COMMENTS OF THE COMPETITIVE ENTERPRISE INSTITUTE REGARDING THE TENTATIVE DETERMINATION REGARDING PARTIALLY HYROGENATED OILS: DOCKET NUMBER FDA-2013-N-1317.

BY ELECTRONIC MAIL [http://www.regulations.gov]
Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852
Re: The tentative determination regarding partially hydrogenated oils: Docket No. FDA–2013–N–1317

I. Introduction

The Competitive Enterprise Institute (CEI) is non-profit organization based in Washington, D.C., that has a longstanding interest in protecting and expanding consumer choice and in opposing overregulation and unnecessary burdens on commercial activity. We recognize that heart disease, which kills more Americans than any other condition, is a serious problem and understand the desire to take action, in order to prevent loss of life. However, we ardently oppose the U.S. Food and Drug Administration's (FDA) tentative determination to revoke the Generally Recognized as Safe (GRAS) status of partially hydrogenated oil (PHOs), also known as trans fats. We believe this would result in a de facto ban on the use of all trans fats as a food additive; ostensibly, the goal of the GRAS revocation. We believe the case for revoking PHOs GRAS status is based on flawed science and political pressure.

Furthermore, such a ban will not improve Americans' heart health and lead to a host of negative unforeseen consequences, from increased food prices to greater sugar and saturated fat consumption. It represents a dangerous sea change in how the FDA defines "harm," by banning additives, not because they are "unsafe," but that might be "unhealthy" if consumed in excess and represent potential increased health risks due to overconsumption throughout the life of a consumer. This opens the door to revoke the GRAS status of virtually any food substance, not prior-sanctioned, that FDA regulators deem as "unhealthy" in any way.

In recent years, consumption of PHO has decreased dramatically, thanks to consumer education and demand for healthier food options. As the FDA noted in its press release, "[T]rans fat intake among American consumers has declined from 4.6 grams per day in 2003 to about 1 gram per day in 2012."[1]

The American Heart Association (AHA) recommends eating a maximum of 2 grams of trans fats per day.[2] That includes industrially produced trans fats, such as those in partially hydrogenated oils, and naturally occurring trans fats or ruminant trans fats (rTFA) found in beef products, including cheese, milk, and butter. But are natural trans fats associated with the same health risks as industrially produced trans fats? Based on the limited available research, it appears that natural trans fats are not associated with increased heart disease risk and may provide some health benefits.

A 2011 study found that, "[R]esults from epidemiological studies generally have shown an inverse or no association between rTFA intake and CHD across multiple geographical locations."[3] Furthermore emerging research suggests that consuming low amounts of ruminant trans fatty acid—less than 2 percent of daily energy intake—may be associated with cardiovascular benefits,[4] and that, "the intake of ruminant *trans* fats may decrease body weight and reduce fat deposition."[5]

Moreover, looking at just the amount of artificial trans fats the average American consumes daily, the rate is far below the AHA suggested limit and declining. Additionally, the average American consumes about 1.2 grams of ruminant trans fat daily, putting the total daily average at 2.2 grams—just slightly over the recommended limit.[6]

Clearly, our understanding of the health effects of consuming natural trans fats is still evolving. Giving consumers information about the latest research and current understanding of nutrition allows them to use their own judgment in determining the risks of certain foods and make their own choices. Considering that the amount of trans fat in the food supply has declined by more than 75 percent since 2005, this approach appears to be more effective than forcing a one-size-fits-all "healthy diet" on the whole country.[7]

When public health advocates demonize certain food products or regulators ban them, consumers and food companies may switch to alternatives, but it doesn't mean those alternatives will be healthier. Indeed, this was the case when Americans switched from animal fats to trans fats at the urging of public health advocates. Thus, we strongly urge the FDA to reconsider its determination on partially hydrogenated oils.

