

2007

## Safe But Not Wholesome: The Troubling State of Trans Fat Regulation

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### Recommended Citation

Williams, R. (2021). Safe But Not Wholesome: The Troubling State of Trans Fat Regulation. *Journal of Food Law & Policy*, 3(1). Retrieved from <https://scholarworks.uark.edu/jflp/vol3/iss1/4>

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# SAFE BUT NOT WHOLESOME: THE TROUBLING STATE OF TRANS FAT REGULATION

*Ross Williams\**

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## I. PREFACE: THE STARBUCKS PROBLEM

On March 7, 2007, the *New York Times* reported that Starbucks, the retail coffee chain which sells millions of baked goods every day from its over 8,700 U.S. stores, had asked its suppliers to eliminate all trans fats from their products by the end of the year.<sup>1</sup> The big story for New York readers, though, was not that Starbucks was requiring the elimination of trans fats from its baked goods. In fact, New York City had just passed an ordinance strictly limiting the use of *artificial* trans fats, the type present in partially hydrogenated vegetable oil (PHVO), by virtually all of the city's food service establishments.<sup>2</sup> Rather, the "scoop" for New York readers was the source of the trans fats being eliminated by Starbucks' bakeries—butter.<sup>3</sup>

The article reported that U.S. wholesale bakeries were being forced to take butter out of their recipes because it contains small amounts of *natural* trans fats (the type present in products developed from the fat of ruminants), even though a large body of evidence suggests that those fats may actually be beneficial to health.<sup>4</sup>

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\* Ross Williams will receive his J.D. from the University of Texas School of Law in May of 2008. He would like to thank Professor Thomas McGarity for all of his help and encouragement in preparing this article.

1. Kim Severson, *Trans Fat Fight Claims Butter as a Victim*, N.Y. TIMES, Mar. 7, 2007, at F1.

2. New York City Health Code § 81.08 (effective July 1, 2007); see also New York, N.Y., Dep't of Health & Mental Hygiene, Board of Health—Notice of Adoption of an Amendment (§ 81.08) to Article 81 of the New York City Health Code, available at <http://www.nyc.gov/html/doh/downloads/pdf/public/notice-adoption-hc-art81-08.pdf>.

3. See Severson, *supra* note 1.

4. See Janet Raloff, *Trans Fats are Bad, aren't they?* (Dec. 16, 2006), <http://www.sciencenews.org/articles/20061216/food.asp> (last visited Dec. 28,

Apparently, Starbucks' request was causing great confusion in the food industry. Matthew Reich, a supplier of baked goods to 500 Starbucks locations from Philadelphia to Hartford, complained that the request was "causing problems for every big baker in the country," and that he personally "didn't even know where to find trans-free margarine."<sup>5</sup> Because of the short notice, many bakeries were reacting by hastily replacing butter with palm oil,<sup>6</sup> margarine, and other processed substances high in saturated fat—a type of fat generally known to have a significant negative effect on heart health.<sup>7</sup>

Starbucks company spokesman Brandon Borman was quoted as saying that "for [Starbucks], it's easier for the customer to walk in and see zero grams trans fat rather than zero grams artificially created trans fat."<sup>8</sup> The *New York Times* article explained that while the New York City ordinance only covers artificial trans fats, the Food

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2007) (discussing the potential health benefits of the non-regulated trans fat, linoleic acid (CLA), which occurs and is *de facto* eliminated from recipes with the regulated natural trans fat, vaccenic acid); Janet Raloff, *The Good Trans Fat: Will One Family of Animal Fats Become a Medicine?*, 159 (9) *SCI. NEWS* 136 (2001); Food Labeling: *Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims*, 68 *Fed. Reg.* 41433, 41461 (July 11, 2003) (codified at 21 C.F.R. pt. 101) (acknowledging that vaccenic acid metabolizes onto CLA in the human body); FOOD & NUTRITION BD., INST. OF MED. OF THE NAT'L ACADS. (IOM), *DIETARY REFERENCE INTAKES FOR TRANS FATTY ACIDS* (2002), at 14, <http://www.iom.edu/Object.File/Master/13/083/TransFattyAcids.pdf> (last visited Dec. 28, 2007) [hereinafter *DIETARY REFERENCE INTAKES*] (suggesting that eliminating all trans fat, including that from ruminant sources, might introduce undesirable effects, such as inadequate intake of protein and micronutrients); S. Banni et al., *Vaccenic Acid Feeding Increases Tissue Levels of Linoleic Acid and Suppresses Development of Premalignant Lesions in Rat Mammary Gland*, 41(1-2) *NUTR. CANCER* 91, 91-97 (2001); E. Thom et al., *Conjugated Linoleic Acid Reduces Body Fat in Healthy Exercising Humans*, 29(5) *J. INT'L MED. RES.* 392, 392-96 (2001); H. Blankson et al., *Conjugated Linoleic Acid Reduces Body Fat Mass in Overweight and Obese Humans*, 130(12) *J. NUTRITION* 2,943, 2,943-48 (2000); Letter from Gregory D. Miller, Senior Vice Pres. of Nutrition & Prod. Innovation, Nat'l Dairy Council, & Peter J. Huth, Dir. of Reg. & Res. Transfer, Nat'l Dairy Council, to Div. of Dkts. Mgt., Food & Drug Admin. (June 18, 2004) (on file with author); D. Mozzafarian et al., *Trans Fatty Acids and Cardiovascular Disease*, 354 (15) *NEW ENG. J. MED.* 1,601, 1,601-13 (2006) (stating that "the sum of the current evidence suggests that the public health implications of consuming trans fats from ruminant products are relatively limited" but warning that that this may be the result of relatively low consumption of trans fats from animal sources compared to artificial ones).

5. Severson, *supra* note 1.

6. *See id.*

7. *See* WORLD HEALTH ORG. (WHO), *DIET, NUTRITION AND THE PREVENTION OF CHRONIC DISEASES*, WHO TECHNICAL REPORT SERIES 916, at 82 (Geneva 2003), available at <http://www.who.int/dietphysicalactivity/publications/trs916/en/>.

8. Severson, *supra* note 1.

and Drug Administration (FDA) labeling regulation recognizes no difference between artificial and natural trans fats and covers them both. Aside from illustrating a general lack of awareness as to the FDA regulation's coverage,<sup>9</sup> this reaction demonstrates the way in which large producers like Starbucks treat the FDA regulation, and illustrates the local efforts to regulate trans fats as a de facto ban on trans fat *generally*, removing potentially beneficial natural trans fats from food and hastily replacing them with substances known to be more harmful to heart health simply because the natural trans fat sources are covered by the federal, and potentially some local, regulations.

The *New York Times* article also provides a quote that is symptomatic of the wider public misunderstanding regarding trans fat regulation: Marion Nestle, nutrition professor at New York University and author of *Safe Food: Bacteria, Biotechnology, and Bioterrorism*, said that "this is an important issue because anything made with animal fats will have trans fats and make it impossible to claim trans fat-free. Milk has trans fats, after all, and you can see what a mess **this** is going to cause."<sup>10</sup> This statement is inaccurate for several reasons: there is no definition of "trans fat free" in the current FDA regulations;<sup>11</sup> at the current serving size, whole milk and whipped butter are both allowed to claim that they contain zero grams of trans fat per serving;<sup>12</sup> and products made with animal fats can still claim that they contain zero grams trans fat on their nutrition label as long as the individual serving size of the products contains less than 0.5 grams of the regulated type of natural trans fat per serving.<sup>13</sup>

Ultimately, the article raises two key issues: the widespread misunderstanding regarding trans fat regulation, and the way in which the current federal regulation<sup>14</sup> interacts with a myriad of recently passed local ordinances<sup>15</sup> to influence Starbucks and other

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9. The FDA regulation actually covers only nonconjugated trans fatty acids, one type of trans fat present in animal fats. See 68 Fed. Reg. at 41461.

10. Severson, *supra* note 1.

11. Indeed, the sections referring to it were intentionally removed by the drafters. See 68 Fed. Reg. at 41434.

12. 21 C.F.R. § 101.9(c)(2)(ii) (2006).

13. *Id.*; see also 21 C.F.R. § 101.12 (2006).

14. 21 C.F.R. § 101.9(c)(2)(ii) (2006).

15. See New York City Health Code (N.Y.) § 81.08 (2006). See also Nat'l Rest. Ass'n, *Trans Fat Legislation*, [http://www.restaurant.org/government/state/nutrition/bills\\_trans\\_fat.cfm](http://www.restaurant.org/government/state/nutrition/bills_trans_fat.cfm) (last visited Dec. 28, 2007) (listing current efforts by states to regulate trans fats).

national food producers and suppliers to remove both artificial and natural trans fats in favor of processed oils high in saturated fats, which may result in a negative net effect on public health.<sup>16</sup> The latter issue may also be affected by businesses' overreaction to potential tort suits regarding the continued use of trans fats.<sup>17</sup> This article explores these issues and others regarding the current state of trans fat regulation and suggests possible avenues for change.

## II. INTRODUCTION

Thanks to advances in technology, the American food system has grown from an amalgamation of discrete, local supply chains into a system organized on a regional, national, and global scale.<sup>18</sup> While our food system has become increasingly complex, the sources that supply it have decreased significantly in number: more and more Americans are being fed by fewer and fewer food facilities.<sup>19</sup> Food safety regulation has evolved along with our food system. The development of a national market for food and the desire for uniform regulations to combat unsanitary conditions engendered the early twentieth century movement away from a predominant reliance on state and local regulation of food safety and toward

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16. A negative net effect on public health may result from the harmfulness of saturated fat on heart health in conjunction with the potential detriments of removing natural trans fat sources. See DIETARY REFERENCE INTAKES, *supra* note 4, at 14; Banni et al., *supra* note 4, at 392-96; Blankson et al., *supra* note 4, at 2,943-48; Miller, *supra* note 4; Mozzafarian et al., *supra* note 4, at 1,601-13.

17. Given the new scientific evidence and public and industry awareness of the dangers of trans fats, food producers and restaurants may be overreacting in ways similar to Starbucks out of recognition that reliance on rulings similar to those that insulated them from previous tort suits may be misplaced if the producers and restaurants continue to use trans fats in their foods. See Ctr. for Sci. in the Pub. Interest (CSPI), *Petition for Rulemaking to Revoke the Authority for Industry to use Partially Hydrogenated Vegetable Oil in Food* at 30-31 (filed May 18, 2004), available at [http://cspinet.org/new/pdf/trans\\_fat\\_petition\\_final\\_may\\_18.pdf](http://cspinet.org/new/pdf/trans_fat_petition_final_may_18.pdf) (arguing that in the future, private parties may sue restaurants or food companies for continuing to use partially hydrogenated vegetable oils when healthier alternatives exist; citing for comparison *Pelman v. McDonald's*, 237 F. Supp. 2d 521, 532 (S.D.N.Y. 2003) (holding that 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), and *BanTransFats.com v. Kraft Foods N. Am., Inc.*, CV 032041 (Martin County Super. Ct. Cal. May 2003)).

18. COMM. TO ENSURE SAFE FOOD FROM PROD. TO CONSUMPTION, IOM, ENSURING SAFE FOOD FROM PRODUCTION TO CONSUMPTION 17-18 (Nat'l Acad. Press 1998).

19. *Id.* at 19.

the gradual creation of the large federal regulatory bureaucracy of today.<sup>20</sup> As much as the public relies on that bureaucracy to ensure the safety of the food supply, the increasingly oligarchical food industry has come to rely on federal regulations as well because of the uniformity and relative predictability that they provide to the huge operations that supply food to the national market.

