber." At this time, FDA has insufficient scientific information to establish nutrient content claims for *trans* fat. Such claims are permitted, however, for saturated fat and cholesterol.

Q: What are the highlights of the *trans* fat rule?

A: This final rule is the first significant change to the Nutrition Facts panel since the Nutritional, Labeling, and Education Act regulations were finalized in 1993. Some significant highlights are:

- This final rule requires manufacturers of conventional foods and some dietary supplements to list *trans* fat on a separate line, immediately under saturated fat on the nutrition label.

- As of January 1, 2006, food manufacturers must list *trans* fat on the nutrition label. The phase-in period, from the date the final rule issued (July 2003) to the effective date (January 2006), minimized the need for multiple labeling changes, allowed small businesses to use current label inventories, and provided economic savings.

- FDA's regulatory chemical definition for *trans* fatty acids is all unsaturated fatty acids that contain one or more isolated (i.e., nonconjugated) double bonds in a *trans* configuration. Under the Agency's definition, conjugated linoleic acid would be excluded from the definition of *trans* fat.

- Dietary supplement manufacturers must also list *trans* fat on the Supplement Facts panel when their products contain reportable amounts (0.5 gram) of *trans* fat. Examples of dietary supplements with *trans* fat are energy and nutrition bars.

Q: It is after January 1, 2006. Why do some products not declare *trans* fat on their labels?

A: There may be two reasons why you are not seeing *trans* fat on a product's label.

First, products entering interstate commerce on or after January 1, 2006 must be labeled with *trans* fat. As this is happening, FDA realizes that it will take some time for food products to move through the distribution chain to a store shelf. Thus, it may take a few months for products that are listing *trans* fat on their label to show up on a store shelf. However, you will see many products with *trans* fat listed since companies have already begun to declare *trans* fat on their products' labels.

Second, FDA has granted enforcement discretion to some firms to use old label stock that do not declare *trans* fat after the effective date of January 1, 2006. In these cases, food firms followed the required process described in FDA's guidance for industry and FDA entitled, "Guidance for Industry and FDA: Requesting an Extension to Use Existing Label Stock after the *Trans* Fat Labeling Effective Date of January 1, 2006 (Revised)". For each request, FDA is considering whether the declared label value for *trans* fat is 0.5 g or less per serving. This information is important because lower amounts of *trans* fat would have less impact on public

health than higher amounts of *trans* fat. Thus, *trans* fat information in the Nutrition Facts panel will be missing on some products (that contain lower amounts of *trans* fat) throughout the next year.

If *trans* fat is not declared on the label and you are curious about the *trans* fat content of a product, contact the manufacturer listed on the label.

Q: I am a food manufacturer. Can I use my old label stock that does not include *trans* fat after the compliance date of January 1, 2006?

FDA understands that some businesses may experience hardship in meeting the compliance date for *trans* fat labeling. Thus, FDA is allowing firms to request enforcement discretion to use existing label stock that does not include *trans* fat after January 1, 2006. See "Guidance for Industry and FDA: Requesting an Extension to Use Existing Label Stock after the Trans Fat Labeling Effective Date of January 1, 2006 (Revised)."

Q: What is the scientific evidence that supports this rule?

A: In finalizing this rule, FDA relied on scientific reports, expert panels, and studies from the Institute of Medicine/National Academies of Science (IOM/NAS), the National Cholesterol Education Program, and DHHS and USDA (Dietary Guidelines for Americans 2000). These reports concluded that consumption of *trans* fatty acids contribute to increased LDL ("bad") cholesterol levels, which increase the risk of coronary heart disease.

The IOM/NAS report on macronutrients recommended that "trans fatty acid consumption be as low as possible while consuming a nutritionally adequate diet."

An expert panel for the National Cholesterol Education Program (NCEP) Report for persons with high risk of CHD in 2001 recommended that intakes of *trans* fatty acids should be kept low and encouraged the use of liquid vegetable oil and soft margarine instead of butter, stick margarine, and shortening.

The Dietary Guidelines for Americans 2000 makes the following statements regarding *trans* fatty acids and food sources of *trans* fat: "Foods high in *trans* fatty acids tend to raise blood cholesterol. These foods include those high in partially hydrogenated vegetable oils, such as many hard margarines and shortenings. Foods with a high amount of these ingredients include some commercially fried foods and some bakery good. Aim for a total fat intake of not more than 30 percent of calories, as recommended in previous Guidelines. If you need to reduce your fat intake to achieve this level, do so primarily by cutting back on saturated and *trans* fats."

Findings from human feeding studies and epidemiological studies show a positive association between the intake of *trans* fatty acids and the incidence of CHD. These studies are described in the *trans* fat final rule. For more detailed information on these studies, see the *trans* fatty acid final rule.

Q: How do I find more detailed information about this rule?

A: The full text of this rule is available online (*Trans* Fatty Acids in Nutrition Labeling,

Nutrient Content Claims, and Health Claims) or on display at the FDA's Dockets Management Branch (Dockets Management Branch, HFA-305, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852).

Q: Is the FDA considering any other regulations about nutrition labeling of *trans* fatty acids?

A: Yes, the Food and Drug Administration (FDA) issued an advance notice of proposed rulemaking (ANPRM) in the Federal Register (Food Labeling: *Trans* Fatty acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements) to solicit information and data that potentially could be used to establish new nutrient content claims about *trans* fat, to establish qualifying criteria for *trans* fat in current nutrient content claims for saturated fat and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol raising fats, and, in addition, as disclosure and disqualifying criteria to help consumers make heart-healthy food choices. The agency is also requesting comments on whether to consider statements about *trans* fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the Nutrition Facts panel or as a disclosure statement in conjunction with claims to enhance consumers' understanding about such cholesterol-raising lipids and how to use the information to make healthy food choices. Information and data obtained from comments and from consumer studies conducted by FDA may be used to help draft a proposed rule that would establish criteria for certain nutrient content or health claims or require the use of a footnote, or other labeling approach, about one or more cholesterol-raising lipids in the Nutrition Facts panel to assist consumers in maintaining healthy dietary practices.

Section 4 - Diet and Coronary Heart Disease

Q: How do saturated and *trans* fats, unsaturated fats, and dietary cholesterol relate to heart disease?

A: Higher intakes of saturated and *trans* fats, and dietary cholesterol raise low density lipoprotein (LDL or "bad") cholesterol in the blood. An elevated LDL cholesterol increases the risk of developing coronary heart disease (CHD). To decrease LDL cholesterol and the risk of CHD, substitute monunsaturated and polyunsaturated fats for saturated and *trans* fats and decrease the intake of cholesterol.

Q: Do saturated and *trans* fats affect blood cholesterol in different ways?

A: Yes. Like saturated fat, *trans* fat also raises the low density lipoprotein (LDL or "bad") cholesterol in the blood. But, unlike saturated fat, *trans* fat lowers high density lipoprotein (HDL or "good") cholesterol in the blood. An elevated LDL cholesterol increases the risk of developing coronary heart disease.

Q: Is it better to eat butter instead of margarine to avoid *trans* fat?

A: No, because the combined amount of saturated fat and *trans* fat (the cholesterol-raising fats) and cholesterol for butter is usually higher than margarine, even though some margarines contain more *trans* fat than butter.

It is better to eat softer or liquid margarines that contain a lower combined amount of saturated fat and *trans* fat and a lower amount of cholesterol. For a healthful alternative, nonstick cooking spray can be substituted for other fats when "greasing" the pan.

The table compares the amounts and types of fats and amount of cholesterol in butter and some margarines.

FAT TYPE PER SERVING (*)
(Serving Size - 1 tbsp.)

Product	Total Fat g	Saturated Fat g	*Trans* Fat g	Combined Saturated and *Trans* Fats g	Cholesterol mg
Butter*	10.8	7.2	0.3	7.5	31.1
Margarine, stick†	11	2.1	2.8	4.9	0
Margarine, spread†	9.7	1.8	2.7	4.5	0
Margarine, tub†	6.7	1.2	0.6	1.8	0.1
Margarine, bottle‡	0.4	0.1	0	0.1	0.2

(*) Butter values from FDA Table of *trans* Values, dated 1/30/95.
† Values derived from 2002 USDA National Nutrient Database for Standard Reference, Release 15.
‡ Prerelease values derived from 2003 USDA National Nutrient Database for Standard Reference, Release 16.

Answer: Choose the product with the lower combined amount of saturated fat and *trans* fat and the lower amount of cholesterol. In this case, the correct answer is margarine in a bottle.

Q: Is there a shortage of oils that do not contain *trans* fat?

A: Based on informal reports from industry, the requirement to declare *trans* fat on product labeling is already changing consumer demand and prompting product reformulation, which was anticipated by FDA. Representatives from industry have indicated to FDA that the transition from use of oils containing *trans* fats to healthier oils that are both suitable for various processing techniques and continue to meet consumer taste preferences will take time as supplies of healthier oils catch up with demand. High consumer demand for healthier oils, and the accompanying industry response, is a testament to the success of the agency's *trans* fat labeling rule and industry's move to using healthier oils.

Q: When I eat or order out, how do I know if the food contains saturated and *trans* fats?

A: You may not know unless you ask. Restaurants are not required to provide full nutrition

labeling for their food products, unless nutrient claims are made, such as "Low Fat" or "Low Sodium." To know which fats are being used in the preparation of the food you're eating or ordering, a good tip to remember is "**ask before you order**". Also, many fast food or chain restaurants have tables of the nutritional content of their food products that they will provide upon request.

Section 5 - Background about FDA's Trans Fat Regulation

Q: What is the history of the *trans* fatty acid labeling regulation?

A: In 1994, the Center for Science in the Public Interest (CSPI), a consumer advocacy organization, filed a petition (amended in July 1998) with the FDA requesting that the agency take steps to require *trans* fat to be listed on nutrition labels and claims.

In response to the CSPI petition, FDA issued a proposed rule in the Federal Register on November 17, 1999. In that proposed rule, FDA proposed to amend the regulations to require that *trans* fat be listed on nutrition labels.

On December 5, 2000, FDA reopened the comment period for the rule to obtain comments about "reduced claims." FDA reopened another comment period on November 15, 2002, to receive comments about use of footnote with the statement "Intake of *trans* fat should be as low as possible." In total, FDA received over 2,700 comments that addressed the scientific, economic, policy and legal basis for the rule.

In finalizing this rule, FDA relied on scientific reports, expert panels, and studies from the Institute of Medicine/National Academies of Science, 2001 Report of the National Cholesterol Education Program, and the 2000 Dietary Guidelines for Americans.

Q: What legal authority does FDA have to require *trans* fatty acids in nutrition labeling?

A: The Food, Drug and Cosmetic Act (FD&C Act) provides the FDA with statutory authority to require food and nutrition labeling. Specifically, two sections of the FD&C Act provide the legal authority, as follows:

> **Sec. 403(a) of FD&C Act** - requires foods to be adequately labeled and that material facts be disclosed to consumers.
>
> **Sec. 403(q)(2)(A) of FD&C Act** - gives the Secretary authority to require additional nutrients to be included in nutrition labeling if such information will "assist consumers to maintain healthy dietary practices."

Q: Why is FDA addressing *trans* fat?

A: The *trans* fat nutrition labeling rule responds, in part, to a citizen petition from the Center for Science in the Public Interest (CSPI), and is based on recently published human studies and health expert advice on *trans* fat.

Recently the Institute of Medicine, National Academies of Science (IOM/NAS) published a

report that found that *trans* fatty acids increase low density lipoprotein (LDL or "bad") cholesterol, thereby increasing the risk of coronary heart disease. The IOM/NAS report recommended that "*trans* fat consumption be as low as possible while consuming a nutritionally adequate diet." Similar recommendations are made for saturated fat and cholesterol.

This regulation will provide information on food labels about the amount of *trans* fat in foods so that consumers can select foods with lower levels of *trans* fat and thereby lower their intake of *trans* fat as part of a heart-healthy diet. FDA estimates that 3 years after the effective date, *trans* fat labeling would prevent from 600 to 1,200 cases of CHD and 250-500 deaths each year. It takes about 3 years for lower LDL-cholesterol to result in lower CHD risk.

Q: Does this rule mean that FDA is banning *trans* fat from food?

A: No, FDA is not banning food manufacturers from using *trans* fat in packaged foods. FDA is requiring food manufacturers, processors, and distributors to label the amount of *trans* fat in a serving of food on the Nutrition Facts panel. As a result, Americans will have information they need to reduce their intake of *trans* fat, saturated fat, and cholesterol.

Q: What are the public health benefits and costs of the *trans* fat final rule?

A: FDA estimates that 3 years after the effective date, January 2006, *trans* fat labeling would annually prevent from 600 to 1,200 heart attacks and save 250-500 lives. Based on this estimate, this rule will realize a cost savings of $900 million to $1.8 billion per year in medical costs, lost productivity, and pain and suffering.

FDA estimates that industry will incur a one-time cost of approximately $140 to $250 million. These costs include: determining the amount of *trans* fat in the food products, relabeling the Nutrition Facts panel to add *trans* fat, and reformulating products voluntarily to decrease the amount of *trans* fat.

If You Need More Information?

- Federal Register Final Rule: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims (July 11, 2003)
- FDA Acts to Provide Better Information to Consumers on Trans Fats
- Guidance on How to Understand and Use the Nutrition Facts Panel on Food Labels.
- Advanced Notice of Proposed Rule Making: Food Labeling: *Trans* Fatty acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements (July 11, 2003)

Disclaimer: FDA is issuing this document as general information for the public. FDA intends this document to aid the public in understanding how to use the declaration of *trans* fatty acids in the nutrition label of conventional foods and dietary supplements.

This document was issued in July 2003 and updated March 2004, June 2004, August 2005, September 2005, and January 2006
For more information on Food Labeling
See http://www.cfsan.fda.gov/label.html

Declaration of Erich O. Grosz

Exhibit 5

Case No. 1:07-CV-01092 (RJL)

U.S. Food and Drug Administration

FDA News

FOR IMMEDIATE RELEASE
P06-74
June 2, 2006

Media Inquiries:
Sebastian Cianci, 301-827-6242
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888-INFO-FDA

FDA Receives Keystone Forum Report on Away-From-Home Foods

Improving Consumers Ability to Manage Calorie Intake Key to Anti-Obesity Efforts

The U.S. Food and Drug Administration (FDA) has received a report that could help American industry and consumers take important steps to successfully combat the nation's obesity problem. The report is titled, the "Keystone Forum on Away-From-Home Foods: Opportunities for Preventing Weight Gain and Obesity." It provides recommendations from experts in industry, government, civic sector organizations, and academia, for improving consumers' ability to manage calorie intake from foods prepared and purchased away-from-home. The Keystone Report offers recommendations related to: 1) understanding and influencing consumer behavior; 2) increasing the availability of lower-calorie products, menu items, and meals; and 3) providing consumers with nutrition information.

"The recommendations may help industry members, educators, researchers, government, and health care professionals take steps to reduce the obesity rate and the health and economic burdens that come with it," said Acting FDA Commissioner Andrew C. von Eschenbach, M.D.

Since the late 1980s, adult obesity has steadily increased to the point at which more than 65 percent of all Americans are now overweight and over 30 percent are obese. Also, 15 percent of children and adolescents aged 6 to 19 are overweight -- nearly double the rate of two decades ago. Overweight and obesity increase the risk of coronary heart disease, type 2 diabetes, and certain cancers. According to some estimates, obesity results in thousands of deaths a year and accounts for $117 billion in U.S. health care expenses annually.

The Department of Health and Human Services, in an effort to help Americans live long, better, healthier lives, is committed to reducing overweight/obesity, poor nutrition, and physical inactivity. FDA is working in concert with the Department to achieve this goal. In 2004 FDA's Obesity Working Group (OWG) developed an action plan to address the overweight/obesity problem within the scope of FDA's regulatory authorities. The OWG recommendations centered on the scientific fact that weight control is primarily a function of caloric balance and therefore "calories count" when combating overweight/obesity. One recommendation was that FDA work through a facilitator to provide a forum for stakeholders to seek consensus-based solutions to specific aspects of the obesity epidemic in the United States, with a particular focus on food consumed away from home.

The impact of away-from-home foods is significant. Americans spend approximately 46 percent of their food budget on food prepared away from home and take in 32 percent of their calories from such foods. In light of these facts, FDA contracted with the Keystone Center, a non-profit organization that specializes in bringing together diverse participants to develop consensus on pressing public policy issues, to convene a Forum on Away-from-Home Foods. The Forum met to consider what can be done, given what is currently known, to support consumers' ability to manage their energy intake, with respect to preventing undue weight gain and obesity, within the scope of away-from-home foods.

The report reflects the input of the forum's participants, and highlights approaches that multiple stakeholders can take to address one aspect of America's obesity problem and build a healthier U.S.

####

Additional Information
Audio of Press Briefing: (available in WAV (21 MB), or MP3 (13MB))
Keystone Forum on Away-From-Home Foods -- Final Report (pdf, 740 KB)
Backgrounder
Questions & Answers
FDA's Plan to Tackle U.S. Obesity

RSS Feed for FDA News Releases [what's this?]

Get free weekly updates about FDA press releases, recalls, speeches, testimony and more.

Declaration of Erich O. Grosz

Exhibit 6

Case No. 1:07-CV-01092 (RJL)

Letter Report on Dietary Reference Intakes for *Trans* Fatty Acids

Drawn from the Report on

Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids

A Report of the
Panel on Macronutrients,
Subcommittees on Upper Reference Levels of Nutrients
and on Interpretation and Uses of Dietary Reference Intakes, and the
Standing Committee on the Scientific Evaluation
of Dietary Reference Intakes

Food and Nutrition Board

INSTITUTE OF MEDICINE

NOTICE: The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

This project was funded by the U.S. Department of Health and Human Services Office of Disease Prevention and Health Promotion, Contract No. 282-96-0033, TO #4; Health Canada; the U.S. Food and Drug Administration; the National Institutes of Health; the Centers for Disease Control and Prevention; the U.S. Department of Agriculture; the Department of Defense; the Institute of Medicine; and the Dietary Reference Intakes Corporate Donors' Fund. Contributors to the Fund include Roche Vitamins Inc, Mead Johnson Nutrition Group, Daiichi Fine Chemicals, Inc, Kemin Foods, Inc, M&M Mars, Weider Nutrition Group, and Natural Source Vitamin E Association. The opinions or conclusions expressed herein do not necessarily reflect those of the funders.

This letter report has been posted as a pdf file on the National Academies websit at **www.iom.edu/fnb**. It is excerpted from the full report, *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids*, which will be available for sale in late summer from the National Academy Press, 2101 Constitution Avenue, N.W., Box 285, Washington, DC 20055; call (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area), or visit the NAP's on-line bookstore at **http://www.nap.edu**.

For more information about the Institute of Medicine, visit the IOM home page at **www.iom.edu.**

The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The serpent adopted as a logotype by the Institute of Medicine is a relief carving from ancient Greece, now held by the Staatliche Museen in Berlin.

Knowing is not enough; we must apply.
Willing is not enough; we must do.
—Goethe

INSTITUTE OF MEDICINE

Shaping the Future for Health

THE NATIONAL ACADEMIES

National Academy of Sciences
National Academy of Engineering
Institute of Medicine
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The **National Academy of Sciences** is a private, nonprofit, self-perpetuating society of distinguished scholars engaged in scientific and engineering research, dedicated to the furtherance of science and technology and to their use for the general welfare. Upon the authority of the charter granted to it by the Congress in 1863, the Academy has a mandate that requires it to advise the federal government on scientific and technical matters. Dr. Bruce M. Alberts is president of the National Academy of Sciences.

The **National Academy of Engineering** was established in 1964, under the charter of the National Academy of Sciences, as a parallel organization of outstanding engineers. It is autonomous in its administration and in the selection of its members, sharing with the National Academy of Sciences the responsibility for advising the federal government. The National Academy of Engineering also sponsors engineering programs aimed at meeting national needs, encourages education and research, and recognizes the superior achievements of engineers. Dr. Wm. A. Wulf is president of the National Academy of Engineering.

The **Institute of Medicine** was established in 1970 by the National Academy of Sciences to secure the services of eminent members of appropriate professions in the examination of policy matters pertaining to the health of the public. The Institute acts under the responsibility given to the National Academy of Sciences by its congressional charter to be an adviser to the federal government and, upon its own initiative, to identify issues of medical care, research, and education. Dr. Harvey Fineberg is president of the Institute of Medicine.

The **National Research Council** was organized by the National Academy of Sciences in 1916 to associate the broad community of science and technology with the Academy's purposes of furthering knowledge and advising the federal government. Functioning in accordance with general policies determined by the Academy, the Council has become the principal operating agency of both the National Academy of Sciences and the National Academy of Engineering in providing services to the government, the public, and the scientific and engineering communities. The Council is administered jointly by both Academies and the Institute of Medicine. Dr. Bruce M. Alberts and Dr. Wm. A. Wulf are chairman and vice chairman, respectively, of the National Research Council.

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FOOD AND NUTRITION BOARD

DIETARY REFERENCE INTAKES FOR *TRANS* FATTY ACIDS

ORIGIN OF THIS REPORT

At the request of the U.S. Food and Drug Administration (FDA), the Food and Nutrition Board of the Institute of Medicine (IOM) has prepared this letter report on *trans* fatty acids. It is based on part of the chapter, Dietary Fats: Total Fat and Fatty Acids, contained in the forthcoming IOM report, *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids.*

We hope this letter report will be helpful to FDA as it considers a petition to label foods with their *trans* fatty acid content. While this report might not be identical to the corresponding section of the full report once it is released, any changes will be editorial in nature. The findings in this letter report have full standing as an IOM report.

BACKGROUND ON *TRANS* FATTY ACIDS

Trans fatty acids are unsaturated fatty acids that contain at least one double bond in the *trans* configuration. The *trans* double bond configuration results in a greater bond angle than the *cis* configuration. This results in a more extended fatty acid carbon chain more similar to that of saturated fatty acids rather than that of *cis* unsaturated double bond containing fatty acids. The conformation of the double bond(s) impacts on the physical properties of the fatty acid. Those fatty acids containing a *trans* double bond have the potential for closer packing or aligning of acyl chains, resulting in decreased mobility; hence fluidity is reduced when compared to fatty acids containing a *cis* double bond. Partial hydrogenation of polyunsaturated oils causes isomerization of some of the remaining double bonds and migration of others, resulting in an increase in the *trans* fatty acid content and the hardening of fat. Hydrogenation of oils, such as corn oil, can result in both *cis* and *trans* double bonds, anywhere between carbon 4 and carbon 16. A major *trans* fatty acid is elaidic acid (9*trans* 18:1), but during hydrogenation of polyunsaturated fatty acids, small amounts of several other *trans* fatty acids (9*trans*,12*cis* 18:2; 9*cis* and 12*trans* 18:2) are produced. In addition to these isomers, dairy fat and meats contain 9*trans* 16:1 and conjugated dienes (9*cis*,11*trans* 18:2). Foods containing hydrogenated oils tend to have a higher *trans* fatty acid content than those that do not contain hydrogenated oils (Emken, 1995).