II. Government's Poor Track Record on Dietary Advice

While public health advocates' education campaigns deserve some credit for the decreased use of trans fats, they also share part of the blame for introducing these now "harmful" fats into the American diet in the first place. In the 1980s, responding to the flawed research connecting dietary saturated fat and cholesterol with increased heart disease risk, activist organizations—including the Center for Science in the Public Interest (CSPI) and National Heart Savers Association (NHSA)—campaigned against corporations' use of saturated fats. CSPI's 1988 report, "Saturated Fat Attack," described trans fats as "more healthful," something we now know to be false. Current research has shown that saturated fat is by no means a "poison," and that trans fat is not a healthier alternative.[8]

Then in 1994, without any sense of irony, CSPI petitioned the U.S. Food and Drug Administration (FDA) to mandate that trans fats be labeled on packaged foods and held a press conference criticizing food companies for doing what it had pushed for in the first place: replace natural fats with partially hydrogenated oils. As Dr. Elizabeth Whelan of the American Council on Science and Health described it,

"They've called a press conference to complain about a 'problem' that they themselves were responsible for creating!"[9]

CSPI's belief in a connection between dietary saturated fat and heart disease is understandable, because the U.S. government had been perpetuating the myth of a causal link between dietary fat and cholesterol and increased heart disease risk since 1977. That year, the Senate Select Committee on Nutrition and Human Needs published its report, "Dietary Goals for the United States," better known as the McGovern Report, which recommended increased consumption of complex carbohydrates and naturally occurring sugars and reduced consumption of refined and processed sugars, total fat, saturated fat, cholesterol, and sodium.[10] The report based its recommendations on the University of Minnesota scientist Ancel Keys's "lipid hypothesis," which supposed a direct and causational relationship between dietary cholesterol and fat with the development of arteriosclerosis.

The committee published its recommendations despite scientists' and physicians' testimony pointing out the flaws in the research making this connection and pleas to wait for more research. However, Sen. George McGovern (D-S.D.), who headed the select committee, declared that he and his colleagues don't have "the luxury that a research scientist has, of waiting until every last shred of evidence is in." This tendency to not want to wait for scientific proof has been driving bad nutritional legislation, which can be partially blamed for the increase in preventable diseases in the last four decades.

Then the U.S. Department of Agriculture (USDA), despite being advised by metabolism expert Philip Handler, then-president of the Food and Nutrition Board of the National Academy of Sciences, that the McGovern report was "nonsense," published recommendations for how Americans could implement the McGovern report guidelines—thus perpetuating the advice to avoid fat and eat more grains. Americans, listening to the government's recommendations—reduced their consumption of cholesterol and fat and increased their consumption of carbohydrates. Since the McGovern Report's publication, the lipid hypothesis has been invalidated and modern clinical research and meta-analyses have been unable to show an association of saturated fat intake with cardiovascular disease risk.[11]

This track record of making policy based on shaky science is not limited to the issue of dietary fat. In 1977, the federal government mandated placing warning labels on products containing saccharine, claiming it caused cancer. It took the government 20 years to admit this was wrong. The Dietary Guidelines for Americans, published by the USDA in 1980, eventually became the USDA Food Pyramid, which was supposed to advise Americans on the composition of a healthy diet. It recommended eating less meat and fat and more carbohydrates. Many Americans heeded this advice. Since then, rates of obesity, diabetes, and numerous other ailments have skyrocketed.

More recently, in July 2013, the Centers for Disease Control and Prevention (CDC) amended its recommendation that consumers eat no more than 1,500 mg of sodium a day. This came after an Institute of Medicine (IOM) committee that convened at the CDC's request found no evidence to suggest that consuming more than 2,300 mg of sodium was correlated with any increase in risk for heart

disease, stroke, or death.[12] And recently, a study published by researchers at the Arnold School of Public Health at the University of South Carolina claimed that 40 years' worth of CDC data about Americans' consumption habits are invalid due to a flawed method of data collection. The report deemed the National Health and Nutrition Examination Survey, a research program that has been informing government nutritional research for the past four decades years, not "physiologically credible."[13]

III. Flawed basis for GRAS revocation: No evidence that further reduction in trans fat consumption will improve health outcomes

With regard to trans fats, the evidence of its effects on the human diet is by no means settled. A comprehensive review of studies of trans fats published in 2006 in the *New England Journal of Medicine* reports a strong and reliable connection between trans-fat consumption and coronary heart disease (CHD), concluding, "On a per-calorie basis, trans fats appear to increase the risk of CHD more than any other macronutrient, conferring a substantially increased risk at low levels of consumption (1 to 3% of total energy intake)." However, as the FDA noted in its press release, the intake of trans fats in the average American's diet has fallen to below 1 percent of total energy intake—about 0.6 percent. And most studies—included those cited by FDA in its notice[14]—look at the effects of trans fat consumption at much higher rates.