The resulting system is a fragile one; a single major incident can easily have national effects.<sup>21</sup> The widespread public recognition that trans fats are deleterious to health, which followed implementation of the Food and Drug Administration (FDA) regulation requiring the listing of trans fat content on food labels, is an example of just such an incident: a nearly omni-present ingredient in our food, partially hydrogenated vegetable oil, was making us sick. Labels and ingredient lists on food packages in grocery stores across the nation seemed to change overnight. Growing public concern over the presence of trans fats and the absence of a federal regulation requiring producers to limit or eliminate trans fats from our food supply led state and local governments to pass regulations to fill the regulatory gap.<sup>22</sup>

As a result of such efforts, food producers from the largest corporations to the smallest street vendors in some localities were effectively forced to change one of the bedrock principles of their food preparation procedures: the fat they cook with. Today, the businesses that supply our national food system, including the bakeries that supply Starbucks, face both a federal regulation defining trans fats in a potentially overbroad way and a patchwork of local regulations limiting the presence of trans fats in the food supply, rather than a single preemptive federal standard limiting the presence of trans fat in our food in a uniform manner. To comply efficiently with the numerous local regulations, to respond effectively to public hysteria, and potentially out of concern for the tort consequences of continued trans fat use,<sup>23</sup> many food producers are making rapid changes based on the FDA's definition of trans fats, changes that might result in an overall negative effect on public health.<sup>24</sup>

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20. *Id.* at 21-22.

21. *Id.* at 19.

22. See Janet Frankston Lorin, Associated Press, *Legislating food becoming issue du jour in state, city government*, Feb. 18, 2007, available at [http://www.boston.com/news/local/connecticut/articles/2007/02/17/legislating\\_food\\_becoming\\_issue\\_du\\_jour\\_in\\_state\\_city\\_government/](http://www.boston.com/news/local/connecticut/articles/2007/02/17/legislating_food_becoming_issue_du_jour_in_state_city_government/).

23. See CSPI, *supra* note 17.

24. See DIETARY REFERENCE INTAKES, *supra* note 4; see also WHO, *supra* note 7.

This article explores the history, current regulations, ongoing debate, and potential future regulations concerning trans fat in foods, ultimately recommending that the FDA remove the “generally recognized as safe” (GRAS) status of artificial trans fat sources, limit or eliminate their presence in our national food supply through appropriate preemptive regulations, amend its definition of trans fatty acid pending the completion of further research to determine whether natural trans fats pose risks similar to artificial varieties, and sponsor industry and consumer education on this subject, among other things. These steps would protect public health and insure the uniformity and predictability that the food industry needs to provide safe *and* wholesome foods on a national level. Additionally, this article analyzes the legal and policy issues that such action, or continued inaction, would raise.

This article begins with a brief description of the science and history behind the use of trans fatty acids: the types of trans fats and their sources, the movement that led to the nearly universal adoption of artificial trans fat-containing substances for use in cooking, the subsequent backlash against their use, and the scientific evidence supporting the idea that artificial trans fats are dangerous.<sup>25</sup> I then turn to a discussion of the history, pros and cons, and current state of the federal government’s regulation of trans fats, followed by an analysis of the current grassroots movement to regulate trans fats at the state and local government levels in the face of the federal government’s inactivity.<sup>26</sup>

Next, this article analyzes the FDA citizen action “Petition for Rulemaking to Revoke the Authority for Industry to use Partially Hydrogenated Vegetable Oils in Foods” filed by the Center for Science in the Public Interest (CSPI) in depth, supplemented by CSPI Executive Director Michael Jacobson’s thoughts on the current state of trans fat regulation and the FDA’s involvement therein.<sup>27</sup> Finally, I discuss whether the FDA must, or at least should, grant the CSPI petition or a similar alternative, additional steps that the FDA should take, the issues of federalism that such a regulation would implicate, whether any resulting regulation should be preemptive, and the potential consequences of passage on the area of tort litigation.<sup>28</sup>

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25. See *infra* notes 29-72 and accompanying text.

26. See *infra* notes 73-139 and accompanying text.

27. See *infra* notes 140-178 and accompanying text.

28. See *infra* notes 179-207 and accompanying text.



### III. BACKGROUND

To understand the regulations regarding trans fats, it is first necessary to have some basic understanding of what trans fats are. The following section provides a brief overview of the different types of trans fats; their origins, characteristics, and effects on human health; and also explains their relation to the current regulations.

#### A. *Natural Sources of Trans Fat: Partially Covered by the FDA Regulations*

Humans have consumed trans fats for as long as they have eaten ruminants. Indeed, many people do so at birth, as trans fats are found in the breast milk of mothers in amounts proportional to their dietary intake.<sup>29</sup> The 2-5% of total fat in ruminants that is technically trans fat<sup>30</sup> can be subdivided into two categories: conjugated linoleic acid (CLA)<sup>31</sup> and non-conjugated linoleic acid in the form of vaccenic acid.<sup>32</sup>

This is an important distinction, because the Food and Drug Administration (FDA) regulatory definition of trans fats covers only non-conjugated trans fats.<sup>33</sup> Thus, while the content per serving of *non-conjugated* trans fats derived from ruminant sources must be given on a product's nutrition label if the product contains 0.5 grams or more per serving, the amount of *conjugated* trans fat (CLA) in the same food product is not regulated and need not be reported on the nutrition label, regardless of the product's CLA content per serving.<sup>34</sup> Because these two types of fat occur together in products derived from ruminant fats, businesses like Starbucks that eliminate trans fats altogether in an effort to attain broad compliance with potential local ordinances limiting the use of trans fats end up eliminating CLA de facto, even though it is not included in the trans

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29. Sheila M. Innis & D. Janette King, *Trans Fatty Acids in Human Milk are Inversely Associated with Concentrations of Essential All-cis n-6 and n-3 Fatty Acids and Determine Trans, but not n-6 and n-3, Fatty Acids in Plasma Lipids of Breast-fed Infants*, 70(3) AM. J. CLINICAL NUTRITION 383 (1999).

30. TRANS FAT TASK FORCE OF HEALTH CANADA, TRANSFORMING THE FOOD SUPPLY (June 2006), at 4, available at [http://www.hc-sc.gc.ca/fn-an/nutrition/gras-trans-fats/tf-ge/tf-gt\\_rep-rap\\_e.html](http://www.hc-sc.gc.ca/fn-an/nutrition/gras-trans-fats/tf-ge/tf-gt_rep-rap_e.html).

31. T.R. Dhiman et al., *Linoleic Acid (CLA) Content of Milk from Cows Offered Diets Rich in Linoleic and Linolenic Acid*, 83(5) J. DAIRY SCI. 1,016 (2000).

32. 68 Fed. Reg. at 41461.

33. *Id.*

34. 21 C.F.R. § 101.9(c)(2)(ii) (2006).

fatty acid content listed on nutrition labels and may actually be beneficial to human health.<sup>35</sup>

### B. *The Risks and Benefits of Natural Trans Fats*

Scientific evidence suggests that natural trans fats may not have the same negative health effects that are associated with artificial trans fats.<sup>36</sup> Indeed, CLA in particular may be beneficial to human health.<sup>37</sup> Studies have shown that CLA may reduce body fat in both healthy and overweight humans<sup>38</sup> and may also prevent breast<sup>39</sup> and colorectal cancer.<sup>40</sup> Additionally, vaccenic acid (the non-conjugated trans fat contained in ruminant meat and covered by the FDA regulations) is actually converted to CLA when it reacts with chemicals in the body during digestion,<sup>41</sup> and some research suggests that vaccenic acid intake may reduce the risk of breast cancer.<sup>42</sup>

Some scientific evidence, however, suggests that trans fats from ruminant sources might also have negative effects. One study suggests that CLA may have negative effects on cardiovascular health and insulin resistance in obese men,<sup>43</sup> and a 2006 review of the literature on natural trans fat sources in the *New England Journal of*

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35. See Banni et al., *supra* note 4; Thom et al., *supra* note 4; Blankson et al., *supra* note 4; Miller, *supra* note 4; Mozzafarian et al., *supra* note 4.

36. See Miller, *supra* note 4; see also Mozzafarian et al., *supra* note 4.

37. See Thom et al., *supra* note 4; see also Blankson et al., *supra* note 4.

38. See *id.*

39. See M.M. Ip et al., *Prevention of Mammary Cancer with Linoleic Acid: Role of the Stroma and the Epithelium*, 8(1) J. MAMMARY GLAND BIOLOGY & NEOPLASIA 103, 103-18 (2003) (stating that, taken together, the current data suggest that CLA may be an excellent candidate for the prevention of breast cancer); but see L.E. Voorrips et al., *Intake of Linoleic Acid, Fat, and other Fatty Acids in Relation to Postmenopausal Breast Cancer: the Netherlands Cohort Study on Diet and Cancer*, 76(4) AM. J. CLINICAL NUTRITION 873, 873-82 (2002) (stating that the suggested anticarcinogenic property of CLA in animal and tissue studies was not confirmed in humans through review of data from a cohort study conducted in the Netherlands).

40. Susanna C. Larsson et al., *High-fat Dairy Food and Linoleic Acid Intakes in Relation to Colorectal Cancer Incidence in the Swedish Mammography Cohort*, 82(4) AMER. J. CLINICAL NUTRITION 894, 894-900 (2005) (concluding that prospective data suggests that high intakes of high-fat dairy foods and CLA might reduce the risk of colorectal cancer).

41. 68 Fed. Reg. at 41461; see also Banni et al., *supra* note 4.

42. See Banni et al., *supra* note 4.

43. See Ulf Risérus et al., *Supplementation With Linoleic Acid Causes Isomer-Dependent Oxidative Stress and Elevated C-Reactive Protein*, 106 CIRCULATION 1,925 (2002).

*Medicine* noted that their limited negative effect on public health might be due to their low occurrence in the diet.<sup>44</sup>

Despite the evidence on both sides regarding the benefits and risks of natural trans fat consumption, these fats may provide important indirect benefits to public health as well: the Institute of Medicine (IOM) has acknowledged that any potential benefits of removing natural trans fat from the diet, including that from ruminant sources, might introduce undesirable effects, such as inadequate intake of protein and micronutrients.<sup>45</sup> Consequently, even though natural trans fat sources may have some negative public health effects, their elimination from the food supply might result in a negative net effect on public health by removing the indirect benefits that they provide. While the FDA includes natural trans fat sources in its labeling regulation regardless of this information, some local U.S. governments have chosen to exclude natural trans fat sources from their regulations while awaiting further study.<sup>46</sup>

### *C. Artificial Trans Fats: Sources and Creation Through Hydrogenation*

Hydrogenation is the process whereby hydrogen atoms are added to a molecule through a chemical process involving a catalyst and pressure.<sup>47</sup> A fat molecule can only carry a certain number of hydrogen atoms, and once it carries the maximum number it is referred to as a saturated fat because it is saturated with hydrogen.<sup>48</sup> Thus, partially hydrogenated oils contain unsaturated fats and are very low in saturated fats.

Partially hydrogenated vegetable oils (PHVO) are the main source of artificial trans fats and dietary trans fats generally.<sup>49</sup> Until recently, PHVO was a basic building block of many food products, either as oil for frying, as shortening for baked goods, or as margarine for spreads.<sup>50</sup> Whereas natural trans fats occur in animal fat at a level of 2-5% of total fat, artificial trans fats occur in PHVO products as up to 45% of total fat content.<sup>51</sup>

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44. Mozzafarian et al., *supra* note 4, at 1,609.

