

**Public Interest Comment on**  
**The Food and Drug Administration's**  
**Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient**  
**Content Claims, and Health Claims; Proposed Rule**<sup>\*</sup>

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The Regulatory Studies Program (RSP) of the Mercatus Center at George Mason University is dedicated to advancing knowledge of regulations and their impacts on society. As part of its mission, RSP produces careful and independent analyses of agency rulemaking proposals from the perspective of the public interest. Thus, the program's comments on the FDA's proposed revisions to nutrition labeling requirements for trans fatty acids do not represent the views of any particular affected party or special interest group, but are designed to protect the interests of American citizens.

On November 17, 1999, the FDA proposed revisions to nutrition labeling requirements to include information about the presence of trans fatty acids. For purposes of disclosure, trans fats would be included with saturated fats on the nutrition label, along with a footnote that identifies the amount of trans fats separately. Similarly, for purposes of calculating the percentage of the daily value (DV) of saturated fats, trans fats would be counted as saturated fats. Moreover, for most (but not all) nutrient content and health claims where the amount of saturated fat affects the regulatory status of the claim, trans fats would be included with saturated fats. Thus, under the proposal, trans fats would essentially be treated as a subset of saturated fats, even though they are not in fact saturated fats.

Trans fats are not saturated fats chemically, and FDA does not conclude that they are the same as saturated fats in their biological effects. Indeed, the cost-benefit analysis suggests they are not. Nonetheless, in this proposal, different nutrients are, in effect, grouped under a common heading, most accurately described in terms other than those used on the label—bad fats.

This comment does not attempt to evaluate the scientific evidence on the relationship between trans fats and disease risk. Generally, the comment assumes FDA's conclusion that trans fats are associated with increased risk of heart disease. Nonetheless, some aspects of the relationship are crucial to devising an efficient regulatory policy. Section I of this comment considers briefly the key factual issues regarding the relationship between saturated fat, trans fats, and serum cholesterol, and points out why they are important to developing an appropriate regulatory strategy. Section II considers the proposed rule from the perspective of existing information problems, and analyzes information problems that the proposed rule is likely to create. Section III addresses several issues in the Regulatory Impact Analysis of the proposal.

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## **I. The Relationship Between Serum Cholesterol, Saturated Fat, and Trans Fat**

This comment does not analyze FDA's conclusion that trans fats have adverse effects on serum cholesterol levels, and therefore increase the risks of coronary heart disease ("CHD"). It assumes that conclusion is correct. Nevertheless, the quantitative relationship between different fats and disease risks, as well as the degree of scientific certainty about those relationships, are crucial questions in the design of an appropriate labeling policy for trans fat.

It is well established that saturated fat raises serum cholesterol, particularly LDL cholesterol ("LDL-C"), and that increased serum cholesterol is a risk factor for heart disease. If trans fats have identical effects, both qualitatively and quantitatively, there would be little reason for labeling to distinguish between saturated fats and trans fats. If, however, the effects are not identical, then substitution between saturated fats and trans fats would affect the magnitude of the risks that consumers face. Similarly, if the quantitative relationship is uncertain, new evidence may indicate that substitution between fats is relevant to the risk consumers face.

In its proposal, FDA appears to be somewhat schizophrenic about the relative importance of saturated and trans fats. Its review of the scientific evidence reveals uncertainty as to the relative effects of trans fats. In summarizing the intervention studies, FDA notes that "these studies do not conclusively show whether, on a gram-for-gram basis, the rise in LDL-C from trans fatty acids is as great as the risk that results from saturated fatty acids."<sup>1</sup> Its review of all of the evidence concludes that "the magnitude of the effect of trans fatty acids on serum LDL-C compared to the increase resulting from consumption of diets containing saturated fat is not known."<sup>2</sup>

Despite the cautious discussion of the scientific evidence, however, the cost-benefit analysis estimates that saturated fat and trans fats are virtually identical in their impact on LDL cholesterol. The Mensink and Katan regression equations used in the cost-benefit analysis imply that substituting monounsaturated fat for saturated fat reduces LDL-C by 1.52 mg/dL for each one percent of energy, compared to 1.50 mg/dL for substituting monounsaturated fat for trans fat.<sup>3</sup> Substitutions between saturated fats and trans fats would therefore have virtually no impact on risk.

The cost-benefit analysis also considers the effects of different fats on HDL cholesterol ("HDL-C"). Higher levels of HDL-C are associated with reduced risks of coronary heart disease. Again relying on the Mesnik and Katan regressions, the agency estimates that when substituted for one percent of energy from monounsaturated fat, saturated fats raise HDL-C by 0.13 mg/dL, while

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<sup>1</sup> Federal Register Notice, Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims, November 17, 1999 ("FR") at 62751.

<sup>2</sup> FR at 62754.