Conjugated linoleic acid (CLA) is a collective term for a group of geometric and positional isomers of linoleic acid in which the *trans/cis* double bonds are conjugated; that is, the double

bonds occur without an intervening carbon atom not part of a double bond. At least nine different isomers of CLA have been reported as minor constituents of food (Ha et al., 1989), but only two of the isomers, *cis*-9,*trans*-11 and *trans*-10,*cis*-12, possess biological activity (Pariza et al., 2001). There is limited evidence to suggest that the *trans*-10,*cis*-12 isomer reduces the uptake of lipids by the adipocyte and that the *cis*-9, *trans*-11 isomer is active in inhibiting carcinogenesis. Similarly, there are limited to data to show that *cis*9,*trans*11 and *trans*10,*cis*12 isomers inhibit atherogenesis (Kritchevsky et al., 2000).

CLA is naturally present in dairy products and ruminant meats as a consequence of biohydrogenation in the rumen. *Butyrivibrio fibrisolvens*, a ruminant microorganism, is responsible for the production of the *cis*-9,*trans*-11 CLA isomer that is synthesized as a result of the biohydrogenation of linoleic acid (Noble et al., 1974). The *cis*-9,*trans*-11 CLA isomer may be directly absorbed or further metabolized to *trans*-11 octadecenoic acid (vaccenic acid) (Pariza et al., 2001). After absorption, vaccenic acid can then be converted back to *cis*-9,*trans*-11 CLA within mammalian cells by Δ9 desaturase (Adlof et al., 2000; Chin et al., 1994; Griinari et al., 2000; Santora et al., 2000). Additionally, the biohydrogenation of several other polyunsaturated fatty acids has been shown to produce vaccenic acid as an intermediate (Griinari and Bauman, 1999), thus providing additional substrate for the endogenous production of *cis*-9,*trans*-11 CLA. Griinari and coworkers (2000) estimate that approximately 64 percent of the CLA in cow milk is of endogenous origin.

Verhulst and coworkers (1987) isolated a microorganism, *Propionibacterium acnes*, that appears to have the ability to convert linoleic acid to *trans*-10,*cis*-12 CLA, an isomer of CLA that is found in rumen digesta (Fellner et al., 1999). *Trans*-10 octadecenoic acid is formed in the rumen via biohydrogenation of *trans*-10,*cis*-12 CLA, and both have been reported to be found in cow milk (Griinari and Bauman, 1999). However, endogenous production of *trans*-10,*cis*-12 CLA from *trans*-10 octadecenoic acid does not occur because mammalian cells do not posses the Δ12 desaturase enzyme (Adlof et al., 2000; Pariza et al., 2001). Therefore, any *trans*-10,*cis*-12 CLA isomer that is reported in mammalian tissue or sera would likely originate from gastrointestinal absorption.

Small amounts of *trans* fatty acids and CLA are present in all diets. They can serve as a source of fuel energy for the body. However, there are no known requirements for *trans* fatty acids and CLA for specific body functions.

Absorption

Similar to other fatty acids, the coefficient of absorption of elaidic acid (18:1*t*) is about 95 percent (Emken, 1979). Studies in humans using pure triacylglycerols containing deuterated *cis* and *trans* octadecenoic acid isomers varying in melting point and double bond position suggest that the presence of *trans* double bond(s) in the fatty acyl chain has no measurable effect on efficiency of absorption (Emken, 1979, 1984).

Transport

Trans fatty acids are transported similarly to other dietary fatty acids and are distributed within the cholesteryl ester, triacylglycerol, and phospholipid fractions of lipoproteins (Vidgren et al., 1998). Platelet lipids also contain *trans* fatty acids, and their composition reflects *trans* fatty acid intake as do other tissues, with the exception of the brain (Mensink and Hornstra, 1995).

Metabolism

The *trans* isomers of oleic acid and linoleic acid that are formed during partial hydrogenation of unsaturated vegetable oils have been suggested to have potential adverse effects in fetal and infant growth and development through inhibition of the desaturation of linoleic acid and α-linolenic acid to arachidonic acid and docosahexaenoic acid (DHA), respectively (Koletzko, 1992; van Houwelingen and Hornstra, 1994). Many animal and in vitro studies, however, have involved much higher amounts of *trans* than all *cis* polyunsaturated fatty acids (Hwang et al., 1982; Shimp et al., 1982). Other animal studies have suggested that the deleterious effects seen with high intakes of *trans* fatty acid intake do not occur with amounts comparable to those consumed in a normal human diet containing sufficient amounts of linoleic acid (Bruckner et al., 1982; Zevenbergen et al., 1988).

Available animal and human data indicate that adipose tissue *trans* fatty acid content reflects the content of the diet, and that selective accumulation does not occur (Emken, 1984). More recent attention has been focused on validating the use of adipose *trans* fatty acid content as a measure of long-term dietary intake. In a study of Canadian subjects, Chen and colleagues (1995b) reported that adipose tissue *trans* fatty acid patterns, particularly those isomers found in partially hydrogenated vegetable fat, reflected dietary sources. Garland and coworkers (1998) also reported that adipose tissue *trans* fatty acid patterns correlated with intake and noted a stronger relationship with the isomers found in vegetable rather than animal fat. The authors cautioned that the later conclusion may have been due to the smaller between-person variability with animal versus vegetable *trans* fatty acid intake. In a letter to the editor regarding this study, Aro and Salminen (1998) suggested that the stronger correlation between adipose tissue *trans* fatty acid isomers found in hydrogenated vegetable rather than animal fat may be attributable to different rates of metabolism of the *trans* isomers. Two groups have used adipose tissue *trans* fatty acid to corroborate dietary *trans* fatty acid intake derived from food frequency questionnaires and found a strong relationship (Lemaitre et al., 1998; London et al., 1991). Despite these observations, it should be noted that adipose tissue *trans* fatty acid profiles can be confounded by the retention of intermediate products of β-oxidation (Emken, 1995).

Excretion

Trans fatty acids are completely catabolized to carbon dioxide and water.

Impact of *Trans* Fatty Acids on *n*-6 and *n*-3 Metabolism

The *trans* isomers of oleic acid and linoleic acid, which are present in hydrogenated vegetable oils and meats, have been suggested to have adverse effects on growth and development through inhibition of the desaturation of linoleic acid and α-linolenic acid to arachidonic acid and DHA, respectively (Sugano and Ikeda, 1996). Desaturation and elongation of *trans* linoleic and α-linolenic acid isomers containing a double bond at the *cis*-12 and *cis*-15 position, respectively, with formation of 20 and 22 carbon chain metabolites that could be incorporated into membrane lipids, has also been suggested. In vitro studies and studies with animals fed diets high in *trans* fatty acids have found evidence of reduced essential *n*-6 and *n*-3 fatty acid desaturation (Cook, 1981; Rosenthal and Doloresco, 1984). An inverse association between total *trans* fatty acids and arachidonic acid and DHA concentrations in plasma cholesteryl esters, and between plasma cholesteryl esters, elaidic acid (18:1*trans*), and birth

weight of premature infants has been reported (Koletzko, 1992). Studies in term infants found no relation between *trans* fatty acids and length of gestation, birth weight, or birth length (Elias and Innis, 2001). Similarly, an inverse association between plasma phospholipid *trans* fatty acids and arachidonic acid has been found for children aged 1 to 15 years (Decsi and Koletzko, 1995). The industrial hydrogenation of vegetable oils results in destruction of *cis* essential *n*-6 and *n*-3 fatty acids and the formation of *trans* fatty acids (Valenzuela and Morgado, 1999). It is not clear if differences in dietary intakes of *n*-6 and *n*-3 fatty acids, rather than inhibition of linoleic acid and α-linolenic acid desaturation by *trans* fatty acids, explains the statistical inverse associations between *trans* and *n*-6 and *n*-3 fatty acids reported in some studies (Craig-Schmidt, 2001). Based on the much greater affinity of the Δ6 desaturase for *cis* *n*-3 and *n*-6 fatty acids than monounsaturated fatty acids (Brenner, 1974; Castuma et al., 1977) and experimental work to show inhibition of the Δ6 desaturation of linoleic acid is not of concern with linoleic acid intakes above about 2 percent of energy (Zevenbergen et al., 1988), it seems unlikely that inhibition of essential fatty acid metabolism by *trans* fatty acids is of concern for practical human diets.

FINDINGS BY LIFE STAGE AND GENDER GROUP

There are no data available to indicate a health benefit from consuming *trans* fatty acids. Therefore, an Adequate Intake, Estimated Average Requirement, and Recommended Dietary Allowance are not established for *trans* fatty acids.

FOOD SOURCES OF *TRANS* FATTY ACIDS

Reports listing the *trans* fatty acid level in selected food items are available from the United States (Enig et al., 1990; Litin and Sacks, 1993; Michels and Sacks, 1995), Canada (Ratnayake et al., 1993), and Europe (Aro et al., 1998a, 1998b, 1998c; Michels and Sacks, 1995; van Erp-baart et al., 1998; van Poppel et al., 1998). More recently, a comprehensive U.S. database was compiled by the U.S. Department of Agriculture's Agricultural Research Service (ARS, 2001), which included a description of the methodology used to formulate the nutrient values (Schakel et al., 1997). *Trans* fatty acids are present in foods containing traditional stick margarine (3.04 g *trans* fatty acids/serving) and vegetable shortenings (2.54 g/serving) that have been subjected to hydrogenation, as well as in milk (0.22 g/serving), butter (0.40 g/serving), and meats (0.01 to 0.21 g/serving) (Emken, 1995). Therefore, foods that are contributors of *trans* fatty acids include pastries, fried foods (e.g., doughnuts and french fries), dairy products, and meats. Human milk contains approximately 1 to 5 percent of total energy as *trans* fatty acids (Table 1).

DIETARY INTAKE OF *TRANS* FATTY ACIDS

Estimating the amount of *trans* fatty acids in the food supply has been hampered by the lack of an accurate and comprehensive database on which to derive the data and the trend towards the reformulation of products over the past decade to reduce levels. This later issue complicates analysis of historical food intake data. Additionally, the variability in the *trans* fatty acid content of foods within a food category is extensive and can introduce substantial error when the calculations are based on food frequency questionnaires that heavily rely on the grouping of similar foods (Innis et al., 1999). *Trans* fatty acid intake is not currently collected in U.S. national surveys.

TABLE 1 *Trans* Fatty Acid Content in Term Human Milk of Women in the United States and Canada

Reference	Study Population/Stage of Lactation[a]	*Trans* Fatty Acid	Content in Human Milk	
			% of Total Fatty Acids	% of Total Energy[b]
Gibson and Kneebone, 1981	120 women, 40–45 d pp	16:1	Trace	Trace
		18:1	~10	~5.46
Chappell et al., 1985	7 women, 1–37 d pp	18:1(9)	2.6 ± 0.4	1.42
		18:1(7)	0.1 ± 0.03	0.05
		18:1(5)	0.1 ± 0.04	0.05
		18:2(6) c,t + t,c[c]	0.1 ± 0.4	0.05
		Total	2.9	1.57
Chen et al., 1995a	198 samples, 3–4 weeks pp	Total *trans*	7.19 ± 3.03	3.92
Innis and King, 1999	103 women, 2 mo pp	Total *trans*	7.1 ± 0.32	3.88

[a] pp = postpartum.
[b] Calculated using the following values: 40g fat/L milk, 8.87 kcal/g fat, 650 kcal/L milk.
[c] c,t + t,c = *cis, trans* and *trans, cis*.

Early reports suggested a wide range of *trans* fatty acid intakes, 2.6 to 12.8 g/day (Emken, 1995). The lower estimated intakes tended to be derived from food frequency data, whereas the higher estimated intakes tended to be derived from food availability data. More recent data from food frequency questionnaires collected in the United States suggest average *trans* fatty acid intakes of 1.5 to 2.2 percent of energy (Ascherio et al., 1994; Hu et al., 1997) or 5.2 percent of total dietary fat (Lemaitre et al., 1998). Intakes of about 1 to 2 percent of energy have been reported for women in Canada, although the range of intake was wide (Elias and Innis, 2001, 2002). Most recently, *trans* fatty acid intake was estimated using data from the Continuing Survey of Food Intakes by Individuals (Allison et al., 1999). The mean *trans* fatty acid intake for the U.S. population aged 3 years and older was 2.6 percent of total energy intake.

ADVERSE EFFECTS OF *TRANS* FATTY ACIDS

Hazard Identification

Total and Low-Density Lipoprotein Cholesterol Concentrations

Prior to 1980 there was generally little concern about the trend toward increased consumption of hydrogenated fat in the U.S. diet, especially when the hydrogenated fats displaced fats relatively high in saturated fatty acids (Denke, 1995). During the early 1980s studies showed a hypercholesterolemic effect of *trans* fatty acids in rabbits (Kritchevsky, 1982; Ruttenberg et al., 1983). Renewed interest in the topic of hydrogenated fat in human diets, or more precisely *trans* fatty acid intake, started in the early 1990s. The availability of a methodology able to distinguish the responses of individual lipoprotein classes to dietary

modification expanded the depth to which the topic could be readdressed. A report from the Netherlands suggested that a diet enriched in elaidic acid (a subfraction of 18:1 *trans*), compared to one enriched in oleic acid (18:1 *cis*), increased total and low-density lipoprotein (LDL) cholesterol concentrations and decreased high-density lipoprotein (HDL) cholesterol concentration, hence resulting in a less favorable total cholesterol/HDL cholesterol ratio (Mensink and Katan, 1990). Consumption of a diet enriched with saturated fatty acids resulted in LDL cholesterol concentrations similar to those observed after subjects consumed a diet high in elaidic acid, but HDL cholesterol concentrations were similar to those observed after subjects consumed the diet high in oleic acid. A number of studies on the topic have been published since then and have reported that hydrogenated fat/*trans* fatty acid consumption increases LDL cholesterol concentrations (Aro et al., 1997; Judd et al., 1994, 1998; Louheranta et al., 1999; Müller et al., 1998; Sundram et al., 1997) (Tables 2, 3, and 4). Recent data have demonstrated a dose-dependent relationship between *trans* fatty acid intake and the LDL:HDL ratio and when combining a number of studies, the magnitude of this effect is greater for *trans* fatty acids compared to saturated fatty acids (Figure 1) (Ascherio et al., 1999).

Similar to the metabolic/clinical trial data, studies in free-living subjects asked to substitute hydrogenated fat for other fat in their habitual diet resulted in higher concentrations of total and LDL cholesterol (Table 4) (Nestel et al., 1992b; Noakes and Clifton, 1998; Seppänen-Laakso et al., 1993).

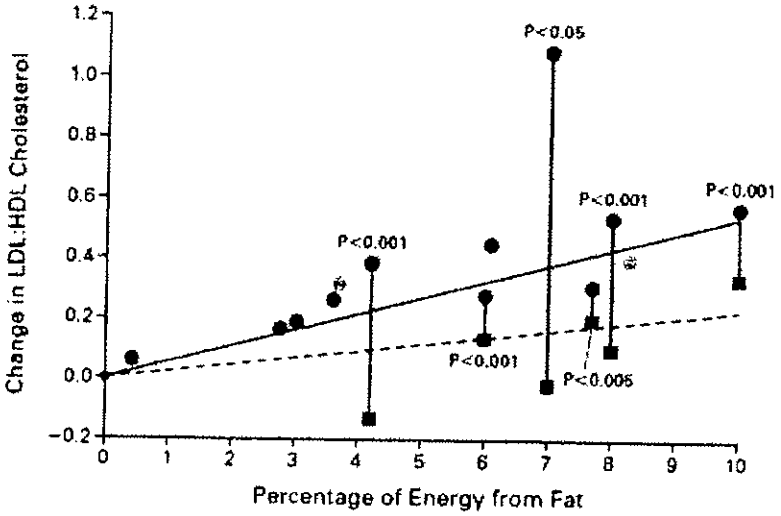

FIGURE 1 Change in the low-density lipoprotein (LDL):high-density lipoprotein (HDL) cholesterol concentration with increasing energy intake from saturated and *trans* fatty acids. Solid line represents the best-fit regression for *trans* fatty acids. Dotted line represents the best-fit regression for saturated fatty acids. Reprinted, with permission, from Ascherio et al. (1999). Copyright 1999 by the Massachusetts Medical Society.

TABLE 2 Dietary *Trans* Fatty Acids (TFA) and Blood Lipid Concentration: Controlled Feeding Trials

Reference	Study Population	Diet[a]	TFA (% of energy)	Blood Lipid Concentrations[b] LDL-C (mmol/L)	HDL-C (mmol/L)	Lp(a) (mg/L)
Mensink and Katan, 1990; Mensink et al., 1992	79 men and women, avg 25–26 y	3-wk crossover, 40% fat				
		10% 18:1	0	2.67[c]	1.42[c]	32[c]
		10% SFA	1.8	3.14[d]	1.42[c]	26[d]
		10% TFA	10.9	3.04[e]	1.25[d]	45[e]
Zock and Katan, 1992	56 healthy men and women	3 wk crossover, 41% fat				
		18:2	0.1	2.83[c]	1.47[c]	
		18:0	0.3	3.00[d]	1.41[d]	
		TFA	7.7	3.07[d]	1.37[d]	
Judd et al., 1994	58 men and women	6-wk crossover, 40% fat				
		18:1	0.7	3.34[c]	1.42[c]	
		SFA	0.7	3.64[d]	1.40[c,d]	
		moderate TFA	3.8	3.54[e]	1.47[c]	
		high TFA	6.6	3.60[d,e]	1.38[d]	
Aro et al., 1997	80 healthy men and women, 20–52 y	5-wk intervention, 33% fat				
		18:0	0.4	2.89[c]	1.42[c]	270[c]
		TFA	8.7	3.13[d]	1.22[d]	308[d]
Sundram et al., 1997	27 men and women, 19–39 y	4-wk crossover, 31% fat				
		18:1	0	3.17	1.25	128.3
		16:0	0	3.15	1.26	122.0
		12:0 + 14:0	0	3.57	1.18	134.3
		TFA	6.9	3.81	1.05	153.3
Louheranta et al., 1999	14 healthy women, avg 23 y	4-wk crossover, 37% fat				
		18:1	0	2.53	1.37	225 (units/L)
		TFA	5.1	2.64	1.31	220 (units/L)

[a] SFA = saturated fatty acid.
[b] LDL-C = low-density lipoprotein cholesterol, HDL-C = high-density lipoprotein cholesterol, Lp(a) = lipoprotein(a).
[c,d,e] Different lettered superscripts within each study indicates values were significantly different.

TABLE 3 Hydrogenated Fat Intake and Blood Lipid Concentrations: Controlled Feeding Trials

Reference	Study Population	Diet[a]	TFA[b] (% of energy)	Blood Lipid Concetrations[c] LDL-C (mmol/L)	HDL-C (mmol/L)	Lp(a) (mg/L)
Lichtenstein et al., 1993	14 men and women, 44–78 y	32-d crossover, 30% fat				
		Baseline	0.77	3.96[d]	1.24[d]	140[d]
		Corn oil	0.44	3.23[e]	1.14[e]	160[d]
		Corn oil margarine	4.16	3.49[e]	1.11[e]	130[d]
Almendingen et al., 1995	31 men, 21–46 y	3-wk crossover, 33–36% fat				
		Butter	0.9	3.81[d]	1.05[d]	194[d]
		PHFO	8.0	3.94[d,f]	0.98[e]	234[e]
		PHSO	8.5	3.58[e]	1.05[d]	238[e]
Judd et al., 1998	46 men and women, 28–65 y	5-wk crossover, 34% fat				
		PUFA-M	2.4	3.21[d]	1.24[d]	197[d]
		Butter	2.7	3.44[e]	1.27[d]	186[e]
		TFA-M	3.9	3.27[f]	1.24[d]	202[d]
Müller et al., 1998	16 healthy females, 19–30 y	14-d crossover, 31–32% fat				
		Vegetable oil	1.1	2.63[d]	1.32[d]	212[d]
		PHFO	7.7	2.87[e]	1.28[d]	225[d]
Lichtenstein et al., 1999	36 men and women, > 50 y	35-d crossover, 30% fat				
		Soybean oil	0.55	3.98[d]	1.11[d,e]	230
		Semiliquid margarine	0.91	4.01[d,e]	1.11[d,e]	230
		Butter	1.25	4.58[f]	1.16[e]	220
		Soft margarine	3.30	4.11[d,e]	1.11[d,e]	240
		Shortening	4.15	4.24[e]	1.11[d,e]	240
		Stick margarine	6.72	4.34[e]	1.01[d]	240

[a] PHFO = partially hydrogenated fish oil, PHSO = partially hydrogenated soybean oil, PUFA-M = margarine containing polyunsaturated fatty acids, TFA-M = margarine containing *trans* fatty acids.
[b] TFA = *trans* fatty acids.
[c] LDL-C = low-density lipoprotein cholesterol, HDL-C = high-density lipoprotein cholesterol, Lp(a) = lipoprotein(a).
[d,e,f] Different lettered superscripts within each study indicates values were significantly different.

High-Density Lipoprotein Cholesterol Concentrations

The data related to the impact of hydrogenated fat/*trans* fatty acids compared to unhydrogenated oil /*cis* fatty acids on HDL cholesterol concentrations are less consistent than for LDL cholesterol concentrations (Tables 2, 3 and 4). As reported for LDL cholesterol concentrations, the effect of hydrogenated fat/*trans* fatty acids on HDL cholesterol concentrations, if present, is likely to be dose dependent (Judd et al., 1994). The preponderance of the data suggest that hydrogenated fat/*trans* fatty acids, relative to saturated fatty acids, result in lower HDL cholesterol concentrations (Ascherio et al., 1999; Zock and Mensink, 1996; Zock et al., 1995). Because of the potentially differential effects of hydrogenated fat/*trans* fatty acids on LDL and HDL cholesterol concentrations, concern has been raised regarding their effect on the total cholesterol or LDL cholesterol:HDL cholesterol ratio (Ascherio et al., 1999). However, with respect to dietary fat recommendations, the strategy to improve the total cholesterol or LDL cholesterol:HDL cholesterol ratio would not be different from that to decrease LDL cholesterol concentrations.

Lipoprotein(a) Concentrations

Lipoprotein(a) (Lp(a)) concentrations in plasma have been associated with increased risk for developing cardiovascular and cerebrovascular disease, possibly via inhibition of plasminogen activity (Lippi and Guidi, 1999; Nielsen, 1999; Wild et al., 1997). Lp(a) is a lipoprotein particle similar to LDL with respect to its cholesterol and apolipoprotein B100 content, but it also contains an additional apolipoprotein termed apo(a) (Lippi and Guidi, 1999; Nielsen, 1999). Lp(a) concentrations have been reported by some investigators to be increased after the consumption of diets enriched in hydrogenated fat/*trans* fatty acids (Tables 2, 3, and 4) (Almendingen et al., 1995; Aro et al., 1997; Lichtenstein et al., 1999; Mensink et al., 1992; Nestel et al., 1992b; Sundram et al., 1997), but not all (Chisholm et al., 1996; Judd et al., 1998; Lichtenstein et al., 1993; Louheranta et al., 1999; Müller et al., 1998). The magnitude of the mean increases in Lp(a) concentrations associated with *trans* fatty acid intake would not have a physiologically significant effect on cardiovascular disease risk. However, an unresolved issue at this time is the potential effect of relatively high levels of *trans* fatty acids in individuals with initially high concentrations of Lp(a).