45. DIETARY REFERENCE INTAKES, *supra* note 4, at 14.

46. See New York, N.Y., Dep't of Health & Mental Hygiene, *supra* note 2.

47. RAYMOND CHANG, ESSENTIAL CHEMISTRY 375 (McGraw Hill 1996).

48. MARY K. CAMPBELL, BIOCHEMISTRY 198-99 (3d ed. Saunders C. Publishing 1999).

49. New York, N.Y., Dep't of Health & Mental Hygiene, *supra* note 2.

50. *Id.*

51. TRANS FAT TASK FORCE OF HEALTH CANADA, *supra* note 30.

#### D. Introduction of Artificial Trans Fats into the Food Supply

The process for hydrogenating liquid oils was brought to America when Proctor and Gamble acquired the U.S. patent and began marketing the first Crisco in 1911.<sup>52</sup> By the 1960s, PHVO had replaced animal fat as the most commonly used fat in the U.S., and health advocates began to argue that the unsaturated fats that they contained were healthier than saturated fats. Food producers like PHVO because it can be used as a malleable fat, is solid at room temperature, melts when baked or consumed, is very low in saturated fat, is cheap, and increases shelf life.<sup>53</sup>

Despite PHVO's widespread popularity among food producers, fast food restaurants continued to use beef fats and tropical oils high in saturated fats.<sup>54</sup> But in 1984, the Center for Science in the Public Interest (CSPI) and other consumer groups began a six-year campaign to end the use of those oils in fast food.<sup>55</sup> By 1990, most of the fast food industry had switched from oils high in saturated fats to PHVO.<sup>56</sup>

#### E. Widespread Use, Warning Signs, and Enactment of the Current Regulation

By 1987, comments in CSPI's *Nutrition Action* newsletter showed just how integral PHVO had become in our food supply.<sup>57</sup> In the newsletter, CSPI acknowledged that PHVO played a vital role in the nation's food supply, but reassured its readers that PHVO is not harmful to human health, is relatively benign, and is not a cause of heart disease.<sup>58</sup> In fact, CSPI claimed that food producers were actually "(i)mproving on (n)ature" through hydrogenation and ultimately averred that the safety of PHVO was "cause for thanks, because these fats are everywhere."<sup>59</sup> In 1988, the first scientific evidence that the trans fats contained in PHVO could have harmful

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52. Crisco, *History/Timeline*, <http://www.crisco.com/about/history/1911.asp> (last visited Dec. 28, 2007).

53. See TRANS FAT TASK FORCE OF HEALTH CANADA, *supra* note 30, at 12.

54. Mary G. Enig, *The Tragic Legacy of Center for Science in the Public Interest (CSPI)* (Dec. 6 2003), <http://www.westonaprice.org/knowyourfats/cspi.html> (last visited Dec. 28, 2007).

55. *Id.*

56. *Id.*

57. *Id.*

58. *Id.*

59. See Enig, *supra* note 54.

effects began to emerge, but the advocates who had pushed for the switch away from saturated fats and toward PHVO defended the healthfulness of trans fats up until 1994, when scientists estimated that approximately 30,000 American deaths from heart disease annually were attributable to trans fat consumption.<sup>60</sup> Shortly thereafter, CSPI called a news conference to condemn the use of PHVO and filed its first FDA citizen action petition regarding trans fats on February 14, 1994, requesting that the FDA require mandatory labeling of trans fatty acid content in foods.<sup>61</sup> The petition resulted in action in 2003 that culminated in the labeling rule implemented in 2006, nearly twelve years after the initial petition was filed.<sup>62</sup>

#### F. Artificial Trans Fat's Negative Health Effects

While some critics continue to doubt even the most convincing evidence that artificial trans fats have a negative effect on health,<sup>63</sup> these fats are now generally recognized as harmful to cardiovascular health in particular.<sup>64</sup> Moreover, a mounting body of evidence suggests that they may have a deleterious effect on health in other ways as well.

A 2006 article published in the *New England Journal of Medicine* reviewed the scientific evidence and concluded that there is strong proof that a connection exists between trans fat consumption and an increased risk of coronary heart disease (CHD).<sup>65</sup> Specifically, the scientific evidence shows that trans fat is markedly more harmful to cardiovascular health than saturated fats when the two substances are consumed in similar amounts, and that replacement of trans fats

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60. W.C. Willett & A. Ascherio, *Commentary: Trans fatty acids: are the effects only marginal?*, 84 AM. J. PUB. HEALTH 722 (1994).

61. Letter from John M. Taylor, III, Assoc. Commr. for Reg. Affairs, FDA, to Dr. Michael F. Jacobson, Exec. Dir., Ctr. Sci. Pub. Interest, *Re: Docket No. 94P-0036* (Dec. 19, 2003).

62. 21 C.F.R. § 101.9(c)(2)(ii) (2006).

63. See Steven Milloy, *Trans Fat Hysteria could be Lawsuit Bonanza* (Nov. 9, 2006), <http://www.foxnews.com/story/0,2933,228537,00.html> (last visited Dec. 28, 2007); see also Gary Becker, *The Becker-Posner Blog*, *Comment on the New York Ban on Trans Fat-Becker* (Dec. 21, 2006), [http://www.becker-posner-blog.com/archives/2006/12/comment\\_on\\_the\\_4.html](http://www.becker-posner-blog.com/archives/2006/12/comment_on_the_4.html) (last visited Dec. 28, 2007).

64. See Mozaffarian et al., *supra* note 4, at 1,613; see also TRANS FAT TASK FORCE OF HEALTH CANADA, *TRANSFORMING THE FOOD SUPPLY: APPENDIX 9iii, CONSULTATION ON THE HEALTH IMPLICATIONS OF ALTERNATIVES TO TRANS FATTY ACIDS, SUMMARY OF RESPONSES FROM EXPERTS* (2006), available at [http://www.hc-sc.gc.ca/fn-an/nutrition/gras-trans-fats/tf-ge/tf-gt\\_app9iii\\_e.html](http://www.hc-sc.gc.ca/fn-an/nutrition/gras-trans-fats/tf-ge/tf-gt_app9iii_e.html).

65. See Mozaffarian et al., *supra* note 4, at 1,613.

with non-trans unsaturated fats could cut a person's risk of CHD by as much as 53%.<sup>66</sup> Additionally, trans fats have been shown to have a sinister effect on cholesterol levels, a key indicator of heart health: while trans fat consumption increases the level of LDL (bad) cholesterol, it also decreases the level of HDL (good cholesterol), resulting in a negative effect on cholesterol levels that is significantly larger than that caused by saturated fat consumption.<sup>67</sup>

In addition, trans fats may be harmful to more than just heart health. Though there is no scientific consensus, some studies have suggested that trans fat consumption may also result in higher risks of obesity,<sup>68</sup> type II diabetes,<sup>69</sup> infertility,<sup>70</sup> and even cancer.<sup>71</sup> Given these and other findings, the IOM's recommendation that dietary trans fats be as low as possible<sup>72</sup> seems warranted. The next section discusses the current state of regulations concerning these substances.

#### IV. CURRENT REGULATION OF TRANS FATS

There are two basic sources of the current statutes concerning trans fats: the federal government (via the Food and Drug Administration's (FDA) authority over food labeling), and state and local governments. Rather than focusing on the effect that different types of trans fats have in the human body, the FDA has chosen to regulate a chemical structure, with the result that the amount of certain types of natural trans fats must be factored into a product's to-

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66. See F.B. Hu et al., *Dietary Fat Intake and the Risk of Coronary Heart Disease in Women*, 337(21) NEW ENG. J. MED. 1491 (1997).

67. See A. Ascherio et al., *Trans Fatty Acids and Coronary Heart Disease*, 340(25) NEW ENG. J. MED. 1994 (1999).

68. See Anna Gosline, *Why Fast Foods are Bad, even in Moderation* (June 12, 2006), <http://www.newscientist.com/channel/health/dn9318-why-fast-foods-are-bad-even-in-moderation.html> (last visited Dec. 28, 2007); see also *Six Years of Fast-food Supersizes Monkeys*, 2556 NEW SCIENTIST 21 (June 17, 2006), available at <http://www.newscientist.com/channel/health/mg19025565.000-six-years-of-fastfood-fats-supersizes-monkeys.html>.

69. See TRANS FAT TASK FORCE OF HEALTH CANADA, *supra* note 64; but see R.M. van Dam et al., *Dietary Fat and Meat Intake in Relation to Risk of Type 2 Diabetes in Men*, 25(3) DIABETES CARE 417, 422 (2002) (suggesting no such correlation when confounding factors were factored into the analysis).

70. See Jorge Chavarro et al., *Dietary Fatty Acid Intakes and the Risk of Ovulatory Infertility*, 85(1) AM. J. CLINICAL NUTRITION 231-37 (2007).

71. See Jorge Chavarro et al., *A Prospective Study of Blood Trans Fatty Acid Levels and Risk of Prostate Cancer*, 47 PROC. AMER. ASSOC. CANCER RES. (2006); but see TRANS FAT TASK FORCE OF HEALTH CANADA, *supra* note 64.

72. See DIETARY REFERENCE INTAKES, *supra* note 4, at 14.

tal trans fat content, leading big companies like Starbucks to remove them even though those fats may actually be beneficial to human health.<sup>73</sup> As the Starbucks story attests, these natural fats are often hastily replaced with processed fats high in saturated fat but lacking in the beneficial fats that the natural ingredients contain. Consequently, the current regulatory situation may result in a negative net effect on public health.<sup>74</sup>

Aside from the effect that the federal regulations have on large producers, there is a second force effecting large food producers and retailers in a similar way: the necessity of complying with multiple local ordinances, some of which might require the removal of the natural trans fats covered by the FDA, may prompt national businesses such as Starbucks to play it safe by going to the extreme of eliminating all of the trans fats that the FDA labeling requirement covers in hopes of achieving broad compliance. The sweeping changes resulting from these two forces may have a negative effect on the safety and wholesomeness of the food supply because they are resulting in natural trans fats being eliminated (even though scientific evidence suggests that such fats may be beneficial to consumer health) by large producers and retailers such as Starbucks in exchange for added saturated fats from the substituted palm oils, margarines, and interesterified fats that are either known to be detrimental to heart health<sup>75</sup> or are potentially deleterious.<sup>76</sup> This section will analyze each of these regulatory sources in turn—their history and coverage—to expose their individual shortcomings and the problems created by their simultaneous operation.

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73. See 68 Fed. Reg. at 41461.

74. See *supra* § III.B.

75. See WHO, *supra* note 7, at 88.

76. See Ben Harder, *A Trans Fat Substitute Might Have Health Risks Too* (Feb. 10, 2007), 171(6) SCIENCE NEWS ONLINE, <http://www.sciencenews.org/articles/20070210/food.asp> (last visited Dec. 28, 2007) (citing K. 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*, 4 NUTRITION & METABOLISM 3 (2007), available at <http://www.nutritionandmetabolism.com/content/4/1/3>). Michael Jacobson points out that the study cited “had a ‘bizarrely high’ proportion of saturated fatty acids,” and states that “(i)t looks to me like the palm oil industry was looking for a way to put a potential competitor in a bad light [by using] unrealistic conditions.” *Id.*

A. *The Current Federal Regulations: Overbroad in Scope but Under-Regulatory*

While the current FDA regulation requiring the listing of trans fat content on the nutrition facts label of food products has indirectly led producers to limit the amount of trans fat contained in their products to an amount lower than 0.5 grams per serving (the amount below which trans fat content can be claimed as “zero”),<sup>77</sup> it is flawed for several reasons: the 0.5 grams per serving allowance is too high; the definition of trans fats is too broad; and the regulation merely requires the labeling of a food’s trans fat content rather than directly limiting the amount of trans fat that a given food product may contain, leading local governments to pass a multitude of different regulations to fill in the regulatory gaps left by the FDA. This section looks at the history and current state of the federal regulation regarding trans fat and discusses its benefits and shortcomings.

