May 21, 2015

Food and Drug Administration (FDA)
Office of the Ombudsman
10903 New Hampshire Avenue
WO Building 32, room 4260
Silver Spring, MD 20993
Sent via E-mail: Ombuds@OC.FDA.gov

RE: Request for Correction of Information Disseminated to the Public that Improperly Attributed a Study to the Centers for Disease Control and Prevention (CDC)

Dear Sir or Madam:

I am hereby submitting[1] this request for correction of information pursuant to the Information Quality Act,[2] as implemented through the Office of Management and Budget (OMB),[3]United States Department of Health and Human Services,[4] and the Food and Drug Administration.[5]

Information that is disseminated must meet the requirement of "objectivity."[6] According to the HHS Guidelines, "'objectivity' involves a focus on ensuring that information is accurate, reliable and unbiased and that information products are presented in an accurate, clear, complete and unbiased manner." The information identified fails to meet this requirement.

Locations of Inaccurate Information

In numerous locations, and in its "Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information,"[7] the FDA improperly attributes a study and conclusions from that study to the CDC.

[1] The views I have expressed in this request are my own, and should not be construed as representing any official position of The Heritage Foundation.
[2] Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, P.L. 106-554.
[3] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8452 (Feb. 22, 2002). ("OMB Guidelines") at http://www.whitehouse.gov/sites/default/files/omb/assets/omb/fedreg/reproducible2.pdf (accessed May 20, 2015).
[4] HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public at http://aspe.hhs.gov/infoquality/Guidelines/index.shtml (accessed May 20, 2015).
[5] Guidelines for Ensuring the Quality of Information Disseminated to the Public, Food and Drug Administration, at http://aspe.hhs.gov/infoquality/Guidelines/fda.shtml (accessed May 20, 2015).
[6] See the statutory language and the various Guidelines.
[7] Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information, 78 Fed. Reg. 67169 (November 8, 2013) at https://www.federalregister.gov/articles/2013/11/08/2013-26854/tentative-determination-regarding-partially-hydrogenated-oils-request-for-comments-and-for (accessed May 20, 2015).

1) "Questions and Answers Regarding *Trans* Fat"
http://www.fda.gov/food/populartopics/ucm373922.htm
http://www.fda.gov/downloads/Food/PopularTopics/UCM385846.pdf

Statement: "[T]he Centers for Disease Control and Prevention estimates that eliminating intake of *trans* fat from partially hydrogenated oils could prevent up to 20,000 cases of coronary heart disease (CHD) and up to 7,000 deaths annually."

2) "FDA Targets Trans Fat in Processed Food
http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm372915.htm

Statement: "The Centers for Disease Control and Prevention estimates that a further reduction of *trans* fat in the food supply can prevent an additional 7,000 deaths from heart disease each year and up to 20,000 heart attacks each year."

3) News for Educators (January 2014)
http://content.govdelivery.com/accounts/USFDA/bulletins/9e4a34

Statement: "CDC estimates that removal of PHOs from the food supply could prevent an additional 7,000 deaths and up to 20,000 heart attacks *each year*."

4) Narrative by Activity (pages 30-31—this document is used to justify appropriations[8])
http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/reports/budgetreports/ucm394622.pdf

Statement: "The Centers for Disease Control and Prevention estimates that eliminating artificial trans-fat in processed foods could prevent up to 7,000 deaths from heart disease each year and up to 20,000 heart attacks each year."

5) Tentative Determination
https://www.federalregister.gov/articles/2013/11/08/2013-26854/tentative-determination-regarding-partially-hydrogenated-oils-request-for-comments-and-for

Statement: "In addition, according to the Centers for Disease Control and Prevention (CDC), elimination of PHOs from the food supply could prevent 10,000 to 20,000 coronary events and 3,000 to 7,000 coronary deaths annually, if the marginal benefits of continuing to remove trans fats from food items remain constant."

[8] FY 2015 FDA Justification of Estimates for Appropriations Committees at http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/BudgetReports/ucm395076.htm (accessed May 20, 2015).

Why the Information is Inaccurate and Fails to Meet Objectivity Requirements

The study is not a CDC study, and the CDC did not make any of the estimates that the FDA has widely promoted. Two authors who worked at the CDC published a study[9] in the Journal of the American Medical Association (JAMA) in which they made the estimates. At the end of the published study, it expressly states: "The findings and conclusions in this report are those of the authors and do not necessarily reflect the official position of the US Centers for Disease Control and Prevention."[10] In the Tentative Determination, the FDA explains that the data comes from the CDC, and then cites the JAMA study to support this claim—the same study that is expressly not a CDC report. The FDA clearly should have known that the study was not a CDC study, especially when it cited a JAMA study for the alleged CDC claim.