Hemostatic Factors

The effect of *trans* fatty acids on hemostatic factors has been assessed by a number of investigators (Almendingen et al., 1996; Mutanen and Aro, 1997; Sanders et al., 2000; Turpeinen et al., 1998; Wood et al., 1993b) (see Table 5). In general, these researchers have concluded that hydrogenated fat/*trans* fatty acids had little effect on a variety of hemostatic variables. Similarly, Müller and colleagues (1998) reported that hemostatic variables were unaffected by the substitution of a vegetable oil-based margarine relatively high in saturated fatty acids when compared to a hydrogenated fish oil-based margarine.

Susceptibility of Low-Density Lipoprotein to Oxidation

Hydrogenated fat/trans fatty acids have consistently been reported to have little effect on the susceptibility of LDL to oxidation (Cuchel et al., 1996; Halvorsen et al., 1996; Nestel et al., 1992b; Sørensen et al., 1998) (Table 5).

TABLE 4 Dietary *Trans* Fatty Acids (TFA), Hydrogenated Fat, and Blood Lipid Concentrations: Free Living Trials

Reference	Study Population	Diet[a]	TFA (% of energy)	Blood Lipid Concentrations[c] LDL-C (mmol/L)	HDL-C (mmol/L)	Lp(a) (units/L)
Nestel et al., 1992a	26 mildly hypercholesterolemic men, 27–57 y	4-wk crossover, 42% fat				
		Control 1	3.8	4.13[c]	1.11[c]	
		Control 2	3.7	4.03[c,d]	1.15[c]	
		Blend 1	6.7	3.92[d,e]	1.10[c]	
		Blend 2	6.6	3.83[e]	1.11[c]	
Nestel et al., 1992b	27 mildly hypercholesterolemic men, 30–63 y	3-wk crossover, 36–37% fat				
		Control	< 1	4.22[c]	0.98[c]	235[c]
		18:1	1.4	3.90[d]	0.98[c]	236[c]
		TFA	5.7	4.27[c]	0.98[c]	296[d]
		16:0	< 1	4.16[c]	1.09[d]	249[e]
Seppänen-Laakso et al., 1993	57 men and women, middle-aged	12-wk crossover to 1 of 2 diets, 39–43% fat		Change from baseline	Change from baseline	
		Margarine	2.9	–0.20	+0.05	
		Rapeseed	0	–0.30	–0.01	
		Olive oil	0	–0.32	0.00	
Wood et al., 1993a	38 healthy men, 30–60 y	6-wk crossover, 38% fat				
		Butter	2.1	3.78[c]	1.22[c]	
		Butter-sunflower	1.0	3.49[d]	1.19[c]	
		Butter-olive	1.0	3.59[d]	1.22[c]	
		Hard margarine	11.1	3.47[d]	1.16[c]	
		Soft margarine	0	3.26[e]	1.16[c]	
Wood et al., 1993b	29 healthy men, 30–60 y	6-wk crossover, 37% fat				
		Butter	0.2	3.52[c]	1.03[c]	
		Crude palm	0	3.36[c]	1.03[c]	
		Margarine	3.0	3.36[c]	1.00[c]	
		Refined palm	0	3.41[c]	1.06[d]	
		Refined palm+sunflower	0	3.41[c]	1.03[c]	
		Sunflower oil	0	3.23[d]	1.00[c]	

Chisholm et al., 1996	49 hypercholesterolemic men and women, avg 47 y	6-wk crossover, 26–27% fat				
		Butter	1.4	4.21[c]	1.26[c]	223[c]
		Margarine	3.6	3.82[d]	1.24[c]	249[c]
Noakes and Clifton, 1998	38 mildly hyperlipidemic men and women	3-wk crossover, 2 groups, 31–35% fat				
		Canola + TFA	3.3	3.64[c]	1.19[c]	
		TFA-free canola	0	3.61[c]	1.28[c]	
		Butter	1.1	4.14[d]	1.20[c]	
		PUFA + TFA	3.6	4.23[c]	1.17[c]	
		TFA-free PUFA	0	3.98[d]	1.23[c]	
		Butter	1.2	4.70[e]	1.27[c]	

[a] PUFA = polyunsaturated fatty acids
[b] LDL-C = low-density lipoprotein cholesterol, HDL-C = high-density lipoprotein cholesterol, Lp(a) = lipoprotein(a).
[c,d,e] Different lettered superscripts within each study indicates values were significantly different.

TABLE 5 *Trans* Fatty Acid (TFA) Intake and Blood Clotting, Blood Pressure, and Low-Density Lipoprotein (LDL) Oxidation

Reference	Study Population	Diet[a]	TFA (% of energy)	Results[b]		Comments
Clotting						
Wood et al., 1993b	29 men, 30–60 y	6-wk crossover, 37% fat		TXB_2 (pg/mL)	6-keto-$PGF_{1\alpha}$ (pg/mL)	
		Butter	0.2	35[c]	89[d]	
		Crude palm oil	0	41[c]	94[c]	
		Margarine	3.0	40[c]	86[d]	
		Refined palm oil	0	40[c]	87[d]	
		Refined palm+sunflower	0	36[c]	100[c]	
		Sunflower oil	0	62[c]	95[c]	
Almendingen et al., 1996	31 men, avg 27 y	3-wk crossover, 33–36% fat		Fibrinogen (g/L)	PAI-1 activity (units/mL)	For PHSO, greater PAI-1 activity than PHFO or butter
		PHSO	8.5	3.0	13.5	Increased fibrinogen with butter diet
		PHFO	8.0	2.9	10.7	No significant difference in factor VII, fibrinogen peptide A, β-thromboglobulin, or tissue plasminogen activator
		Butter	0.9	3.1	8.8	
Mutanen and Aro, 1997	80 men and women, 20–52 y	5-wk crossover to 1 of 2 diets, 33–34% fat		Fibrinogen (g/L)		No marked difference in factor VII coagulation activity, tissue type plasminogen activity, or PAI-1 activity
		High 18:0	0.4	3.62		
		High TFA	8.7	3.61		
Turpeinen et al., 1998	80 men and women, 20–52 y	5-wk crossover to 1 of 2 diets, 32–34% fat				No difference in TXB_2 production or adenosine diphosphate-induced platelet aggregation in vitro
		18:0	0.4			Significant increase in collagen induced aggregation with 18:0 diet
		TFA	8.7			
Sanders et al., 2000	16 men and women, 18–32 y	1 test-meal crossover, 7% or 65% fat		$FVII_c$ (% standard)	$FVII_a$ (ng/mL)	No significant differences in factor VII coagulation activity; factor VII-activated concentrations were significantly higher with 18:1, 18:1 *trans*, 18:0, and 16:0 diets
		18:1	0.1	124	2.7	
		18:1 *trans*	24.7	122	1.9	
		18:0	0	114	1.9	

		16:0	0.2	112	2.1	
		MCT	0	112	1.5	
		Low fat	0	99	1.4	
Oxidation						
Cuchel et al., 1996	14 men and women, 44–78 y	32 d crossover, 30% fat				No difference in susceptibility to LDL oxidation
		Corn oil	0.44			
		Corn oil+margarine	4.16			
Halvorsen et al., 1996	29 men, 21–46 y	19-d crossover, 33–36% fat		Dienes (nmol/mg LDL)	Formation rate (nmol/mg LDL × min)	No significant differences in conjugated dienes, lipid peroxides, uptake by marcophages, or electrophoretic mobility of LDL
		Butter	0.9	1,020	10	
		PHSO	8.5	1,034	10	TFA does not alter susceptibility to LDL oxidation
		PHFO	8.0	1,107	10	
Sørensen et al., 1998	47 men, 29–60 y	4 wk, consumed 30 g/d of 1 of 2 margarines	(mol % of fat)	Dienes (nmol/g)	Oxidation rate (nmol/mg × min)	Fish oil consumption compared with sunflower oil margarine had no effect on LDL size and led to minor changes in LDL oxidation resistance
		Sunflower oil	0.79	445	10.4	
		Fish-oil, enriched	0.98	468	10.2	
Blood Pressure						
Mensink et al., 1991	59 men and women, 19–57 y, normo-tensive	3-wk crossover, 39–40% fat		SBP (mmHg)	DBP (mmHg)	No effect of TFA intake on blood pressure
		18:1	0	113	66	
		TFA	10.9	112	67	
		SFA	1.8	112	67	
Zock et al., 1993	55 men and women, 19–49 y	3-wk crossover, 40–43% fat		SBP (mmHg)	DBP (mmHg)	No effect of TFA intake on blood pressure
		18:2	0.1	114	68	
		18:0	0.3	113	70	
		TFA	7.7	113	69	

[a] PHSO = partially hydrogenated soy bean oil, PHFO = partially hydrogenated fish oil, MCT = medium-chain triacylglycerol, SFA = saturated fatty acid.
[b] TXB_2 = thromboxane B_2, 6-keto-$PGF_{1\alpha}$ = 6-keto-prostaglandin $F_{1\alpha}$, PAI-1 = plasminogen activator inhibitor type 1, $FVII_c$ = factor VII coagulant activity, $FVII_a$ = factor VII activated, SBP = systolic blood pressure, DBP = diastolic blood pressure.
[c,d] Different lettered superscripts within each study indicates values were significantly different.

Blood Pressure

A few reports addressed the issue of trans fatty acid intake and blood pressure (Mensink et al., 1991; Zock et al., 1993) (Table 5). The authors concluded that consumption of diets high in saturated, monounsaturated, or trans fatty acids resulted in similar diastolic and systolic blood pressures.

Coronary Heart Disease

Similar to saturated fatty acids, there is a positive linear trend between *trans* fatty acid intake and LDL cholesterol concentrations (Judd et al., 1994; Lichtenstein et al., 1999; Zock and Katan, 1992). Some evidence also suggests that *trans* fatty acids result in lower HDL cholesterol concentrations (Table 6). Hence, the net result is a higher total cholesterol (or LDL cholesterol):HDL cholesterol ratio (Judd et al., 1994; Lichtenstein et al., 1999; Zock and Katan, 1992). This finding, combined with data from prospective cohort studies (Ascherio et al., 1996; Gillman et al., 1997; Hu et al., 1997; Pietinen et al., 1997; Willett et al., 1993) (Table 6), has lead to the concern that dietary *trans* fatty acids are more deleterious with respect to coronary heart disease than saturated fatty acids (Ascherio et al., 1999).

Summary

There is a positive linear trend between *trans* fatty acid intake and total and LDL cholesterol concentration, and therefore increased risk of CHD, thus suggesting a Tolerable Upper Intake Level (UL) of zero. Because *trans* fatty acids are unavoidable in ordinary diets, achieving such a UL would require extraordinary changes in patterns of dietary intake. Such extraordinary adjustments may introduce other undesirable effects (e.g., elimination of foods, such as dairy products and meats, that contain *trans* fatty acids may result in inadequate intakes of protein and certain micronutrients) and unknown and unquantifiable health risks may be introduced by any extreme adjustments in dietary pattern. For these reasons, no UL is proposed. Nevertheless, it is recommended that *trans* fatty acid consumption be as low as possible while consuming a nutritionally adequate diet.

TABLE 6 Dietary *Trans* Fatty Acids (TFA): Epidemiological Studies

Reference	Study Design[a]	Dietary and Other Information	Results[b]			Comments
Lipoprotein concentration						
Siguel and Lerman, 1993	47 CAD cases 56 controls Case-control	No dietary intake information	Plasma TFA (%) HDL (mmol/L) LDL (mmol/L) TAG (mmol/L)	Case 1.38 0.88 3.78 1.78	Control 1.11 1.34 2.97 0.97	TFA negatively associated with HDL TFA positively associated with LDL and TAG
Coronary heart disease (CHD)						
Hudgins et al., 1991	76 men, 23–78 y Cross sectional	No dietary intake information	Total TFA in adipose tissue was 4.4% of total fatty acids			Total TFA content in adipose tissue was not significanlty related to risk factors of CHD (e.g, age, body mass index, LDL, cholesterol, blood pressure)
Troisi et al., 1992	748 men, 43–85 y Cross sectional	Food frequency questionnaire, multivariate analysis	TFA intake was directly related to total (r = 0.07, P = 0.04) and LDL (r = 0.09, P = 0.01) cholesterol			An increased TFA intake from 2.1 to 4.9 g/d increased the risk of MI by 27%
Willett et al., 1993	Women, 431 CHD cases Cohort, 8-y follow-up,	Food frequency questionnaire, multivariate analysis	TFA intake (% energy) 1.3 1.8 2.2 2.6 3.2		RR of CHD 1.0 1.4 1.25 1.55 1.8	Positive association with TFA intake and risk of CHD
Ascherio et al., 1994	239 MI cases 282 controls Case-control	Food frequency questionnaire, multivariate analysis	TFA intake (g/d) 1.69 2.48 3.35 4.52 6.51		RR of MI 1.0 0.73 1.24 1.63 2.28	Positive association of TFA intake and risk of myocradial infarction

continues

TABLE 6 Continued

Reference	Study Design[a]	Dietary and Other Information	Results[b]		Comments
Kromhout et al., 1995	12,763 men, 40–59 y Cohort, 25-y follow-up	Weighed food record	Correlation between 18:1*trans* intake and CHD mortality is 0.78 ($p < 0.001$)		
Ascherio et al., 1996	43,757 men, 40–75 y Cohort, 6-y follow-up	Food frequency questionnaire, multivariate analysis	TFA intake (g/d) 1.5 2.2 2.7 3.3 4.3	RR of MI 1.0 1.20 1.24 1.27 1.40	TFA intake directly associated with risk of MI
Hu et al., 1997	Women, 34–59 y 939 MI cases Cohort, 14-y follow-up	Food frequency questionnaire, multivariate analysis	TFA intake (% energy) 1.3 1.7 2.0 2.4 2.9	RR of MI 1.0 1.07 1.10 1.13 1.27	RR for 2% increment in energy from TFA intake was 1.93
Gillman et al., 1997	Men, 45–64 y 267 CHD cases Cohort, 21-y follow-up	24-h recall, multivariate analysis	Margarine intake (tsp/d) 0 1–4 ≥ 5	No. of events (/1,000) Period 1 / Period 2 77 / 65 42 / 35 18 / 30	RR for CHD for each increment of 1 tsp/d was 0.99 for follow-up period 1 and 1.12 for period 2 Modest risk of CHD with increasing margarine intake
Pietinen et al., 1997	Smoking men, 50–69 y 1,399 coronary events 635 coronary deaths Cohort, 6.1-y follow-up	Food frequency questionnaire, multivariate analysis	TFA intake (g) 1.0 1.7 2.0 2.7 6.2	RR of major coronary event 1.00 1.10 0.97 1.07 1.14	Positive association between TFA intake and risk of coronary death

			TFA intake (g) 1.0 1.7 2.0 2.7 6.2	RR of coronary death 1.00 1.05 1.12 0.90 1.39	
Tavani et al., 1997	Women, 18–74 y 429 MI cases 866 controls Case-control	Questionnaire on selected indicator foods, multivariate analysis	Margarine intakes No or low Medium or high	RR of MI 1.0 1.5	The association with margaine could explain about 6% of MI in this population
Cancer					
Kohlmeier et al., 1997	Women, 50–74 y 291 breast cancer cases 407 controls Case-control	No diet information	Adipose TFA concentration TFA TFA within lowest PUFA tertile TFA within highest PUFA tertile	OR of breast cancer 1.46 3.65 0.97	Risk for breast cancer is based on the relative concentration of TFA and PUFA
Tuyns et al., 1988	35–75 y 453 colon cancer cases 365 rectal cancer cases 2,851 controls Case-control	Dietary history			There was no increased risk of either cancers from with increased consumption of margarine

[a] CAD = coronary artery disease, MI = myocardial infarction.
[b] HDL = high-density lipoprotein cholesterol, LDL = low-density lipoprotein cholesterol, TAG = triacylglycerol, RR = relative risk, OR = odds ratio, PUFA = polyunsaturated fatty acid.

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Declaration of Erich O. Grosz

Exhibit 7

Case No. 1:07-CV-01092 (RJL)

Nutrition Subcommittee of the
Food Advisory Committee[1]
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)

SUMMARY MINUTES
April 27 & 28, 2004
Loew's L'Enfant Plaza
Washington, DC

Members Present
Norman I. Krinsky, Ph.D., Chair
Susan S. Baker, Ph.D.
R. Jean Hine, Ph.D.
Susan T. Mayne, Ph.D.
Suzanne Pelican, M.S., R.D.
Barbara M. Shannon, Ph.D.
Michael J. McGinnis, M.D., M.P.P. (April 28, 2004)
Guy Johnson, Ph.D.
Eric Rimm, Ph.D.[2]
Alice Lichtenstein, Ph.D.[2]

FDA Staff Present
Jeanne E. Latham, R.D., M.S., Executive Secretary
Robert E. Brackett, Ph.D. (April 28, 2004)
Virginia Wilkening, R.D.
Kathleen C. Ellwood, Ph.D.
Paula Trumbo, Ph.D.
Amy Odegaard, M.S.
Kathleen Smith, R.D.

Agenda

April 27, 2004

The Nutrition Subcommittee ("Subcommittee") of the Food Advisory Committee met on April 27 and 28, 2004, at Lowes L'Enfant Plaza Hotel. Norman I. Krinsky, Chair, Ph.D., called the meeting to order at 12:30 p.m., Tuesday, and introduced the Subcommittee members. Ms. Virginia Wilkening, Deputy Director of the Office of Nutritional Products, Labeling, and Dietary Supplements (ONPLDS), CFSAN, welcomed everyone and made introductory remarks. Jeanne Latham, Executive Secretary, read the conflict of interest statement into the record, announced the appointment of the temporary voting members, and reviewed the FDA policy regarding the disclosing of personal financial interests by public commenters.

[1] The entire meeting was open to the public. For the verbatim transcript of the meeting, contact FDA Dockets Management Branch (HFA-305), 12420 Parklawn Drive, Rockville, Maryland 20857.
[2] Temporary voting member.

Dr. Kathleen Ellwood gave an overview of FDA's activities relative to *trans* fatty acid labeling, provided background information as a context for the questions, and presented the charges and questions to the Subcommittee. Regarding the first question, Dr. Ellwood described some of the health claims that bear a low total fat criterion, some of the exemptions that FDA has made and the basis for those exemptions. She stated that there seems to have been a shift in the current scientific evidence relative to heart disease, such as the Dietary Guidelines for Americans 2000 and the recent Institute of Medicine (IOM)/National Academy of Sciences macronutrient report, from looking at total fat to the need to consider the type of fat in the diet. Dr. Ellwood indicated that the agency would like to know what scientific evidence suggests in terms of total fat intake and risk of coronary heart disease (CHD), keeping in mind that FDA continues to apply disqualifying levels for low saturated fat and cholesterol for health claims pertaining to heart disease risk. Regarding the second question to the Subcommittee, Dr. Ellwood stated that in the absence of having a Daily Value for *trans* fatty acids, the agency needs to know whether scientific evidence supports a level of one percent of energy (2 g per 2,000 calories) from *trans* fatty acids, as is being proposed by the Dietary Guidelines Committee. Regarding the third question, the agency would like to know if, when compared to saturated fatty acids, *trans* fatty acids are considered to be more, less, or similarly adverse with respect to CHD.

Dr. Krinsky began the meeting by asking for comments and discussion about the three FDA questions to the Subcommittee.

Questions to the Subcommittee

Question #1: One eligibility criterion that FDA has applied to most health claim regulations pertaining to heart disease risk is that foods bearing these claims must be low in total fat. What does the current evidence suggest in terms of total fat intake and risk of coronary heart disease?

Question #2: The Dietary Guidelines Committee may suggest that less than 1% of energy should be obtained from *trans* fatty acids (2 g per day for a 2,000 kcal diet). Does the scientific evidence support this level?

Question #3: When compared to saturated fatty acids, are *trans* fatty acids considered to be more, less or similarly adverse with respect to coronary heart disease?

Public Comment

Dr. Krinsky commenced the open public hearing at 4:35 p.m. He read into the record the statement regarding FDA's policy about disclosure of financial relationships for public commenters. The following members of the public made oral presentations: Robert Earl, Senior Director of Nutrition Policy at the National Food Processors Association (NFPA); Martin Hahn of Hogan and Hartson, on behalf of GFA Brands, Inc.; and Mary Enig, Ph.D., Vice President and Science Advisor of the Weston A. Price Foundation.

Mr. Earl discussed the NFPA's position and principles about disqualifying levels of nutrients for health claims and perspectives on data needs and utility of a DV for *trans* fatty acids. Mr. Hahn discussed the scientific evidence establishing the importance of considering the blend of fatty acids in the total diet when considering risk factors for heart disease. Dr. Enig addressed the

second and third questions to be discussed by the Subcommittee on the level of *trans* fatty acids in the diet and the health effects of *trans* fatty acids on risk of coronary heart disease.

The Subcommittee discussed the three questions and voted on Question 3.

Dr. Krinsky adjourned the meeting on Day 1, at 6:00 p.m.

April 28, 2004

Dr. Krinsky called the meeting to order at 8:00 a.m. on Wednesday, April 28, 2004. Dr. Brackett, Director of CFSAN, welcomed the Subcommittee members and provided opening remarks. Dr. Michael McGinnis joined the meeting as a non-voting participant.

The Subcommittee again discussed and voted on Questions 1 and 2, and provided comments to Question 3.

Dr. Krinsky adjourned the meeting on Day 2 at 11:00 a.m.

Subcommittee Deliberations, Recommendations, and Vote:

Question #1: One eligibility criterion that FDA has applied to most health claim regulations pertaining to heart disease risk is that foods bearing these claims must be low in total fat. What does the current evidence suggest in terms of total fat intake and risk of coronary heart disease?

With respect to Question 1, the Subcommittee discussed what scientific evidence exists and the strength of the evidence that links total fat intake to risk of coronary heart disease (CHD). Dr. Lichtenstein stated that the data support the impact of different fatty acids on CHD risk and the effect of the total fat content of the diet is far less significant, if not at all. As a matter of background, Dr. Lichtenstein shared that some of the initial reasoning behind recommending diets low in total fat, saturated fat and cholesterol was that by decreasing total fat, at least in the U.S., saturated fat is decreased. The low total fat recommendation took on a life of its own independent of the low saturated fat recommendation. There was a proliferation of products low in total fat that had not been high in saturated fat to begin with. Use of these products resulted in a net increase in carbohydrate intake, primarily as refined carbohydrate and simple carbohydrates without much impact on saturated fat intake. Because of this unexpected trend in the marketplace, the total fat issue was reassessed during the deliberations of the 2000 Dietary Guidelines Committee.