### 1. History

The road that led to the current regulation of trans fat was a long one. Following the revelation that approximately 30,000 deaths result from coronary heart disease (CHD) due to trans fat consumption annually,<sup>78</sup> the Center for Science in the Public Interest (CSPI) changed its position on PHVO and filed a citizen action petition on February 14, 1994, urging the FDA to require that a product’s trans fat content be reported on its nutrition facts label.<sup>79</sup> A proposed rule appeared in the Federal Register on November 17, 1999, suggesting that the nutrition labeling regulations be amended to require that the amount of trans fats in a food be included in the amount and percentage daily value declared for saturated fat with a footnote indicating trans fat content per serving when it exceeded 0.5 grams.<sup>80</sup>

Three comment periods were successively opened for the proposed rule.<sup>81</sup> On September 18, 2001 (over seven years after the initial citizen action petition was filed), the Office of Information

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77. 21 C.F.R. § 101.9(c)(2)(ii) (2006).

78. See Willett & Ascherio, *supra* note 60.

79. Taylor, *supra* note 61.

80. Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims, 64 Fed. Reg. 67246, at 62755-56 (Nov. 17, 1999) (codified as amended in 21 C.F.R. pt. 101). This proposed rule was dramatically amended. See *infra* § IV.A.2.

81. 68 Fed. Reg. at 41436.



and Regulatory Affairs of the Office of Management and Budget sent a letter to the Secretary of Health and Human Services requesting that the FDA give greater priority to the November 1999 proposed rule “in light of the growing body of scientific evidence suggesting that consumption of *trans* fatty acids in foods increases the consumer’s risk of developing CHD.”<sup>82</sup> The letter went on to state that such evidence strongly supported “the interests of the Government to lower the incidence of and economic burden of CHD in the United States” by limiting the presence of trans fats in the food supply.<sup>83</sup>

Following this letter, the FDA requested a report from the Institute of Medicine (IOM) on trans fats. In response to the FDA’s request, the IOM issued a report in July of 2002.<sup>84</sup> In its report, the IOM concluded that there is no known requirement for trans fatty acids to facilitate specific body functions,<sup>85</sup> and that because of the increased risk of CHD that accompanies consumption of trans fats, their Upper Tolerable Intake Level (UL) should be “zero.”<sup>86</sup> However, the IOM also acknowledged the following:

Because *trans* fatty acids are unavoidable in ordinary diets, achieving [a UL of zero] would require extraordinary changes in patterns of dietary intakes. 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.<sup>87</sup>

Thus, while the IOM recommended, on the basis of evidence that trans fatty acids (and particularly artificial trans fatty acids) are deleterious to health, that all trans fatty acid intake be zero, it acknowledged that there may be indirect negative health effects resulting from removing natural sources of trans fats from the diet that would make complete elimination of all trans fatty acids from the diet ill-

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82. *Id.*

83. *Id.*

84. DIETARY REFERENCE INTAKES, *supra* note 4.

85. *Id.* at 2.

86. *Id.* at 14.

87. *Id.*

advised.<sup>88</sup> Following the first IOM report from July 2002, the FDA published a final rule in the Federal Register on July 11, 2003.<sup>89</sup>

In a second report issued in December 2003 (shortly after the FDA passed its current labeling regulation) at the request of Health and Human Services, the Department of Agriculture, and Health Canada, the IOM provided guiding principles for nutrition labeling and fortification and stated “diets can be planned that provide less than [one] percent of calories from [trans fatty acids] provided that the only sources of [trans fatty acids] are naturally occurring (i.e., in meats, poultry, and dairy products).”<sup>90</sup> Consequently, this second report both reiterated the IOM’s earlier observation that the elimination of natural trans fat sources from the diet would be ill-advised and implied that the elimination of all artificial trans fat sources would be feasible.<sup>91</sup> In other words, the report implied that the optimum diet in terms of balancing trans fat content with overall wholesomeness would be one that eliminated all artificial trans fat sources while retaining natural trans fat sources for their overriding nutritional benefits.<sup>92</sup>

“To minimize the need for multiple label changes and to provide additional time for compliance by small businesses,” the FDA set the effective date for the regulation as January 1, 2006—nearly twelve years after CSPI filed its initial petition.<sup>93</sup> By comparison, it only took the FDA three years from the passage of the Nutrition Labeling and Education Act of 1990 to issue and implement a final rule setting standards for the listing of all of the other nutrients that are provided on food labeling.<sup>94</sup> If the 1994 estimates<sup>95</sup> were accurate, approximately 360,000 Americans died from CHD attributable to trans fat consumption in the time between the filing of CSPI’s initial petition and publication of the final rule. At the time that the final rule was published, the FDA estimated the economic benefit to

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88. *See id.*

89. 68 Fed. Reg. 41434.

90. FOOD & NUTRITION BD., IOM, DIETARY REFERENCE INTAKES: GUIDING PRINCIPLES FOR NUTRITION LABELING AND FORTIFICATION 100 (Dec. 2003), available at [http://www.nap.edu/catalog.php?record\\_id=10872](http://www.nap.edu/catalog.php?record_id=10872) [hereinafter GUIDING PRINCIPLES].

91. *See id.*

92. *See id.*

93. 68 Fed. Reg. at 41466.

94. *Id.* at 41434.

95. *See Willett & Ascherio, supra* note 60.

cost ratio of the labeling requirement would be sixty-five to one.<sup>96</sup> While it is not clear exactly how much was spent on CHD attributable to trans fat consumption in the time that it took the FDA to approve the CSPI petition, the estimated mortality total and benefit to cost ratio suggests that the economic cost of bureaucratic red tape may have been daunting.

## 2. The Coverage of the Current Regulation

The current regulation<sup>97</sup> was passed pursuant to the Nutrition Labeling and Education Act of 1990's provisions allowing the Secretary of Health and Human Services to add or delete nutrients included in the food label through the regulatory power of the FDA, provided that the Secretary or the FDA finds such action necessary to assist consumers in maintaining healthy diet practices.<sup>98</sup> It defines trans fat as "all unsaturated fatty acids that contain one or more isolated (i.e., nonconjugated) double bonds in a trans configuration," thereby including both artificial and (to a partial extent) natural sources of trans fat.<sup>99</sup> The regulation goes on to provide that where a product contains less than 0.5 grams of trans fat per serving, no trans fat content need be listed if the product makes no claims about fat, fatty acid, or cholesterol content, and that if such claims are made the product must include a value for trans fat content on the nutrition label and must list that value as zero.<sup>100</sup> Finally, if a statement of a product's trans fat content is not required and not listed, a footnote must be placed at the bottom of the label stating "not a significant source of trans fat."<sup>101</sup> Consequently, the current regulation requires labeling only within the parameters described above: any elimination of trans fat is an indirect result and is voluntary as far as the FDA is concerned.

## 3. Analysis of the Current Regulation

As the Starbucks article attests, the current regulation has resulted in several positive steps: many producers have reformulated

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96. E-mail from Dr. Michael F. Jacobson, Exec. Dir., CSPI, to Ross Williams (Mar. 11, 2007, 15:50:12 CST) (on file with author).

97. 21 C.F.R. § 101.9(c)(2)(ii) (2006).

98. 68 Fed. Reg. at 41434.

99. 21 C.F.R. § 101.9(c)(2)(ii) (2006).

100. *Id.*

101. *Id.*

their recipes to exclude artificial trans fats, and the level of general public awareness of the dangers posed by trans fats has grown appreciably since passage of the regulation. At first glance, this is perhaps the best-case scenario for a regulation that seeks to limit the inclusion of a harmful substance in food indirectly by requiring producers to disclose the amount of the substance present in their products. However, the regulation also has significant shortcomings that may offset the benefits and that deserve comment and, ultimately, amendment.

*a. The FDA's definition of "trans fatty acid" is too broad*

Perhaps the most important flaw in the current regulation, the FDA's definition of trans fatty acid appears overbroad in that it covers natural sources of trans fats, leading to their elimination from the recipes of many food producers and potentially to negative net effects on health.<sup>102</sup> Indeed, the soundness of both the FDA's regulation of natural trans fat in general, and their regulation of non-conjugated linoleic acid (but not conjugated linoleic acid (CLA)) in particular, deserve closer scrutiny.

On one hand, while the FDA definition of trans fatty acids covers non-conjugated trans fats generally, it excludes the ruminant fat CLA—a substance shown to have numerous health benefits.<sup>103</sup> On the other hand, the regulation covers the non-conjugated vaccenic acid found simultaneously in the same animal fat deposits, even though the FDA acknowledges that vaccenic acid is converted into CLA in the body.<sup>104</sup> But because both vaccenic acid and CLA occur together in animal fat, CLA is regulated de facto, even though it is technically not covered under the FDA regulations. Consequently, it would seem imprudent to include natural trans fats in the definition of trans fats that must be reported on nutrition labels, since such labeling might mislead consumers into avoiding products containing only natural trans fats (both CLA and vaccenic acid) that might actually be beneficial to them in several different ways.<sup>105</sup> While some evidence suggests that natural trans fat consumption might also have its risks, both the July 2002 IOM report published prior to the issuance of the current FDA labeling regulation and the December 2003 IOM report published shortly after issuance of the

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102. See *supra* § III.B.

103. 68 Fed. Reg. at 41461.

104. *Id.*

105. Mozaffarian et al., *supra* note 4.

regulation suggest that the elimination of natural trans fats from the diet might not be advisable because of the indirect health benefits that attend natural trans fat consumption.<sup>106</sup> Indeed, some local U.S. regulations seem to have followed the IOM's observations in those reports by excluding natural trans fat sources from their trans fat definitions.<sup>107</sup>

Moreover, the FDA's justification for this overbroad definition seems to conflict with the purpose for passing the regulation in the first place. The FDA's explanation for only requiring food producers to list some parts of a cow's fat on the nutrition label is that it is regulating a chemical structure, rather than the functional or metabolic aspects of the different types of trans fats.<sup>108</sup> However, this explanation seems to betray a short sighted approach by the FDA: these regulations are, after all, being passed in response to recognition of the negative health effects of trans fat consumption, i.e. their negative functional or metabolic effect in the human body. Given that impetus, it may be unwise to define trans fats in a way that might confuse the public as to the wholesomeness and safety of a food product containing only natural trans fats. Consequently, it seems that the way in which trans fatty acids are defined clashes with the intent of the current regulation—"to provide information to assist consumers in maintaining healthy dietary practices"<sup>109</sup>—because it might actually lead them to adopt less healthy practices by eliminating natural trans fats from their diets and substituting harmful processed oils high in saturated fats in their place.

In light of this apparent disconnect between the stated purpose of the rule and the definition that drives it, an appropriate remedy may involve changing the definition of "trans fats" to cover only artificial trans fat sources. This action would also help to divert the wholesale removal of natural trans fat sources from the food supply, though it is not clear that such action would be entirely effective because, as the Starbucks article attests, the food industry has already begun the removal process in response to public concern.

