The validity of the epidemiological data is open to question on several grounds, but it is sufficient here to consider two of them: confounding by indication and selection bias. The confounding is ubiquitous. It arises because, at least since the early 1960s, people perceived to be at increased risk of coronary heart disease (e.g., because of chest pain, obesity, electrocardiogram abnormality, family history) have tended to use margarine in preference to butter; early perception of an increased risk could have “caused” margarine use, rather than the reverse. When the indication for the exposure and the outcome are confounded, the data can seldom, if ever, be adequately unconfounded by any means other than randomization. Selection bias arises because some of the studies have relied wholly or partly on endpoints of angiographically diagnosed coronary disease or lipoprotein levels; people selectively consuming margarine could also selectively have been subjected to angiography or have had their lipoprotein levels measured. For these reasons, three cross-sectional studies cited in the commentary and one uncited case-control study must be rejected as uninformative.

Willett and Ascherio rely principally on two of their own studies of myocardial infarction (an endpoint that is relatively free of selection bias), one of them a large follow-up study and the other a case-control study. Both identified increased risks of about 1.5- to 2-fold for the highest quintile of trans fatty acid intake relative to the lowest. Such low-order increases in risk, however, could readily have been due to residual uncontrolled confounding by indication, and indeed there was evidence to suggest its presence. For example, in the follow-up data, the risks were opposite when the intake of trans fatty acids was from vegetable fats (increased) or animal fats (decreased), a phenomenon most readily explicable by those perceived to be at increased risk consuming margarine in preference to butter. Similarly, in the case-control study, among a total of 521 subjects (239 case patients, 282 control patients), 100 (19%) were on special diets. Patients predisposed to myocardial infarction because of obesity, or because of other reasons for dieting (e.g., diabetes mellitus), would almost certainly have preferred margarine to butter.

In short, while the metabolic data raise the suspicion that trans fatty acids may increase the risk of coronary disease, the epidemiological evidence is question-able. Moreover, it is unlikely that a definitive answer can be obtained by any means other than a randomized controlled trial. Contrary to the opinion expressed in the commentary, I believe that such a trial would be both ethical and feasible, with the proviso that the metabolic data, when fully evaluated, are deemed to be sufficiently suggestive to justify the considerable effort involved.

Finally, the estimate that at least 30,000 coronary deaths per year may be due to trans fatty acids is based not only on insecure data but on so many additional assumptions that it amounts to nothing more than speculation.

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Note. The author reviewed the evidence concerning trans fatty acids and coronary heart disease while acting as a consultant to Froster & Gamble.

References

3. What Should We Tell Consumers?

The trans fatty acid controversy has been a major issue in nutrition for the last several years. While there is no consensus on the health effects of trans fatty acids, the evidence, as summarized in Willett and Ascherio's commentary, appropriately raises concerns. Unfortunately, the print and electronic media messages that translated this commentary into news for the public basically promulgated the message that "we should stop using the margarine and go back to butter." Although we believe that this was not the message Willett and Ascherio wished to convey, the result has been widespread consumer confusion.

The lack of scientific consensus on the health effects of trans fatty acids has made public health policymakers reluctant to dictate specific public health recommendations about trans fatty acids. Willett and Ascherio suggest national policy recommendations that would require food manufacturers to reduce the use of partially hydrogenated vegetable fats and/or require trans fatty acid labeling on foods. Although these recommendations are future possibilities, substantially more research data as well as regulatory and/or consumer pressure will be required before such policies will become viable.

In the meantime, what do we tell the general public? The available research on trans fatty acids certainly does not suggest that switching from margarines (which may or may not contain trans fatty acids) to butter would be beneficial to blood cholesterol levels or cardiovascular health. (We have used the term "margarine" in this letter to include margarines meeting the Food and Drug Administration standard of identity as well as "light" and fat-free margarines and spreads because consumers consider all of these products to be margarines.) Rather than scaring consumers away from margarine, public health recommendations should encourage people to lower their trans fatty acid intake in the context of lowering their overall fat intake, the cornerstone of national dietary guidelines to reduce the risk of heart disease and cancer. The No. 1 educational priority should be to provide consumers with information on how to reduce quantity of fat by choosing lower fat and fat-free foods in supermarket and restaurants, cooking with less fat of all kinds, and using fat-free spreads and condiments. Decreasing total fat intake
will automatically decrease trans fatty acid intake. When fats are used, quality of fat is also an issue. Recommendations should encourage consumers to use 100% vegetable oils in cooking and on bread (when appropriate) instead of butter, margarine, and solid shortening. When oil is not acceptable, we can recommend "light" liquid and tub margarines (with 0 to 7 g of fat per tablespoon) that list a "liquid oil" (instead of a "partially hydrogenated oil") as the first oil ingredient and have a polyunsaturated to saturated fat ratio of at least 2:1. The trans fatty acid issue need not cause consumers to throw all previous dietary recommendations "out the window." Let's not go back to butter! Kim M. Gans, PhD, MPH, LD 
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References

4. Willett and Ascherio Respond

We agree that concern about trans fats should not be reason to consume butter. However, because trans fats have clear adverse effects on cholesterol subfractions, probably raise lipoprotein (a), and may unfavorably influence thrombotic mechanisms, it is possible that margarines with high amounts of trans fats are worse than butter. However, in our commentary we intended to encourage the availability of healthier margarines. In England, for example, a widely available margarine now contains only 1% trans fat and 17% saturated fat. The present US food label law, which includes only the saturated fat, does not encourage such products.

Reducing total fat intake is not likely to be an effective way to reduce trans fat intake or heart disease itself; the type of fat, rather than the total amount, is of greatest importance. In the last decade, fat intake has decreased only from 38% to 34% of energy despite intensive messages; such a decrease, in itself, would only slightly reduce trans fat consumption. Much greater reductions can be achieved by changes in manufacturing processes and food choices that substitute natural vegetable oils for trans and saturated fats.

Dr Leviton misread our commentary; we did not use the relative risk from the Nurses' Health Study for our estimate of 30,000 deaths per year due to trans fat. Had we done so, the estimated number of deaths would have been far higher. Our conservative calculation was based on the metabolic study of Mensink and Katan that examined the effects of trans fats on serum cholesterol fractions. Since our commentary, Judd et al. have also examined the effects of trans fats on blood lipids. Figure 1 summarizes the effects of saturated and unsaturated fats on the ratio of total/high-density lipoprotein cholesterol levels in these two experiments and the other such study. These studies clearly indicate a linear relationship between trans fat intake and change in the lipid ratio; very similar estimates of the slope would be obtained from any single study or the overall slope. Moreover, trans fats had significantly worse effects on the total cholesterol/high-density lipoprotein ratio than did saturated fat in each study, and the overall slope was approximately twice that for saturated fat.

Shapiro appeals to the authority of another letter writer to assert that the data on trans fats and blood lipids are inconclusive; however, that letter was written before publication of the confirmatory results just noted. At present, the evidence that trans fats adversely affect blood lipid levels can be considered virtually conclusive, and, even without

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