The CDC does list the estimates on their web site, but they specifically cite the source and do not claim that they came up with these estimates.[11] There did appear to be one instance though where the CDC did not cite the study while using the data. In a document called "Winnable Battles Progress Report: 2010-2015,"[12] the CDC explained, "CDC has concluded that 10,000–20,000 heart attacks and 3,000–7,000 coronary heart disease deaths each year in the U.S. could be prevented by removing artificial trans fat from processed foods."

After an IQA Request for Correction I made to the CDC, and follow-up Request for Reconsideration, the CDC now states in the "Winnable Battles" report, "CDC **researchers** have concluded that 10,000–20,000 heart attacks and 3,000–7,000 coronary heart disease deaths each year in the U.S. could be prevented by removing artificial trans fat from processed foods. ***See* Dietz, WH, Scanlon, KS. Eliminating the Use of Partially Hydrogenated Oil in Food Production and Preparation. *JAMA*; 308(2): 143-144.**"[13] [Emphasis added].

The CDC's correction confirms that the study is not properly classified as a CDC study. In its response to my Request for Reconsideration that I received May 14, 2015, the CDC explains "To clarify that the numbers presented in the Winnable Battles report came from this paper [Dietz et al. paper], the report now indicates that the numbers are obtained from the paper by Dietz et al."[14] They conclude, "In response to your previous request, the *Winnable Battles Progress Report: 2010-2015* now provides the appropriate reference to the paper."

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[9] Dietz WH, Scanlon, KS. 2012. Eliminating the Use of Partially Hydrogenated Oil in Food Production and Preparation. JAMA. 2012;308(2):143-144.
[10] Ibid.
[11] "Trans Fat," CDC web site, at http://www.cdc.gov/nutrition/everyone/basics/fat/transfat.html (accessed May 20, 2015); "trans Fat: The Basics, Centers for Disease Control and Prevention, at http://www.cdc.gov/nutrition/downloads/trans_fat_final.pdf (accessed May 20, 2015).
[12] The text of the report has changed, as discussed, but the original language was found at http://www.cdc.gov/winnablebattles/targets/pdf/winnablebattlesprogressreport.pdf
[13] http://www.cdc.gov/winnablebattles/targets/pdf/winnablebattlesprogressreport.pdf (accessed May 20, 2015).
[14] My requests and CDC's responses can be accessed on the HHS IQA requests web site, http://aspe.hhs.gov/infoquality/requests.shtml (accessed May 20, 2015).

The Impact of Improperly Attributing the Data and Study to the CDC (Including the Impact on the Requester)

The FDA is incorrectly claiming the data is from a CDC study thereby improperly giving the data much greater legitimacy due to the imprimatur of the government. This characterization of the data as coming from the CDC impacts public perception. If it was clarified that the study was not a CDC study, it is far less likely that the FDA would be using it as a major justification for its Tentative Determination that, by the agency's own estimates, will result in billions of dollars in costs and benefits, which will impact me along with all Americans.

An ingredient in food that is available to me and to the public would effectively be banned if the FDA decides to revoke GRAS status for PHOs. Some companies may not be able to transition away from PHOs, or if they do, it will come at great cost and altered product quality. This great cost to companies would also be incurred by employees (through lost jobs) and consumers (through higher prices).

Recommended Corrections

At a minimum, the FDA should edit or remove the documents and web pages identified in this Request.[15] The corrected information should also be communicated to the public and policymakers in a prompt manner before any action is taken on its Tentative Determination. Since 2013, the FDA has been miscommunicating this critical information and the only way to even remotely rectify the problem is to prominently acknowledge the error in a manner that will likely reach interested parties.

In addition, the Tentative Determination itself included an inaccurate claim that the FDA was relying on a CDC study; the public's lone chance to provide comments were based on this critical misunderstanding. This mistake is not simply a clerical problem; the FDA improperly attributed the imprimatur of the government to a study playing a central role in the Tentative Determination. Interested parties may not have even bothered to challenge the study in comments or were heavily influenced by the inaccurate claims (e.g. being swayed because the CDC allegedly asserted health benefits) thereby influencing comments.

Absent providing a new comment period for a Tentative Determination based on accurate information regarding this study, the public will be severely harmed.[16] Therefore, the FDA should allow the public to provide comments based on this accurate information.

I appreciate your consideration of this request.

[15] The FDA should make whatever edits are legally authorized to be made to the Tentative Determination as published in the Federal Register, noting any changes to readers.
[16] The proper action, regardless of the IQA, is to have this new comment period.

Sincerely,

Daren Bakst
Research Fellow in Agricultural Policy
Thomas A. Roe Institute for Economic Policy Studies
The Heritage Foundation
Phone: (202) 608-6163
Email: daren.bakst@heritage.org