Even if the studies linking trans fat consumption to heart disease risk are accurate, there is no evidence to assert that reducing consumption further will benefit public health. In the FDA's tentative determination regarding partially hydrogenated oils[15], the agency notes that a 2002 Institute of Medicine (IOM) report[16] found a positive linear trend between trans fat intake, LDL-C concentration, and heart disease. It also cites a CDC study that claims the elimination of PHOs from the food supply could prevent 10,000 to 20,000 coronary events and 3,000 to 7,000 coronary deaths each year[17]. However, both the IOM report and the CDC study are based on other studies that examined consumption levels far greater than that of the average American.

In all of the studies that demonstrated any correlation between trans fat consumption and negative human health outcomes, those negative health effects were associated with trans fat consumption accounting for more than 5 percent of total energy intake. As noted by the FDA, as of 2012, the average American consumes less than 1 gram or 0.6 percent of total energy each day in the form of trans fat—likely less at this point since as the FDA states, the evidence shows that the trend is downward.

Furthermore, the FDA seems to be basing its proposed revocation of GRAS status for trans fats on the assumption that this correlation will continue at lower levels than those studied. However, such an assumption should not form the basis for FDA action. As Dr. Eric Decker, Head of the Department of Food Science at the University of Massachusetts noted, "[T]he pharmokinetics of the biological effects of trans fatty acids are difficult if not impossible to confirm since most studies that show adverse effects of trans fatty acids had to use dietary trans levels in excess of 5 percent of total energy." He goes on to warn, "[I]t is very common for kinetics to not be linear especially at extremely low or high

concentrations of bioactive agents. Therefore, it does not seem scientifically prudent to make a bold statement of how many deaths a food ingredient is causing without any clinical data."[18]

The Institute of Medicine, in its 2005 book—on which the FDA is largely[19] basing its revocation of GRAS—is cautious about recommending action to reduce trans fat consumption.[20] IOM notes that trans fatty acids are "not essential and provide no known benefit to human health," but also that because trans fats are part of any ordinary non-vegan diet, completely eliminating the nutrient would require "significant changes in patterns of dietary intake" that may have undesirable consequences and "unknown and unquantifiable health risks."[21]

IV. A trans fat ban will have unknowable unintended consequences

Education about the possible of risks associated with trans fat consumption has worked, by all accounts. Consumer demand has led to labelling and reduction of the use of trans fats by food companies. As a result, consumers have reduced their daily intake from 4.6 grams of trans fats in 2003 to less than 1 gram a day in 2012.. Consumers have learned to spot trans fats or partially hydrogenated oils on labels and to avoid products containing them when possible.

So what will happen in the wake of a trans fat ban? Presumably, the FDA hopes that food companies will eliminate the ingredient and consumers will continue to reduce their intake of the potentially risky ingredient, resulting in decreased rates of cardiovascular disease and death. But this assumes that consumers will not consume alternatives to trans fats that could be equally or more harmful to their health. Unfortunately, that is often the outcome when an ingredient or product is banned.

For example, when New York City banned trans fats, consumption of the ingredient did decrease and the rate of heart disease in the city did fall by about 7.3 percent over four years. The ban was hailed as a success. However, the national rate of mortality due to heart disease fell by 9.3 percent in the same period, and had already been failing before the ban. As Baylen Linnekin at Reason.com noted in 2006, the year New York's ban went into effect, "[T]he national decline—the rate of which was 21.5% higher nationwide than that found in New York City—can't be attributed to a national trans fat ban that has yet to take place."[22]

So, what kinds of replacements will food companies seek out to replace trans fats? Because the educational campaign about the risks associated with trans fats have worked well, consumers know how to read labels and generally avoid foods containing partially hydrogenated vegetable oils. The replacements companies use as substitutes for PHOs will likely not be as visible for consumers and the effects of consuming the alternatives is not known.

When trying to determine whether banning a product or ingredient will improve public health, it is crucial to consider what alternatives people will seek out and what the public health effects would be. For example, when saturated fat was demonized, consumers and producers switched to trans fats—not a good outcome as we see now. Alternately, food companies might replace the trans fats with sugar,

something we have already seen with "fat free foods," thus increasing Americans' sugar consumption—not a desirable outcome.

