October 9, 2014

Centers for Disease Control and Prevention (CDC)
CDC/ATSDR
Attn: MASO, MS-E11
1600 Clifton Road, N.E.
Atlanta, GA 30333

Sent via E-mail: InfoQuality@cdc.gov

RE: Information Quality Request for Correction of Inaccurate Information Disseminated to the Public

Dear Sir or Madam:

The Grocery Manufacturers Association (GMA) hereby requests that the CDC promptly remove the report titled "Winnable Battles Progress Report: 2010-2015" (CDC Report) from the agency's website, or revise that report to make clear that certain conclusions regarding morbidity and mortality reportedly associated with artificial *trans* fat are not the conclusions of the CDC.

Further, GMA asks that CDC promptly communicate that removal or correction to the U.S. Food and Drug Administration (FDA) to help ensure the integrity of any further action taken by that agency with respect to the regulatory status of partially hydrogenated oils (PHOs).

We make this request for removal or correction of information pursuant to requirements stipulated in the Information Quality Act (IQA)[1] and guidelines implemented by the Office of Management and Budget (OMB),[2] the United States Department of Health and Human Services (HHS),[3] and the Centers for Disease Control and Prevention (CDC).[4]

[1] Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554, § 515(a), 114 Stat. 2763, 2763A-153–54.
[2] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8452 (Feb. 22, 2002).
[3] *HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public*, U.S. DEP'T HEALTH & HUM. SERVICES, http://aspe.hhs.gov/infoquality/Guidelines/index.shtml (last visited Sept. 17, 2014) [hereinafter HHS Guidelines].

The IQA and OMB guidelines require that information disseminated by CDC must meet the standard of "objectivity" articulated in the above-mentioned guidelines.[5] According to the CDC IQA Guidelines, "objectivity" means that "CDC provides assurance that information is accurate, reliable, and unbiased. Objectivity is achieved through existing review and clearance procedures and, in many cases, the peer review of disseminated information."[6] That definition tracks the HHS IQA Guidelines, which state that "'[o]bjectivity includes whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner. This involves whether the information is presented within a proper context."[7] The HHS Guidelines further state that "the agency needs to identify the sources of the disseminated information."[8] The HHS definition of "objectivity" is consistent with that included in the OMB IQA Guidelines.[9]

The information posted on the CDC website[10] that concerns GMA fails to meet this standard. The CDC Report is "covered information" as that term is defined in the CDC IQA Guidelines because it is an official report that does not include a disclaimer to distinguish it from CDC views and positions.[11]

The CDC Report Inaccurately Attributes Conclusions in a Scientific Article to CDC

In the CDC report "Winnable Battles Progress Report: 2010-2015", CDC states: "*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."[12] This statement by CDC inaccurately represents that the cited conclusions are those of the CDC when in fact, they are not. Rather, they are the conclusions documented a scientific publication entitled "Eliminating the Use of Partially Hydrogenated Oil in Food Production and Preparation"[13] (JAMA Article), authored by CDC employees Dietz and Scanlon that was published in the Journal of the American Medical Association (JAMA) with the following explicit disclaimer: "The findings and conclusions in this report are those of the authors and do

---

[4] *Guidelines for Ensuring the Quality of Information Disseminated to the Public: D. Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry*, U.S. DEP'T HEALTH & HUM. SERVICES, http://aspe.hhs.gov/infoquality/Guidelines/cdcinfo2.shtml (last visited Sept. 17, 2014) [hereinafter CDC Guidelines].
[5] *See* § 515(a), 114 Stat. at 2763A-153–54; 67 Fed. Reg. at 8458; HHS Guidelines, *supra* note 3, § D.4.d; CDC Guidelines, *supra* note 4, § V.A.
[6] Supra, n. 4, at § V.A.
[7] HHS Guidelines, *supra* note 3, § D.2.c.
[8] Id.
[9] 67 Fed. Reg. at 8459.
[10] CENTERS FOR DISEASE CONTROL & PREVENTION, WINNABLE BATTLES PROGRESS REPORT: 2010-2015 (n.d.), *available at* http://www.cdc.gov/winnablebattles/targets/pdf/winnablebattlesprogressreport.pdf.
[11] CDC Guidelines, § II.
[12] *Id* (emphasis added).
[13] Dietz WH, Scanlon, KS. 2012. Eliminating the Use of Partially Hydrogenated Oil in Food Production and Preparation. JAMA. 2012;308(2):143-144.

not necessarily reflect the official position of the US Centers for Disease Control and Prevention."[14]

The inaccurate attribution of these results to the CDC is of critical importance for two reasons. First, the use of this disclaimer signals that the JAMA Article is not an official CDC publication, and if true, the use of the disclaimer would exempt the JAMA Article from the CDC IQA Guidelines. Second, CDC's innacurate representation has put FDA in a position where it too has repeatedly misrepresented the source of the data in its tentative determination on the safety of partially hydrogenated oils.