<sup>3</sup> FR at 62769. Mesnik and Katan combined data from several feeding studies of the effects of trans fats on serum cholesterol to estimate their regressions.

trans fat reduce HDL-C by 0.40 mg/dL. These estimates imply that saturated fat poses less risk than trans fats. Substituting saturated fat for trans fats would increase HDL-C by .53 mg/dL for each one percent of energy substituted.<sup>4</sup> Given the FDA’s estimate that each mg/dL increase in HDL-C reduces the risk of CHD by 2.5 percent, substituting saturated fat for trans fats would reduce CHD risk by approximately 1.3 percent, per one percent of energy substituted. This risk reduction is hardly trivial, since replacing one percent of energy from trans fats with monounsaturated fats reduces CHD risk by a total of 2.9 percent.<sup>5</sup>

FDA’s scientific review did not consider the effect of trans fats on HDL-C, because it concluded that effects on LDL-C would provide the strongest evidence and should be the primary criterion for evaluating trans fats.<sup>6</sup> Nonetheless, effects on HDL-C account for about half of the estimated total benefits of the rule when they are considered.<sup>7</sup> Such significant effects should influence the design of the proposed regulation.

In contrast to the documentation of differences between saturated and trans fats in the cost-benefit analysis, significant portions of the proposed regulation effectively assume that they are identical in their effects. Counting trans fats against the saturated fat DV, for example, assumes they are quantitatively the same. If substitution between saturated and trans fats is potentially important, however, they should be distinguished, not grouped. Similarly, the revised criteria for “low saturated fat” claims, for cholesterol claims, and the disqualifying and disclosure levels of saturated fat treat trans and saturated fats as identical. Again, this treatment is not appropriate if substitution between saturated and trans fats is potentially important.

In contrast, FDA’s proposed regulation of “reduced” claims would not allow claims that saturated fats are reduced unless both the total of saturated and trans fats and, independently, saturated fats, are reduced at least 25 percent. This distinction only makes sense if the fats differ in their effects. Thus, different portions of the proposed regulation proceed from different, and inconsistent, premises about the relative significance of trans and saturated fats. FDA should decide whether it believes they are the same, or different, and regulate accordingly. Moreover, the cost-benefit analysis should reflect FDA’s conclusion. It is logically indefensible to ignore effects on HDL-C in deciding how to regulate, and then use those same effects to roughly double estimated benefits.

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<sup>4</sup> This estimate considers the switch from trans fat to saturated fat as a two step process, and uses the regression estimates reported in the cost-benefit analysis at 62769. For each one percent of energy, switching from trans fats to monounsaturated fats would raise HDL-C an estimated 0.40 mg/dL. Switching from monounsaturated fat to saturated fat would raise HDL-C by 0.13 mg/dL. The effect of both switches is the sum of the two separate effects.

<sup>5</sup> Calculated from Table 2, FR at 62767. Under method 2 of the cost-benefit analysis, the reduction in CHD risk from a 2.91 percent decrease in average trans fat intake is 8.36 percent, assuming the trans fats are replaced with monounsaturated fat. The risk reduction per one percent of energy replaced is therefore  $8.36/2.91 = 2.87$  percent.

<sup>6</sup> FR at 62750.

<sup>7</sup> The precise ratio varies in different scenarios, particularly when the cost-benefit analysis considers substitutions of nutrients other than monounsaturated fats for trans fats (Table 3, FR at 62770).

## II. Information Problems

### A. FDA Should Allow Truthful Nutrient Content Claims.

FDA's proposal to revise the labeling for products containing trans fats is intended to solve an information problem in the marketplace. The source of that problem, however, is not a market failure. Rather, the lack of information is due in substantial part to a government failure – existing FDA rules prohibit the provision of some truthful information about nutrient content. In particular, 21 CFR 101.9(c) limits the content of the nutrition label to identified nutrients that either must be included or may be included voluntarily. Trans fats are not on the list. Moreover, Section 101.62(a) permits claims about fat or fatty acid content only if they use defined terms, and there are no defined terms for trans fats.

The present rulemaking demonstrates the folly of attempting to develop an exhaustive list of permissible nutrient claims. Even if the proposal were the perfect solution to providing information about trans fats, it does nothing to correct the underlying problem. Furthermore, static lists do not account for new and changing information and scientific progress. The benefits of correcting this particular instance of the general prohibition are in fact an example of the **costs** of the existing rule. Some information about trans fats would likely have emerged in the marketplace as scientific knowledge grew, but the rules prevent this normal market process. Predictably, there will be other instances when additional information will be useful to consumers as scientific knowledge about nutrition in general, and fatty acids in particular, continues to grow. For example, producers may wish to identify particular saturated fatty acids, such as stearic acid, that apparently have less adverse health effect than others.<sup>8</sup>

Whatever else it does, FDA should revise its rules to remove prohibitions on the provision of truthful nutrient information. Ideally, additional information should be permitted within the confines of the nutrition label itself, since that is the obvious place for consumers to look for nutrient information. Standardization of the labels could be preserved by allowing any additional truthful nutrient content information to be included in an optional “additional information” section of the label. Although the statute restricts claims that “characterize” the level of nutrients to terms that FDA has defined, it does not require FDA to bar truthful claims about the actual content of nutrients. There is no reason to do so.