Other bad outcomes could result as well. Will foods taste worse? Will foods be more likely to go rancid—and what are the health effects of consumers eating spoiled foods? Let's look at some likely trans fat alternatives and their associated health risks.

As trans fats have been increasingly viewed as unhealthy, food companies, responding to consumer demand, have voluntarily removed it, except where no reasonable alternative exists. Substitutes for trans fats have emerged in recent years for baked and fried foods, but the consequences of switching to any alternative are not yet known.[23] The three most likely replacements for trans fats are:

1. Palm oil;
2. Interesterified fats; and
3. High fructose corn syrup.

Palm Oil: In foods that require solid fats "for function," such as shelf life for baked goods, the most likely alternative to partially hydrogenated oils is palm oil, which is high in saturated fat. Some will argue that this is fine as trans fats are worse, but, as Dr. Eric Decker of the Department of Food Science at the University of Massachusetts notes, oils are "partially hydrogenated so that small amounts of the unsaturated fatty acids are removed and thus they can contain significant amounts of polyunsaturated fatty acids (>30%) compared to palm oil (<10%)." Polyunsaturated fats have been associated with a *decreased* risk of heart disease.

Palm oil and other vegetable oils also contain higher levels of saturated fatty acids (>45%) than partially hydrogenated oil (<20%). For example, while tub margarine has 0.5 grams more trans fat than palm oil, it has almost five fewer grams of saturated fats and more monounsaturated fats and polyunsaturated fats per serving than palm oil.[24] What will be the consequences of replacing trans fats with these tropical oils for people who already consumed large amounts of trans fat products? What about the consequences for diets already low in trans fats? Will food companies use *more* palm oil than trans fats since consumers are less concerned about it?

Interesterified Fats: Interesterification, a process to make fat harder that is similar to hydrogenation, can imbue natural fats with the qualities trans fats provide. It makes natural fats less likely to spoil and stable enough to use for frying without high levels of saturated fat. But it is expensive, which will likely increase food costs for consumers. And research has shown that the consumption of interesterified fats (compared to saturated fats) can lead to increased fasting blood glucose and raise LDL/HDL ratios—harbingers for diabetes and heart disease.[25] Even if a consumer is savvy enough to be aware of this potential risk, how likely is it that food companies will list "interesterified fats" on food labels?

High-fructose corn syrup: In many products that once contained small amounts of trans fats, the inability to use this ingredient may result in increased use of sugar—most likely high-fructose corn syrup

to make up for flavor lost by the reduction of fat. While the label may now tout the ingredient as "trans fat free," it will certainly not be a healthier item for consumers, though they may think it is. Short-term controlled clinical studies have concluded that increased sugar consumption increases the risk of heart disease.[26] A 2011 study published in the *Journal of Clinical Endocrinology & Metabolism* that examined 48 adults between the ages of 18-40 years found that within two weeks, participants consuming 25 percent of their daily calories in fructose or high fructose corn syrup showed increased blood levels of cholesterol and triglycerides, indicators of increased heart disease risk.[27]

As for newer fats and methods of fat replacement, the link is less clear. That doesn't necessarily mean there is no link, only that we don't know because the research simply doesn't exist yet. As Dr. David C. Klonoff, medical director at the Diabetes Research Institute at Mills-Peninsula Health Services, noted in his examination of trans fat replacements, these ingredients "require close scrutiny to ascertain whether they will also turn out to be linked with cardiovascular disease."[28] The FDA should heed Dr. Klonoff's advice and do more research on the possible alternatives to trans fats before attempting to wholly eliminate trans fats from Americans'diet—which may not have any health benefit at all.