Dr. Rimm recalled an issue discussed by the IOM Panel on Macronutrients, that it is difficult to interpret the effects of a high fat versus low fat diet, depending upon what nutrients are substituted for fat. He pointed out that the evidence, including the Nurses Health Study, supports that there is essentially no association between total fat and risk of CHD within the range of what people eat. Rather it is saturated and *trans* fatty acids that are implicated in heart disease risk. Additionally, he said that current evidence suggests that the fatty acid component in the diet is more important than the total amount of fat. The Subcommittee members recognized that there

are studies underway that may identify a relationship between total fat in the diet and other chronic diseases, like cancer and obesity.

The Subcommittee had a difficult time trying to answer the question as originally stated. As agreed to by the Subcommittee and FDA and so that the Subcommittee could provide a yes or no answer, Question 1 was revised by FDA to read:

Does the current scientific evidence suggest a relationship between total fat intake and risk of coronary heart disease?

The Subcommittee continued its discussion addressing the revised question. Various members suggested further modifications to the question. Dr. Johnson stated that what needs to be addressed is should there be an across-the-board requirement or eligibility criterion that foods that make cardiovascular health claims be low in fat. He mentioned that FDA already has eligibility criteria for saturated fat and cholesterol with respect to cardiovascular disease health claims.

Vote on Question 1: Dr. Krinsky called for a vote on the FDA revised question. There were six members that voted no, two members abstained.

Following the vote, Ms. Pelican suggested that it should be made clear that dropping the requirement for health claims for foods to be low in total fat is based on evidence for CHD only, and should not be inferred to mean that total fat is not an important consideration in other areas of intake, e.g., energy density and energy balance.

Question #2: The Dietary Guidelines Committee may suggest that less than 1% of energy should be obtained from *trans* fatty acids (2 g per day for a 2,000 kcal diet). Does the scientific evidence support this level?

Regarding Question 2, the Subcommittee discussed several scientific papers that point to different levels of *trans* fatty acids as percent of calories consumed and their impact on changes in blood lipoprotein concentrations and relative risk of CHD. Dr. Lichtenstein began the discussion and stated that in the studies, among the lower levels of *trans* fatty acids, the differences with respect to the increase in low density lipoprotein (LDL) cholesterol levels were not statistically distinguishable. She added that no studies have really focused on the range of *trans* fatty acid intake of between zero and 3-4 percent of calories to indicate that 1 percent is more efficacious than 0.5 or 1.5 percent. She stated that the evidence indicates that intake of *trans* fatty acids raises LDL cholesterol levels and decreases high density lipoprotein (HDL) cholesterol levels, whereas saturated fats only raise LDL cholesterol levels. Dr. Lichtenstein shared that the estimated average intake of *trans* fatty acids is between about 1.5 and 2.6 percent of calories.

Dr. Rimm pointed out that the IOM Panel, in interpreting the science, could not come up with a health reason for having *trans* fatty acids in the diet. Based on scientific data that indicated that with increased intake of cholesterol, saturated and *trans* fatty acids, there was an increased risk of CHD, the IOM Panel recommended that *trans* fatty acid intake, as well as saturated fat and cholesterol intakes, should be as low as possible. Dr. Lichtenstein added that the IOM report

indicated that it is essentially impossible to have a nutritionally adequate diet by totally eliminating *trans* fatty acids. Dr. Rimm also pointed out that natural *trans* fatty acids that occur in ruminant animals are not associated with CHD, and their contribution to a person's daily intake is small, about 1 gram per day. Dr. Rimm put forward that the totality of evidence suggests a dose response between increasing *trans* fatty acid intakes, increasing biological markers and increasing CHD.

The Subcommittee recognized that some companies have begun to reduce or eliminate *trans* fatty acids from their products, but there are no recent data on dietary intakes of *trans* fatty acids in the U.S., so the impact of the current food supply is not known.

For the benefit of the Subcommittee, Ms. Wilkening explained how *trans* fatty acids will appear on the Nutrition Facts Panel of food products, the fact that there is currently no percent Daily Value (%DV), and the FDA request for comment regarding whether to list one joint %DV for both saturated fat and *trans* fatty acids. The Subcommittee discussed how additional label information on *trans* fatty acids might be helpful versus confusing to consumers.

As part of the discussion, many members agreed that education about *trans* fatty acids has to be an important component of the advisory committee recommendations. Some of the members felt that it is important to communicate information about both *trans* and saturated fatty acids, since they are not the same.

Vote on Question 2: Dr. Krinsky called for a vote on Question 2. There were five members that voted no; three members voted yes.

The majority of Subcommittee members agreed to transmit a statement to the FDA, as an addendum to Question 2, that although current scientific evidence does not indicate a specific acceptable daily intake for *trans* fatty acids, it is consistent with reducing *trans* fatty acid intake to a level of less than 1 percent of energy (2 grams per day for a 2,000 kilocalorie diet).

Question #3: When compared to saturated fatty acids, are *trans* fatty acids considered to be more, less or similarly adverse with respect to coronary heart disease?

With respect to Question 3, Dr. Rimm pointed out that intervention studies show that *trans* fatty acid intake increases LDL or LDL/HDL ratio - risk factors of CHD - in a dose-dependent manner by about two to three-fold that of saturated fatty acids. With observational studies, the risks associated with a 1 percent increment in *trans* fatty acid is about three to four times that observed for a 1 percent increase in saturated fatty acid. In the interventional studies, that magnitude of change is unlikely to have a measurable biological effect, at least in the short term. Additionally, Dr. Rimm stated that when looking at diabetes research, it seems that there is an impact for *trans* fatty acids and not for saturated fat. Insulin sensitivity research suggests that there is an adverse effect for *trans* fatty acids and not necessarily for saturated fat. With regard to inflammatory markers, there are a number of biological studies, some observational and some experimental, that would suggest that *trans* fatty acids are very different from saturated fat. Within the range of 1 to 6 percent of energy of *trans* fatty acids, there is a very big difference in the impact of *trans* fatty acids compared to saturated fat on measurable biological effects (lipids). Dr. Lichtenstein pointed out that at low levels of intake of *trans* fatty acids, e.g., at one and two

percent of energy, there seems to be little difference in the effect of *trans* fatty acids versus saturated fatty acids on risk of CHD. She indicated that in intervention studies there is less of an effect than seen in observational studies. So, in the interventional studies that magnitude of change is unlikely to have a measurable biological effect, at least in the short term.

Dr. Krinsky added that, as stated in earlier discussion, at higher intake levels, a marked difference between *trans* fatty acids and saturated fatty acids is observed, with *trans* fatty acids being more adverse with respect to CHD.

Dr. Rimm pointed out that *trans* fatty acids are different than saturated fat, and *trans* fatty acids will be quantitatively listed on the label. He indicated that consumers need to be aware that at very low intake levels of *trans* fatty acids intake, the impact on blood lipids is not different than saturated fat; however, at higher intake levels, the impact of *trans* fatty acids is more adverse than saturated fat. Dr. Mayne suggested that there is a continuum when looking at effects of *trans* fatty acids versus saturated fat, i.e., the difference is more magnified as intake levels increase, keeping in mind that datapoints are lacking.

Dr. Johnson added that the *trans* fatty acid message needs to be communicated by more than just the nutrition label, and this should be a shared responsibility with FDA, other government agencies, the Dietary Guidelines Committee and industry. Other members of the Subcommittee agreed that the public needs more education regarding *trans* fatty acid intake.

Vote on Question 3: Dr. Krinsky called for a vote on Question 3. The vote was 8 yes's, zero no's, zero abstentions, that *trans* fatty acids are more adverse with respect to CHD.

Dr. Johnson provided an additional comment on Question 3. He indicated that the "yes" answer does not reflect the considerable uncertainty discussed by the Subcommittee as to whether this difference is significant from a public health perspective at the level of *trans* fatty acid intake that is typical in the United States.

I certify I attended the April 27-28, 2004 meeting of the Nutrition Subcommittee of the Food Advisory Committee, and these summary minutes accurately reflect what transpired.

Jeanne E. Latham, R.D., M.S. 05/26/04

Jeanne E. Latham, R.D., M.S. Date
Executive Secretary

Norman I. Krinsky 05/25/04

Norman I. Krinsky, Ph.D. Date
Chair

Declaration of Erich O. Grosz

Exhibit 8

Case No. 1:07-CV-01092 (RJL)

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Petition for Rulemaking to Revoke
the Authority for Industry to
Use Partially Hydrogenated
Vegetable Oils in Foods

Docket No. _____

submitted by the

CENTER FOR SCIENCE IN THE PUBLIC INTEREST

May 18, 2004

Michael F. Jacobson, Ph.D.
Executive Director
Suite 300
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Washington, D.C. 20009
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Contents

Dockets Management Branch
United States Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

CITIZEN PETITION

I. PRELIMINARY STATEMENT

The Food and Drug Administration ("FDA") concluded in November 1999 that 2,500 to 5,600 lives could be saved each year if the amount of trans fatty acids in packaged foods – but not food served in restaurants[1] – were disclosed,[2] and it concluded in July 2003 that 240 to 480 or more lives will be saved each year because of its requirement that beginning in 2006 the amount of trans fatty acids in packaged foods be disclosed.[3] It is now incumbent on the FDA to take the next step toward protecting the public health: revoking the legal authority for industry to

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[1] Section 403(q)(5) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. 343(q)(5), generally prohibits the FDA from applying its 2003 trans-fat labeling requirement to food either served in a restaurant or processed and sold in a retail establishment for consumption elsewhere. However, the FDA's food labeling regulations do apply to restaurants that make a health or nutrient content claim. Section 403(r)(1)(A) of the FFDCA, 21 U.S.C. 343(r)(1)(A), says that a food is misbranded if its label contains a claim that has not been approved by the FDA, and the FDA's regulations provide that, if an approved claim is made by a restaurant, the restaurant must "provide information on the nutrient that is the basis for the claim, e.g., 'low fat, this meal contains 10 grams of fat.'" *A Guide for Restaurants and Other Retail Establishments* (FDA Center for Food Safety and Applied Nutrition February 1996) (question 73 interpreting 21 C.F.R. 101.10). The FDA has not yet approved any nutrient content or health claim for trans fat, other than establishing that products that contain less than 0.5 grams per serving can be considered to contain no trans fat. 68 Fed. Reg. at 41502.

[2] 64 Fed. Reg. 62746-62825 (November 17, 1999). (proposed rule to require that trans fatty acids be declared in the nutrition label)

[3] 68 Fed. Reg. 41434-41499 (July 11, 2003) (final rule requiring that trans fatty acids be declared in the nutrition label of conventional foods and dietary supplements). As discussed elsewhere, the 1999 and 2003 estimates were based on different assumptions and cannot be compared.

use partially hydrogenated vegetable oils[4] in both packaged foods and foods served in restaurants and other food-service establishments (where Americans now consume about 38 percent of their total fat intake[5]). Our extrapolation from the FDA's 1999 and 2003 analyses indicates that that step could save upwards of 11,000 to 30,000 additional lives each year.[6]

While some trans fatty acids[7] occur naturally in the dairy and meat products from ruminant animals, the FDA concluded in 2003 that about 80 percent of dietary trans fat comes from partially hydrogenated vegetable oils.[8] Those vegetable oils are subjected to chemical hydrogenation to increase their melting point, shelf and fry life, and flavor stability. As the FDA explained in 1999, "Through hydrogenation, oils (i.e., fats in liquid form), such as soybean, safflower, and cottonseed oil, which are rich in unsaturated fatty acids, are converted to semi-solids and solids that are useful in margarines and vegetable shortenings."[9]

This petition does not request any limitation on the trans fat that either occurs naturally in meat and dairy fats or forms during the production of nonhydrogenated oils,[10] because those

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[4] For stylistic convenience we use the term vegetable oils throughout this petition even though, in some contexts, the term includes menhaden oil, which is a fish oil, and partially hydrogenated lard.

[5] Lin B, Guthrie J, Frazao E., *Away-From-Home Foods Increasingly Important to Quality of American Diet* (United States Department of Agriculture, Economic Research Service Information Bulletin No. 749, 1999) Table 3 at 5. In 1995, 38 percent of total fat consumption occurred away from home, as compared to 18 percent in 1977-78.

[6] See *infra* sections III.C. and III.G.

[7] We agree with the FDA's 2003 definition of trans fatty acids: all unsaturated fatty acids – regardless of origin – that contain one or more isolated double bonds in a trans configuration. 68 Fed. Reg. at 41461. The FDA notes that its definition is not identical to the one used by the Institute of Medicine. In this petition we use the terms trans fat and trans fatty acids interchangeably.

[8] Calculated from data in Table 1 at 68 Fed. Reg. at 41470. CSPI is not concerned about fully hydrogenated oils, which do not contain trans fatty acids.

[9] 64 Fed. Reg. at 62749 (November 17, 1999).

[10] And so it differs from the citizen petition filed in June 2003 by Diana E. Kelly and denied, without prejudice, by the FDA in December 2003. Docket Number 2003P-0289/CPI. That petition asked the FDA to prohibit in food products trans fatty acids from any source.

amounts are small and apparently unavoidable.[11] Nor does it affect either fully hydrogenated oils, which contain negligible amounts of trans fat, or partially hydrogenated oils that may be produced by new technologies that result in negligible amounts of trans fat in the final product.

II. ACTION REQUESTED

The Center for Science in the Public Interest[12] ("CSPI") requests[13] that the FDA – consistent with its regulations[14] – immediately initiate a rulemaking to:

(1) revoke all the "generally recognized as safe" statuses[15] of partially hydrogenated oils in foods – including shortening,[16] soybean oil,[17] menhaden oil,[18] and partially

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[11] Consumers could avoid naturally occurring trans fat by eating low-fat or non-fat meat and dairy products or not eating those foods at all. Further research is needed on the health effects of the naturally occurring isomers of the trans fatty acids in beef and dairy products. The mix of isomers is different from the isomers in partially hydrogenated oil and might have different effects on health.

[12] Petitioner Center for Science in the Public Interest, a nonprofit organization based in Washington, D.C., is supported by about 850,000 members in the United States and Canada who subscribe to its *Nutrition Action Healthletter*. CSPI has been working to improve the nation's health through better nutrition and safer food since 1971.

[13] This petition is submitted pursuant to section 4(e) of the Administrative Procedure Act, 5 U.S.C. 553(e), and 21 C.F.R. 10.25 and 10.30.

[14] 21 C.F.R. 170.6(c) provides that ingredients "which have been considered in the past by the Food and Drug Administration to be safe under the provisions of section 402(a)(1) [of the Federal Food, Drug, and Cosmetic Act], or to be generally recognized as safe for their intended use, or to have prior sanction or approval, or not to be food additives under the conditions of intended use, must be reexamined in the light of current scientific information and current principles for evaluating the safety of food additives if their use is to be continued."

[15] Section 201(s) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(s), excludes from the legal definition of a food additive an ingredient that "is generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown...to be safe under the conditions of its intended use." An ingredient can be classified as "generally recognized as safe" by a public formal determination by the FDA, a letter from the FDA, or a self-determination by a food company.

[16] The FDA approved the use of shortening in bread, rolls, and buns when in 1977 it established a "standard of identity" for bread, rolls, and buns. 21 C.F.R. 136.110(c)(5).

[17] The FDA approved the use of vegetable oils in semi-solid foods in 1977 when it established "standards of identity" for mayonnaise, 21 C.F.R. 169.140, salad dressing, 21 C.F.R.

hydrogenated low erucic acid rapeseed oil (canola oil)[19] – so that they would be legally classified as food additives. Absent a regulation "prescribing the conditions under which such additive may be safely used," it would then be illegal to continue using those food additives;[20]

(2) revoke the current "safe conditions" for those partially hydrogenated vegetable oils that the FDA has approved as food additives;[21] and

(3) prohibit the use of any partially hydrogenated vegetable oil which is not classified as a food additive because the FDA sanctioned or approved its use prior to September 6, 1958.[22]

The FDA should also immediately announce that it will complete this rulemaking by the last year of the next Administration, *i.e.*, by 2008. This deadline seems reasonable in light of the overwhelming scientific evidence that establishes the public health risks of partially hydrogenated vegetable oil and would give the FDA two years to observe the impact of its mandatary trans-labeling requirement. Industry should be given two additional years to switch to other ingredients.

CSPI also urges the FDA immediately (prior to deciding on the merits of the regulatory actions requested in this petition) to develop a program to encourage food manufacturers and restaurants to replace partially hydrogenated oils with the most healthful ingredients possible.

160.150, and margarine. 21 C.F.R. 166.110(a)(1) .

[18] 21 C.F.R. 184.1472(b).

[19] 21 C.F.R. 184.1555(c).

[20] Section 409(a)(2) of the FFDCA, 21 U.S.C. 348(a)(2). Absent a regulation establishing the conditions whereby a food additive can be safely used, a food that contains a food additive is adulterated and, accordingly, cannot legally be introduced into interstate commerce. See sections 402(a)(2)(C)(i), 409, and 301(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 342(a)(2)(C)(i), 348, and 331(a).

[21] Such as partially hydrogenated methyl ester of rosin. 21 C.F.R. 172.515(b) and 172.615.

[22] The FDA's current regulations provide that "Based upon scientific data or information that shows that use of a prior-sanctioned food ingredient may be injurious to health,...the Commissioner will establish or amend an applicable prior sanction regulation to impose whatever limitations or conditions are necessary for the safe use of the ingredient, or to prohibit use of the ingredient." 21 C.F.R. 181.1(b).

As part of the requested rulemaking or if any party objects to the FDA's proposal as requested in this petition, the FDA could invite public comment on tolerances for trans fat. Considering that even conventionally processed liquid vegetable oils contain low levels of trans fat, FDA might wish to set a *de minimus* level of trans fat in conventional (refined, bleached, deodorized) oils and fully hydrogenated oils and apply the same tolerance to partially hydrogenated oils. As discussed below in section III.F., the Danish government recently limited the amount of trans fat from partially hydrogenated oils to two percent of the total fat or oil in the food.

III. BACKGROUND

A. The FDA's approval or informal acceptance of various uses of partially hydrogenated vegetable oils relied on scientific evidence from the 1980s, 1970s, and earlier that indicated that consumption of trans fat did not cause any human health problem.

Although partially hydrogenated vegetable oils had been used since the 1930s, in 1976 the Federation of American Societies for Experimental Biology ("FASEB"), at the request of the FDA, reviewed the scientific literature on the health aspects of using "hydrogenated" soybean oil as a food ingredient.[23] The FASEB was informed by the FDA in July 1976 that the FDA had given "unpublished approval" for the use of hydrogenated soybean oil as a Generally Recognized As Safe (GRAS) food ingredient because the FDA considered it to be safe and had, in particular, approved its use in food dressings and in margarine.[24] The FASEB then concluded "There is no evidence in the available information on hydrogenated soybean oil that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when it is used as a direct or indirect food ingredient at levels that are now current or that might reasonably be expected in the future."[25]

The FDA approvals for using [partially] hydrogenated vegetable oils in food dressings and margarine were published in 1977 and are still in effect.[26]

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[23] Federation of American Societies for Experimental Biology, *Evaluation of the Health Aspects of Hydrogenated Soybean Oil As A Food Ingredient* (1976) at 4. Though the report refers to hydrogenated oil, the text clearly indicates that it was *partially* hydrogenated soybean oil that was being evaluated.

[24] *Id.* at 2.

[25] *Id.* at 30.

[26] See standards of identity at 21 C.F.R. 169.115 for French dressing, 21 C.F.R. 169.140 for mayonnaise, 21 C.F.R. 169.150 for salad dressing, and 21 C.F.R. 166.110 for margarine. None of these standards of identity explicitly refers to partially hydrogenated vegetable oil, but the nature of the products indicate that it is partially hydrogenated vegetable oil.

In August 1985 the FASEB, at the request of the FDA, reviewed the scientific literature on the health aspects of industrially produced trans fat as a food ingredient. The FASEB concluded "that the available scientific information suggests little reason for concern with the safety of dietary trans fatty acids *both* at their present and expected levels of consumption and at the present *and* expected levels of consumption of dietary linoleic acid..." (emphasis in original).[27]

The FDA relied in part on that FASEB report when it concluded in 1989 that partially hydrogenated menhaden oil – which was then used in margarine in Europe – is generally recognized as safe.[28] The FDA also said that partially hydrogenated menhaden oil "is qualitatively comparable to partially hydrogenated common edible vegetable oils, such as partially hydrogenated soybean oil, that have a long history of safe use in this country."[29]

B. In October 1993, the Center for Science in the Public Interest asked the FDA to require disclosure of the amount of trans fat and to stop misleading health claims after more refined studies done in the early 1990s that showed that consumption of trans fatty acids increased the risk of coronary heart disease, and in February 1994 CSPI petitioned the FDA to require label disclosure of the amount of trans fatty acids and to prevent misleading label claims.

In October 1993, CSPI wrote to the FDA's Commissioner, David Kessler, that ten scientific studies done in the 1990s suggested that "trans fatty acids raise blood cholesterol levels, increasing the risk of cardiovascular disease." CSPI asked the FDA both to require labels to disclose the trans fatty acid content of foods and to stop misleading labeling claims.

Four months later, in February 1994, CSPI formally petitioned the FDA to require trans fat to be labeled together with saturated fat for inclusion on nutrition labels and to limit health and nutrition claims for foods that contain significant levels of trans fatty acids.

C. In November 1999, the FDA proposed a trans-fat labeling rule for packaged foods.

In November 1999 the FDA, in response to CSPI's petition, proposed amending its labeling regulations for packaged foods (1) to require that for those foods containing at least

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[27] Federation of American Societies for Experimental Biology, *Health Aspects of Dietary Trans Fatty Acids* (August 1985) at 85.

[28] 54 Fed. Reg. 38219 (September 15, 1989) at 38220. Codified at 21 C.F.R. 184.1472(b).

[29] 54 Fed. Reg. 38220.

0.5 grams of trans fat per serving the amount of trans fat in the food be included in the amount and percent Daily Value declared for saturated fatty acids and (2) to limit health claims on foods containing significant amounts of trans fat.[30]

The FDA observed in 1999 that "Reports from the Federal Government and the NAS [National Academy of Sciences] in the late 1980's concluded that *trans* fatty acids did not appear to have deleterious health effects."[31] However, after reviewing more recent studies, the FDA concluded in 1999 "that under conditions of use in the United States, consumption of *trans* fatty acids contributes to increased serum LDL-C [low-density lipoprotein cholesterol] levels, which increases the risk of CHD [coronary heart disease]...Moreover, the similar impact on LDL-C evidenced for *trans* fatty acids, as is known for saturated fatty acids, warrants serious attention from a public health perspective."[32]

The FDA then went on to estimate the benefits of its proposed labeling rule for packaged foods. Using 1995 United States Department of Agriculture data, the FDA first estimated the sources of trans fat in the average adult diet for various products.[33] The FDA then made three alternative assumptions about how much voluntary reformulation of three products would occur as a result of the mandatory labeling on food packages.[34] Under the FDA's "maximum" scenario 100 percent of margarine would be reformulated (as compared to 30 percent of all margarine that had then been reformulated), 3 percent of bread and rolls would be reformulated, and 15 percent of cookies and crackers would be reformulated.[35] Under the "minimum" scenario, the FDA assumed only that all margarines would be reformulated.[36]

The FDA then combined these three alternative estimates of the changes in trans fat consumption with two alternative methods of estimating the subsequent decrease in coronary heart disease: One method considered the effects on only LDL-C levels; the other method examined the impact on both LDL-C and HDL-C [high-density lipoprotein cholesterol]. The FDA concluded that under the first method the reduction in the risk of coronary heart disease would range – depending on how much reformulation occurs – from 0.61 percent to 0.86 percent

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[30] 64 Fed. Reg. 62746-62825 (November 17, 1999).