### B. In Essence, the Proposal Seeks to Mislead Consumers for Their Own Good.

FDA rightly expresses concern that consumers do not understand the nature or significance of trans fatty acids. Rather than facilitating provision of this information, however, the proposal seeks to take a “free ride” on what consumers already believe—that saturated fat is bad. Trans fats would be included in the quantitative disclosure of saturated fat, and counted against the daily recommended value for saturated fat. For descriptive claims that are currently limited to products meeting certain saturated fat levels, trans fat would count against those levels. Trans fats, however, are not saturated fats chemically, and, at least in the proposal, FDA is not yet

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<sup>8</sup>See Beatrice Trum Hunter, “Food Labeling for Fats is Misleading,” *Consumers' Research Magazine*, 81(4), April, 1998, p. 24.

willing to conclude that they are the same as saturated fats in their biological effects. Indeed, the cost-benefit analysis suggests they are not. Thus, different nutrients are, in effect, grouped under a common heading, most accurately described in terms other than those used on the label—bad fats.

To be sure, a fine print footnote would enable consumers to discover the trans fat content, and, by subtraction, the actual saturated fat content of a product. If the product makes claims about cholesterol or fatty acid content, trans fat content itself can already be determined by subtraction. As FDA notes, however, “this calculation ... is too cumbersome for most consumers to be expected to accomplish.”<sup>9</sup> Under the proposed rule, the calculation is no simpler. To determine *actual* saturated fat, consumers must subtract trans fat content (identified in the footnote) from the number *labeled* saturated fat. If consumers are interested in the percentage of the DV *for saturated fat* the product actually provides, however, the calculations are considerably more complex. They must subtract the trans fat, determine the allowable amount of saturated fat, and divide.

Perhaps the clearest example of misleading consumers for their own good is FDA’s treatment of daily values. Absent an independent recommendation for daily intake of trans fats, FDA has three choices. First, it could establish its own “DV” for trans fats. A possible basis for such a value could be the United Kingdom’s 1994 Department of Health recommendation “that, on average, trans fatty acids should provide no more than the current average of about 2% of dietary energy ...”<sup>10</sup> FDA does not explicitly consider developing an independent DV, though it does indicate willingness to revise its position if the organizations that are the source of the current DVs indicate that it should.

Second, FDA could increase the DV for total fat to accommodate the trans fats that were not recognized as an independently significant group when the DVs were developed. Given the estimate that trans fats average 2.9 percent of energy,<sup>11</sup> this would amount to increasing the DV for fat by approximately 10 percent. FDA indicates that it “does not believe” it should change the DV for fat, but it offers no basis for that belief. Instead, it proposes to adopt a far larger change in the DV for saturated fat.

Third, FDA could adopt the approach it proposes, counting trans fats against the current DV for saturated fat (10 percent of calories), on the grounds that the physiological effects of these fats are similar. Given current average consumption of trans fats, this amounts to a reduction in the current DV for saturated fats of approximately 30 percent. If the original DV was based on sound scientific evidence about the effects of *saturated* fats, the emergence of new evidence about the effect of *trans* fats provides no basis for change.<sup>12</sup> Trans fats were presumably ignored

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<sup>9</sup> FR at 62754.

<sup>10</sup> Quoted in FR at 62753.

<sup>11</sup>As FDA notes, estimates of average trans fat consumption in the US vary. The 2.9 percent value is the one used in the FDA’s cost-benefit analysis.

<sup>12</sup>If the DV for saturated fat is not based on scientific evidence about the actual effects of saturated fat, there is no basis for enshrining it in the nutrition labeling regulations.

in developing the DV, because they are not saturated and the evidence of their adverse effects is recent.<sup>13</sup> The fact that they may have similar adverse effects does not provide any basis for concluding that saturated fats are now sufficiently worse than previously believed to justify a 30 percent reduction in recommended intakes. The reason for proposing this approach has more to do with marketing than science—consumers know saturated fats are bad, and reductions would be good for them.

FDA should recognize that it is in effect constructing a “bad fat” index, without establishing the scientific foundation for such an index. If the effects of different fatty acids were known with sufficient certainty, an index based on the adverse and beneficial effects of fat components would undoubtedly be simpler for consumers than requiring them to sort through the details of fat composition. An index, however, presumes that different fatty acid profiles resulting in the same index value are of no consequence, a presumption that the cost-benefit analysis belies. Unless that presumption is correct, the index encourages the cheapest and easiest changes to improve the value of the index, rather than the changes that would most benefit consumers.<sup>14</sup>

Even if it could be justified on present knowledge, the free rider solution to the consumer information problem is short sighted. The current state of scientific knowledge about trans fats is almost certain to change. To appreciate the significance of the evolving evidence, consumers will need to understand the differences between trans and saturated fats, and the possible differences in their effects. Regulation should seek to facilitate and encourage the emergence of accurate information about the relevant details, rather than suppressing scientifically relevant differences on the grounds that consumers do not “need to know.”