V. Evidence that PHOs are Prior Sanctioned

Applicable Prior Sanctions

As Daren Bakst of the Heritage Foundation notes in his comments to the FDA, the agency may only take action against substances are prior sanctioned if it can show the ingredient proves "poisonous or deleterious."[29] Prior sanction exists if explicit approval was granted for use of a substance in food prior to September 6, 1958, by the Food and Drug Administration or the United States Department of Agriculture. Prior sanction can be established through standards of identity. A good example is salt. Michael R. Taylor, FDA's Deputy Commissioner for Foods and Veterinary Medicine, explains:

> In its 1982 Policy Notice on salt, FDA noted that a number of uses of salt in processed food had received FDA's approval prior to 1958, primarily in FDA standards of identity, and thus could be deemed to be "prior sanctioned" and excluded from food additive regulation on that basis.[30]

Prior Sanction through Standards of Identity

While food standards of identity do not specifically refer to PHOs in several of the products listed, PHOs were understood to be used in their manufacture: shortening in bread [21 CFR 136.110(c)(5)], French dressing (21 CFR 169.115), mayonnaise (21 CFR 169.140), and margarine (21 CFR 166.110). The FDA maintains that because none of these products "require" the use of PHOs as an ingredient, industry's ability to comply with the standards would not be affected under a trans fat ban. However, we believe the standards of identity still provide proof of prior sanction, thus requiring the FDA to demonstrate that PHOs are "poisonous or deleterious" before taking action to forcibly remove them from the food supply.

CFR110: Shortening as used in Bread, white bread, and rolls, white rolls, or buns, white buns:

According to CFR110, " Bread, white bread, and rolls, white rolls, or buns, white buns; identity; label statement of optional ingredients…Each of such foods is seasoned with salt, and in its preparation one or more of the optional ingredients prescribed by subparagraphs (1) to (14), inclusive, of this paragraph may be used: (1) Shortening, in which or in conjunction with which may be used lecithin, mono- and diglycerides of fatforming fatty acids (except lauric acid…"[31]

While the standards of identity for shortening do not specifically mention partially hydrogenated vegetable oil, historical evidence shows that in 1956, shortening was generally understood to consist of partially hydrogenated oil or *incompletely hydrogenised [sic] vegetable oil* in the early 20th century. John J. Burchenal's 1910 patent filing for a hardened cooking fat, described what would ultimately be sold under the trademark "Crisco" as "a food product consisting of a vegetable oil, preferably cottonseed oil, partially hydrogenized and hardened to a homogeneous white or yellowish semi-solid closely simulating lard"[1] Subsequent court battles regarding the patentability of shortening by Proctor & Gamble repeatedly refer to both Crisco and its competitors, like Krisp-Cream, as "incomplete hydrogenation of vegetable oils."

1. **CFR182 Margarine/oleomargarine**

CFR 182 states "Oleomargarine, margarine; identity; label statement of optional ingredients.(a) Oleomargarine, margarine is the plastic food prepared with one or more of the optional fat ingredients named in subparagraph (1) (1), (it), (iii), and (iv) of this paragraph, as follows…"[32]

There is no doubt that prior to 1958, it was generally understood that margarine and oleomargarine consisted of partially hydrogenated oil, as patent filings, court documents, and the USDA's own statements show. For example, a 1945 USDA report on staple foods makes clear that PHOs were understood to be an integral part of margarine. The report, "Foods- Enriched, Restored, Fortified," lists oleomargarine among its list of staple foods and defines oleomargarine thus:

"What is Oleomargarine? Even before the Food and Drug Administration adopted a standard for oleomargarine, the Supreme Court recognized a certain brand to be "a nutritious and pure article of food, with a well-established place in the dietary. Margarine was first made in 1869 in response to an offer of a prize by Napoleon III for a nutritious, economical, and appetizing fat for table use. As it is made by 41 manufacturing plants in the United States, margarine contains a mixture of animal fats and vegetable oils or one or the other—fats that have been used as food for centuries. These are partially hydrogenated and blended to give the right spreading consistency."[33]

[1] Serial no. 591,726 (record number 1,135,351) pdfpiw.uspto.gov/.piw?Docid=1135351&idkey=NONE&homeurl=http%3A%252F%252Fpatft.uspto.gov%252Fnetahtml%252FPTO%252Fpatimg.htm

COMPETITIVE ENTERPRISE INSTITUTE

VI. Conclusion

As PHOs have been in use since the early 20th century, we believe the long history of use proves general safety of the substance. We believe that FDA is taking the unprecedented action in revoking GRAS, not because there is a question about trans fat's "safety," but rather in its "healthfulness"—a question we believe is not in FDA's purview. Furthermore, we are concerned that, in an attempt to address a public health problem, FDA has not thoroughly considered the repercussions of this action, which we believe will be a net negative to public health. Most worrying, this action appears to be evidence of the increasing influence that politics and health advocates have over the agency; pushing it to make policy based on unsound science. Furthermore, we worry what this action means for other consumer goods. If all it takes for FDA to remove GRAS status of a product is for any number of scientist to suggest that consuming any substance carries a small amount of risk, is there any ingredient that the agency would consider GRAS? It seems that what FDA is asking for is proof of absolute harmlessness, which, as we mentioned before is an impossibility.

