

March 7, 2014

Margaret Hamburg, MD
Commissioner
U.S. Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2013-N-1317

Dear Commissioner Hamburg:

On behalf of our physician and medical student members, the American Medical Association (AMA) is grateful for the opportunity to offer comments to the Food and Drug Administration (FDA) in support of its conclusion that partially hydrogenated oils, the major dietary source of artificial trans fats in processed foods, are no longer “generally recognized as safe” (GRAS). We support this finding as a step in the right direction but strongly urge the FDA to take the next step and impose strict limits on the amount of trans fats in processed foods.

Consumption of trans fats has been conclusively linked to accelerated atherosclerosis and an increased risk of coronary heart disease (CHD). Trans fats are formed during the partial hydrogenation of vegetable oils and are present in large amounts in deep-fried fast foods, bakery products, packaged snacks, margarines, and crackers. According to a scientific review published by Mozaffarian et al. in the *New England Journal of Medicine* (N Engl J Med 2006;354:1601-1613), “The consumption of trans fats raises levels of LDL cholesterol, reduces levels of HDL cholesterol, and increases the ratio of total cholesterol to HDL cholesterol, a powerful predictor of the risk of CHD. Trans fats also increase the blood levels of triglycerides as compared with the intake of other fats, increase levels of Lp(a) lipoprotein, and reduce the particle size of LDL cholesterol, each of which may further raise the risk of CHD.”

In addition to the harmful effects of trans fats on serum lipids, trans fats also increase CHD risk by increasing systemic inflammation and endothelial dysfunction (J Intern Med 2012; 272:13-24). Research also suggests that “Replacing saturated and trans unsaturated fats with unhydrogenated monounsaturated and polyunsaturated fats is more effective in preventing coronary heart disease in women than reducing overall fat intake” (N Engl J Med 1997;337: 1491-1499). The vast body of research on the harmful effects of trans fats led the Institute of Medicine to declare that “There is a positive linear trend between trans fatty acid intake and total and LDL cholesterol concentration, and therefore increased risk of CHD, thus suggesting a Tolerable Upper Intake Level (UL) of zero...it is recommended that trans fatty acid consumption be as low as possible while consuming a nutritionally adequate diet” (Food and Nutrition Board of the Institute of Medicine, *Letter Report on the Dietary Reference Intakes for Trans Fatty Acids* (July 10, 2002)). Based on compelling evidence from epidemiologic, clinical trial, animal, and in vitro

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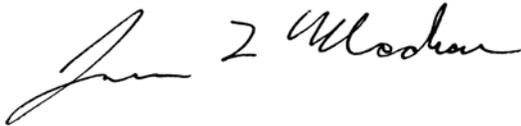
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studies, the Centers for Disease Control and Prevention estimates that a further reduction of trans fats in the food supply could prevent an additional 7,000 deaths from heart disease annually and up to 20,000 heart attacks each year.

AMA policy strongly supports past actions that the FDA took that required nutrition labels to include information about trans fats starting in 2006. In addition, the AMA has called for years for the reduction of trans fats in the American diet in order to maintain good health and lower the incidence of CHD, and supports banning the use of artificial trans fats in restaurants and bakeries in the United States.

Giving the food industry several more years to reduce trans fats would result in thousands of potentially avoidable heart attacks and premature deaths. Declaring partially hydrogenated oils, the major dietary source of artificial trans fats, no longer GRAS is a step in the right direction. However, the AMA strongly recommends that the FDA proceed rapidly from declaring partially hydrogenated oils as no longer GRAS to imposing strict limits on the amount of trans fats in processed foods. The FDA has the scientific evidence and the authority it needs to set an aggressive but realistic timetable for the food industry to substantially reduce trans fats in processed foods. The FDA's proposal, based on reasoned and sound science, should be finalized without further delay.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is written in a cursive style with a large initial "J" and "M".

James L. Madara, MD