### **C. FDA Should Facilitate Provision of Information Regarding the Significance of Trans Fats.**

In competitive markets, sellers with an advantage on trans fat content would have an incentive to convey that information to consumers. As proposed, the rule does little to exploit that incentive. The only specific claim that FDA proposes for claims about trans fat is “trans fat free.” As proposed, however, “trans fat free” is synonymous with “saturated fat free” because only products with less than 0.5 grams saturated fat would be allowed to make a trans fat free claim. Such products also meet the definition of “saturated fat free.” Faced with the choice of claiming a benefit that consumers know little about or using the much more familiar “saturated fat free” claim, most producers are likely to choose the familiar. To facilitate market provision of information about trans fats, FDA should make four changes.

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<sup>13</sup>FDA hints that trans fat consumption may have increased, but offers no evidence. Other sources indicate (also, apparently, without specific data) that trans fat consumption has been roughly constant since the 1960s. See Ascherio et al., “Trans Fatty Acids and Coronary Heart Disease,” *The New England Journal of Medicine*, Vol. 340(25), pp. 1994-1998 (June 24, 1999). Even if consumption has increased, there is no apparent scientific reason for reducing the recommended intake of fats that are truly saturated.

<sup>14</sup>See Beales, Craswell, and Salop, “The Efficient Regulation of Consumer Information,” *Journal of Law and Economics*, vol. 24, No. 3 (December, 1981), pp. 481-539.

**First, FDA should approve a health claim about the relationship between trans fats and CHD.** If consumers are to make informed choices about products with differing levels of trans fats, they need information about why trans fats are significant. Undoubtedly, some of that information can and will come from government-sponsored consumer education campaigns. As the experience with claims about fiber has demonstrated, however, market provision of information by sellers with an interest in conveying that information is likely to be far more effective in getting the message out.<sup>15</sup>

The claim should also permit sellers to inform consumers about the relative importance of saturated fats and trans fats, to the extent that reasonable conclusions are possible based on the present scientific evidence. The statute would clearly allow such a claim.<sup>16</sup> If there is sufficient scientific agreement to warrant required disclosure of the presence of trans fats, surely there is sufficient scientific agreement to inform consumers about why they should care. Moreover, given the limited information available to consumers at present, such a claim would “assist consumers in maintaining healthy dietary patterns.”<sup>17</sup> At best, the rule as proposed could provide information about the amount of trans fats, but information about why that matters would have to come from somewhere else. Permitting a health claim would close the loop.

**Second, FDA should expand the available claims regarding trans fat content, and expand the sellers who are permitted to make them.** As proposed, saturated fat free and trans fat free are synonymous. Even with a health claim, there is no reason for sellers to bear the costs of educating consumers about trans fat when they can claim the same advantage using terms that are already familiar to consumers. Like the FDA’s proposal, sellers would have every incentive to free ride on the information consumers already have about saturated fat.

To create incentives for claims about trans fats, FDA should revise the definition of trans fat free to permit such claims for products that have less than 2 grams saturated fat, rather than limiting claims to products that are “saturated fat free.” Products with less than 2 grams saturated fat are permitted to claim they are “cholesterol free,” even though both cholesterol and saturated fat are relevant to serum cholesterol levels.<sup>18</sup> Allowing trans fat free claims for such products would potentially provide an incentive for sellers of products that contain saturated fat, but not trans fat, to inform consumers about trans fats.<sup>19</sup> Because the level of saturated fat is low enough to pose

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<sup>15</sup>See Pauline M. Ippolito and Alan D. Mathios, “Information, Advertising and Health Choices: A Study of the Cereal Market,” *Rand Journal of Economics*, vol 21 (Autumn, 1990) pp. 459-80. Similarly, seller provided information about fats and fatty acids led to significant declines in saturated fat consumption. See Pauline M. Ippolito and Alan D. Mathios, “Information and Advertising: The Case of Fat Consumption in the United States,” *American Economic Review* vol. 85 (May 1995), pp. 91-95.

<sup>16</sup>See J. Howard Beales and Timothy J. Muris, *State and Federal Regulation of National Advertising*, at 59-60 (Washington: AEI Press) (1993).

<sup>17</sup> Food Drug and Cosmetics Act, Section 403(r)(3)(a)(ii).

<sup>18</sup>E.g., 21 CFR 101.62(d)(1)(i)(A).

<sup>19</sup>Assessing the potential magnitude of the incentive is difficult because of the lack of data about the distribution of trans fats in the food supply. It is not clear how many additional products would be able to make trans fat free claims under the criteria suggested.

minimal concern, the claim would not be misleading, any more than would a “cholesterol free” claim for the product.

In addition, FDA should define a “reduced trans fat” claim. For products where elimination of trans fats is not technically feasible, such a claim would provide incentives for product improvements that would reduce health risk. It would also increase the information available to consumers about trans fats and their significance.