Virtually any food or ingredient can increase the risks of illness or harm, if consumed in large enough quantities for a long enough period of time. Every activity we engage in has some measure of risk. While the proper role of the FDA may be to disseminate information about the potential risk of foods to certain group so consumers, we believe the ultimate risk assessment and decision making ought to be left to the individual, not taken away by a government agency.

While we understand the FDA's desire to advocate for lower consumption of trans fats, we urge the agency to continue with its educational efforts, which have been successful to date, and avoid the unforeseen negative consequences that would result from an outright ban.

Sincerely,

Michelle Minton
The Competitive Enterprise Institute
1899 L St. NW
Floor 12
Washington, DC 20036

COMPETITIVE ENTERPRISE INSTITUTE

[1] "FDA takes step to further reduce *trans* fats in processed foods" FDA, press release, November 7, 2013 www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm373939.htm
[2] American Heart Association, "Trans Fats Q & A," accessed February 14, 2014 http://www.heart.org/HEARTORG/GettingHealthy/FatsAndOils/Fats101/Trans-Fats_UCM_301120_Article.jsp
[3] Gauber et al. Effects of Ruminant trans Fatty Acids on Cardiovascular Disease and Cancer: A Comprehensive Review of Epidemiological, Clinical, and Mechanistic Studies http://advances.nutrition.org/content/2/4/332.full
[4] Malpuech-Brugère C et al. Differential impact of milk fatty acid profiles on cardiovascular risk biomarkers in healthy men and women. *Eur J Clin Nutr* 2010;64(7):752-9. http://peer.ccsd.cnrs.fr/docs/00/53/76/78/PDF/PEER_stage2_10.1038%252Fejcn.2010.73.pdf
[5] Hansen CP et al. Intake of ruminant trans fatty acids and changes in body weight and waist circumference. *Eur J Clin Nutr* 2012;66(1):1104-9. http://www.ncbi.nlm.nih.gov/pubmed/22805493
[6] Specifically, conjugated linoleic acid (CLA) and vaccenic acid. Report of the DGAC on the Dietary Guidelines for Americans 2010 Appendix E-1 Major Conclusions http://www.cnpp.usda.gov/Publications/DietaryGuidelines/2010/DGAC/Report/E-Appendix-E-1-Conclusions.pdf
[7] Center for Science in the Public Interest, "Trans Fats," accessed February 14, 2014 http://www.cspinet.org/transfat/
[8]David Schleifer, "The Perfect Solution: How Trans Fats Become the Healthy Replacement for Saturated Fats," 2012 The Society for the History of Technology, 2012, accessed on February 14, 2014 www.academia.edu/1429225/The_Perfect_Solution_How_Trans_Fats_Became_the_Healthy_Replacement_for_Saturated_Fats
[9] American Council on Science and Health "Trans Fatty Acids: Just the Latest Scare du Jour Served up by CSPI" August 7, 1996 accessed on February 14, 2014, acsh.org/1996/08/trans-fatty-acids-just-the-latest-scare-du-jour-served-up-by-cspi/
[10] David Schleifer, "The Perfect Solution: How Trans Fats Become the Healthy Replacement for Saturated Fats," 2012 The Society for the History of Technology, 2012, accessed on February 14, 2014 www.academia.edu/1429225/The_Perfect_Solution_How_Trans_Fats_Became_the_Healthy_Replacement_for_Saturated_Fats
[11] Siri-Tarino et al. "Saturated fat, carbohydrate, and cardiovascular disease," *American Journal of Clinical Nutrition*, 2010 http://ajcn.nutrition.org/content/early/2010/01/20/ajcn.2008.26285.short
[12] Institute of Medicine of the National Academies "Sodium Intake in Populations: Assessment of Evidence" March 14, 2013 accessed on February 14, 2014 http://www.iom.edu/Reports/2013/Sodium-Intake-in-Populations-Assessment-of-Evidence/Report-Brief051413.aspx?page=1
[13] Edward Archer, "A Wolf in Sheep's Clothing: Nutrition research must overcome pseudoscientific measures and self-interest to make progress in the fight against obesity," *The Scientist,* October 22,2013 http://www.the-scientist.com/?articles.view/articleNo/37918/title/Opinion--A-Wolf-in-Sheep-s-Clothing/
[14] *Federal Register*, Vol. 78, No. 217 (November 8, 2013), pp. 67169-67175
[15] *Ibid.*
[16] IOM/NAS, "Dietary Reference Intakes for Energy Carbohydrate, Fat, Fatty Acids, Cholesterol, and Amino Acids (Macronutrients)," chapters 8 and 11, National Academies Press, Washington DC, 2002/2005 (Internet address: *http://www.nap.edu*).
[17] William Dietz and Kelley Scanlon, "Eliminating the Use of Partially Hydrogenated Oil in Food Production and Preparation," The Journal of the American Medical Association, Vol. 308, No. 2 (July 11, 2012), pp. 143-144, http://jama.jamanetwork.com/article.aspx?articleid=1216486 accessed March 6, 2014.
[18] Eric Decker, "The Impact and Consequences of banning Trans Fatty Acids," *Food Tech ePerspective,* November 13, 2013, http://foodtecheperspective.wordpress.com/2013/11/13/the-impact-and-consequences-of-banning-trans-fatty-acids/