If the CDC Wishes to Represent the Conclusions of the JAMA Article As Its Own, Then That Article Must First be Classified and Reviewed as a Highly Influential Scientific Assessment

Pursuant to OMB's "Final Information Quality Bulletin for Peer Review" (OMB Bulletin), information that is considered to be a highly influential scientific assessment must be classified as such and undergo a rigorous and systematic peer review.[15] According to the OMB Bulletin:

> A scientific assessment is considered "highly influential" if the agency or the OIRA Administrator determines that the dissemination could have a potential impact of more than $500 million in any one year on either the public or private sector or that the dissemination is novel, controversial, or precedent-setting, or has significant interagency interest. One of the ways information can exert economic impact is through the costs or benefits of a regulation based on the disseminated information.[16]

The JAMA Article qualifies as "highly influential" because it is:

- Novel (there is no comparable government report);
- Controversial (the article states significant conclusions about the health impact of food ingredients that have been used for many years); and
- Precedent-Setting (the article is being used to inform policy decisions and potential regulatory actions as seen with FDA's "Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information,"[17] and could influence actions taken by other nations). The JAMA Article is central to the FDA's potential revocation of Generally Recognized as Safe (GRAS) status for partially hydrogenated oils (PHOs). According to the FDA, the costs and the benefits of such an action would greatly exceed $500 million in any one-year threshold: "We estimate the

[14] *Id.*, emphasis added.
[15] OFF. MGMT. & BUDGET, FINAL INFORMATION QUALITY BULLETIN FOR PEER REVIEW (2004), *available at* http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf.
[16] *Id.* at 23.
[17] Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information, 78 Fed. Reg. 67,169 (November 8, 2013).

> 20-year net present value of costs to be between $12 and $14 billion, where the upper and lower estimates are calculated at 3 and 7 percent discount rates. Using the same method, we estimate benefits between $117 and $242 billion."[18]

There is no publicly available information to suggest that CDC classified the JAMA Article as a "highly influential scientific assessment," or subjected that article to a peer review process that conforms to the OMB Bulletin.[19]

Therefore, until CDC takes the steps needed to conform to the OMB Bulletin, CDC cannot properly represent the conclusions of the JAMA Article as its own, or represent that article as an official CDC publication.

The Impact of Inaccurately Attributing the Conclusions in the JAMA Article to the CDC (Including the Impact on the Requester)

In reliance on CDC's inaccurate representation of the conclusions of the JAMA Article as its own, the FDA is also widely disseminating the conclusions of the JAMA Article and inaccurately representing those conclusions as CDC's own. Those inaccurate representations lend added weight to the conclusions of the JAMA Article, and thereby distort the benefit of any proposal to reduce levels of trans fat in the food supply.

If CDC and FDA wish to represent the conclusions in the JAMA Article as those of the CDC, or to represent the JAMA Article as an official CDC publication, then it is critical that the article first be classified and reviewed as a highly influential scientific assessment, consistent with the OMB Bulletin. Until those steps are completed, neither CDC nor FDA can properly make those representations, nor take any other action premised on the view that the conclusions in the JAMA Article are those of the CDC or that the article is an official CDC publication.

In conclusion, given the significance of the JAMA Article's conclusions and their potential influence on policy decisions and regulatory actions that could have highly significant economic and other consequences, it is imperative that those conclusions be accurately represented.

For the same reasons, if the CDC wishes to represent the conclusions in the JAMA Article as its own or represent that article as an official CDC publication, then the IQA and OMB guidance requires that the article be classified and reviewed as highly influential scientific information in accord with the OMB Bulletin *before those representations are made*.

[18] *Id.* at 67,173-74.
[19] CDC maintains documents it has classified as "highly influential scientific assessments" on its website. *See CDC/ATSDR Peer Review Agenda*, CENTERS FOR DISEASE CONTROL AND PREVENTION, http://www.cdc.gov/od/science/quality/support/peer-review.htm (last updated Aug. 21, 2014).

Accordingly, GMA requests that the CDC promptly remove the CDC Report from its website, or correct that report as requested above. Further, GMA requests that the CDC promptly communicate the removal or correction of the information to FDA.

Sincerely,

/S/

Emilia C. Lonardo, PhD
Vice President
Consumer Product Safety and Science Policy
Grocery Manufacturers Association
1350 I Street NW, Suite 300
Washington, DC 20005
elonardo@gmaonline.org

cc: Michael Taylor, Deputy Commissioner, FDA
Michael Landa, Director, CFSAN – FDA
Dennis Keefe, PhD, Director, OFAS – FDA