A claim for “reduced” trans fats should not be conditioned on a reduction in saturated fat as well. The data used in the cost-benefit analysis indicated that even a gram for gram substitution of saturated fat for trans fat would offer meaningful health benefits. If so, there is nothing misleading about a truthful claim that trans fats have been reduced even if the reduction is achieved entirely by increasing saturated fat. The case for a “reduced” claim is even more compelling when trans fats are reduced without changing saturated fat content. Encouraging such product changes would clearly advance the objective FDA seeks. Just as claims for reduced total fat or reduced cholesterol are permitted even if saturated fat is not reduced, claims that trans fats are reduced should be permitted when that is the case.<sup>20</sup> Adding comparative data on saturated fat content to the disclosures that must accompany any “reduced” claim would remove any possibility of a misleading impression.

**Third, FDA should facilitate the flow of information about trans fats by revising the disqualifying criteria for health claims about fatty acid content.** In particular, the agency should remove or substantially relax the disqualifying criterion for total fat content.<sup>21</sup>

The products that will have the greatest incentives to provide information about trans fats are those where competing products in the category have significant amounts of trans fats, where the category contributes a significant amount of trans fat to the diet, and where reformulation to reduce or eliminate trans fats is relatively easy. Based on the data in the cost-benefit analysis, the only product that clearly fits these criteria is margarine. Margarines account for an estimated 13 percent of average trans fat consumption.<sup>22</sup> Reformulations that eliminate trans fats already

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<sup>20</sup>Reduced cholesterol claims are limited to products with less than 2 grams of saturated fat per serving. If FDA believes restrictions on “reduced trans fat” claims are necessary, permitting such claims when either saturated fat is reduced, **or** when saturated fat is less than 2 grams per serving would be preferable to requiring 25 percent reductions in both saturated and trans fats. In either case, consumers would clearly receive the health benefit they seek.

<sup>21</sup>For most products, health claims are prohibited if the product contains more than 13 grams of fat, 4 grams of saturated fat, 60 milligrams of cholesterol, or 280 mg of sodium, per label serving size. For foods with serving sizes less than 30 grams, claims are also prohibited if the product contains more than the specified amounts of risk increasing nutrients per 50 grams of the product. See 21 CFR 101.14(a)(5). All margarines fail the total fat test per 50 grams of the product, because they are basically all fat. Some, and perhaps most, may also fail the saturated fat test per 50 grams. If all margarines fail the saturated fat test per 50 grams of the product, FDA should relax this criterion as well.

<sup>22</sup>Calculated from the data in Table 1, FR at 62765, using the average percent of energy from trans fats.



account for 30 percent of the market;<sup>23</sup> these products would have strong incentives to educate consumers about trans fats if they are given the opportunity.

The key disqualifying criteria for margarine is total fat per 50 grams.<sup>24</sup> Based on the cost-benefit analysis, there is no reason for any restriction on total fat content. Indeed, reformulations that replace trans fats with carbohydrates (rather than monounsaturated or polyunsaturated fats) actually *reduce* the estimated benefits of the rule under either method of estimation, and particularly reduce benefits when the effects on HDL-C are considered.<sup>25</sup> There is no reason to require product changes that *increase risk* as a condition for making a health claim.

Even if FDA is unwilling to revise the disqualifying levels of fat across the board, it should permit margarines to make health claims about trans fats. Under the statute, the agency can permit health claims if they would “assist consumers in maintaining healthy dietary practices.” Given the need to educate consumers about trans fats, health claims from the products that have the greatest incentive to provide the information would clearly meet this standard. Moreover, under all of the realistic scenarios evaluated in the cost-benefit analysis, margarine reformulation accounts for at least two thirds of the total estimated benefits of the rule.<sup>26</sup> Health claims for margarines that allow producers to explain to consumers why trans fats matter would significantly increase the likelihood of achieving this benefit.

As consumers learn about the benefits of reducing trans fats from margarine producers, incentives to reduce trans fats in other product categories will increase. Identifying a product feature that consumers know is a benefit is an easier selling proposition than the need to explain why the feature is important. Harnessing the incentives of margarine manufacturers to provide the initial education will likely encourage more far reaching changes in other product categories than FDA’s approach of manipulating the criteria for qualifying for various saturated fat claims.

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<sup>23</sup>FR at 62781.

<sup>24</sup>The basis for the “per 50 gram” test was FDA’s belief that consumers should avoid multiple servings of nutrient dense foods that are high in “bad” nutrients. The disqualifying levels themselves, however, already took into account the number of servings in the typical daily diet likely to contain each nutrient. Thus, the “per 50 gram” test was unnecessary and overly restrictive to begin with. The issue is discussed in more detail in Beales and Muris, *supra* note 15, at 64-70.

<sup>25</sup>See Table 3, FR at 62770. Under Scenario 2, for example, with some reformulation and some behavioral change, replacing trans fats with monounsaturated fats reduces CHD risk 0.86 percent, considering only the effects on LDL-C. If half of the replacement is high carbohydrate, the reduction in CHD risk falls to 0.79 percent. Considering the effect on HDL-C as well, the risk reduction is 1.67 percent with all monounsaturated fats, and 1.26 percent with half carbohydrates.