Unfortunately, it appears that this problem could have been prevented proactively had the FDA considered the potential negative effect of the broad scope of its trans fat definition in light of the IOM's recommendations and amended the definition accordingly

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106. See DIETARY REFERENCE INTAKES, *supra* note 4, at 14; see also GUIDING PRINCIPLES, *supra* note 90.

107. See New York, N.Y., Dep't of Health & Mental Hygiene, *supra* note 2.

108. 68 Fed. Reg. at 41461.

109. *Id.* at 41434.

prior to approving the final rule. After the IOM suggested that any consumption of trans fats increases the risk of CHD,<sup>110</sup> the FDA warned that it would “exercise its enforcement discretion” to prevent manufacturers from either labeling their products with a trans fat content prior to the passage of the final rule, or including the proposed footnote stating that “intake of trans fats should be as low as possible.”<sup>111</sup> In other words, the FDA was threatening to punish manufacturers if they attempted to inform consumers about their product’s content of a substance acknowledged by the IOM to be harmful at any level of consumption on the rationale that such forewarning might encourage consumers to eliminate all intake of trans fatty acids, which the IOM had stated was not desirable.<sup>112</sup> However, the FDA’s inclusion of natural trans fats in its trans fat definition has led manufacturers to eliminate natural trans fats in response to public concern *de facto*. Thus, the FDA’s threat of enforcement action exposed the fallacy of the definition of trans fatty acids in the regulation—it includes natural sources of trans fats, leading the public and businesses such as Starbucks to call for their elimination, even though the IOM has stated, and the FDA acknowledges, that such elimination is undesirable. Because this elimination is effectively happening now, it seems that the FDA should have been more concerned with the over-breadth of its definition in light of the IOM report, rather than with the possibility that food producers would give consumers advance notice of harmful substances in their food. By threatening to punish producers who sought to eliminate all trans fats from their products, the FDA only delayed the inevitable (and left the consumer uninformed longer), whereas a change in the definition could have prevented the current problem by addressing its root cause.

*b. The “less than 0.5 grams” labeling standard*

Another apparent shortcoming of the current regulation is its allowance of a zero gram trans fat content listing on nutrition labels when as much as 0.49 grams of trans fat is present in a food.<sup>113</sup> This shortcoming raises several issues.

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110. Hence its observation that the ideal UL for trans fats would be “zero.” DIETARY REFERENCE INTAKES, *supra* note 4, at 14.

111. 68 Fed. Reg. at 41434.

112. *Id.* at 41459.

113. 21 C.F.R. § 101.9(c)(2)(ii) (2006).

- i. The standard allows continued use of PHVO at relatively high levels

One major problem with this standard is that it is high enough to allow for significant continued use of PHVO. The trans fat to total fat ratio of PHVO depends upon the method of hydrogenation used.<sup>114</sup> Hydrogenation at twenty p.s.i., the former industry standard, results in PHVO that contains 40% of its total fat as trans fat.<sup>115</sup> This is very high in comparison to natural sources, for instance, wherein 2-5% of the total fat is composed of trans fat.<sup>116</sup> Consequently, PHVO produced through low pressure hydrogenation cannot meet the requirement that a serving contain less than 0.5 grams of trans fat to be labeled zero grams trans fat. However, hydrogenation at higher pressures (200 p.s.i.) yields PHVO that contains as low as 17% of its total fat as trans fat.<sup>117</sup> At this low level, PHVO can be blended with liquid soybean oil to create oil containing less than 0.5 grams per serving.<sup>118</sup> Indeed, inspection of ingredient lists at most local supermarkets will reveal oils and spreads containing this type of blend. As a result, artificial trans fats contained in PHVO are allowed to remain in the food supply even though the IOM has stated that they are harmful to heart health at any level of consumption.<sup>119</sup>

However, if the FDA had followed the lead of other governments that have passed regulations limiting the presence of trans fats in food, this loophole could have been largely avoided. At the very least, the blended oils would be allowed to contain even less PHVO. The Canadian standard, for instance, requires less than 0.2 grams of trans fat per serving in order to state that it contains zero grams of trans fat on the label,<sup>120</sup> an amount high enough to be met by most natural trans fat sources but low enough that the current blended oils may not pass. CSPI Executive Director Michael Jacobson believes that while the current less than 0.5 grams standard has

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114. F.J. Eller, *Preparation of Spread Oils meeting USFDA Labeling Requirements for Trans Fatty Acids via Pressure-Controlled Hydrogenation*, 53(15) J. AGRIC. & FOOD CHEMISTRY 5,982, 5,982-84 (2005).

115. *Id.*

116. *Id.*

117. *Id.*

118. *Id.*

119. DIETARY REFERENCE INTAKES, *supra* note 4, at 14.

120. CANADIAN FOOD INSPECTION AGENCY, *Information Letter: Labelling of Trans Fatty Acids*, <http://www.inspection.gc.ca/english/fssa/labeti/inform/20050914e.shtml> (last visited Feb. 6, 2008).

brought about positive changes, a less than 0.2 grams standard would have been preferable.<sup>121</sup> The practical effect of the current regulation is that, while American consumers can be sold food containing as much as 0.49 grams of artificial trans fat *per serving* under the guise of zero grams trans fat, if the Canadian standard were followed producers could only include 0.19 grams of trans fat per serving to make similar claims. Considering the IOM's recommendation to limit trans fat intake as much as possible, it is almost a truism that a change in the standard to less than 0.2 grams per serving would be beneficial. This would accomplish the dual benefits of even lower PHVO content in foods and lower overall trans fat consumption by the American public. Given the large expense of health care, particularly heart surgery and rehabilitation therapy, such a change would almost certainly result in a positive net economic benefit.<sup>122</sup>

ii. The standard is mandatory, leaving consumers in the dark

Another issue raised by the regulations is that they actually mandate that the nutrition label for any food containing less than 0.5 grams trans fat per serving report the product's trans fat content as zero grams.<sup>123</sup> This means that a food literally containing zero grams trans fat is indistinguishable to the average consumer from a food containing 0.49 grams trans fat per serving. This requirement puts health-conscious consumers at a considerable disadvantage, because it prevents them from effectively monitoring the trans fat content of their food or eliminating it altogether without going to considerable trouble. Granted, the producer must still list PHVO on the ingredients list, but that puts the onus on the consumer to doubt the veracity of the nutrition facts label and then be informed enough to know that a food product contains artificial trans fat when its ingredient list includes "partially hydrogenated vegetable oil." Consequently, the potential confusion engendered by a requirement such as this one, effectively forcing producers to keep consumers in the dark regarding the actual trans fat content of their foods and placing the burden on consumers to decipher a mislead-

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121. E-mail from Michael Jacobson, *supra* note 96.

122. See Richard Posner, *The Becker-Posner Blog, Comment on the New York Ban on Trans Fats - Posner* (Dec. 17, 2006), [http://www.becker-posner-blog.com/archives/2006/12/the\\_new\\_york\\_ci.html](http://www.becker-posner-blog.com/archives/2006/12/the_new_york_ci.html) (last visited Dec. 28, 2007) (discussing an analogous economic benefit resulting from the New York ordinance limiting the presence of trans fat in foods).

123. 21 C.F.R. § 101.9(c)(2)(ii) (2006).



ing nutrition label, conflicts with the stated purpose behind the government's grant of authority to the FDA to amend its rules "to assist consumers in maintaining healthy diet practices."<sup>124</sup> On the contrary, the current situation seems to thwart such consumer attempts rather than assist them by misleading consumers as to the trans fat content of their food.

Again, given that the IOM has stated that any amount of trans fat consumption is harmful to health,<sup>125</sup> and that trans fat has been shown to be considerably more detrimental to health than saturated fat in comparable amounts,<sup>126</sup> the FDA's mandate that levels of trans fat in food up to 0.49 grams per serving be reported as zero grams may result in considerable negative effects on consumer health relative to other countries. The average health conscious American consumer eating three meals with three servings each per day, believing all along that they have consumed zero grams trans fat, could actually consume as much as 150% more trans fat daily than a Canadian consumer eating foods making the same claims but regulated under the Canadian standard. Consequently, the current rule would go further toward meeting the goal of the statutory grant of authority if it was amended to require producers to list the actual amount of trans fat contained in their products to the nearest 0.1 grams if the content per serving is 0.2 grams or above. Increased consumer awareness, in turn, might lead to a further reduction in CHD attributable to trans fat consumption, and a concomitant economic benefit.

iii. The current standard distorts the wholesomeness of high saturated fat foods

Additionally, the current regulations are inherently deceptive to consumers for another reason—they can make high saturated fat foods seem more wholesome than they really are. As Michael Jacobson has pointed out, the current regulations allow food producers to claim "zero grams trans fat" on the front of food packaging, even though the food may contain any amount of saturated fat, which is generally known to be very detrimental to heart health.<sup>127</sup> The practical effect of this change is well-illustrated by the Starbucks example. Because Starbucks removed all trans fat from its baked goods,

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124. 68 Fed. Reg. at 41434.

125. DIETARY REFERENCE INTAKES, *supra* note 4, at 14.

126. See Hu et al., *supra* note 66.

127. E-mail from Michael Jacobson, *supra* note 96.

it can claim zero grams trans fat even though it switched to high saturated fat oils that may (because the amount of saturated fat in them is greater than the amount of trans fat formerly in their recipes) have similar or even more deleterious negative health effects. The result is that consumers buy a product thinking that it is more beneficial to their health, when in reality it is potentially just as harmful or even more harmful than the same product made with the discarded trans fat-containing recipe. As Jacobson points out, because the FDA never finalized a rule to end this deception by preventing zero grams trans fat claims on food packaging, such marketing continues to the potential detriment of consumers.<sup>128</sup>

*c. The current regulations do not address restaurants and other food vendors*

One of the biggest gaps in the current regulation is its failure to address retail food service, including street vendors, fast food, delivery, and fine dining establishments. Many Americans dine out or have their food delivered to them pre-prepared: the food industry will make \$1.5 billion in sales on the average day in 2007, and four out of five consumers agree that going out to a restaurant is a better way to use their leisure time than cooking and cleaning up.<sup>129</sup> In fact, restaurants contribute more than one-third of the trans fats in the American diet.<sup>130</sup> The current federal labeling regulations do nothing to directly address the large percentage of the average American's daily caloric intake that comes from these sources. As a result, consumers would have to do a considerable amount of independent research to find out how much trans fat they are getting from foods prepared at the lunch counter. To combat this oversight in the current federal regulations, state and local governments have stepped into the regulatory gap left by the FDA and have started limiting the amount and types of trans fats that retail establishments may use in preparing their foods.

*B. Local Efforts to Limit the Amount of Trans Fat in the Food Supply*

In addition to the FDA's failure to address trans fat in the context of food service establishments, state and local regulations have

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128. *Id.*

129. Nat'l Rest. Ass'n, *Restaurant Industry Facts*, [http://www.restaurant.org/research/ind\\_glance.cfm](http://www.restaurant.org/research/ind_glance.cfm) (last visited Dec. 28, 2007).