[31] 64 Fed. Reg. at 62753.

[32] 64 Fed. Reg. at 62754.

[33] 64 Fed. Reg. at 62765.

[34] In addition to reformulation, the FDA assumed under all its scenarios that 45 percent of consumers would adjust their consumption slightly away from non-reformulated packaged foods based on the label information. Table 2 at 64 Fed. Reg. 62767.

[35] Column 3 of Table 2 at 64 Fed. Reg. 62767.

[36] Column 5 of Table 2 at 64 Fed. Reg. 62767.

and under the second method the reduction would range from 1.20 percent to 1.67 percent.[37] The FDA estimated that about 360,000 Americans die each year from coronary heart disease,[38] which implies that the FDA's proposed labeling rule for packaged foods would reduce the risk of coronary heart disease by between 2,196 and 3,096 annual deaths considering only the impact of LDL-C and by between 4,320 and 6,012 annual deaths considering the impact on both LDC-C and HDL-C. The FDA then took a weighted average of this range of estimates and concluded that within ten years its proposed labeling rule would prevent 7,600 cases of coronary heart disease and 2,500 deaths a year considering only the impact on LDL-C and 17,100 cases of coronary heart disease and 5,600 deaths a year considering the impact on both LDL-C and HDL-C.[39]

Those reductions can be put into context by looking at the FDA's 1999 estimate of the health impact of eliminating *all* trans fat. Using FDA's first method (considering only the impact on LDL-C), there would be an annual reduction in coronary heart disease deaths of 15,408; using the FDA's second method (considering the impact on both LDL-C and HDL-C), there would be an annual reduction of 30,096 deaths.[40] Those estimates assume that companies would replace partially hydrogenated oils in all foods with the same mixture of oils that the FDA presumed companies would use in the reformulation of margarine and baked goods. A further consideration concerns which particular saturated fatty acids would be in the replacement. Stearic acid has little or no effect on LDL-C, while lauric, myristic, and palmitic acids increase LDL-C.[41]

It is noteworthy that in 1992 Grundy estimated that the estimated 3 percent of calories contributed to the American diet by trans fat raises LDL-C by 8 milligrams per deciliter, and that

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[37] Table 2 at 64 Feb. Reg. 62767.

[38] 64 Fed. Reg. 62772.

[39] 64 Fed. Reg. at 62772.

[40] Calculated from data for scenario 1 (column 2) in Table 2 at 64 Fed. Reg. 62767. The actual benefit would be slightly less, because the trans fat that is naturally present in vegetable oil and produced during the refining, bleaching, and deodorizing process would remain in the diet.

[41] Panel on Macronutrients, Institute of Medicine. Dietary reference intakes for energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein, and amino acids. Washington, D.C. 2002. at p. 8-49. Also, while early research suggested that stearic acid might increase the risk of thrombosis, subsequent research found no evidence for that concern. Lefevre M, Kris-Etherton PM, Zhao G, et al. J Am Diet Asso. 2004;104:410-9.

that increase translates into an 8 percent increase in CHD risk, or 23,000 deaths per year (adjusted by CSPI for the approximately one-fifth of trans fat that comes from natural sources).[42]

D. In 2002, the Health Council of the Netherlands recommended that trans fat should be limited to 1 percent of calories.

In a report on dietary reference intakes, the Health Council of the Netherlands recommended, among other things, that trans fat should be limited to 1 percent of calories. That amounts to about 2 grams per day for a person consuming a 2,000-calorie diet.[43]

E. In July 2002, the Institute of Medicine concluded that the consumption of trans fat is at least as unhealthful as the consumption of saturated fats and that consumption of trans fat in any amount increases the risk of heart disease.

In July 2002, the Institute of Medicine ("IOM") of the National Academies, at the request of the FDA, reviewed the scientific evidence on trans fat and concluded that "There is a positive linear trend between *trans* fatty acid intake and total and LDL cholesterol concentration, and therefore increased risk of CHD [coronary heart disease], thus suggesting a UL [Tolerable Upper Intake Level] of zero."[44] The IOM concluded that trans fat is at least as harmful to health as saturated fat[45] and recommended that "*trans* fatty acid consumption be as low as possible while consuming a nutritionally adequate diet."[46]

F. In March 2003, the Danish government announced that as of January 2004 the amount of trans fat from partially hydrogenated oil would be limited to two percent of the total amount of fat or oil in the food.

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[42] Grundy, S. M. (1992). "How much does diet contribute to premature coronary heart disease?" Atherosclerosis IX. Proceedings of the 9th International Symposium on Atherosclerosis, Stein et al., eds., Creative Communications Ltd., Tel Aviv, Israel: 471-8.

[43] Health Council of the Netherlands. Nutrition and health–recommendations of the Health Council of the Netherlands regarding energy, proteins, fats, and carbohydrates. Ned Tijdschr Geneeskd. 2002;146:2226-9. It is unclear if the 1% figure includes naturally occurring trans fatty acids.

[44] Food and Nutrition Board of the Institute of Medicine, *Letter Report on the Dietary Reference Intakes for Trans Fatty Acids* (July 10, 2002) at 34.

[45] The IOM said "The preponderance of the data suggest that [partially] hydrogenated fat/*trans* fatty acids, relative to saturated fatty acids, result in lower HDL cholesterol concentrations." *Id.* at 13.

[46] *Id.* at 34.

In 1994, the Danish Nutrition Council ("the Council") "concluded that *trans* fatty acids in the diet promote arteriosclerosis at least as much as equivalent amounts of saturated fats and probably more....An agreement was...concluded with the Danish margarine industry to reduce the *trans* fatty acid content of margarines produced in Denmark."[47]

Nine years later, in 2003, the Council concluded that "studies indicate that, gram for gram, the intake of *trans* fatty acids [from partially hydrogenated fat] as compared with saturated fatty acids is associated with an approximately 10-fold higher risk increment for the development of heart disease."[48]

The Council observed in 2003 that "a bag of popcorn, a doughnut and a large portion of French fries can...together contain about 20 grams of industrially produced *trans* fatty acids....If such food is consumed several times a week, the average daily intake of industrially produced *trans* fatty acids over months or years may be on a scale that increases the risk of heart disease considerably and may cause other health problems."[49] Accordingly, the Council recommended "that the use of industrially produced *trans* fatty acids in foodstuffs be ceased as soon as possible."[50]

In March 2003, the Danish Veterinary and Food Administration issued a final order that bans – beginning January 1, 2004 – the sale of a food if it contains trans fatty acids (other than those occurring naturally in animal fat) in excess of 2 percent of the total oil or fat in the food.[51] That ban applies to all foods, including those sold by catering establishments, restaurants, and bakeries.[52] The order also declares that the trans-fat content of a food product claiming to be free of trans fat must be less than 1 percent of the total fat or oil in the food.[53]

G. In July 2003, the FDA issued a final trans-fat labeling rule, and extrapolation from the FDA's estimate of the benefits of that rule indicates that upwards of 22,000 lives could be saved each year if trans fatty acid from partially hydrogenated vegetable oils were replaced by other fatty acids.

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[47] *The Influence of Trans Fatty Acids on Health*, 4th ed. (Danish Nutrition Council 2003) at 9.

[48] *Id.* at 9.

[49] *Id.* at 42, 43.

[50] *Id.* at 10.

[51] The text of the final order is at *Id.* at 50.

[52] *Id.* at 50.

[53] *Id.* at 51.

After reviewing the public comments on its 1999 proposed trans labeling rule and having its analysis reviewed by the Interagency Economic Peer Review, the FDA concluded in July 2003 that its final trans-fat labeling rule would save between 240 to 480 deaths a year[54] (as compared to its earlier estimate of saving 2,500 to 5,600 lives a year[55]). In 2003 the FDA estimated that Americans suffer 1.1 million heart attacks annually, with 40 percent of them fatal.[56] In 2003, the FDA said that decreasing trans fat intake by 0.5 grams per day would decrease the risk of coronary heart disease by 0.29 percent to 0.57 percent,[57] or by 1,276 to 2,508 deaths a year, and it repeatedly emphasized that those were conservative estimates.[58] The FDA also said in 2003 that current average daily consumption of trans fat from partially hydrogenated vegetable oil is 5.36 grams for men and 3.89 grams for women,[59] or an average of about 4.6 grams for both sexes.[60] Extrapolating from those findings, if the average daily consumption of trans fatty acids from partially hydrogenated oils were reduced from 4.6 grams to zero (and replaced by a mixture of saturated, monounsaturated, and polyunsaturated fatty acids), the annual number of fatal coronary heart disease cases would fall by 11,739 to 23,074,[61]

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[54] 68 Fed. Reg. at 41488. This final rule only requires disclosure of the amount of trans fat. In July 2003 the FDA announced that it was scrapping the rest of its 1999 proposed rule and published an advanced notice of proposed rulemaking on how to put this disclosure in context and on new nutrient-content claims. 68 Fed. Reg. 41507 (July 11, 2003).

[55] The two estimates cannot be directly compared. As discussed above in section III.C., reformulation of only margarines was just one of three scenarios assumed by the FDA in 1999. In 2003 the FDA assumed only reformulation of margarines. 68 Fed. Reg. at 41487. Judging from recent product reformulations by Frito-Lay, Nabisco, Ruby Tuesday's, and other major companies, even in 1999 the FDA underestimated the degree to which its labeling rule would influence companies to replace partially hydrogenated vegetable oil with less harmful ingredients. Voluntary company action, though, does not mitigate the need for the regulatory action that we request.

[56] 68 Fed. Reg. at 41488.

[57] 68 Fed. Reg. at 41483.

[58] See, for example, 68 Fed. Reg. at 41485 and 41488.

[59] 68 Fed. Reg. at 41469.

[60] That average consumption obscures the fact that some people who eat large amounts of foods made with partially hydrogenated oil consume much larger amounts of trans fat and have a higher than average risk of heart disease.

[61] As the FDA recognized (Table 10 at 68 Fed. Reg. at 41487), the magnitude of the health benefit from reducing the use of partially hydrogenated oil depends on what ingredients replace that oil. A probabilistic model was used by the FDA in 2003 to estimate how partially hydrogenated oil would be replaced in margarine. Our calculations assume that the same average replacement would be made in all other foods. While saturated fat might increase in

depending on whether trans fat's effects on only LDL-C or both LDL-C and HDL-C were considered. Thus, after taking into account the 240 to 480 deaths a year that will not occur because of trans-fat labeling, one gets an additional annual reduction of 11,499 to 22,594 deaths from coronary heart disease by eliminating from the diet trans fat from partially hydrogenated oils.

In 2003, the FDA also calculated the dollar value of the health benefits from requiring disclosure of the amount of trans fat, looking at both the dollar value of the extension of longevity and the savings in medical costs associated with reductions in nonfatal cases of coronary heart disease. Using a discount rate of 3 percent and depending on which assumptions are used, the FDA estimated the cumulative total of the benefits of its labeling rule over 20 years at $13.1 billion to $26.8 billion (compared to cumulative costs over 20 years of $139 million to $275 million),[62] depending on assumptions concerning blood lipids. As discussed above, the benefits of our proposed ban on partially hydrogenated oils appear to be about 47 times the benefits of the FDA's trans-labeling rule. Thus, a simple extrapolation indicates that the discounted cumulative dollar value (over 20 years) of the benefits of such a ban would be $616 billion to $1.260 trillion.

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some foods where solid shortenings are needed, saturated fat might decrease in other foods, such as fried foods, for which low-saturated-fat alternatives are readily available. Considering the data presented in Appendix 3, we believe our basis for estimating health benefits is reasonable.

[62] Table 12 at 68 Fed. Reg. 41490.

H. In December 2003, the Institute of Medicine concluded that it is feasible to exclude from the diet trans fat from partially hydrogenated vegetable oil.

In December 2003, the Institute of Medicine ("IOM") of the National Academies – in a report to the Department of Health and Human Services, the Department of Agriculture, and Health Canada – noted its 2002 conclusion that trans fatty acids ("TFA") are "not required in the diet" (though the IOM cautioned that eliminating all trans fat, including that from ruminant sources, might introduce undesirable effects, such as inadequate intake of protein and micronutrients).[63] The IOM went on to conclude in 2003 that "diets can be planned that provide less than 1 percent of calories from TFA provided that the only sources of TFA are naturally occurring (i.e., in meat and dairy products)."[64]

I. In April 2004, the Nutrition Subcommittee of the FDA's Food Advisory Committee concluded that trans fat is "more adverse" than saturated fat with respect to coronary heart disease.

In April 2004, the Nutrition Subcommittee of the FDA's Food Advisory Committee, in response to a question posed by the FDA, unanimously concluded that trans fat is "more adverse" than saturated fatty acid with respect to coronary heart disease.[65]

IV. TRANS FAT INCREASES LDL-CHOLESTEROL LEVELS AND THE RISK OF HEART DISEASE.

The central concern about trans fatty acids is that they promote heart disease by raising LDL-C levels.[66] The evidence that accumulated during the 1980s and 1990s has been evaluated by several expert committees, all of which recognized that trans fat raises LDL-C levels and the risk of heart disease.

The Report by the 2000 Dietary Guidelines for Americans Advisory Committee stated:

> These results provide convincing confirmation that LDL cholesterol is a direct cause of coronary heart disease. ... trans fatty acids are included [in a box] because a definitive body of recent experimental evidence indicates that *trans*

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[63] *Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification* (Food and Nutrition Board of the Institute of Medicine, December 2003) at 5-13

[64] *Id.* at 5-14.

[65] *Food Chemical News* (May 3, 2004) at 27.

[66] 68 Fed. Reg., especially at 41442-9, 41478-89.

fatty acids raise the concentration of the most dangerous form of serum cholesterol (LDL-cholesterol).[67]

The National Cholesterol Education Program stated:

LDL is the major atherogenic lipoprotein and has long been identified by NCEP as the primary target of cholesterol-lowering therapy. This focus on LDL has been strongly validated by recent clinical trials, which show the efficacy of LDL-lowering therapy for reducing risk for CHD. ... Substantial evidence from randomized clinical trials indicates that trans fatty acids raise LDL cholesterol levels, compared with unsaturated fatty acids.[68]

The American Heart Association's 2000 dietary guidelines states:

... that high total and LDL cholesterol levels are strongly related to coronary artery disease and that reductions in LDL levels are associated with reduced coronary disease risk .... The major food components that raise LDL cholesterol are saturated fatty acids, trans-unsaturated fatty acids, and, to a lesser extent, cholesterol. ... It has been established that dietary trans-unsaturated fatty acids can increase LDL cholesterol ...[69]

In 2002, the Institute of Medicine's committee on macronutrients stated:

Similar to saturated fatty acids, there is a positive linear trend between trans fatty acid intake and LDL cholesterol concentration, and therefore increased risk of CHD. A UL [Tolerable Upper Intake Level] is not set for trans fatty acids because any incremental increase in trans fatty acid intake increases CHD risk.[70]

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[67] Dietary Guidelines Advisory Committee, Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, to the Secretary of Health and Human Services and the Secretary of Agriculture, U.S. Department of Agriculture, 2000 at pages 34, 37.

[68] Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III), Chapter II, "Rationale for Intervention," and Chapter V, "Adopting Healthful Lifestyle Habits to Lower LDL Cholesterol and Reduce CHD Risk," NIH Publication No. 01-3670. May 2001. At pages II-1, V-9. (http://www.nhlbi.nih.gov).

[69] Krauss, R. M., R H. Eckel, B. Howard, et al. American Heart Association Dietary Guidelines, Revision 2000: A Statement for Healthcare Professionals From the Nutrition Committee of the American Heart Association. Circulation. 2000;102:2284-99.

[70] Panel on Macronutrients, Institute of Medicine. Dietary reference intakes for energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein, and amino acids. *op. cit.* at p. 8-66.

Trans fat's effect on LDL cholesterol and the risk of coronary heart disease provides ample reason to take regulatory action to minimize the amount of trans fat in the food supply.[71]

V. TRANS FAT MAY BE MORE HARMFUL THAN SATURATED FAT.

In addition to promoting heart disease by raising LDL-C levels, studies suggest that trans fat promotes heart disease through other mechanisms. Preliminary evidence also suggests that trans fat may cause health problems other than heart disease.

A. Trans fat has greater adverse effects than saturated fat on blood lipids.

The FDA recognized in its final trans-fat labeling rule that trans fats not only raise LDL-C levels, but also *lower* HDL-C levels.[72] The FDA cites studies by Zock and colleagues[73] that show:

> a negative linear trend between trans fat intake and HDL-C. ... FDA finds that, for the purposes of economic analysis, it is appropriate to quantify the health benefits of trans fat labeling using regression equations describing a positive linear trend between trans fat intake and LDL-C and a negative linear trend between trans fat intake and HDL-C.[74]

A 1999 "Sounding Board" article in *The New England Journal of Medicine* by five prominent researchers who have studied trans fat stated:

> Because trans fatty acids increase LDL cholesterol to levels similar to those produced by saturated fatty acids and also decrease HDL cholesterol levels, the

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[71] While this petition focuses on reducing trans fat, it is also important to address saturated fat, a major dietary contributor to heart disease. Saturated fat constitutes 11 to 12 percent of calories in American adult diets, several-fold more than the approximately 2.6 percent of calories coming from trans fat in the average diet of Americans three years and older. (Panel on Macronutrients, Institute of Medicine. *op. cit.* pages 8-41, 8-46) Major public education campaigns, voluntary industry action, changes in government feeding programs, and regulatory actions should be brought to bear to reduce consumption of foods containing significant amounts of saturated fat (from dairy, pork, beef, tropical oils, and other sources).

[72] 65 Fed. Reg. at 41486.

[73] Katan MB, Zock PL, Mensink RP. trans fatty acids and their effects on lipoproteins in humans. Ann Rev Nutr. 1995;15:473-93. Zock PL, Katan MB, Mensink RP. Dietary trans fatty acids and lipoprotein cholesterol. Am J Clin Nutr. 1995;61:617. Zock, PL, Mensink RP. Dietary trans-fatty acids and serum lipoproteins in humans. Current Opinions in Lipidology. 1996;7:34-7.

[74] 68 Fed. Reg. at 41486.

> net effect of trans fatty acids on the ratio of LDL cholesterol to HDL cholesterol is approximately double that of saturated fatty acids. ... The effect of trans fatty acids on the ratio of LDL cholesterol to HDL cholesterol was significantly larger than that of saturated fatty acids in each of the six studies that allowed a direct comparison. Collectively, these studies provide definitive evidence that trans fatty acids raise this ratio more than do saturated fatty acids.[75]

The Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2000 states: "trans fatty acids also tend to lower a protective form of serum cholesterol (HDL cholesterol)."[76]

Similarly, the American Heart Association's 2000 Dietary Guidelines states: "It has been established that dietary trans-unsaturated fatty acids can increase LDL cholesterol and reduce HDL cholesterol."[77]

Likewise, the National Cholesterol Education Program of the National Heart, Lung and Blood Institute stated in 2001: "These studies also show that when trans fatty acids are substituted for saturated fatty acids, HDL cholesterol levels are lower, with a dose response effect observed." [78] The FDA describes the uncertainty that the National Cholesterol Education Program (NCEP) and others have expressed regarding whether HDL cholesterol is an independent risk factor for heart disease, and the agency concludes that, for the purposes of the final trans-labeling rule, focusing on LDL cholesterol was sufficient.[79] It is worth recognizing, though, the NCEP states that "Low HDL cholesterol is a strong independent predictor of CHD."[80] It also states: "Some evidence indicates that HDL protects against the development of atherosclerosis, although a low HDL level often reflects the presence of other atherogenic

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[75] Ascherio AM, Katan MB, Zock PL, et al. trans fatty acids and coronary heart disease. New Engl J Med. 1999;340:1994-8. The authors also noted that trans fatty acids increase Lp(a) lipoprotein levels when they are substituted for saturated fatty acids and that they increase triglyceride levels. However, the authors noted that it is unclear whether the small increases in Lp(a) induced by trans fatty acids actually increase the risk of CHD. Likewise, the FDA considered the research on those possible additional effects of trans fatty acids to be preliminary. 68 Fed. Reg. at 41449.

[76] Dietary Guidelines Advisory Committee, *op. cit.* p.37.

[77] Krauss, R. M., R H. Eckel, B. Howard, et al., *op. cit.*

[78] Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. *op. cit.*

[79] 68 Fed. Reg. at 41448-9.

[80] Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. *op. cit.* Executive Summary, pages 3, 16, 19.

factors."[81] Moreover, in the proposed and final trans-fat rules, the FDA gave substantial credence to HDL's "possible relationship" to heart disease when it made extensive cost–benefit calculations on the basis of changes in both LDL + HDL cholesterol.

Also, the Food and Nutrition Board of the Institute of Medicine told the FDA in a Letter Report in 2002 that "The preponderance of the data suggest that [partially] hydrogenated fat/trans fatty acids, relative to saturated fatty acids, result in lower HDL cholesterol concentrations."[82]

A recent meta-analysis by Mensink et al. concluded that average partially hydrogenated shortening and stick margarine increase the ratio of total/HDL cholesterol (that is, increased that measure of CHD risk) slightly less than butter, slightly more than palm oil, and substantially more than coconut fat, tub margarine, and palm kernel oil.[83] (See Figure 1.) That is because trans fat increases LDL cholesterol almost as much as lauric, myristic, and palmitic acids, but, relative to those other fatty acids, decreases HDL cholesterol. (See Figure 2.) Also, trans fatty acids, relative to stearic acid, raise LDL cholesterol; trans and stearic have little effect on HDL cholesterol when substituted for carbohydrate.

The authors state:

> The US diet provides, on average, 2.6% of energy from *trans* [monounsaturated fatty acids][84] and nearly 13% of energy from [saturated fatty acids], so that the total replacement of trans fatty acids in the diet with carbohydrates would have a greater effect on total:HDL cholesterol than would total replacement of [saturated fatty acids]. Therefore, even low concentrations of trans [monounsaturated fatty acids] in the diet should deserve attention as a target for efforts to lower [coronary artery disease] risk.

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[81] *Ibid.* p. II-1.

[82] Food and Nutrition Board, Letter Report on Dietary Reference Intakes for trans Fatty Acids. *op. cit.*, at 9.