<sup>26</sup>Margarine reformulation alone would reduce average trans fat consumption by 0.39 percent of energy. Under Scenario 2, the total reduction in trans fat consumption is an estimated 0.58 percent of energy. Thus, margarine reformulation accounts for 67 percent of the estimated benefits under this scenario. Under Scenario 4, margarine reformulation accounts for 92 percent of estimated benefits. See Table 2, FR at 62767. Scenario 1, which assumes total elimination of all trans fats, is not realistic. Even under this scenario, however, margarine reformulation accounts for 13 percent of estimated benefits.

Absent health claims, the benefits of margarine reformulation may not be achieved at all. In the market for cooking oils, the effect of the disqualifying criteria for total fat was to prohibit claims by cooking oils about the health significance of differences in fat composition. In a study of cooking oil sales after the regulations took effect, Mathios found statistically significant reductions in the market share of oils with more monounsaturated fat, and statistically significant increases in the market share of oils with more saturated fat.<sup>27</sup> Thus, there was an increase in the market share weighted average saturated fat content of cooking oils, and a decrease in monounsaturated fat. Both changes tend to increase health risk. If margarine producers remain unable to make a health claim to explain the significance of trans fats to consumers, the reformulation that is essential to achieve significant benefits may not occur.

**Finally, FDA should facilitate market provision of information by providing information about trans fats in a format that clearly differentiates between trans and saturated fats.**

The most straightforward way to accomplish this, without requiring all producers to relabel all products, is to add trans fat information to the table of fat composition that currently identifies monounsaturated and polyunsaturated fat content. Although nominally voluntary, this information is required whenever producers make claims about fatty acid composition.<sup>28</sup> It is likely already present for many of the margarines that would have the most to gain from claims about trans fats, and adding a line for trans fats would be no more costly than FDA's proposal. It would, however, be far clearer to consumers trying to determine the significance of this new information than a fine print footnote to the nutrition label.<sup>29</sup>

Initially, disclosure of trans fats under this approach would be more limited than under FDA's proposal. Most of the estimated benefits, however, come from the products most likely to choose to disclose trans fats under this format. Moreover, as information about trans fats increases in the marketplace, other producers will face increased incentives to disclose, because consumers will likely assume that products that remain silent about trans fats do not have anything good to say. This full disclosure principle, also called the unfolding principle, has risen to the level of textbook economics,<sup>30</sup> and is consistent with the empirical evidence.<sup>31</sup>

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<sup>27</sup>Alan D. Mathios, "The Importance of Nutrition Labeling and Health Claim Regulation on Product Choice: An Analysis of the Cooking Oils Market," *Agricultural and Resource Economics Review*, 27(2), October 1998, pp. 159-68. The study did not examine changes in total consumption of cooking oil.

<sup>28</sup>21 CFR 101.9(c)(2)(ii) and (iii).

<sup>29</sup>Alternatively, FDA could require an additional line on the label identifying trans fats separately, whenever trans fats are present. Like the agency's proposal, this approach would avoid relabeling products that do not contain trans fats, but it would make clear that saturated fats and trans fats are different. Even without a daily value, consumers would learn which values are high or low for a particular product category by comparing labels, and because producers of products that are low in trans fats would highlight that fact.

<sup>30</sup>See, e.g., Robert H. Frank, *Microeconomics and Behavior*, (New York: McGraw Hill) (3<sup>rd</sup> Ed., 1997), at 183-187.

<sup>31</sup>See Pauline M. Ippolito and Alan D. Mathios, "The Regulation of Science-based Claims in Advertising," *Journal of Consumer Policy*, Vol. 13 (1990) at 413.

FDA is quite correct that, at present, there is little incentive for voluntary disclosure by products that have relatively high levels of trans fats. That is because consumers have very little information about the nature or significance of trans fats. With a regulatory environment designed to facilitate the flow of this information to consumers, there are incentives already in place to provide information about trans fats relatively quickly. Incentives are strongest in precisely the places accounting for most of the estimated benefits of the rule. Incentives for product improvement in other categories under the FDA proposal arise primarily from the additional restrictions on saturated fat claims, and those restrictions would remain even without the footnote. FDA should unleash these incentives by facilitating information flows, rather than by attempting to make the square peg of trans fats fit into the round hole of existing rules on saturated fat.

### **III. Cost-Benefit Analysis**

FDA's cost-benefit analysis of the proposed rule is a commendable effort in a difficult area. It does an excellent job of bringing relevant empirical evidence to bear on the issue. As noted above, it identifies a number of issues that need to be resolved before the rule is finalized, and makes it possible to bring out issues that might otherwise escape the critical analysis they deserve. There are, however, areas where the benefit-cost analysis overstates benefits and understates costs. These issues are discussed below.

First, as proposed, the rule is likely to generate less market response than the benefit estimates assume. Although the range of possible product reformulations considered in the various scenarios appears reasonable, the magnitude of consumer response to the labels themselves is probably overstated significantly. The basis for the estimate of the extent to which consumers might change their behavior is a study of shelf tags in a supermarket. Such tags appear on the supermarket shelf, and are more likely to attract consumers' attention than are product labels. Thus, the use of shelf tags is probably higher than the 45 percent of consumers who use product labels. As a result, the observed change in fat consumption in the shelf tag study would imply a smaller behavioral change for each consumer who used the information.<sup>32</sup> The estimates of trans fat reduction due to consumer substitutions are therefore overstated. Overstatement is particularly likely given FDA's proposed format. Trans fat information is confined to a footnote, which is less likely to be noticed and used than other information on the label.

