

December 4, 2013

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Re: Food and Drug Administration  
Docket No. FDA-2013-N-1317

The Center for Effective Government (CEG) is pleased to submit the following comments regarding the Food and Drug Administration (FDA) proposed determination (78FR67169) that partially hydrogenated oils (PHOs), the primary dietary source of industrially-produced *trans* fatty acids, are not generally recognized as safe for any use in foods due the scientific evidence regarding the health risks associated with the consumption of *trans* fatty acids. CEG strongly supports this FDA proposal and believes that final adoption of this determination will result in significant public health benefits. However, we believe there are substantial deficiencies with respect to the economic analysis supporting the proposed determination included in the November 5, 2013 memorandum from Richard Bruns to Mical Honigfort (Docket No. FDA-2013-N-1317, Ref. 46, Estimate of Cost and Benefits PHOs Memorandum From RBruns to MHonigfort November 5 2013; hereafter Bruns 2013 memorandum). Our concerns relate to both the methodology and transparency of the information provided with respect to the economic benefits of the proposed determination.

With regard to the analytical methodology, the Bruns 2013 memorandum indicates that the monetary value of the premature deaths and illnesses was developed in this analysis “using the same method as in the Regulatory Impact Analysis of the 2003 final *trans* fat labeling rule [citation omitted]” (Bruns 2013 memorandum, pg. 6). However, a review of the Regulatory Impact Analysis (RIA) for the 2003 labeling rule (FDA 2003) indicates that several alternative methods and monetized values used for assessing the economic value of the avoided mortalities associated with that rule have not been included in the current economic assessment. The 2003 rule RIA provided analysis of economic benefits utilizing both the value of statistical life (VSL) as well as the value of statistical life years (VSLY) approaches, consistent with the recommendation in OMB Circular A-4 (OMB 2003, pg. 30). However, the current benefits analysis utilizes only the VSLY methodology and no explanation is provided as to the basis for only selecting the VSLY analytical approach.



The 2003 rule utilized VSL amounts of \$5 million and \$6.5 million for the value of statistical life, both of which are substantially greater than the \$1.76 million value for a prevented fatal heart attack provided in the Bruns 2013 memorandum based on the VSLY method. Utilizing the Bruns 2013 memorandum estimate of 5,000 avoided fatal heart attacks and adjusting the 2003 rule VSL values to 2013 dollars (\$6,346,000 and \$8,250,000 respectively), the benefits associated with this rule range from \$31.7 to 41.3 billion in contrast to the \$8.8 to 12 billion range provided in the Bruns 2013 memorandum.

The Bruns 2013 memorandum provides an estimate of the life years lost from fatal heart attacks based on a 7 percent discount rate applied to the 13 life years lost to arrive at the 8 life years lost used for the benefits calculation. We note that the 2003 labeling rule RIA also included analysis based on a 3 percent discount rate applied to the 13 life years lost resulting in 11 life years lost. Applying the additional 3 life years lost provided by the 3 percent discount rate to the current VSLY method results in increasing the value of a prevented fatal heart attack from \$1.76 million to \$2.42 million. However this alternative approach has been omitted from the current analysis and no explanation is provided as to the omission of the 3 percent discount rate or why a 7 percent discount rate should be preferable.

The Bruns 2013 memorandum also provides a figure of \$220,000 for the value of a statistical life year, however no explanation is provided as to the basis for selecting this figure. We note that the 2003 rule RIA provided three alternative figures for the value of a statistical life year - \$100,000, \$300,000, and \$500,000 (FDA 2003 at 41498). However, despite the fact that the 2013 analysis asserts it is utilizing methods for the development of monetized values for death and illness consistent with those of the 2003 rule RIA, no explanation is provided as to why the 2003 rule approach for calculating the VSLY utilizing the three alternative values was not adopted. OMB Circular A-4 recommends the use of larger VSLY figures for senior citizens noting that “senior citizens face larger overall health risks from all causes and they may accumulated savings to spend on their health and safety” (OMB 2003, pg. 30). Since it is likely that the vast majority of the avoided lost life years from fatal heart attacks would occur in seniors<sup>i</sup>, we would like to see an explanation of whether this recommendation has been applied to the 2013 analysis.

In conclusion, we request that FDA revised its economic analysis supporting the proposed determination that partially hydrogenated oils are not generally recognized as safe for any use in foods in the following manner:

- 1) Provide an analysis utilizing a value of statistical life methodology using present value dollars; CEG believes that public health protections should not be based on the age of the population protected. Therefore a VSL method rather than a VSLY method should be applied for evaluating the economic benefits of the proposed determination;
- 2) If a VSLY method is retained, provide a revised analysis:
  - a. utilizing a value of statistical life year methodology that applies as 3 percent discount rate to life years lost;
  - b. utilizing alternative VSLY monetized values consistent with those used in the 2003 *trans* fat labeling rule (adjusted to present value) and that reflects an approach consistent with the recommendations in OMB Circular A-4 with respect to the selection of higher values for health outcomes affecting senior citizens;
- 3) If the \$220,000 value of a statistical life year is retained, provide an explanation as to the basis for this value and how it is consistent with the recommendations in OMB Circular A-4.

Sincerely,

Ronald H. White, M.S.T.  
Director of Regulatory Policy

#### References

Food and Drug Administration; Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information; Federal Register, Vol. 78, No. 217, November 8, 2013.

Food and Drug Administration; Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims; Federal Register, Vol. 68, No. 133, July 11, 2003.

Office of Management and Budget; Circular A-4; September 17, 2003.

FDA Memorandum From RBruns to MHonigfort; Estimate of Costs and Potential Health Effects of Removing Partially Hydrogenated Oils from the US Food Supply; November 5, 2013.

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<sup>i</sup> The 2009 hospital case-fatality rates for acute myocardial infarction for those age  $\geq 65$  is four times that for those  $< 65$  years old (7.6 v. 1.9) (National Institutes of Health; Morbidity and Mortality: 2012 Chart book on cardiovascular, lung and blood diseases; February 2012)