[83] Mensink RP, Zock PL, Arnold DM, et al. Effects of dietary fatty acids and carbohydrates on the ratio of serum total to HDL cholesterol and on serum lipids and apolipoproteins: a meta-analysis of 60 controlled trials. Am J Clin Nutr. 2003;77:1146-55.

[84] This average, of course, obscures the fact that some people consume far more than the average.

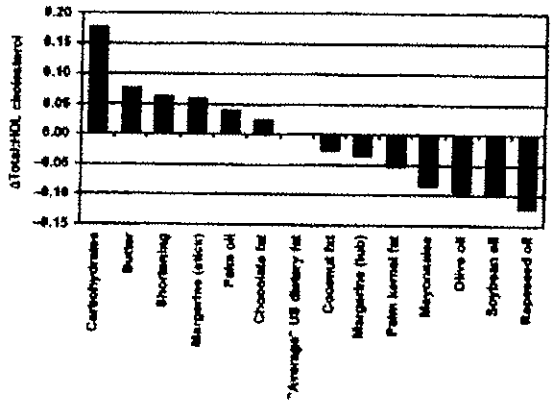

Figure 1. Predicted changes (Δ) in the ratio of serum total to HDL cholesterol when mixed fat constituting 10% of energy in the "average" U.S. diet is replaced isoenergetically with a particular fat or with carbohydrates. (From Mensink, et al., 2003)

The authors also state:

> Palm is an acceptable alternative for the industry, and, in terms of the effect on total:HDL cholesterol, palm oil is still better than the partially hydrogenated vegetable oils used [in margarine and shortening] in the food service industry. However, unhydrogenated vegetable oils produce a much more favorable lipid profile than do either palm oil or hydrogenated oils, and they should be preferred.

Mensink et al. concluded that the trans fatty acids commonly found in partially hydrogenated oils have more-adverse effects on the ratio of total/HDL cholesterol than lauric, myristic, palmitic, and stearic acids, the major saturated fatty acids in food.

In sum, a growing body of evidence, though not conclusive, indicates that trans fat, by lowering HDL-cholesterol, has greater adverse effects on serum lipids, and possibly on CHD risk, than saturated fat. Indeed, if partially hydrogenated oil were being proposed as a new food additive, the fact that it lowers HDL likely would prevent the substance from meeting the "reasonable certainty of no harm" standard for approval. However, trans fat's adverse effects on LDL cholesterol alone provides sufficient grounds to minimize the amount of industrially produced trans fat in the food supply.

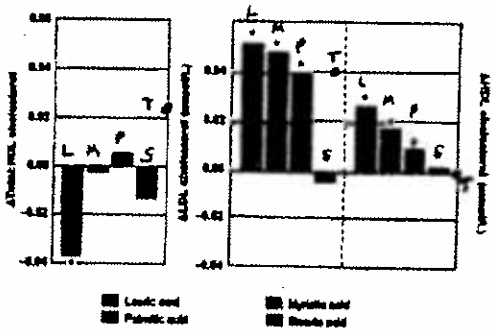

Figure 2. Predicted changes (Δ) in the ratio of serum total to HDL cholesterol and in LDL- and HDL-cholesterol concentrations when carbohydrates constituting 1% of energy are replaced isoenergetically with lauric acid ("L," 12:0), myristic acid ("M," 14:0), palmitic acid ("P," 16:0), or stearic acid ("S," 18:0). *$P < 0.001$. (From Mensink, et al., 2003) The handwritten bullet ("T") is the predicted change due to a similar replacement with trans fat (from Table 2 of the same paper).

B. Partially hydrogenated vegetable oil may be more harmful than saturated fat through mechanisms other than the effects of trans fat on blood lipids.

Beyond its adverse effects on serum lipids, trans fat may promote heart disease in additional ways. Several epidemiologic studies have found a greater association between trans fats and heart disease than would be accounted for by changes in LDL and HDL cholesterol. Though those studies cannot be considered definitive because of possible uncontrolled, confounding factors, in its final trans-fat labeling rule the FDA recognized that:

> ... the prospective studies of trans fat intake and CHD risk consistently reported a greater risk of CHD attributable to trans fat intake than would be accounted for by [changes in LDL and HDL cholesterol]. ... Thus, the results of the prospective studies suggest that there may be additional mechanisms by which trans fat contributes to CHD. ... However, FDA noted that, if there are additional mechanisms by which trans fat contributes to CHD risk, as suggested by the prospective studies, then the actual benefits may be greater than estimated using either Method 1 (changes in LDL-C) or Method 2 (changes in LDL-C and HDLC).[85]

[85] 68 Fed. Reg. at 41479.

The FDA also stated "that the prospective studies do suggest that there may be additional mechanisms, besides changes in LDL-C and HDL-C, by which trans fat contributes to CHD risk."[86]

Judging from a pooling of four prospective studies, a 2% increase in calories from trans fat increases the risk of heart disease by 25%. (See Table 1.) However, in the Nurses Health Study, which some researchers consider to be the best of the four studies because participants filled out dietary questionnaires four times, the increased risk of heart disease due to a 2% increase in calories from trans fat was 93%.[87] Though prospective cohort studies have methodological limitations, the pooled analysis suggests that on a gram-for-gram basis trans fat, compared to saturated fat, is a stronger promoter of heart disease.

The Institute of Medicine, too, has expressed, based on metabolic and prospective cohort studies, the concern that "dietary trans fatty acids are more deleterious with respect to CHD than saturated fatty acids."[88]

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[86] 68 Fed. Reg. at 41485.

[87] Hu FB, Stampfer MJ, Manson JE, et al. Dietary fat intake and the risk of coronary heart disease in women. N Engl J Med. 1997;337:1491-9. As noted earlier, CSPI recognizes that prospective cohort studies have methodological limitations.

[88] Panel on Macronutrients, Institute of Medicine. Dietary reference intakes for energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein, and amino acids. *op. cit.*, at 8-66.

Table 1. Increased Risk of Heart Disease Associated with Trans Fat, as Found in Prospective Cohort Studies[89]

Study	Relative Risk
Health Professionals Follow-up Study[90]	1.13
Alpha-Tocopherol, Beta-Carotene Cancer Prevention Study[91]	1.14
Nurses Health Study[92]	1.62
Zutphen Elderly Study[93]	1.28
Pooled results	***1.25***

The fully adjusted relative risks of coronary heart disease for an increase of 2% of energy in trans fatty acid intake at baseline according to prospective population-based studies and the pooled variance-weighted relative risk.

The mechanisms by which trans fat may be a more powerful cause of heart disease than saturated fat are not clear.[94] But regardless of mechanism, if partially hydrogenated oil were now

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[89] Taken from Oomen CM, Ocké MC, Feskens EMJ, et al. Association between trans fatty acid intake and 10-year risk of coronary heart disease in the Zutphen Elderly Study: a prospective population-based study. Lancet 2001;357:746-51.

[90] Ascherio A, Rimm EB, Giovannucci EL, et al. Dietary fat and risk of coronary heart disease in men: Cohort follow up study in the United States. BMJ 1996;313:84-90.

[91] Pietinen P, Ascherio A, Korhonen P, et al. Intake of fatty acids and risk of coronary heart disease in a cohort of Finnish men. The Alpha-tocopherol, Beta-carotene Cancer Prevention Study. Am J Epidemiol. 1997;145:876-87.

[92] Hu FB, Stampfer MJ, Manson JE, et al. *op. cit.*

[93] Oomen CM, Ocké MC, Feskens EMJ, et al. *op. cit.*

[94] Researchers have speculated that trans fatty acids promote heart disease in ways other than affecting serum cholesterol levels through small effects on lipoprotein(a) and triglycerides and also incorporation into cells involved in cardiac rhythm regulation, leading to a lower threshold for cardiac arrhythmias, a major cause of sudden cardiac death. Clevidence BA, Judd JT, Schaefer EJ, et al. Plasma lipoprotein(a) levels in men and women consuming diets enriched in saturated, cis-, or trans-monounsaturated fatty acids. Arterioscler Thromb Vasc Biol. 1997;17:1657-61. Ascherio AM, Katan MB, Zock PL, et al. *op. cit.* Lemaitre RN, King IB, Raghunathan TE, et al. Cell membrane trans-fatty acids and the risk of primary cardiac arrest. Circulation. 2002;105:697-701. Wenzel DG, Kleoppel JW. Incorporation of saturated and cis- and trans-unsaturated long chain fatty acids in rat myocytes and increased susceptibility to arrhythmias. Toxicology. 1980;18:27-36. de Roos NM, Bots ML, Katan MB. Replacement of dietary saturated fatty acids by trans fatty acids lowers serum HDL cholesterol and impairs

being proposed as a new food additive, the results of the several prospective studies likely would ring such a loud warning bell as to prevent the substance from meeting the "reasonable certainty of no harm" standard for approval. The burden would, and should, be on the applicant to prove that partially hydrogenated vegetable oil did not increase the risk of heart disease.

In addition to promoting heart disease, the hydrogenation of vegetable oil converts some of the vitamin K1 (phylloquinone) to dihydro-vitamin K1.[95] In contrast to vitamin K1, which had the expected effects on measures of bone formation and resorption, the dihydro-vitamin K1 was less absorbed and had no biological effects on bone parameters.[96] The lost vitamin K1 may pose a significant risk to people who consume inadequate levels of that nutrient. (The vitamin-K problem presumably could be solved by fortification.) Furthermore, initial studies have linked consumption of trans fats with diabetes in women (in one major study, the highest-intake quartile had a 56% greater risk than the lowest-intake quartile)[97] and possibly other health problems.[98] Thus, the health benefits from minimizing consumption of trans fatty acids from partially hydrogenated oils might be even greater than the benefits expected based on the research on heart disease.

In sum, in addition to increasing LDL-C, trans fat may increase the risk of heart disease and other health problems by decreasing HDL-C and through other mechanisms. That research, though certainly not conclusive, should be given some weight in considering the health consequences of trans fat. Indeed, in April 2004, the Nutrition Subcommittee of the FDA's Food Advisory Committee unanimously concluded that trans fat is "more adverse" than saturated fatty acid with respect to coronary heart disease.[99] However, trans fat's effect on LDL-C levels alone

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endothelial function in healthy men and women. Arterioscler Thromb Vasc Biol. 2001;21:1233-7.

[95] Booth SL, Davidson KW, Lichtenstein AH, et al. Plasma concentrations of dihydro-vitamin K1 following dietary intake of a hydrogenated vitamin K1-rich vegetable oil. Lipids. 1996;31:709-13.

[96] Booth SL, Lichtenstein AH, O'Brien-Morse M, et al. Effects of a hydrogenated form of vitamin K on bone formation and resorption. Am J Clin Nutr. 2001;74:783-90.

[97] Hu FB, Manson JE, Stampfer MJ, et al. Diet, lifestyle, and the risk of type 2 diabetes mellitus in women. N Engl J Med. 2001 Sep 13;345(11):790-7. Personal communication, Frank Hu, April 8, 2004.

[98] Morris MC, Evans DA, Bienias JL, et al. Dietary fats and the risk of incident Alzheimer disease. Arch Neurol. 2003;60:194-200. Elias SL, Innis SM. Infant plasma trans, n-6, and n-3 fatty acids and conjugated linoleic acids are related to maternal plasma fatty acids, length of gestation, and birth weight and length. Am J Clin Nutr. 2001;73:807-14.

[99] *Food Chemical News. op. cit.*

provides sufficient grounds to minimize the amount of industrially produced trans fat in the food supply.

VI. NUMEROUS ALTERNATIVES TO PARTIALLY HYDROGENATED OILS EXIST OR ARE BEING DEVELOPED.

The public's, and hence the food industry's, concerns about the health effects of the trans fatty acids in partially hydrogenated vegetable oil has spurred the seed, edible oil, and food industries to develop a range of replacements for trans-containing fats. Partially hydrogenated oils can be replaced in many foods by liquid soy, corn, or canola oil. However, such substitutions with a liquid oil are not always possible due to the presence of high levels of polyunsaturated fatty acids, the need for a higher melting point, or other property. Hence, hard fats, from animal fat, tropical oils, or partially hydrogenated vegetable oils, are necessary in the production of certain foods. In recent years, seed companies, oil producers, and other companies have been developing – through breeding and chemistry – substitutes for partially hydrogenated oils (as well as for animal fats and tropical oils) that are suitable for use in most commercial food applications. Examples are shown in Appendix 1.[100]

Increased supplies of alternatives to partially hydrogenated oils will encourage more and more manufacturers and restaurant companies to reformulate some or all of their products to reduce or eliminate trans fats. In most of the cases we have identified, the reformulated product is lower in saturated-plus-trans fat than the original product, resulting in more-heart-healthful products. Examples are shown in Appendix 2.

The practicality of marketing foods without trans fat is evident in a visit to Whole Foods, a national "natural foods" supermarket chain that does not sell any foods that contain trans fats from partially hydrogenated oils.[101] The ingredient lists of various brands of crackers, cookies, and other foods, which in regular grocery stores typically contain partially hydrogenated oils, indicate that many smaller companies have been able to produce trans-free alternatives, as shown in Appendix 3. That appendix also provides examples of low-trans or trans-free foods made by mainstream food producers.

Ideally, industrially produced trans fat would be replaced largely by cis-unsaturated fat. And, as Kraft, Frito-Lay, Ruby Tuesday's, Unilever, and other companies have shown, potato chips, French fries, margarines, and other foods can be made with trans-free, liquid vegetable oils. In some products, though, such as some pastry shells, cookies, frostings, margarine, and chocolate coatings, partially hydrogenated oils can only be replaced by fats that contain sufficient saturated fat to provide the desired performance characteristics. Some such products

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[100] Additional methods for reducing trans fatty acids in oils and shortenings are discussed in "Questions remain over hydrogenated fats." Inform, Vol. 5 (4), April 1994, pp. 358-63. "Tools: hydrogenation, interesterification." Inform, Vol. 5 (6), June, 1994, pp. 668-78. "Stable and healthful frying oil for the 21st century." Inform, Vol. 11, June 2000, pp. 642-7.

[101] Whole Foods store visited in March 2004.

may contain about as much palm oil (one common solid-fat substitute) as similar products contain hydrogenated vegetable oil – and may affect the level of LDL cholesterol to similar degrees. Nevertheless, some researchers, noting the evidence that trans fat may be more conducive to heart disease than saturated fat (as discussed in section V), have stated:

> However, despite the negative effect of saturated fat on blood lipids, even replacement of industrially produced TFAs with saturated fat will, according to present knowledge, lead to a considerable reduction in [ischemic heart disease risk] and other health risks.[102]

The FDA noted in its final trans-fat labeling rule, "... the total amount of saturated fat plus trans fat in the reformulated product is commonly lower than in the original product."[103] With regard to shortenings used in baked goods, the FDA referred to comments received from industry and stated: "In these examples, the shortenings reformulated to be lower in trans fat were higher in saturated fat but were lower in total saturated fat plus trans fat than were the traditional nonreformulated shortenings."[104] Also, "FDA continues to believe that the most plausible replacement for trans fat in baked products is 50 percent cis-monounsaturated fat and 50 percent saturated fat."[105] Some food manufacturers appear to be sensitive to public concerns about saturated and trans fat and, when they are switching away from partially hydrogenated oils, are trying to reduce the total amount of those two types of fats (see Appendixes 2 and 3).[106]

In conclusion, the seed, oilseed-processing, and food industries are working hard to produce commercially viable alternatives to partially hydrogenated oils, and food manufacturers increasingly are using them. Such alternatives generally would cost no more than a fraction of a cent per serving more than partially hydrogenated shortenings.[107] In the several years that it will

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[102] Stender S, Dyerberg, J. Influence of trans fatty acids on health. Ann Nutr Metab. 2004;48:61-6.

[103] 68 Fed. Reg. at 41484.

[104] 68 Fed. Reg. at 41475.

[105] 68 Fed. Reg. at 41475.

[106] Manufacturers also should recognize that the major saturated fatty acids in foods have different effects on blood lipids, with lauric, myristic, and palmitic acids, but not stearic, increasing LDL-C and, to a lesser extent, HDL-C (Figure 2).

[107] Assuming that inter-esterified oil, high-oleic oils, and other specialty oils might cost about five to ten cents per pound more than partially hydrogenated oil, the extra cost at retail (if the cost plus margin were entirely passed along) might be 10 to 20 cents per pound (or 0.02 to 0.04 cents per gram). Cost differences in that range are within the range of price variation for partially hydrogenated oil (personal communications from industry sources). Thus, if a serving of food contains 10 grams of the oil, the increased cost would be 0.2 to 0.4 cents; a 5-serving

take for the FDA to finalize regulations to implement this petition, oilseed breeders, growers (here and abroad), processors, and importers will be responding to the marketplace demand. Over that period, the costs of alternatives likely will decrease. Considering the substantial reduction in health risks and costs that would flow from reducing dietary intake of trans fatty acids, any modest increase in costs to industry (and consumers) would be a smart investment.

VII. THE FDA HAS AMPLE LEGAL AUTHORITY TO BAN THE PRESENCE IN FOODS OF TRANS FAT FROM PARTIALLY HYDROGENATED VEGETABLE OILS.

As discussed above in section III.A., for many years the FDA tacitly accepted the use of partially hydrogenated oils, and in the 1970s and 1980s the FDA formally approved various uses of partially hydrogenated vegetable oils, because the FDA believed at that time, based on prior usages in other foods and the contemporary state of scientific knowledge, that those oils were safe. However, the FDA's regulations provide that ingredients "which have been considered in the past by the Food and Drug Administration to be safe under the provisions of section 402(a)(1) [of the Federal Food, Drug, and Cosmetic Act], or to be generally recognized as safe for their intended use, or to have prior sanction or approval, or not to be food additives under the conditions of intended use, must be reexamined in the light of current scientific information and current principles for evaluating the safety of food additives if their use is to be continued."[108]

A. Partially hydrogenated vegetable oils are no longer "Generally Recognized As Safe" by the FDA and other scientists and so are food additives within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act.

The regulatory scheme established by the Federal Food, Drug, and Cosmetic Act ("FFDCA") divides food ingredients into those that are "food additives" and those that are not. This distinction is important because section 409(a)(2) of the FFDCA provides that the former may be legally used only if the FDA has issued a regulation "prescribing the conditions under which such additive may be safely used."[109]

Section 201(s) of the FFDCA[110] provides, in pertinent part, a two-part test for defining when a substance is a food additive: "any substance [1] 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...[2] if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety,

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package would cost about 1 to 2 cents more. Also, in some cases, companies switching from partially hydrogenated oil to canola or other oil may be able to use *less* oil, thereby actually lowering their oil costs.

[108] 21 C.F.R. 170.6(c)

[109] 21 U.S.C. 348(a)(2).

[110] 21 U.S.C. 321(s).

as having been adequately shown through scientific procedures (or in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use of food) to be safe under the conditions of its intended use..."

The FDA has decided that two partially hydrogenated oils are "generally recognized as safe" and, therefore, are not food additives: partially hydrogenated menhaden oil[111] and partially hydrogenated low erucic acid rapeseed oil.[112] The FDA has also determined that partially hydrogenated methyl ester of rosin is a safe food additive.[113] The FDA has also long accepted the use of other partially hydrogenated vegetable oils, presumably because – at one time – either the FDA believed such use was safe or food companies self-determined that such use was "generally recognized as safe."

There is no dispute that the intended use of any partially hydrogenated vegetable oil satisfies the first part of the legal definition of a food additive, as its intended use is to become "a component or otherwise affect the characteristics of food."

The new scientific evidence discussed both above (in sections III.E., III.H., III.I., IV., and V.) and in the FDA's final rule on trans-fat labeling demonstrates that partially hydrogenated vegetable oils now also meet the second part of the legal definition of a food additive, because they can no longer be considered Generally Recognized As Safe. Those who wish to continue using such oils – which cause thousands of deaths a year (see section III.G. above) – can no longer meet their burden [114] of showing that the oil is Generally Recognized As Safe "under the [current] conditions of its intended use." Moreover, as discussed above in section III.E., the Institute of Medicine concluded in July 2002 that any amount of trans fat intake increases the

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[111] 21 C.F.R. 184.1472(b).

[112] 21 C.F.R. 184.1555(c)(2).

[113] 21 C.F.R. 172.515(b) and 172.615.

[114] The FDA's regulations provide that the Commissioner, after reviewing the evidence, will revoke the GRAS status of an ingredient "[i]f he concludes that there is a lack of convincing evidence that the substance is GRAS or is otherwise exempt from the definition of a food additive in section 201(s) of the Act..." 21 C.F.R. 170.38(b)(3). Citing *United States v. Article of Food and Drug...Coli-Trol 80*, 518 F.2d 743,745 (5th Cir. 1975), the FDA said in 1997 that the proponent of an exemption from the definition of a food additive "has the burden of proving that the use of the substance is 'generally recognized' as safe." 62 Fed. Reg. 18937 (April 17, 1997) at 18939. However, in 1980 the FDA said – in its proposed regulation to eliminate caffeine from the list of substances that it considered to be GRAS and from the standard of identity for soda water – that "it is FDA's legal burden to take the appropriate steps to end its use as a GRAS substance." 45 Fed. Reg. 69816 (October 21, 1980) at 69819. In any event, the current scientific evidence on the public health risks of partially hydrogenated oils is so overwhelming that the FDA need not be concerned about whether it or the food industry has the burden of proof.

risk of heart disease,[115] and a federal Court of Appeals has held that the absence of a safe level justifies the FDA's determination that a product is unsafe.[116]

Consequently, the FDA should declare that all partially hydrogenated vegetable oils are food additives [117] (with the exceptions of those approved for use prior to September 6, 1958[118]). That includes both those partially hydrogenated oils whose uses the FDA has formally permitted[119] – shortening,[120] soybean oil,[121] menhaden oil,[122] and partially hydrogenated low

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[115] The IOM also stated that any amount of saturated fat increases the risk of heart disease. However, saturated fatty acids are integral to countless natural and traditional foods, whereas about 80 percent of trans fat is industrially produced and introduced into the diet by partially hydrogenated oil, an unnecessary ingredient. This petition does not address naturally occurring trans fat, nor does it address the low levels of trans fat that are in natural or refined, bleached, and deodorized vegetable oils. Also, it is possible that hydrogenation processes will be developed that do not introduce significant levels of trans fat. Oils produced in such ways could be considered GRAS.

[116] A federal court held that uncontradicted expert testimony that there was no known level of exposure to aflatoxin that could be considered safe supported the FDA's conclusion that corn was adulterated when it contained more than 20 parts per billion of aflatoxin. *United States v. Boston Farm Center, Inc.*, 590 F.2d 149, 151 (5th cir. 1979).

[117] Pursuant to section 409(a)(2) of the FFDCA, 21 U.S.C. 348(a)(2), the FDA could, of course, establish a "safe condition" for the use of such food additives. Section 409(a)(2) bars the use of a food additive unless "there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used."

[118] Section 203(s) contains six specific exemptions from the definition of a food additives. We discuss below – in section VII.C. – the only one that may be relevant to this petition: "any substance used in accordance with a sanction or approval granted [by the FDA] prior to" September 6, 1958.