Second, FDA indicates uncertainty about whether the effects of trans fats on LDL-C are really the same as the effects of saturated fat, and suggests that trans fats may not have as much adverse effect as saturated fats. This uncertainty is not reflected in the benefit estimates, which all assume either identical effects or that saturated fat is significantly better than trans fats. If there is uncertainty, FDA should estimate benefits under the assumption that trans fats have smaller effects on serum cholesterol than do saturated fats.

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<sup>32</sup>In the shelf study, there was a one percent overall decrease in total fat and saturated fat consumption. It then estimates the change per label reader to achieve an overall one percent decrease as  $(.01)/(.45) = 2.2$  percent. The proper denominator, however, is shelf tag users, not label users. If the denominator is larger, the change in behavior for the average consumer will be smaller.

Third, the benefit analysis suggests that actual benefits may be higher than FDA's estimates suggest, because epidemiological studies find a relative risk that is significantly higher than the calculated change in CHD risk used in the analysis. This claim appears to rest on a misinterpretation of the relative risk results. In particular, relative risk will depend on the base risk used for comparisons. If the base risk is lower, the relative risk will be higher for a given incremental risk. The study by Hu *et al.* that the analysis cites, for example, is based on women 34 to 59 with no known disease in 1980. Base risk for this group is likely to be lower than the base risk for the population as a whole. FDA's estimates apply to the base risk of the entire population, but the relative risk estimates from Hu *et al.* do not. Similarly, relative risks based on comparing the top quintile of trans fat consumption to the bottom quintile may tell us that there is an effect of trans fat consumption, but it cannot be applied to average trans fat consumption. In addition, probability estimates in the logistic models that underlie the relative risk estimate are nonlinear. The effect of a change in the independent variables therefore depends on the level of risk.<sup>33</sup> Again, the relative risk cannot be applied directly to the average risk for the population as a whole.

In addition to overstating benefits, the benefit-cost analysis understates costs. In particular, the estimated labeling costs assume that products with no trans fats will not disclose, and therefore will not relabel. As knowledge of trans fats disseminates, however, rational consumers will assume that nondisclosure of trans fats means there is nothing good to say.<sup>34</sup> Rather than have consumers assume their products are high in trans fats, producers of products with no trans fats will have incentives to modify their labels to disclose the absence of trans fats. In product categories where trans fats are important, virtually all products are likely to change their labels to disclose the absence of trans fats. Thus, over time, more products will incur labeling costs than the analysis assumes, at least in those product categories where trans fats are important.

Second, but far more important, the analysis neglects certain health costs arising from restrictions on claims that are currently permitted. The proposed rule will prohibit some current claims regarding nutrient content or health benefits. As a result, consumers will lose the benefits of these claims. For example, under the rule, fewer products will be allowed to make saturated fat free or reduced saturated fat claims, because of the addition of the criteria for trans fat content. In the extreme, if the effect of the rule were to prohibit all claims of low or reduced saturated fat, saturated fat consumption would likely increase, and with it, the risks of CHD. More generally, locating low saturated fat products will become more difficult, depending on how many products find their claims restricted. This effect could be quite significant. Although FDA apparently has no hard data, the cost analysis of changes in principal display panels assumes that *half* of existing saturated fat and cholesterol claims would be lost.<sup>35</sup> If this

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<sup>33</sup>In particular, the derivative of the probability of the outcome variable with respect to independent variable  $i$  is equal to  $\beta_i \pi(1-\pi)$ , where  $\beta_i$  is the logistic coefficient and  $\pi$  is the probability. The estimated impact of changing an independent variable will therefore change depending on the probability. See Takeshi Amemiya, "Qualitative Response Models: A Survey," *Journal of Economic Literature*, Vol. 19 (December, 1981), p. 1482.

<sup>34</sup>See Frank, *supra* note 30, and Ippolito and Mathios, *supra* note 31.

<sup>35</sup>FR at 62780.

assumption is correct, locating low saturate fat and low cholesterol products will be significantly more difficult. The resulting increases in saturated fat and cholesterol consumption would increase the health risks that the rule seeks to reduce.

When FDA adopted standardized definitions of terms such as “free” and “reduced” in 1993, it contended that the definitions offered significant benefits, because they would better enable consumers to locate products that would reduce health risks.<sup>36</sup> Indeed, FDA stated its belief that “the bulk of such benefits may come with changes to the PDP [principal display panel] where nutrient content claims and some health claims will be displayed.”<sup>37</sup> Given that sensible and probably accurate assessment, the costs from losses of claims on the principal display panel may overwhelm the benefits attributed to the specific information on the revised label. The reduced ability to locate products that are useful to reduce the risk of CHD will tend to increase health risks, a cost that is more significant than the cost of reprinting the principal display panel.