130. New York, N.Y., Dep't of Health & Mental Hygiene, *supra* note 2, at 2.

also attempted to fill the gap left by the federal regulation's more general shortcoming—its failure to directly limit the presence of trans fats in the food supply. To fill these gaps, many state and city governments have begun legislating food issues in general, and trans fats in particular.<sup>131</sup> These efforts range from initiatives by small towns urging their local food service establishments to voluntarily switch from artificial trans fats,<sup>132</sup> to regulations by huge cities such as New York universally preventing all local food service establishments from using any ingredients containing 0.5 grams or more of artificial trans fat per serving.<sup>133</sup>

While New York's regulation has been lauded by consumer activists such as CSPI's Michael Jacobson,<sup>134</sup> other locales have either soft-pedaled regulatory efforts (for instance, Chicago's regulation of food service establishments at different levels depending on their yearly income)<sup>135</sup> or used extreme rhetoric broadly comparing trans fats to food contaminants such as *E. coli*.<sup>136</sup> Even though such statements may be made to support bans limited to artificial trans fat use, when they are made without qualification they could potentially lead to uninformed consumers discontinuing use of products that list trans fat content that is composed only of natural trans fats that must be reported under the federal regulation. And nothing is stopping state or local governments from seizing on such rhetoric and the inclusion of natural trans fat sources in the federal regulation's definition to fashion a ban on the use of all trans fats by local food service establishments.

Because so many restaurants are part of national chains that use pre-prepared components shipped in from large manufacturers, these local regulations can affect large restaurant and commercial food supply businesses that operate at the national level by forcing them to comply broadly so that their franchises may comply locally. And because of the lack of education on the part of the government, smaller local businesses faced with impending compliance deadlines are forced to hastily switch to processed fats that may be only

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131. See Lorin, *supra* note 22.

132. Ban Trans Fats, *Project Tiburon: America's First Trans Fat-Free City!!!*, <http://www.bantransfats.com/projecttiburon.html> (last visited Dec. 28, 2007).

133. New York, N.Y., Dep't of Health & Mental Hygiene, *supra* note 2.

134. E-mail from Michael Jacobson, *supra* note 96.

135. See Greg Brown, *Proposed Trans Fat Ban Irks Chicago Restaurants*, Health Care News (Oct. 2006), available at <http://www.heartland.org/Article.cfm?artId=19744>.

136. See Lorin, *supra* note 22 (noting that Connecticut State Senator Andrew Roraback has said that trans fats are "as much a contaminant as *E. coli*.").

slightly healthier than the trans fats they are meant to replace.<sup>137</sup> Consequently, the local regulations can have regional or national implications.

Ultimately, the current regulatory situation is one of profound uncertainty for the businesses that supply our national food system. Faced with myriad local regulations and the potential for more and varied regulations daily, food suppliers look to the federal government for uniformity and certainty. Finding that the federal government has included natural trans fats in their definition, and fearing that public hysteria will lead local governments to do the same in directly banning or limiting the presence of trans fats in their local food supplies, producers and retailers may seek broad preemptive compliance by taking steps similar to those taken by Starbucks: they may eliminate all trans fats from their products, even though the IOM has suggested that such action could have significant negative consequences.<sup>138</sup> These natural trans fat sources might then be replaced with processed oils high in saturated fats and lacking in nutrients that would otherwise prevent vitamin and nutritional deficiencies. The result is a food supply of increasing safety yet decreasing wholesomeness, and a step backward for public health.<sup>139</sup> The next section discusses current efforts urging the FDA to take further action on trans fat regulation to address this problem.

## V. THE CSPI PETITION

In an effort to address the gaps in the Food and Drug Administration's (FDA) labeling regulation and in recognition of the potential for passage of multifarious local regulations (a fear that has come to fruition), the Center for Science in the Public Interest (CSPI) filed a citizen action "Petition for Rulemaking to Revoke the Authority for Industry to Use Partially Hydrogenated Vegetable Oils

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137. See E. Charles Hunt, Executive Vice Pres. of N.Y. State Rest. Ass'n, *Testimony at Public Hearing by City Council Committee on Health* (Oct. 30, 2006), available at <http://www.restaurant.org/pressroom/pressrelease.cfm?ID=1332> (quoting the Chair of the American Heart Association's Nutrition Committee's conclusion that "consumers should avoid increasing their intake of saturated fat in an effort to minimize trans fat," and asserting that the New York regulation, phased in over eighteen months, would force food service establishments to take that step); but see E-mail from Michael Jacobson, *supra* note 96 (asserting that restaurants will not have to take such drastic steps because initial enforcement following the effective date of the ban will take more than a year).

138. See DIETARY REFERENCE INTAKES, *supra* note 4, at 14.

139. See Hunt, *supra* note 137.

in Foods” on May 18, 2004.<sup>140</sup> While the petition requests rulemaking to bring about several important changes that should be granted by the FDA, it also explicitly endorses the FDA’s current definition of trans fats.<sup>141</sup> Consequently, even if the petition is granted (which is unlikely) it may not go far enough to address the problems with the current regulatory situation. Moreover, CSPI’s desire for prompt action exposes the time sensitive nature of its requests: because the FDA has failed to act, CSPI’s requests, if granted, may no longer be fully effective in addressing the problems raised by the current state of trans fat regulation, as many of the dangers that its requests were designed to avoid (such as state and local regulation) have already come to pass.

### A. CSPI’s Requests

Although CSPI’s petition explicitly approves of the FDA’s current definition of trans fatty acid,<sup>142</sup> it does request that the FDA take three major actions to limit the use of artificial (but not natural) trans fats in the food supply:

#### 1. Initiate a rulemaking to:

- a. revoke the “generally recognized as safe” (GRAS) status<sup>143</sup> of partially hydrogenated oils in foods, “so that they would be legally classified as food additives” and so that their continued use would be made illegal absent a regulation “prescribing the conditions under which such additives may be safely used”;<sup>144</sup>

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140. CSPI, *supra* note 17, at 9.

141. *Id.* at 2 n.7.

142. Presumably, this approval is to avoid coming across as unreasonable in their requests. *See id.*

143. “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 a safe’ by a public formal determination by the FDA, a letter from the FDA, or a self-determination by a food company.” *Id.* at 3 n.15.

144. *Id.* at 3-4. “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.” *Id.* at 4 n.20 (explaining FFDCA § 409(a)(2), 21 U.S.C. § 348(a)(2)).

- b. "revoke the current 'safe conditions' for those partially hydrogenated vegetable oils that the FDA has approved as food additives";<sup>145</sup> and
- c. "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."<sup>146</sup>

2. Announce that the rulemaking will be completed by 2008 given the strong scientific evidence establishing the public health risks of partially hydrogenated vegetable oil (PHVO), thus allowing two years to observe the impact of the labeling regulation.<sup>147</sup> Industry should be given two years to adapt before the new regulation becomes effective.<sup>148</sup>

3. Immediately (prior to deciding on the merits of the regulatory actions requested) develop a program to encourage the food industry to replace partially hydrogenated vegetable oils with the most healthful ingredients possible.<sup>149</sup>

4. In the alternative, institute rulemaking or request comments on setting tolerance levels for trans fats.<sup>150</sup>

### B. Analysis of CSPI's Requests

1. A Narrowed Scope Allows CSPI's Tolerance Proposal to Swallow its Requests for GRAS Removal, "Safe Condition" Revocation, and Prior Use Prohibition

CSPI's request to remove the GRAS status, "safe conditions" of use, and prior use exemptions for the various types of artificial trans fats contained in PHVO seems appropriate because strong scientific evidence suggests that the FDA should exercise its authority to take such action.<sup>151</sup> However, CSPI inexplicably qualifies its request for GRAS removal in a way that essentially allows it to be swallowed by

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145. CSPI, *supra* note 17, at 4.

146. *Id.*

147. *Id.*

148. *Id.*

149. *Id.*

150. CSPI, *supra* note 17, at 5. CSPI's petition points out that the Danish government limits trans fats to 2% of the total fat in foods. *Id.* at 10.

151. *See id.* at 25 (citing 21 C.F.R. § 170.6(c)). Note that the FDA can initiate rulemaking *sua sponte*, rather than waiting to rule on a filed petition. *See* 21 C.F.R. § 10.25 (2006).

the alternative request for the establishment of partially hydrogenated oil (PHO)<sup>152</sup> tolerance levels.

On its face, CSPI's request for GRAS removal seems straightforward and well-founded. The FDA distinguishes generally between substances that are food additives and those that are not.<sup>153</sup> Substances classified as food additives cannot be legally used unless the FDA has issued a regulation "prescribing the conditions under which such additive may be safely used."<sup>154</sup> A substance will be deemed a food additive where: (a) its use or intended use results or can be reasonably expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, and (b) it is not generally recognized among experts qualified by scientific training and experience to evaluate its safety as having been adequately shown through scientific procedures to be safe under the conditions of its intended use.<sup>155</sup>

As the CSPI points out in its petition, PHOs clearly satisfy the first prong because their intended use directly results in their becoming a component in food.<sup>156</sup> Additionally, PHOs satisfy the second prong because they are not generally recognized by scientists to be safe under the conditions of their intended use: the IOM concluded that any amount of trans fat intake increases the risk of coronary heart disease (CHD), and a federal court of appeals has held that the absence of a safe level of a substance in food justifies the FDA's determination that the product is unsafe.<sup>157</sup> Consequently, the CSPI makes a strong case that artificial trans fats are food additives. Moreover, it makes an equally strong argument that, as a food additive, PHO should not be GRAS because the current scientific evidence should prevent it from meeting the "reasonable certainty of no harm" standard for approval.<sup>158</sup>

However, the CSPI limits the scope of its request in a way that may render it a request for tolerances rather than for an effective ban. Specifically, the CSPI points out that it intends to exclude from the proposed rulemaking saturated fats (because of their ubiquitousness and natural origin), natural trans fats (presumably because of their potential direct and indirect nutritional benefits), and PHO

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152. PHO includes PHVO, but also encompasses Menhaden (fish) oil.

153. 21 U.S.C. § 321(s) (2006) (defining "food additive").

154. *Id.* at § 348(a)(2) (2006).

155. CSPI, *supra* note 17, at 25-26 (citing 21 U.S.C. § 321(s)).

156. *Id.* at 26.

157. *See id.* at 5-27.

158. *Id.* at 18.

*produced by new methods containing insignificant amounts of artificially produced trans fat.*<sup>159</sup> While the first two categories make sense, the third category essentially requests that the FDA establish an artificial trans fat tolerance rather than an outright ban. But it seems internally inconsistent for the CSPI to suggest that some PHOs should be exempted merely because they contain less trans fat per serving, given the contention of the Institute of Medicine (IOM) (cited in the CSPI petition) that the Upper Tolerable Intake Level (UL) of trans fats be zero.<sup>160</sup> Indeed, this qualification essentially allows CSPI's alternative request—that the FDA establish tolerance levels for artificial trans fats—to swallow its main request for a ban on PHO use through GRAS removal. Consequently, CSPI's main request and its alternative request essentially reach the same result of tolerance proposals, though they do so through different means (the former by virtue of its definition of PHO, the latter explicitly). The main difference between the two requests, then, is that if the FDA was to grant the explicit tolerance request, it could forego the formality of removing the GRAS status for PHO.

It is important to note that the CSPI petition does not address naturally occurring trans fat (presumably because of the IOM's observations), nor does it address the de minimis amount of trans fat occurring in conventionally processed (non-PHO) vegetable oils.<sup>161</sup> The exclusion of the trans fats in conventional vegetable oils from the proposed rulemaking may stem from two rationales: a realization that any food produced with such oils will still contain some amount of trans fats,<sup>162</sup> and a desire to focus on trans fats from sources shown to be deleterious to health—the partially hydrogenated variety. Indeed, both rationales would make sense; while the former makes practical sense, the latter seems to comport with the impetus for trans fat regulation—the protection of public health. However, these rationales do not explain CSPI's exclusion of trans fat from PHVO produced through new processing methods, as those oils contain the same trans fats from the same source (albeit in slightly lower amounts) as the trans fat widely recognized as being harmful to health.