[119] This permission occurs either in the standards of identity for certain foods (in parts 130 *et seq.* of 21 C.F.R), in the list of substances that are generally recognized as safe by the FDA (in 21 C.F.R. part 182), in the affirmation by the FDA that a food substance is generally recognized as safe (in 21 C.F.R. part 184), or in the FDA's failure to object to a food company's self-determination that an ingredient is generally recognized as safe.

[120] The FDA approved the use of shortening in 1977 when it established a "standard of identity" for bread, rolls, and buns. 21 C.F.R. 136.110(c)(5).

[121] The FDA approved the use of vegetable oils in semi-solid foods in 1977 when it established "standards of identity" for mayonnaise, 21 C.F.R. 169.140, salad dressing, 21 C.F.R.

erucic acid rapeseed oil (canola oil)[123] – and those partially hydrogenated oils whose uses the FDA has tacitly accepted.

B. The FDA should revoke the current safe conditions for those partially hydrogenated vegetable oils that it now considers to be a food additive.

Section 409(d) of the FFDCA provides that "The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons thereof."[124] The FDA's regulations provide that ingredients "which have been considered in the past by the Food and Drug Administration to be safe...must be reexamined in the light of current scientific information and current principles for evaluating the safety of food additives if their use is to be continued."[125]

The new scientific evidence discussed both above (in sections III.E. III.H., III.I., IV., and V.) and in the FDA's final rule on trans-fat labeling demonstrates that it can no longer be considered safe to use any partially hydrogenated vegetable oil[126] as a food additive, unless conditions are established to ensure that the amount of trans fat is minimal.

C. The FDA should declare that any use of partially hydrogenated vegetable oil for which the FDA issued a prior sanction or approval before September 6, 1958 is now deemed to be "unsafe" within the meaning of section 402 of the Federal Food, Drug, and Cosmetic Act.

Section 203(s)(4) of the FFDCA excludes from the definition of a food additive "any substance used in accordance with a sanction or approval granted prior to" September 6, 1958.[127] As partially hydrogenated vegetable oil has, according to the FDA, been used since the 1930s, it is possible that particular companies received such a "sanction or approval" for particular uses.[128]

160.150, and margarine. 21C.F.R. 166.110(a)(1) .

[122] 21 C.F.R. 184.1472(b).

[123] 21 C.F.R. 184.1555(c).

[124] 21 U.S.C. 348(d).

[125] 21 C.F.R. 170.6(c).

[126] Such as partially hydrogenated methyl ester of rosin. 21 C.F.R. 172.515(b) and 172.615.

[127] 21 U.S.C. 321(s)(4).

[128] The FDA has not listed any partially hydrogenated vegetable oil as having a prior sanction or approval. See 21 C.F.R. Part 181, Subpart B. However, a company that has such an

Section 402(a)(2)(A) of the FFDCA provides, in pertinent part, that a food is adulterated "if it bears or contains any...added deleterious substance (other than a substance that is...a food additive...) that is unsafe...."[129] Relying on section 402 of the FFDCA, the FDA's current regulations provide that "Based upon scientific data or information that shows that use of a prior-sanctioned food ingredient may be injurious to health,...the Commissioner will establish or amend an applicable prior sanction regulation to impose whatever limitations or conditions are necessary for the safe use of the ingredient, or to prohibit use of the ingredient."[130]

The new scientific evidence discussed both above (in sections III.E., III.H., III.I., IV., and V.) and in the FDA's final trans-fat labeling rules demonstrates that trans fat "may be injurious to health." The FDA should, therefore, abide by its own regulations and prohibit any use of trans fat that was sanctioned or approved by the FDA prior to September 6, 1958.

VIII. THE FDA SHOULD INITIATE A PROGRAM TO ENCOURAGE FOOD MANUFACTURERS AND RESTAURANTS TO SWITCH FROM PARTIALLY HYDROGENATED OILS TO MORE HEALTHFUL OILS.

Many companies, especially small and mid-sized ones, do not understand the harmfulness of partially hydrogenated oils and may not have the expertise to identify and use safer substitutes for such oils. Also, many companies may not understand that different saturated fatty acids have different effects on the body. Hence, the FDA should develop a program to encourage food manufacturers and restaurants of all sizes to reformulate products that are now made with partially hydrogenated oils. That program should start immediately (even prior to finalizing action on the instant petition), because companies may want to reformulate their products before the 2006 deadline for labeling trans fat.

The program should encourage companies to switch to the most healthful alternatives that provide the desired characteristics (recognizing the need for solid fats in some foods), minimizing the use of both partially hydrogenated oils and oils high in LDL-cholesterol-raising saturated fatty acids. Such a program to facilitate the transition to more-healthful oils should use a broad range of approaches, such as letters to all food processors, seminars in different regions of the country, information on FDA's web site, and speeches at industry conferences. Explaining how some companies have been able to switch to more healthful ingredients could be a great help to other companies.

IX. ABDICATION BY THE FDA OF ITS RESPONSIBILITY TO PROTECT THE PUBLIC HEALTH FROM THE RISKS OF PARTIALLY HYDROGENATED VEGETABLE OILS MAY LEAD STATES OR PRIVATE PARTIES TO ACT.

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approval or sanction is free to present it to the FDA. 21 C.F.R. 181.1(a).

[129] 21 U.S.C. 342(a)(2)(A).

[130] 21 C.F.R. 181.1(b).

State and local governments are legally free to set standards that are more protective of public health than the FDA has established in those areas – such as the safety of food ingredients – for which Congress has not explicitly pre-empted such action.[131] In 1984 the Massachusetts Supreme Court upheld the ban by the Massachusetts Department of Health on the sale of any food containing ethylene dibromide ("EDB") in excess of one part per billion ("ppb"). While noting that the FDA had set a tolerance for EDB on soybeans of one ppb, the Court held that Massachusetts' statute authorized the Department's broad ban on EDB "even though Federal law allows its use." *American Grain Products Processing Institute v. Department of Public Health*, 392 Mass. 309, 315, 467 N.E.2d 455, 462 (1984). The Massachusetts Supreme Court's opinion did *not* rely on the fact that the FFDCA does not explicitly pre-empt state regulation of food additives. However, a year after the Massachusetts Supreme Court's decision, the United States Supreme Court unanimously reversed a Court of Appeals decision and held that, absent such an explicit statutory pre-emption clause, a local government can establish its own regulations governing the safety of blood plasma from paid blood donors that go beyond the FDA's standards for the collection of plasma. *Hillsborough County, Florida v. Automated Medical Laboratories, Inc.*, 471 U.S. 707 (1985). *See also Whitehall Laboratories Division of American Home Products Corporation v. C. J. Wilbar*, 397 Pa. 223, 154 A.2d 596 (1959) (upholding Secretary of Health's decision to require – pursuant to a Pennsylvania statute – that Primatene be dispensed only by prescription even though the FDA permits it to be dispensed without prescription if its label has a warning).

Private parties may in the future sue restaurants (which under the FDA's trans fat rule will not even have to disclose the amount of trans fat in their products[132]) or food companies for continuing to use partially hydrogenated vegetable oils when healthier alternatives exist. *Compare Pelman v. McDonald's*, 237 F. Supp.2d 512, 532 (S.D.N.Y. 2003) (complaint would state a tort claim "if McDonald's products are so extraordinarily unhealthy that they are outside the reasonable contemplation of the consuming public or that the products are so extraordinarily unhealthy as to be dangerous in their intended use."); *BanTransFats.Com. v. Kraft Foods North*

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[131] By contrast Congress has provided that in certain areas a state or local government cannot have a requirement different from one established by the FDA unless the FDA grants a petition for a waiver. See, for example, standards of food, specified food labeling, medical devices, and cosmetics. Sections 403A(a)(1), 403A(a)(2)-(5), 521, and 752 of the FFDCA, 21 U.S.C. 343-1(a)(1), 343-1(a)(2)-(5), 360k, and 379s.

[132] That exemption applies unless the restaurant were to make an approved nutrient content or health claim about trans fat. In that event, the FDA's regulations provide that "restaurants must provide information on the nutrient that is the basis for the claim, e.g., 'low fat, this meal contains 10 grams of fat.'" *A Guide for Restaurants and Other Retail Establishment* (FDA Center for Food Safety and Applied Nutrition February 1996) (question 73 interpreting 21 C.F.R. 101.10). The FDA has not yet approved any claim for trans fat, other than establishing that products that contain less than 0.5 grams per serving can be considered to contain no trans fat. 68 Fed. Reg. at 41502.

America, Inc. CV 032041 (Marin County Superior Court of California May 2003)(alleging in paragraph 44 that trans fat meets the standard of California Civil Code section 1714.45, which provides that a manufacturer or seller is subject to product liability for a consumer product if the product is not known to be unsafe by the ordinary consumer who consumes the product with the ordinary knowledge common to the community).

In sum, prompt restrictions by the FDA on the use of partially hydrogenated vegetable oils might remove the incentive for state (or local) governments or private parties to act.

X. CONCLUSION

For the reasons stated above, the FDA should immediately initiate (a) a rulemaking to revoke the legal authority for industry to use partially hydrogenated vegetable oils in foods[133] and (b) a program to encourage food manufacturers and restaurants to switch to safer ingredients.

XI. ENVIRONMENTAL IMPACT

The action requested is subject to a categorical exclusion under 21 C.F.R. 25.30 and 25.32 and therefore does not require the preparation of an environmental assessment.

XII. ECONOMIC IMPACT

No statement of the economic impact of the requested action is presented because none has been requested by the Commissioner.[134]

XIII. CERTIFICATION

The undersigned certify that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

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Executive Director

Benjamin Cohen
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[133] As mentioned in section II., as part of the requested rulemaking or if any party objects to the FDA's proposal as requested in this petition, we recognize that the FDA might invite public comment on whether it should approve partially hydrogenated oil as a food additive. CSPI would oppose that unless the amount of trans fat were limited to a *de minimus* level, similar to the Danish government's limit of two percent by weight of the total fat in a food. (Though the FDA states that under 0.5 grams of trans fat per serving of food cannot be reliably measured, it is clear that such a level would allow partially hydrogenated oils that contain 10 percent or even more trans fat. Reliable techniques are available for detecting much lower levels of trans fat.)

[134] 21 C.F.R.10.30(b).

Appendix 1. Commercially Available Substitutes for Partially Hydrogenated Vegetable (and Other) Solid and Liquid Oils
High-oleic canola, corn, soy, sunflower (NuSun), and safflower oils are relatively low in linoleic and linolenic fatty acids (which promote rancidity and reduce fry life)
Inter-esterification (ADM, others) of various oils (corn, palm, and others) with fully hydrogenated soybean oil yields products suitable for formulation of trans-free margarines and shortenings.[135]
Kraft's K-Blazer is a fat substitute made from egg white and milk protein that can be used in some baking applications.[136] Similarly, Simplesse (CP Kelco) is made from whey protein or a combination of milk and egg proteins and can be used in certain baked products.[137] Dairy-Lo, made by Parmalat, is a modified whey protein product that functions like fat in certain baked goods.[138]
Salatrim (Benefat made by Danesco), a solid at room temperature and providing fewer calories per gram than fat, consists of triglycerides made of long- (usually stearic acid) and short-chain fatty acids and can be used in some cookies, cake products, and chocolate systems.[139]
Diacylglyceride (DAG; Enova, made by ADM), made from oleic and linoleic acids, can replace some of the partially hydrogenated oil in baking shortening; it contains less than 2% trans fat by weight.[140]
Use of very long chain fatty acids (such as behenic acid, mixed with stearyl alcohol, used in Thixo, Ltd.'s oil) and emulsifiers may provide effective shortenings without trans.[141]

[135] List GR. Decreasing *trans* and saturated fatty acid content in food oils. Food Technology. 2004;58(1):23-31.

[136] Gupta MK. *Trans*-forming shortenings. Baking & Snack. Nov. 2003, 61-6.

[137] Ibid.

[138] Ibid.

[139] Ibid. Zammer CM. The trans fat dilemma. Food Processing, 2003;64(5):S30

[140] Gupta MK. Op. cit.

[141] FDA, Agency Response Letter, GRAS Notice No. GRN 000069, May 14, 2001.

Appendix 2. Products That Have Been Reformulated with Little or No Partially Hydrogenated (PH) Oil and Trans Fat[1]	
Au Bon Pain	Announced in October 2003 that it would feature trans-free muffins in which PH oil was replaced with non-hydrogenated canola oil.
Burger King	In Denmark, replaced PH oil with non-hydrogenated canola oil for frying.
Frito-Lay	Replaced PH oil with non-hydrogenated vegetable oil in numerous snack foods (including **Doritos**, **Cheetos**, **Tostitos**).
Kraft Foods	Plans to reduce or eliminate PH oil from most of its cookies and crackers by 2004 or 2005. Although the original **Oreo** still contain PH oil, in April 2004 announced three new varieties of trans-free **Oreo** cookies will be released, **New Improved Reduced Fat Oreo**, **Golden Oreo Original**, and **Golden Uh Oh! Oreo**; also in April 2004, the company announced that PH oil in seven varieties of **Triscuits** (**Original Triscuits**, **Reduced Fat**, **Low Sodium Triscuits**, **Deli-Style Rye Triscuits**, **Garden Herb Triscuits**, **Roasted Garlic Triscuits**, **Thin Crisps Triscuits**) was being replaced with non-hydrogenated soybean oil. In May 2004, Kraft said it would soon introduce trans-free **Ritz** and **Saltines** crackers, **Wheat Thins**, and **Nilla Wafers**.
Legal Sea Foods	Eliminated virtually all trans fat in crackers, frying oil, parfried french fries.
Masterfoods (U.K.)	In May 2003, Masterfoods UK announced the removal of PH vegetable oil from the **Mars** and **Snickers** candy bars in the UK (substitute unknown).
McCain Foods USA	In August 2003, McCain began changing from hydrogenated oil to non-hydrogenated canola oil for its **frozen potato products**.
Nestlé (U.K.)	In July 2003, Nestlé announced it would remove PH oils from its **Rolo** and **Toffee Crisp** candy bar (substitute unknown).
New York Fries (Canada)	In March 2004, this 180-outlet company replaced partially hydrogenated canola oil with non-hydrogenated sunflower oil in its **French fries**, eliminating trans and reducing saturated fat by one-third.

[t] Information from the media, companies, and supermarket surveys. Some foods marketed as trans free actually are made with partially hydrogenated oil and contain up to 0.5 grams of trans fat per serving.

Pepperidge Farm	In February 2004, the company announced a new version of Goldfish (**Goldfish Crisps**) made with non-hydrogenated sunflower and/or non-hydrogenated canola oil, instead of the PH oil used in Goldfish. All **Goldfish** cracker varieties will be trans-free by September 2004. The company eliminated PH oil from its "**Natural Whole Grain**" line of breads and plans to eliminate trans in all breads by the end of 2004.
Ruby Tuesday	In November 2003, switched from PH soybean oil to non-hydrogenated canola oil for all fried foods, including French fries. Suppliers of desserts and baked goods also will be required to eliminate PH oils.
Tyson	In February 2004 announced that over a 3-month period, it would remove PH oils from its retail breaded chicken products, such as nuggets, patties, and tenders, and its school foodservice foods, and instead use non-hydrogenated canola and other oils.
Unilever BestFoods	**Promise** margarines, are all made with liquid sunflower oil, some fully hydrogenated soy oil and PH soy oil, and trans-free **I Can't Believe It's Not Butter** spreads are "trans-free" but do contain PH soybean oil.
Voortman Cookies, Ltd.	Replaced PH soy and/or PH cottonseed oil with canola, soy, sunflower, modified palm, or palm oil (all trans-free) in several varieties of wafers and cookies.

Appendix 3. Trans-Containing and Trans-free Versions of Similar Products

Note: Serving sizes of products in a category are not always identical. Data are from labels or other company information, except where indicated. Products made with partially hydrogenated oil are in **bold**; *products containing little or no partially hydrogenated oil are in regular type. All units are grams.*

Product Category	Product	Serving	Oil(s)	Total Fat	Sat. Fat	Trans Fat	Sat. + Trans Fat	Info. Source**
Cookies	**Nabisco Oreo**	**34g**	**PH*** soybean**	7	1.5	2.5	4	
	Nabisco Golden Uh-Oh Oreo	34g	palm, high-oleic canola	7	2	0	2	
	Nabisco Reduced Fat Oreo	34g	high-oleic canola, palm	4.5	1	0	1	
	Frookie Frookwich Chocolate Sandwich Cookies	31g	canola	7	2	0	2	
	Country Choice Sandwich Cremes	27g	high-oleic sunflower and/or safflower	5	0.5	0	0.5	
	365 (Whole Foods) Sandwich Cremes	27g	canola	5	0.5	0	0.5	
	Newman's Own Newman-O's cookies	28g	palm	4.5	1.5	0	1.5	
	Famous Amos Vanilla Sandwich Cookies	**33g**	**PH soybean and/or cottonseed**	**6**	**1.5**	**NA****	**>1.5**	
	Country Choice Vanilla Sandwich Cremes	27g	oleic safflower	5	0.5	0	0.5	
	Frookie Frookwich Vanilla Sandwich Cookies	33g	soybean	6	0.5	0	0.5	
	Nabisco Nilla Wafers	**30g**	**PH soybean**	**6**	**1.5**	**2**	**3.5**	
	Keebler Golden Vanilla Wafers	**31g**	**PH soybean and/or cottonseed**	**6**	**1.5**	**NA**	**>1.5**	
	Country Choice Vanilla Wafers	30g	oleic safflower or oleic sunflower	5	0.5	0	0.5	
	Archway Oatmeal Raisin	**29g**	**PH soybean and/or cottonseed**	**3.5**	**1**	**NA**	**>1**	
	Country Choice Oatmeal Raisin	23g	canola, high-oleic sunflower and/or high-oleic safflower	3	0.5	0	0.5	

**From product labels, telephone calls to companies, or company websites, except where indicated.

***PH=partially hydrogenated

****NA=not available

Product Category	Product	Serving	Oil(s)	Total Fat	Sat. Fat	Trans Fat	Sat. + Trans Fat	Info. Source
	Nabisco Chips Ahoy!	**33g**	**PH soybean**	**8**	**2**	**1.5**	**3.5**	
	Nabisco Reduced Fat Chips Ahoy !	32g	high oleic canola, palm	5	1.5	0	1.5	
	Newman's Own Chocolate Chip Cookies	33g	palm	7	3	0	3	
	Nabisco Fig Newtons	**31g**	**PH soybean**	**2.5**	**0**	**1**	**1**	
	365 (Whole Foods) Organic Fig Bars	38g	soybean	1	0	0	0	
	Nabisco Ginger Snaps	**28g**	**PH soybean**	**2.5**	**0.5**	**1**	**1.5**	
	American Natural & Specialty Brands Mi-Del Ginger Snaps	30g	canola	4	0	0	0	
	Nabisco Teddy Grahams Honey	**31g**	**PH soybean**	**4**	**1**	**1.5**	**2.5**	
	Hain Kidz Chocolate Animal Grahams	30g	oleic safflower	3	0	**0**	0	
	Our Family Farm Wild Animal Vanilla Cookies	33g	soybean	3.5	0.5	0	0.5	
	Hain Kidz Animal Crackers	28g	soybean	2	0.5	0	0.5	
Crackers	**Nabisco Wheat Thins**	**31g**	**PH soybean**	**6**	**1**	**2.5**	**3.5**	
	Giant Food Original Thin Wheats	**29g**	**PH soybean and/or cottonseed**	**6**	**1.5**	**N/A**	**>1.5**	
	Hain Wheatettes	30g	oleic safflower	3.5	0	0	0	
	Nabisco Ritz	**16g**	**PH soybean**	**4**	**1**	**1**	**1**	NAH 9/96*
	Barbara's Rite Lite Round	15g	high-oleic safflower	1	0	0	0	
	Late July Classic Rich Crackers	15g	high-oleic safflower, palm	2	0	0	0	
	Hains Rich Baked Crackers	15g	oleic safflower	2.25*	0.5	0	0.5	
	Kraft Cheese Nips	**30g**	**PH soybean**	**6**	**1.5**	**2**	**3.5**	
	Sunshine Cheez-It	**30g**	**PH soybean and/or cottonseed**	**7.5**	**1.5**	**1.5**	**3**	CR 3/2003*
	Late July Cheddar Cheese Crackers	30g	oleic safflower	5	1.5	0	1.5	
	Nabisco Triscuits	**28g**	**PH soybean**	**5**	**1**	**1**	**2**	
	Triscuits trans-free	28g	soybean	4.5	0.5	0	0.5	Kraft Press Release
	Sunshine Soup & Oyster Crackers	**15g**	**PH soybean and/or cottonseed**	**1.5**	**0**	**NA**	**>1.5**	
	Giant Soup & Oyster Crackers	**15g**	**PH soybean and/or cottonseed**	**1.5**	**0**	**NA**	**>1.5**	
	Hain Oyster Crackers	15g	oleic safflower	1	0	0	0	

* Adapted from label listing 30g serving.