Although such costs may be difficult to quantify, they should not be ignored. At the very least, FDA should conduct a sensitivity analysis to determine the break even point at which increases in saturated fat and cholesterol consumption due the loss of descriptive claims overwhelm the estimated benefits of the rule. Without such an analysis, FDA is only guessing that its proposed rule will in fact reduce health risks.

#### **IV. Conclusions**

FDA’s proposal elevates a convenient marketing fiction over a clear scientific fact: trans fats are not saturated fats. They are not saturated fats chemically, and FDA does not conclude that they are the same as saturated fats in their biological effects. Indeed, the cost-benefit analysis suggests they are not. Nonetheless, in this proposal, different nutrients are, in effect, grouped under a common heading, most accurately described in terms other than those used on the label—bad fats. Rather than seeking to take a free ride on what consumers already know, FDA should remove the problem that gave rise to the need for the proposal: the fact that existing rules prohibit the provision of truthful information

To facilitate the provision of truthful information to consumers, FDA should make four changes. First, it should approve a health claim about the relationship between trans fats and coronary heart disease. Second, FDA should expand the available claims regarding trans fat content, and expand the sellers who are permitted to make them. Third, FDA should facilitate the flow of information about trans fats by revising the disqualifying criteria for health claims about fatty acid content. Finally, FDA should facilitate market provision of information by providing information about trans fats in a format that clearly differentiates between trans and saturated fats.

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<sup>36</sup>See generally FDA’s analysis of comments on the preliminary regulatory impact analysis at 58 Fed. Reg. 2927 (Jan. 6, 1993).

<sup>37</sup> Id. at 2937.

FDA's benefit-cost analysis is a commendable effort in a difficult area. Nevertheless, it overstates benefits by relying on a study of shelf labels, rather than nutrition labels, and fails to reflect the uncertainty about the quantitative effects of saturated fats and trans fats on serum cholesterol levels. It also understates costs, most importantly by neglecting the health risks that would arise if consumers find it more difficult to locate products that are low in saturated fat and cholesterol.

## Appendix I

### RSP Checklist

#### FDA's Trans Fat Labeling Proposal

Element	Agency Approach	RSP Comments
1. Has the agency identified a significant market failure?	FDA's proposal is intended to solve an information problem in the market place.  <b>Fair</b>	The source of the information problem is not a market failure, but a government failure. Existing FDA rules prohibit the provision of some truthful information about nutrient content, including information about trans fats.
2. Has the agency identified an appropriate federal role?	The proposal establishes federal criteria for nutrient claims.  <b>Fair</b>	Since federal regulations are the source of the information problem, federal action is necessary to address it. However, the regulation should place more emphasis on facilitating the flow of information in the marketplace, and should remove the barriers to truthful information that created the need for this proposal.
3. Has the agency examined alternative approaches?	The agency considers several variants on the theme of its proposal, but does not discuss the advantages and disadvantages of significantly different approaches.  <b>Unsatisfactory</b>	To facilitate the flow of information, FDA should approve a health claim about the relationship between trans fats and coronary heart disease. It should also define additional descriptive terms for trans fat content, such as "reduced trans fat," and expand the products that would be permitted to make such claims. It should revise the disqualifying criteria to permit health claims by the products with the most incentive to make them. It should disclose trans fats in a way that clearly distinguishes them from saturated fats.

Element	Agency Approach	RSP Comments
4. Does the agency attempt to maximize net benefits?	<p>Within its approach, the agency considers changes that would increase net benefits.</p> <p><b>Fair</b></p>	<p>FDA’s analysis does not consider alternative approaches that would likely produce larger net benefits. The cost-benefit analysis discusses alternative approaches, but detailed estimates of benefits and costs are only developed for the agency’s proposal.</p>
5. Does the proposal have a strong scientific or technical basis?	<p>FDA’s review of currently available scientific evidence reveals a strong basis for addressing trans fats.</p> <p><b>Fair</b></p>	<p>Although there is a strong scientific base for concern about trans fats, portions of the regulatory approach pay more attention to marketing issues than scientific ones. The agency is in effect creating an index of “bad fats” without establishing the scientific basis for doing so. The cost benefit analysis takes positions on scientific issues that are not entirely consistent with the positions taken in the agency’s discussion of the regulation. Scientific issues that are addressed in the cost-benefit analysis should have influenced the design of the regulation, but were not discussed.</p>
6. Are distributional effects clearly understood?	<p>FDA does not address distributional effects.</p> <p><b>Unsatisfactory</b></p>	<p>Providing incorrect information can make some consumers worse off.</p>
7. Are individual choices and property impacts understood?	<p>By grouping trans fats with saturated fats, FDA seeks to take advantage of consumers’ knowledge about the adverse effects of saturated fat.</p> <p><b>Unsatisfactory</b></p>	<p>The agency’s approach seeks to manipulate choices, rather than encourage provision of the information consumers need to make informed choices. It gives inadequate attention to the incentives of sellers to provide information.</p>