[19] "FDA takes step to further reduce *trans* fats in processed foods" FDA, press release, November 7, 2013 www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm373939.htm
[20] as Baylen Linnekin noted at Reason.com. "The FDA's Ill-conceived Proposal to Ban Trans Fats," *Reason.com,* November 9m 2013 http://reason.com/archives/2013/11/09/the-fdas-ill-conceived-proposal-to-ban-t
[21] Dietary Reference Intakes of Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids, *The National Academies Press,* 2005 http://www.nap.edu/openbook.php?record_id=10490&page=424
[22] Baylen Linnekin, "The FDA's Ill-conceived Proposal to Ban Trans Fats," *Reason.com,* November 9m 2013 http://reason.com/archives/2013/11/09/the-fdas-ill-conceived-proposal-to-ban-t
[23] Replacements for Trans Fats—Will There Be an Oil Shortage? *Journal of Diabetes Science and Technology,* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2769584/
[24] Danilo Alfero, "*Fats: The Good, The Bad and The Ugly,"* http://culinaryarts.about.com/od/culinaryreference/a/fattable.htm
[25] Sundram, et al., "Stearic acid-rich interesterified fat and trans-rich fat raise the LDL/HDL ratio and plasma glucose relative to palm olein in humans" *Nutrition & Metabolism, http://www.nutritionandmetabolism.com/content/4/1/3/abstract*
[26] Fried, et. al., Sugars, hypertriglyceridemia, and cardiovascular disease" *The American Journal of Clinical Nutrition,* ajcn.nutrition.org/content/78/4/873S.long
[27] "Fructose consumption increases risk factors for heart disease," *Science Daiy,* July 28, 2011 www.sciencedaily.com/releases/2011/07/110728082558.htm
[28] Replacements for Trans Fats—Will There Be an Oil Shortage? *Journal of Diabetes Science and Technology,* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2769584/
[29] International Food Additives Council, *How Food Ingredients are Approved,* http://www.foodadditives.org/cultures/FoodIngredientApproval_OnlineExtra.pdf accessed March 7, 2014
[30] Michel Taylor, *FDA Regulation of Added Salt Under the Food Additives Amendment of 1958: Legal Frameworks and Options*, March 30, 2009 http://iom.edu/~/media/Files/Activity%20Files/Nutrition/ReduceSodiumStrat/TaylorSupplemental.pdf accessed March 7, 2014

[31] 21 CFR 110 § 17.1
[32] 21 CFR 182 § 45.1
[33] U.S. Department of Agriculture, "Foods- Enriched, Restored, Fortified," prepared for the USDA by the Bureau of Human Nutrition and Home Economics, 1945, https://ia801704.us.archive.org/19/items/foodsenrichedres39unit/foodsenrichedres39unit.pdf