Product Category	Product	Serving	Oil(s)	Total Fat	Sat. Fat	Trans Fat	Sat. + Trans Fat	Info. Source
Fish Sticks, Frozen	Van de Kamp's Crunchy Fish Sticks	114g	PH soybean	13	2.5	NA	>2.5	
	Mrs. Paul's Crunchy Fish Sticks	95g	PH soybean	12	2.5	NA	>2.5	
	Ian's Lightly Breaded Fish Sticks	93g	soybean	6	1	0	1	
French Fries, Frozen	Ore-Ida Golden Crinkles	84g	PH soybean, cottonseed	3.5	1	0.5	1.5	CR 11/2003*
	McCain Crinkle Cut French Fries	85g	canola	4	0	0	0	
French Fries, Restaurant	Burger King Fries, medium	117g	PH soybean	18	5	4.5	9.5	
	McDonalds Fries, medium	138g	PH soybean	22.5	5	5	10	CR 11/2003
	Ruby Tuesday Fries	117g	canola	18	2	0	2	
Margarine	Fleischmann's Original Margarine (sticks)	1 tbsp.	liquid corn oil, PH soybean	11	2	NA	>2	
	I Can't Believe It's Not Butter 70% Vegetable Oil Spread (stick)	1 tbsp.	PH and liquid soybean oils	10	1.5	2	3.5	CR 3/2003
	Fleischmann's Margarine (tub)	1 tbsp.	liquid corn oil, PH soybean	9	1.5	NA	>1.5	
	Parkay 60% Vegetable Oil Spread (tub)	1 tbsp.	liquid soybean, PH Soybean	8	1.5	NA	>1.5	
	Shedd's Spread Spreadable (Sticks)	1 tbsp.	PH soybean, liquid soybean	8	1.5	NA	>1.5	
	I Can't Believe It's Not Butter 70% Vegetable Oil Spread (tub)	1 tbsp.	liquid soybean, liquid canola, hydrogenated soybean, PH soybean	10	2	0	2	
	Promise New Promise 60% Vegetable Oil Spread (tub)	1 tbsp	liquid soybean, canola, sunflower, palm oil, palm kernel oil	8	1.5	0	1.5	
Pies, Apple	Mrs. Smith's Apple Pie	131g	PH vegetable shortening	17	3.5	4	7.5	NAH 2002*
	Truly Natural Apple Pie	118g	palm, soybean, canola, olive	13	5	0	5	
Pie Crusts, frozen	Giant Foods Pie Shell Crust	1/8 pie	PH soybean and/or cottonseed	7	1.5	NA	>1.5	
	Pillsbury Pet Ritz Pie Crust	1/8 pie	PH lard	5	2	NA	>2	
	Mother Nature's Goodies, Inc., Whole Wheat Pie Shells	25g	canola, soybean	6	1	0	1	

Product Category	Product	Serving	Oil(s)	Total Fat	Sat. Fat	Trans Fat	Sat. + Trans Fat	Info. Source
Pie Crusts, Graham Cracker, shelf-stable	Nabisco Honey Maid Pie Crust	28g	PH oil	7	1.5	3	4.5	
	Nabisco Nilla Pie Crust	28g	PH soybean and/or cottonseed	7	1.5	3	4.5	
	Wholly Healthy Truly Natural Graham Cracker Pie Crust	21g	palm	5	2.5	0	2.5	
Shortening	Crisco	1 tbsp.	PH soybean and/or cottonseed	12	3	1.5	4.5	
	Crisco All Vegetable Oil (Sticks, shelf-stable)	12g	PH soybean, PH cottonseed	12	3	NA	>3	
	Crisco All Vegetable Shortening Zero Trans	1 tbsp.	soybean oil, hydrogenated soybean oil	12	3	0	3	

Declaration of Erich O. Grosz

Exhibit 9

Case No. 1:07-CV-01092 (RJL)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Center for Science in the Public Interest	)	
Plaintiff,	)	
-against-	)	Civil Action No. 07-1092(RJL)
Burger King Corporation	)	
Defendant.	)	

NOTICE OF FILING

PLEASE TAKE NOTICE that the undersigned is filing the Burger King Nutritional Information Poster attached as Exhibit 9 to the Declaration of Erich O. Grosz with the Clerk's Office. Due to size limitations, Exhibit 9 can not be filed electronically and is therefore being filed with the Clerk's Office and served by Federal Express on opposing counsel pursuant to LCvR 5.4(e)(1).

Dated: Washington, D.C.
July 20, 2007

Respectfully submitted,

DEBEVOISE & PLIMPTON LLP

/s/ Ada Fernandez Johnson

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and

Roger E. Podesta
(admitted pro hac vice)
Erich Grosz
(admitted pro hac vice)
919 Third Avenue
New York, New York 10022
Telephone: (212) 909-6000
Facsimile: (212) 909-6836

CERTIFICATE OF SERVICE

I, Terrianne Muenzen, associated with Debevoise & Plimpton LLP, attorneys for defendant herein, certify:

I am over eighteen (18) years of age. On the 20th day of July 2007, I caused to be served copies of the Burger King Nutritional Information Poster attached as Exhibit 9 to the Declaration of Erich O. Grosz by Federal Express to counsel for the plaintiffs to this action at the following addresses:

Steven N. Berk
Chavez & Gertler LLP
1225 Fifteenth Street NW
Washington, D.C. 20005

Stephen Gardner
Center for Science in the Public Interest
5646 Milton Street, Suite 211
Dallas, Texas 75206

I certify under penalty of perjury that the foregoing is true and correct.

Executed on July 20, 2007

/s/ Terrianne Muenzen
Terrianne Muenzen

Declaration of Erich O. Grosz

Exhibit 10

Case No. 1:07-CV-01092 (RJL)

Nutritional Information

Core Menu Items April 2007

NUTRITION: MENU ITEMS

WHOPPER® Sandwiches	Serving Size (g)	Calories	Total fat (g)	Saturated fat * (g)	Trans Fat (g)	Cholesterol (mg)	Sodium (mg)	Total Carbs. (g)	Dietary Fiber(g)	Total Sugars (g)	Protein (g)
WHOPPER® Sandwich	290	670	39	11	1.5	51	1020	51	3	11	28
w/o Mayo	269	510	22	9	1	80	880	51	3	11	28
WHOPPER® Sandwich with Cheese	315	760	47	16	1.5	115	1450	52	3	11	33
w/o Mayo	294	600	30	14	1.5	100	1310	52	3	11	32
DOUBLE WHOPPER® Sandwich	373	900	57	19	2	175	1090	51	3	11	47
w/o Mayo	352	740	39	17	2	160	950	51	3	11	47
DOUBLE WHOPPER® Sandwich with Cheese	398	990	64	24	2.5	195	1520	52	3	11	52
w/o Mayo	376	830	47	22	2	180	1380	52	3	11	52
TRIPLE WHOPPER® Sandwich	456	1130	74	27	3	255	1160	51	3	11	67
w/o Mayo	434	980	57	24	2.5	240	1020	51	3	11	66
TRIPLE WHOPPER® Sandwich With Cheese	480	1230	82	32	3.5	275	1590	52	3	11	71
w/o Mayo	459	1070	65	29	3	260	1450	52	3	11	71
WHOPPER JR.® Sandwich	158	370	21	6	0.5	50	570	31	2	6	15
w/o Mayo	147	290	12	4.5	0	40	490	31	2	6	15
WHOPPER JR.® Sandwich with Cheese	170	410	24	8	1	60	780	32	2	6	18
w/o Mayo	149	330	16	7	0.5	55	710	31	2	6	17
Bacon (1 Strip)	2.5	15	1	0	0	5	50	0	0	0	1

Fire-Grilled Burgers	Serving Size (g)	Calories	Total fat (g)	Saturated fat * (g)	Trans Fat (g)	Cholesterol (mg)	Sodium (mg)	Total Carbs. (g)	Dietary Fiber(g)	Total Sugars (g)	Protein (g)
Hamburger	121	290	12	4.5	0	40	560	30	1	6	15
Cheeseburger	133	330	16	7	0.5	55	780	31	1	6	17
Double Hamburger	164	410	21	9	1	85	600	30	1	6	25
Double Cheeseburger	189	500	29	14	1.5	105	1030	31	1	6	30
Bacon Cheeseburger	138	360	18	8	0.5	60	870	31	1	6	19
Bacon Double Cheeseburger	194	530	31	14	1.5	110	1130	32	1	6	32
BK™ Double Stacker	190	610	39	16	1.5	125	1100	32	1	5	34
BK™ Triple Stacker	250	800	54	23	2	185	1450	33	1	5	48
BK™ Quad Stacker	311	1000	68	30	3	240	1800	34	1	6	62
The Angus Steak Burger	273	640	33	10	1.5	185	1260	55	3	10	33

Chicken, Fish, & Veggie	Serving Size (g)	Calories	Total fat (g)	Saturated fat * (g)	Trans Fat (g)	Cholesterol (mg)	Sodium (mg)	Total Carbs. (g)	Dietary Fiber(g)	Total Sugars (g)	Protein (g)
TENDERGRILL® Chicken Sandwich	258	450	10	2	0	75	1210	53	4	9	37
with Mayo	258	510	19	3.5	0.5	75	1180	49	4	7	37
w/o Sauce	244	400	7	1.5	0	70	1090	49	4	7	36
TENDERCRISP® Chicken Sandwich	286	780	43	8	4	75	1730	73	4	8	25
Spicy TENDERCRISP® Chicken Sandwich	300	720	36	7	4	65	2000	74	5	8	25
w/o Sauce	256	570	21	4.5	3.5	55	1540	73	4	8	25
Original Chicken Sandwich	219	660	40	8	2.5	70	1440	52	4	5	24
w/o Mayo	190	450	17	4	2	50	1250	52	4	5	23
CHICKEN TENDERS® Kid's Meal (4 pc)	62	170	10	2.5	1.5	25	480	11	0	0	9
CHICKEN TENDERS® (5 pc)	77	210	12	3	2	35	600	13	0	0	12
CHICKEN TENDERS® Big Kid's Meal (6 pc)	92	250	15	3.5	2.5	40	720	16	0	0	14
CHICKEN TENDERS® (8 pc)	123	340	20	5	3	55	960	21	<1	1	19
Barbecue Dipping Sauce (1 oz)	28	40	0	0	0	0	310	11	0	10	0
Honey Flavored Dipping Sauce (1 oz)	28	90	0	0	0	0	0	23	0	22	0
Honey Mustard Dipping Sauce (1 oz)	28	90	6	1	0	10	180	8	0	7	0
Sweet and Sour Dipping Sauce (1 oz)	28	45	0	0	0	0	55	11	0	10	0
Ranch Dipping Sauce (1 oz)	28	140	15	2.5	0	5	95	1	0	1	1
BK™ CHICKEN FRIES (6 pc)	85	260	15	3.5	3	35	650	18	2	1	12
9 pc	128	390	23	5	4.5	50	980	26	3	1	18
12 pc	170	520	31	7	6	65	1300	35	4	2	25
Buffalo Dipping Sauce (1 oz)	28	80	8	1.5	0	5	350	2	0	1	0
BK BIG FISH® Sandwich	250	630	30	6	2.5	60	1380	67	4	8	24
w/o Tartar Sauce	222	470	13	3	2	50	1240	65	3	7	23
Spicy BK BIG FISH® Sandwich	250	620	29	6	2.5	60	1540	67	4	7	24
BK VEGGIE® Burger**	215	420	16	2.5	0	10	1100	46	7	8	23
w/ Cheese	228	470	20	5	0	20	1320	47	7	9	25
w/o Mayo	205	340	8	1	0	0	1030	46	7	8	23

Side Orders	Serving Size (g)	Calories	Total fat (g)	Saturated fat * (g)	Trans Fat (g)	Cholesterol (mg)	Sodium (mg)	Total Carbs. (g)	Dietary Fiber(g)	Total Sugars (g)	Protein (g)
MOTT'S® Strawberry Flavored Apple Sauce	113	90	0	0	0	0	0	23	<1	21	0
Onion Rings - Small	43	150	7	2	1.5	0	220	19	1	2	2
Onion Rings - Medium	91	320	16	4	3.5	0	460	40	3	5	4
Onion Rings - Large	130	450	22	6	5	0	660	57	4	7	6
Onion Rings - King	150	520	26	7	6	5	760	66	5	8	7
Zesty Onion Ring Dipping Sauce (1 oz)	28	150	15	2.5	0	15	210	3	<1	2	0
CHEESY TOTS™ - Small (6 pc)	77	210	12	4.5	2	20	650	20	2	1	7
CHEESY TOTS™ - Medium (9 pc)	115	320	18	7	3	30	970	30	2	2	10
CHEESY TOTS™ - Large (12 pc)	153	430	24	9	4	40	1300	40	3	2	14
French Fries - Small (Salted)	74	230	13	3	3	0	380	26	2	1	2
French Fries - Medium (Salted)	116	360	20	4.5	4.5	0	590	41	4	1	4
French Fries - Large (Salted)	150	500	28	6	6	0	820	57	5	1	5
French Fries - King (Salted)	194	600	33	8	7	0	990	69	6	2	6

French Fries - Small (Salt not added)•	74	230	13	3	3	0	240	26	2	1	2
French Fries - Medium (Salt not added)•	116	360	20	4.5	4.5	0	380	41	4	1	4
French Fries - Large (Salt not added)•	160	500	28	6	6	0	530	57	5	1	5
French Fries - King (Salt not added)•	194	600	33	8	7	0	640	69	6	2	6
Ketchup (Packet)	10	10	0	0	0	0	125	3	0	2	0

Salads (w/out dressing or garlic parmesan croutons)	Serving Size (g)	Calories	Total fat (g)	Saturated fat * (g)	Trans Fat (g)	Cholesterol (mg)	Sodium (mg)	Total Carbs. (g)	Dietary Fiber(g)	Total Sugars (g)	Protein (g)
Side Garden Salad	98	15	0	0	0	0	0	3	1	1	1
TENDERGRILL™ Chicken Garden Salad	292	240	9	3.5	0	80	720	8	4	3	33
TENDERCRISP™ Chicken Garden Salad	306	400	21	7	3.5	70	1170	32	5	5	22
Garden Salad (no chicken)	184	90	5	2.5	0	15	125	7	3	3	5

Salad Dressings & Toppings	Serving Size (g)	Calories	Total fat (g)	Saturated fat * (g)	Trans Fat (g)	Cholesterol (mg)	Sodium (mg)	Total Carbs. (g)	Dietary Fiber(g)	Total Sugars (g)	Protein (g)
KEN'S® Light Italian Dressing (2 oz)	57	120	11	1.5	0	0	440	5	0	4	0
KEN'S® Ranch Dressing (2 oz)	57	190	20	3	0	20	560	2	0	1	1
KEN'S® Creamy Caesar Dressing (2 oz)	57	210	21	4	0	25	610	4	0	3	3
KEN'S® Honey Mustard Dressing (2 oz)	57	270	23	3	0	20	520	15	0	14	1
KEN'S® Fat Free Ranch Dressing (2 oz) (Restaurant Option)	57	60	0	0	0	0	740	15	2	5	0
Garlic Parmesan Croutons	14	60	2	0	0	0	120	9	0	1	1

Desserts	Serving Size (g)	Calories	Total fat (g)	Saturated fat * (g)	Trans Fat (g)	Cholesterol (mg)	Sodium (mg)	Total Carbs. (g)	Dietary Fiber(g)	Total Sugars (g)	Protein (g)
Dutch Apple Pie	108	300	13	3	3	0	270	45	1	23	2
HERSHEY®'S Sundae Pie	79	310	19	12	0	10	220	32	1	22	3

Breakfast	Serving Size (g)	Calories	Total fat (g)	Saturated fat * (g)	Trans Fat (g)	Cholesterol (mg)	Sodium (mg)	Total Carbs. (g)	Dietary Fiber(g)	Total Sugars (g)	Protein (g)
CROISSAN'WICH® Egg & Cheese	115	300	17	6	2	145	740	26	<1	5	12
CROISSAN'WICH® Sausage & Cheese	106	370	25	9	2	50	810	23	<1	4	14
CROISSAN'WICH® Sausage, Egg & Cheese	159	470	32	11	2.5	180	1060	26	<1	5	19
CROISSAN'WICH® Ham, Egg & Cheese	149	340	18	6	2	160	1230	26	1	6	18
CROISSAN'WICH® Bacon, Egg & Cheese	122	340	20	7	2	155	890	26	<1	5	15
DOUBLE CROISSAN'WICH™ w/ Sausage, Egg, & Cheese	215	680	51	18	3	220	1600	26	<1	6	29
DOUBLE CROISSAN'WICH™ w/ Bacon, Egg, & Cheese	142	430	27	10	2	175	1250	27	<1	6	21
DOUBLE CROISSAN'WICH™ w/ Ham, Egg, & Cheese	196	420	23	9	2	185	2210	27	1	7	27
DOUBLE CROISSAN'WICH™ w/ Sausage, Bacon, Egg, & Cheese	179	560	39	14	2.5	200	1430	27	<1	6	25
DOUBLE CROISSAN'WICH™ w/ Ham, Bacon, Egg, & Cheese	169	420	24	9	2	180	1600	27	1	7	24
DOUBLE CROISSAN'WICH™ w/ Ham, Sausage, Egg, & Cheese	206	550	37	14	2.5	205	2040	27	1	6	28
Enormous Omelet Sandwich	266	730	45	16	1	330	1940	44	2	8	37
Ham Omelet Sandwich	139	330	14	5	0	90	1130	35	1	9	16

Sausage Biscuit	118	390	26	8	5	35	1020	28	1	2	12
Ham, Egg, & Cheese Biscuit	156	390	22	7	5	145	1410	31	1	4	16
Sausage, Egg, & Cheese Biscuit	183	530	37	12	6	175	1490	31	1	4	20
Bacon, Egg & Cheese Biscuit	146	410	25	8	5	150	1320	31	1	4	16
Hash Browns - Small	84	260	17	4.5	5	0	500	25	2	0	2
Hash Browns - Medium	140	430	28	8	9	0	830	42	4	0	4
Hash Browns - Large	202	620	40	11	13	0	1200	60	6	1	5
CHEESY TOTS™ - See Side Orders											
Cini-minis	108	390	18	5	4	20	560	51	2	19	7
Vanilla Icing (for Cini-minis)	28	110	3	0.5	0.5	0	40	21	0	20	0
French Toast Sticks (3 piece)	65	230	12	2.5	2.5	0	260	27	1	6	4
French Toast Sticks (5 piece)	109	380	19	4.5	4.5	0	430	45	2	11	6
French Toast Kid's Meal (with syrup)	494	660	22	6	4.5	10	580	102	3	57	15
Grape Jam	12	30	0	0	0	0	0	7	0	6	0
Strawberry Jam	12	30	0	0	0	0	0	7	0	6	0
Breakfast Syrup	28	80	0	0	0	0	20	21	0	14	0
Shakes	**Serving Size (g)**	**Calories**	**Total fat (g)**	**Saturated fat * (g)**	**Trans Fat (g)**	**Cholesterol (mg)**	**Sodium (mg)**	**Total Carbs. (g)**	**Dietary Fiber(g)**	**Total Sugars (g)**	**Protein (g)**
Vanilla Milk Shake - Kid's	228	310	11	7	0	45	180	44	0	43	6
Vanilla Milk Shake - Small	296	400	15	9	0	60	240	57	0	55	8
Vanilla Milk Shake - Medium	412	560	21	13	0.5	85	330	79	0	77	11
Vanilla Milk Shake - Large	608	820	30	19	1	125	490	117	<1	114	16
Vanilla Milk Shake - King	785	1070	39	25	1	160	640	151	<1	147	21
Chocolate Milk Shake - Kid's	245	370	11	7	0	40	260	61	1	59	6
Chocolate Milk Shake - Small	315	470	14	9	0	55	320	75	1	72	8
Chocolate Milk Shake - Medium	447	690	20	12	0	75	480	114	2	110	11
Chocolate Milk Shake - Large	640	950	29	19	0.5	115	640	151	2	146	16
Chocolate Milk Shake- King	842	1260	38	24	1	145	870	204	3	197	21
Strawberry Milk Shake - Kid's	244	360	10	7	0	40	180	60	0	58	6
Strawberry Milk Shake - Small	314	460	14	9	0	55	240	73	0	71	7
Strawberry Milk Shake - Medium	444	660	19	12	0	75	330	111	0	109	10
Strawberry Milk Shake - Large	637	930	28	18	0.5	115	490	148	<1	145	15
Strawberry Milk Shake - King	838	1230	36	23	1	145	640	200	<1	195	19

Footnote for "Saturated Fat" (g)":	*Does not include Trans Fat.
Footnote for BK VEGGIE® Burger:**	**Burger King Corporation makes no claim that the BK VEGGIE® Burger or any other of its products meets the requirements of a vegan or vegetarian diet. The patty is cooked in the microwave.
Footnote for "Salt not added-French Fries"	•To reduce sodium, you can order french fries without added salt

CHEESY TOTS™ is a trademark of H.J. Heinz Company and used under license by Burger King Corporation.

Beverages

Cup Serving Size*:	COCA COLA® CLASSIC‡ Kids	Small	Medium	Large	King
Calories	110	140	200	290	390
Carbohydrate (g)	30	39	53	79	104
Sugar (g)	30	39	53	79	104
Sodium (mg)	0	0	0	5	10

Cup Serving Size*:	SPRITE® ‡ Kids	Small	Medium	Large	King
Calories	110	140	200	290	390
Carbohydrate (g)	29	39	53	79	104
Sugar (g)	29	39	53	79	104
Sodium (mg)	25	30	45	65	85

Cup Serving Size*:	DR. PEPPER®‡ Kids	Small	Medium	Large	King
Calories	110	140	190	280	380
Carbohydrate (g)	29	39	52	78	104
Sugar (g)	29	39	52	78	104
Sodium (mg)	25	35	50	70	95

Cup Serving Size*:	DIET COKE® ‡ Kids	Small	Medium	Large	King
Calories	0	0	0	0	5
Carbohydrate (g)	0	0	0	0	0
Sugar (g)	0	0	0	0	0
Sodium (mg)	10	15	20	25	35

Cup Serving Size*:	BK JOE™ Regular Coffee‡ Small	Med	Large
Calories	5	10	10
Carbohydrate (g)	1	1	2
Sugar (g)	0	0	0
Sodium (mg)	15	20	25
Protein (g)	1	1	1

BK JOE™Turbo Coffee‡ Small	Med	Large
10	10	15
1	2	2
0	0	0
20	30	40
1	1	2

BK JOE™ Decaf Coffee‡ Small	Med	Large
5	5	5
0	0	0
0	0	0
5	10	10
1	1	1

*See next page for fluid ounce cup sizes.

Cup Serving Size:	MINUTE MAID® Apple Juice 6.67 oz	MINUTE MAID® Orange Juice 8 oz	AQUAFINA® Water 16 fl oz	ICEE® COCA COLA Small	Medium	ICEE® MINUTE MAID® Cherry‡ Small	Medium
Calories	90	140	0	110	140	110	140
Carbohydrate (g)	23	33	0	31	40	31	40
Sugar (g)	21	30	0	31	40	31	40
Sodium (mg)	15	20	0	10	10	5	10
Protein (g)	0	2	0	0	0	0	0
Vitamin C (mg)	60	42	0	0	0	0	0

These Beverages do not contain fat, saturated fat, trans fat, cholesterol, or fiber.

Footnote for Beverages "‡": These values represent Sodium derived from ingredients other than water. The actual amount of Sodium in the beverages will vary depending on the quantity contained in the water supply where the finished beverages are produced.

Cup Serving Sizes:	fl oz
Kid's	12
Small	16
Medium	22
Large	32
King	42

Declaration of Erich O. Grosz

Exhibit 11

Case No. 1:07-CV-01092 (RJL)

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BURGER KING CORP. ANNOUNCES NATIONWIDE ROLLOUT OF TRANS FAT FREE OIL

07/06/2007

MIAMI – July 6, 2007 – Burger King Corp. (NYSE: BKC) announced today that the company has begun the rollout of a trans fat free cooking oil to its restaurants in the United States. Two trans fat free oil blends have passed the company's rigorous operational, supply and consumer criteria, allowing the company to begin the national rollout.

The company expects that every U.S. restaurant will be using trans fat free cooking oil by the end of 2008. If adequate supply becomes available, the U.S. rollout of trans fat free oils could be completed substantially sooner.

"We are delighted by the outstanding consumer response to our new oil," said Russ Klein, president of global marketing, strategy and innovation. "In tests on over a dozen core items, consumers determined that BURGER KING® products cooked in trans fat free oil tasted the same or better than products cooked in the traditional oil. We are proud to offer a healthier oil with the same great taste."

About Burger King Corporation Inc.

The BURGER KING(R) system operates more than 11,200 restaurants in all 50 states and in more than 65 countries and U.S. territories worldwide. Approximately 90 percent of BURGER KING(R) restaurants are owned and operated by independent franchisees, many of which are family-owned operations that have been in business for decades. To learn more about Burger King Holdings Inc., please visit the company's Web site at www.bk.com.