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**NUTRITION AND FATTY ACID RESEARCH**

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**REF: Trans (TFAs) and Essential Fatty Acids (EFAs)**

I respectfully submit that the current food labels should either be eliminated or changed to include information on TFAs and EFAs,  $\omega 3$  and  $\omega 6$ , and their derivatives.

I respectfully request that you consider my opinions and research, which I have reported several times to the FDA. Based on the huge number of calls I receive, my name and research are often discussed at scientific conferences, in published reports and in the news media. It is thus unfortunate that the FDA has not attempted to make use of my research nor inquired about my forthcoming data.

As I understand it, I am one of the few scientists (probably the only one) who has studied the relationship between lipids, cis and TFAs. I use my patented methods, which produce unique results. Because no other scientist has asked for a license, I must assume that nobody else is using my patented methods. My research indicates that methods other than my own produce misleading and often useless results, as I have often expressed in letters written to scientific journals.

I have data on patients with low and high levels of TFAs in their blood. I have conducted experiments to determine how long it would take to lower elevated levels of TFAs. I also have data on the relationship between TFAs, EFAs, SFAs, MUFAs and PUFAs on Total/HDL cholesterol, based on 500+ participants in the Framingham Heart Study. The relationships I developed are based on my patented methods and are stronger than any data I have seen published or presented at scientific meetings. I believe that EFA insufficiency, which results when consumers eat a diet lacking in EFAs, is associated with significant disease states and may underlie many of the chronic diseases prevalent in western societies. I have shown that in patients with angiographically documented CAD, the indicators of EFAI are highly predictive of CAD. Moreover, EFAI may be the pathophysiological mechanism leading to elevations in LDL and reductions in HDL cholesterol.

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I have written many times to the FDA to explain why food labels ought to include amounts of **EFA**s (both  $\omega 3$  and  $\omega 6$ ) and **TFA**s. I have also explained why the current labels are not just incomplete, they are actually damaging. They are misleading and encourage consumers to eat the wrong foods. Magazine articles and government reports encourage people to look at the labels and select the food lowest in saturated fat and total fat. These same articles and government reports fail to inform the public that they must eat **EFA**s. As a result, people will be eating fewer **EFA**s and the incidence of cardiovascular disease and mental abnormalities will increase. This problem is particularly important in minorities and children who do not know about the need for **EFA**s and are lead to believe that low-fat foods like candy are ‘healthy foods.’ I am afraid that government policies may be creating a generation of children with mental and behavioral abnormalities due to EFA deficiency. These abnormalities may **affect** particularly selected minority groups.

I personally believe that the food labels are useless and that they should be eliminated or else drastically changed. Many people will argue that the new labels incorporate other useful information. I disagree. I have access to some of the most powerful and portable computers, electronic scales, and nutrition data bases. I find it impossible to keep track of how many vitamins and minerals I eat every day. Even if I could use the food labels, food processing and storage will likely alter some of the food compositions of the food. Moreover, I cannot possibly keep track of the amounts of each food I eat almost *every single day of my life*. Occasionally looking at the food labels is useless. I would like to work with the FDA to make the labels useful or else save money to taxpayers by closing that part of the FDA.

Could you please provide me with a list of the organizations and individuals responsible for food labels and the amount of money spent by the FDA on these issues (including enforcement)? How many lives have been saved each year? Can the FDA point to a reduction in Medicare or Medicaid expenses, or a reduction in morbidity or mortality? I believe that the food labels increase health-care expenditures and increase morbidity and mortality because they omit the most important information, levels of **EFA**s and **TFA**s. They mislead people into thinking that **EFA**s and **TFA**s are not important and all that matters is total fat or **SFA**s.

Incidentally, I have read the regulations pertaining to health claims in foods. Although I have an MD, PhD and JD degrees, and experience in reading regulations, I found these regulations confusing and misleading. They ought to be changed.

### **Could you help me with the following issues?**

In a document called Questions and Answers, in response to question N23, the FDA states that information about  $\omega 3$  and related fatty acids can be provided outside the “nutrition” label. Does this mean that the information would lie outside the nutrition label but still on the food label?

What kind of **health claims** can be made for an essential nutrient if it can be used to correct or prevent a deficiency?

Can a food manufacturer state:

"This food contains \_\_\_ of  $\omega 3$  a n d - of  $\omega 6$ , which can be used to correct or prevent EFA deficiency"?

What is the difference between a "**medical food**," a "**supplement**," a "**food**" and a "**food supplement**"?

Do you have definitions in the regulations? Can you provide them?

To be labeled as "**healthy**," a food must meet the definition of 'low fat' according to a document labeled "A Food Labeling Guide," which I received from the FDA (p. 58). In practice, oils such as soybean oil, which are rich in **EFA**s, would not be considered "healthy" while sugar candy with some minerals and vitamins but no fat would be considered 'healthy' (even if high in **TFAs**!). I respectfully submit that the FDA is misleading consumers and should drastically revise its regulations pertaining to food labels, healthy foods, etc.

P. 43 of the guide is not clear, particularly the nutrient content claim and its relationship to CFR 101.13.

Can you tell me what you mean?

What is a "**referral statement**"?

What is a "**disclosure statement**"?

I have, of late, been lecturing to many people and more of my research will be published in the future. Until now, the FDA has ignored the letters I wrote as well as the results of my published research. I consider such inaction to be self-defeating. Ignoring my research findings and continuing with a policy which I consider misdirected will contribute to the backlash against the FDA which is currently underway. It is my position that either the FDA has a useful role to play, or it should be drastically changed. This year or next year, Congress may decide to take action on these topics. I suggest that the FDA should listen to my research or risk becoming an anachronism.

If you are interested in finding out how fatty acids affect lipids and health or disease, and the implications for food labels, please let me know. Otherwise I will continue to inform the public through scientific journals, the news media and Congress.

Sincerely yours,



Edward Siguel, MD, PhD