The IOM reports clearly say that the desirable UL for trans fats is zero, and that it is feasible to plan a diet containing no artificial

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159. *See id.* at 27 n.115.

160. DIETARY REFERENCE INTAKES, *supra* note 4, at 14.

161. CSPI, *supra* note 17, at 27 n.115.

162. *Id.*



trans fats from PHO.<sup>163</sup> The CSPI is not requesting a total ban on all trans fats, and it seems to acknowledge that such a request would be impractical.<sup>164</sup> Rather, the CSPI requests a tolerance level on the use of PHO because of the deleterious trans fats that it contains.<sup>165</sup> But as the IOM reports attest, trans fats from these sources can be eliminated from foods as a practical and as a scientific matter.<sup>166</sup> Consequently, the CSPI petition may not go far enough toward protecting public health by merely requesting tolerances on the use of artificial trans fats contained in PHOs.

Regardless of this apparent problem with CSPI's petition, it goes on to request (on the basis of current scientific evidence and the FDA's "safe ingredient reexamination" commitment)<sup>167</sup> that the FDA remove the "safe conditions" of use established for all PHOs qualified as food additives because the new scientific evidence demonstrates that PHO can no longer be considered safe for use as a food additive, "unless conditions are established to ensure that the amount of trans fat is minimal," again suggesting that a tolerance level would be acceptable.<sup>168</sup> Additionally, the CSPI requests that all PHOs considered safe because they were in use prior to September 6, 1958, now be considered "unsafe" food adulterants.<sup>169</sup> This request seems prudent, because while the CSPI acknowledges that no prior sanction or approval exists for any PHO product, it seeks to prospectively prevent a company that had a prior use from escaping the requested new rule by seeking retroactive prior use approval under 21 C.F.R. section 181.1(a).<sup>170</sup>

Ultimately, while CSPI's request for GRAS removal, "safe condition" revocation, and prior use prohibition seems to be a request for a ban on its face, closer examination reveals that it is actually a request for tolerances. In light of the scientific evidence cited by the CSPI, including its assertion that sufficient substitutes containing no trans fat exist or will be developed by the time the requested rules

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163. DIETARY REFERENCE INTAKES, *supra* note 4, at 14 (stating that the ideal upper UL for trans fats is zero); GUIDING PRINCIPLES, *supra* note 90 (stating that it is feasible to plan a diet wherein the only trans fats are from non-PHO sources).

164. *See* CSPI, *supra* note 17, at 27 n.115.

165. *See id.* at 5-27.

166. GUIDING PRINCIPLES, *supra* note 90.

167. CSPI, *supra* note 17, at 28 (citing 21 C.F.R. § 170.6(c)).

168. *Id.* at 28.

169. *Id.* at 28-29 (citing 21 U.S.C. § 342(a)(2)(A); 21 C.F.R. § 181.1(b)).

170. *Id.* at 29.

take effect,<sup>171</sup> CSPI's narrowing of the scope of the PHO to be covered by its requested regulation seems misguided.

## 2. The Effective Denial of CSPI's Requests for Announcement and Education

FDA inaction since the filing of CSPI's petition has shown that its requests for announcement that rulemaking will be completed by 2008 and for immediate implementation of a far-reaching industry and consumer education program on trans fats and trans fat substitutes have been effectively denied.

First, the FDA's announcement that it will complete rulemaking by 2008, as per CSPI's request, has not been forthcoming. On the contrary, Michael Landa, Deputy Director for Regulatory Affairs for the Center for Food Safety and Applied Nutrition (CFSAN), has stated that he can acknowledge only that the petition was filed and that the FDA is reviewing it.<sup>172</sup> This would suggest that any rulemaking might take place on the same extended time frame that the current labeling regulation endured.

Second, any consumer and industry education by the FDA pursuant to CSPI's request for immediate implementation of a far-reaching, comprehensive program has been minimal. Although some efforts have been made to passively advise these groups via the internet,<sup>173</sup> the proof is in the pudding: stories such as those involving Starbucks abound,<sup>174</sup> suggesting that industry, the public, and even academics remain largely uninformed. Therefore, CSPI's requests on these fronts seem to have been effectively denied, which does not bode well for the disposition of the remainder of their petition.

## 3. CSPI's Prediction of State, Local, and Private Action

As an incentive for the FDA to take prompt action on its petition, the CSPI warned that should the FDA fail to fill the regulatory

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171. CSPI, *supra* note 17, at 23-25.

172. E-mail from Michael Landa, Dep. Dir. Reg. Affairs, Ctr. for Food Safety & Applied Nutrition, to Ross Williams, (Mar. 1, 2007, 15:07:19) (on file with author).

173. FDA, *Revealing Trans Fats*, [http://www.pueblo.gsa.gov/cic\\_text/food/reveal-fats/reveal-fats.htm](http://www.pueblo.gsa.gov/cic_text/food/reveal-fats/reveal-fats.htm) (last visited Dec. 28, 2007).

174. See, e.g., Hunt, *supra* note 137 (quoting the Chair of the American Heart Association's Nutrition Committee's conclusion that "consumers should avoid increasing their intake of saturated fat in an effort to minimize trans fat," and asserting that the New York regulation, phased in over eighteen months, would force food service establishments to take that step).

gaps left by its labeling rule—particularly the allowance for continued use of trans fats by restaurants and food companies—state and local governments might legislate to protect consumers further and private parties might institute suits.<sup>175</sup> This prediction has proven prophetic: since the CSPI filed its petition, numerous state and local governments have passed ordinances prohibiting or limiting the use of trans fats.<sup>176</sup> Moreover, as the CSPI points out, suits that are similar to those dismissed in the past might be successful in the future given the increased state of public and industry awareness of the dangers of trans fats.<sup>177</sup> Because state and local governments have already begun to regulate, engendering reflexive industry actions such as those discussed herein that could lead to negative effects on public health and dampen or substantially offset any potential gains from removing trans fats from the food supply, an effective solution may need to be more drastic than what the CSPI requests in its petition.

Ultimately, CSPI's petition was apt for the time and place in which it was filed. But, as its requests for prompt action reveal, its petition was time sensitive. Because of the FDA's inactivity while it considered the merits of CSPI's petition, the problems created by the current state of federal, state, and local trans fat regulation have been exacerbated to the point that the FDA may need to exercise its authority<sup>178</sup> to go beyond what the CSPI has recommended if it hopes to provide an effective remedy for the current problem.

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175. "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." CSPI, *supra* note 17, at 30 (citing *Hillsborough County, Fla. v. Automated Med. Laboratories, Inc.*, 471 U.S. 707 (1985) (holding that a local government can establish its own regulations beyond those of the FDA absent an explicit statutory pre-emption clause)).

176. See Nat'l Rest. Ass'n, *supra* note 15.

177. See CSPI, *supra* note 17, at 31. (arguing that private parties may in the future sue restaurants or food companies for continuing to use partially hydrogenated vegetable oils when healthier alternatives exist, citing for comparison *Pelman v. McDonald*, 237 F. Supp. 2d 511, 532 (holding that 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); *BanTrans-Fats.com v. Kraft Foods N. Am., Inc.*, CV 032041 (Marin County Super. Ct. Cal. May 2003)).

178. See 21 C.F.R. § 10.25 (2006).

## VI. RECOMMENDATIONS FOR FUTURE ACTION BY THE FDA

The outlook seems bleak for passage of the CSPI petition.<sup>179</sup> But at this point CSPI's petition may actually not request action drastic enough to correct the current problems: federal regulatory inactivity has allowed the window of effectiveness to pass for limited actions such as those requested by the CSPI—state and local governments have started regulating trans fats, and various standards and uncertainty abound among consumers and industry, leading to hasty preventive measures (such as the elimination of all types of trans fats and replacement with processed oils) that may be ill-advised. As a result, more drastic measures may be required if the FDA is to provide uniformity and certainty to the businesses that supply our national food system, and thereby prevent the potential negative health effects that could arise from producers and restaurants overreacting to the current lack of uniformity and fears over the potential tort consequences of continued artificial trans fat use.

While a more libertarian view would advocate allowing the market to work out the problem on its own, the current state of affairs developed from an unregulated state and demonstrates that regulatory inaction is inefficient legally, medically, and economically.<sup>180</sup> The goal of food regulation should be to ensure that the food supply is both safe and wholesome. While the current regulatory conditions ensure the safety of the food supply by eliminating

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179. E-mail from Michael Jacobson, *supra* note 96 (stating that the current FDA will not pass CSPI's petition and will have to be taken to court).

180. Legally, while under the current deregulated state some businesses (such as Kentucky Fried Chicken) will eliminate the use of PHVO and thereby eliminate tort liability, other businesses that have already been involved in tort litigation may naively seek to avoid or delay eliminating trans fat to avoid the appearance of culpability, a move which could potentially lead to further suits with increasing prospects of success. Additionally, challenges to multiple local ordinances could prove costly should a national company choose to resist elimination of PHVO. A preemptive federal regulation limiting or eliminating the use of PHVO could prevent these problems. Medically, a *laissez faire* attitude to regulation could result in two extremes—continued use of PHVO by businesses in some unregulated areas, resulting in continued elevated CHD levels, or complete elimination (as in the Starbucks example) resulting in the vitamin and nutrient deficiencies warned of by the IOM, as well as the loss of the potential benefits of natural trans fat consumption. Economically, the savings realized from decreased CHD costs through elimination of PHVO would be limited by the uneven regulation of those substances from one locale to another, whereas a uniform preemptive federal ban would maximize those benefits. See, e.g., Posner, *supra* note 122 (discussing an analogous economic benefit resulting from the New York ordinance limiting the presence of trans fat in foods); *contra* Milloy, *supra* note 63; Becker, *supra* note 63.

harmful artificial trans fats, they may simultaneously reduce the wholesomeness of the food supply by replacing natural trans fat sources (and their attendant nutritional benefits) with processed oils high in saturated fat (and lacking in those attendant nutritional benefits). Therefore, for the FDA to effectively address the current situation and ensure a food supply that is both safe and wholesome, it should exercise its authority to act *sua sponte*<sup>181</sup> and go beyond CSPI's requests by:

1. amending the current regulatory definition of trans fatty acids to exclude natural sources of trans fat (both non-conjugated vaccenic acid and conjugated linoleic acid (CLA)) from regulation, requiring labeling of only artificial trans fat content;

2. removing the GRAS status, "safe conditions" for use, and/or prior approval of all PHVO products containing detectable amounts of artificial trans fatty acids, effectively banning the use of artificial trans fats while allowing the continued use of natural trans fats (both vaccenic acid and CLA);

3. immediately sponsoring a far reaching education program as per the CSPI petition;

4. following Canada's lead in sponsoring continued research into the effect of natural trans fat sources on the human body;<sup>182</sup>

5. sponsoring further research into the safety of interesterified fats;<sup>183</sup> and

6. giving the regulation preemptive effect.<sup>184</sup>

While the FDA is not required to pass a preemptive regulation in this area, considerations of public policy<sup>185</sup> and federalism strongly support such action.

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181. See 21 C.F.R. § 10.25 (2006).

182. See TRANS FAT TASK FORCE OF HEALTH CANADA, *supra* note 30, at 41.

183. See Harder, *supra* note 76 (citing Sundram et al., *supra* note 76; but quoting Michael Jacobson, who points out that the study cited "had a 'bizarrely high' proportion of saturated fatty acids," and states that "(i)t looks to me like the palm oil industry was looking for a way to put a potential competitor in a bad light [by using] unrealistic conditions.").

184. A full analysis of whether such a regulation would be fully preemptive of state and local laws is beyond the scope of this paper. However, problems may arise in that 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 for which Congress has not explicitly pre-empted such action, and the FFDCFA does not lend preemptive effect to food additive regulations. CSPI, *supra* note 17, at 30. This means that a new law that includes an express preemption provision for food additives may have to be passed to prevent state and local governments from passing laws to regulate trans fats above and beyond the federal regulations—which is the key concern arising in this context.

Our federal system was formed largely in response to the recognition that a decentralized system impeded interstate commerce. Similar concerns support passing a preemptive regulation banning the use of artificial trans fat, as required compliance with multiple local regulations impedes the business of national food producers and restaurants and threatens the nutrition of the average American. Consequently, a single preemptive regulation is needed to provide the uniform standard that the businesses that supply our national food system require to operate efficiently.

By amending the definition of trans fatty acid, the FDA can end Starbucks-type problems;<sup>186</sup> because producers will only have to list the content of artificial trans fats on their labels, they will be less likely to eliminate natural sources of trans fat and replace them with unhealthy processed oils. While this action would result in some hassle for industry as it readjusts yet again to a new standard, the total economic benefit of such action could be substantial: rather than replacing natural trans fat sources that are potentially beneficial to consumer health<sup>187</sup> with processed oils high in harmful saturated fats, the consumers would keep the beneficial substances, resulting in a further reduction in CHD levels. Indeed, the CSPI has estimated that a 47-fold increase in economic benefits over those realized under the current FDA labeling regulation could be realized through a ban on artificial trans fat use.<sup>188</sup> That estimate translates into a net economic benefit to the economy of \$616 billion to \$1.26 trillion over a twenty-year period.<sup>189</sup> Given the high cost of treating such problems, even a slight reduction could result in a net economic benefit. Moreover, the amended definition would better comport with the purpose of the rule and the authority under which it was granted, as discussed above. Consequently, the amendment of the current trans fatty acid definition is crucial to providing for a safer food supply that continues to be wholesome.

Legally, the FDA's commitment that ingredients previously considered GRAS must have their GRAS status re-examined in light of new scientific evidence does not bind the FDA to act.<sup>190</sup> However,

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185. *See id.*

186. *See id.*

187. *See supra* § III.B.

188. CSPI, *supra* note 17, at 12.

189. *Id.*

190. *See* Lars Noah & Richard A. Merrill, *Starting from Scratch?: Reinventing the Food Additive Approval Process*, 78 B.U.L. Rev. 329, 359 (1998) ("To revise or repeal an existing GRAS regulation, the FDA would need to follow only notice-and-comment rulemaking procedures.").

given the strong scientific evidence that artificial trans fats are dangerous, the FDA's refusal to remove the GRAS status of these substances would seem disingenuous and effectively render the FDA's re-examination commitment meaningless. Such refusal would also represent bad public policy by allowing industry to continue to use a substance known to be harmful to consumer health.<sup>191</sup> In that event, suits against the FDA and individual companies to force such action are likely and would be appropriate.<sup>192</sup>

A private party has individual rights to compel the FDA to institute a rulemaking where a significant factual predicate of a prior decision on the subject (either to promulgate or not to promulgate specific rules) has been removed.<sup>193</sup> Such a right has been found where new evidence came out eliminating any question as to whether raw milk consumption is dangerous following regulation of raw milk sales in interstate commerce that was partially stayed so that the Secretary could determine, through a public hearing, whether the consumption of raw milk is safe.<sup>194</sup> Here, shortly after the final rule was passed in July of 2003, the IOM responded to the FDA's request for information by issuing the December 2003 report<sup>195</sup> implying that it would be feasible to exclude PHVO from the diet, recognizing that natural trans fats should be left in the diet, and referring back to its conclusion from the July 2003 report that trans fats are more deleterious than saturated fats.<sup>196</sup> In the situation presented here, the labeling requirement could be viewed as a stay pending IOM results that might warrant a more decisive action. Just as evidence came forward in the raw milk case warranting further rulemaking to ban the sale of raw milk,<sup>197</sup> evidence came to light here following the implementation of the labeling rule that warrants many of the recommendations herein. A suit to compel rulemaking may prove fruitful here on the rationale that this new evidence constitutes the removal of a factual predicate of the original labeling rule.

Were GRAS removal, "safe use" revocation, and prior use prohibition granted, they would effectively constitute a ban on artificial

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191. See *supra* § III.B.

192. See E-mail from Michael Jacobson, *supra* note 96 (wherein Dr. Jacobson states that the CSPI will probably have to take the FDA to court to have their requests met).

193. *Pub. Citizen v. Heckler*, 653 F. Supp. 1,229, 1,241 (D.D.C. 1986).

194. See *id.*

195. See GUIDING PRINCIPLES, *supra* note 90, at 100.

196. See DIETARY REFERENCE INTAKES, *supra* note 4, at 14.

197. See *Heckler*, 653 F. Supp. at 1,232.

trans fat use. Upon such action, artificial trans fats would be considered new food additives, and as such would have to be shown to pose a "reasonable certainty of no harm" before being approved for use.<sup>198</sup> The burden for showing "a reasonable certainty of no harm" rests on the applicant<sup>199</sup>: in this case, a company seeking approval of a PHO would have to show that it did not pose an increased risk of heart disease. There is virtually no likelihood that a company could do this in the face of the current scientific evidence to the contrary, and as a result any GRAS removal would essentially function as a ban on artificial trans fat use. Additionally, if the current evidence linking artificial trans fat consumption to cancer is strengthened, approval following GRAS removal might be prevented by the Delaney Clause.<sup>200</sup>

The key to making trans fat regulation effective in the long term will be education and continued research.<sup>201</sup> Even if artificial trans fats are banned, optimum benefits to public health and the economy will not be realized unless producers and consumers understand the difference between harmful and beneficial trans fats, and are aware of the healthiest substitutes available. In this vein, continued research should be conducted to confirm or refute the preliminary evidence that natural trans fats are beneficial to health, and further research should be conducted on the healthfulness of interesterified fats so that their use may be appropriately curtailed should the preliminary studies prove reliable.

The most important aspect of these recommendations to insure the amelioration of the short-term issues raised in this article is the suggestion that the regulations be made preemptive. Only through lending these changes preemptive effect can the FDA hope to cure the uncertainty and misguided action that industry's attempts to achieve broad compliance with multiple local regulations have engendered. While enforcement of these standards could be left up to local authorities, the definition and limitations upon the use of trans fats should be controlled by one uniform, preemptive federal standard. Aside from the economic and regulatory benefits that a preemptive standard would provide, regulation would also confer a crucial benefit on the public in that it would obviate, to some extent,

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198. See CSPI, *supra* note 17, at 22.

199. *Id.*

200. 21 U.S.C. § 348(c)(3)(A) (2006).

201. Both research and education are addressed by the Canadian Trans Fat Task Force in their recommendations. TRANS FAT TASK FORCE OF HEALTH CANADA, *supra* note 30, at 41.



the need for consumers to be minutely informed to follow the best dietary practices. As Richard Posner has observed, we live in a world of nearly unlimited information, and the individual's ability to absorb and apply all of that information is finite.<sup>202</sup> The bottom line is that a single standard will remove the guesswork from producing and consuming foods that are both safe and wholesome, at least as far as trans fat content is concerned, by consolidating the information assimilation process.

Another issue regarding current trans fat regulation involves its effect on tort litigation. While some commentators have voiced concern that a trans fat ban would start a "lawsuit bonanza,"<sup>203</sup> in reality the FDA's adoption of these or similar recommendations may actually head off such litigation to a large extent.<sup>204</sup> Under the current regulatory system, some producers and restaurants (including McDonald's) have either put off their promises to switch from trans fats or have neglected to do so altogether.<sup>205</sup> Given the early rulings in tort claims for obesity caused by fast food products, the preference of some companies to ignore the "pink elephant" of scientific evidence that trans fats are harmful may actually lead to more lawsuits down the road.<sup>206</sup> On the other hand, a preemptive federal ban on the use of artificial trans fats that explicitly acknowledges their harmfulness would prompt the holdouts to make the switch away from artificial trans fats promptly, as their continued use would no longer be suspect. The faster that this change takes place, the less likelihood that a "lawsuit bonanza" may occur. Think of it as a taxi meter: the more artificial trans fat containing foods that consumers eat during the period that some fast food companies continue to include PHOs in their food despite scientific evidence and public awareness that they are harmful, the more money in terms of potential damages and settlement amounts that accrues against those companies on behalf of consumers that fall ill or die as a result of CHD attributable to trans fat consumption. Considering the Danish Nutrition Council's finding that, gram for gram, consumption of trans fatty acids instead of saturated fats results in a *ten fold* higher

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202. See Posner, *supra* note 122.

203. Milloy, *supra* note 63.

204. See CSPI, *supra* note 17, at 31.

205. Associated Press, *McDonald's Revisits Fat in Fries: New Test Shows Fries Contain a Third More Trans Fat Than Thought* (Feb. 8, 2006), available at <http://www.cbsnews.com/stories/2006/02/08/health/main1299086.shtml>.

206. See CSPI, *supra* note 17, at 30-31 (arguing that private parties may in the future sue restaurants or food companies for continuing to use partially hydrogenated vegetable oils when healthier alternatives exist).

risk increment for the development of heart disease,<sup>207</sup> such accrual could be considerable and the likelihood for claim success significant. The FDA and industry can stop the meter on these claims now by banning artificial trans fats preemptively and doing so as soon as possible. Or they can let the meter continue to run into the hundreds of millions or even billions of dollars.

## VII. CONCLUSION

On balance, only time will tell if industry and consumer practice regarding trans fats has changed to the extent that amending the regulatory system will not yield positive changes. The ball cannot be advanced when an agency buries its head in the sand, as the current state of affairs attests. On the contrary, where an agency abdicates its obligation to provide uniform federal regulations to a national industry, chaos can ensue as state and local governments attempt to regulate the industry via multiple local ordinances. Consumers may have already decided that all trans fats are harmful, and producers may have determined that it is better to simply remove all trans fats from their recipes, even though those actions may not only be misguided, but harmful to public health. Nevertheless, the experience to date with trans fat regulation suggests that a laissez-faire approach does not achieve optimum outcomes. Should the current situation continue unchanged, ten years from now the Institute of Medicine's concern regarding nutritional deficiencies from the elimination of natural trans fat sources<sup>208</sup> may come to fruition, a new round of increasing coronary heart disease may develop from increased use of interesterified fats and processed oils to replace trans fats, and settlement and damages from trans fat tort suits may rival those previously realized in tobacco litigation. The better course—legally, medically, and economically—may be to make the appropriate changes now, cross our fingers, and hope that it is not too late to ensure that, in terms of trans fat content, our food supply will be both safe and wholesome.

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207. STEEN STENDER & JORN DYERBERG, DANISH NUTRITION COUNCIL, *THE INFLUENCE OF TRANS FATTY ACIDS ON HEALTH*, 4th ed., at 9 (2003), available at [http://www.meraadet.dk/gfx/uploads/Rapporter\\_pdf/Trans%20fatty%20acids\\_4.t h%20ed.\\_UK\\_www.pdf](http://www.meraadet.dk/gfx/uploads/Rapporter_pdf/Trans%20fatty%20acids_4.t h%20ed._UK_www.pdf).

208. See *DIETARY REFERENCE INTAKES*, *supra* note 4, at 14.

