**Report from Mark Helfand**
**Background**

A. On September 23, 2015, the *BMJ* published a "BMJ Investigation" by Nina Tiecholz (1) that criticized the report of the U.S. Dietary Guidelines Advisory Committee, or DGAC.(2) On December 17, 2015, the *BMJ* published a letter calling for the retraction of the Teicholz article. The letter was submitted by the Center for Science in the Public Interest (CSPI).(3)

I was asked by the *BMJ* editors to comment on the article and on the issue of retraction. Specifically, I was asked

- In your view is the main thrust of the article by Teicholz sound?
- Does what Teicholz says constitute fair comment on the workings of the Committee?
- Alternatively, do you feel that there is a need for clarification or correction of specific points in the article?
- Or is there sufficient wrong with the article that it is essentially unsound (in which case we should retract it)?

B. I am an expert in systematic reviews and guideline development as well as with scientific communication. I have conducted systematic reviews of preventive services, including reviews of vitamin supplementation to prevent cancer and of screening for cardiovascular disease. However, I have not conducted reviews or other research on dietary patterns, salt, or saturated fat. I have no prior or existing relationship, financial or other, with the *BMJ*; with the Arnold Foundation, which funded Ms. Teicholz' work; with the Center for Science in the Public Interest; or with the US Department of Agriculture, the primary sponsor of the DGAC. In 2011, I served on an Institute of Medicine committee with one of the DGAC members, but I have not worked with and do not know the others. I am the principal investigator on a contract from the Agency for Healthcare Research & Quality in the US Department of Health & Human Services, which is also a sponsor of the US Dietary Guidelines.

C. Teicholz' article argues that the DGAC came to the wrong conclusions about certain topics, including saturated fats, low-carbohydrate diets, vegetarian diets, because it did not interpret the existing science correctly. Specifically, Teicholz believes that the DGAC

- Did not comprehensively review the best science, that is, they ignored or dismissed relevant studies of saturated fats and low-carbohydrate diets.
- Did not follow the "standard systematic review process at the USDA" by relying on systematic reviews from other bodies for saturated fats.
- Was reluctant "to consider any evidence that contradicts the last 35 years of nutritional advice"
- Recommended a vegetarian diet as one of several healthy options even though they had judged the evidence supporting it to be inconclusive.

D. It is entirely legitimate to raise and debate the overarching, central claim that the DGAC did not review the science impartially and consequently drew the wrong conclusions from it. In raising the question of bias, it is also reasonable to contrast the panel's endorsement of a vegetarian diet despite weak evidence with its strong stand against saturated fats despite conflicting evidence. Previous versions of the Dietary Guidelines have been criticized for relying too heavily on observational studies and on expert consensus.(4) The DGAC's conclusions are largely unchanged from the previous Dietary Guidelines, raising the question of whether their modified process has the same problems.(5)

**Findings**

E. In the specifics of these arguments, however, the Teicholz article has major deficiencies. In particular, Teicholz' argument that the panel did not follow its own processes seems contrived and superficial. Transcripts from its public meetings indicate clearly that they defined, *in advance,* the types of evidence, including external systematic reviews, that would be used.(6,7) In general, the use of external systematic reviews is consonant with current standards for conducting systematic reviews and guidelines, which emphasize the need to avoid duplication of effort when possible.(8-10)

F. Teicholz' article in *The BMJ* was based on a report commissioned by the Laura and John Arnold Foundation. She received this funding in the spring of 2015.[1] On May 8, 2015, an early version of the report was submitted as a public comment on the DGAC's report.(11) On September 20, 2015, the author self-published a revised version of the report entitled "A Critical Review of the Science for Key Recommendations in the 2015 Report by the USDA Dietary Guidelines Advisory Committee."(12) The author has written that the editors of the *BMJ* solicited the article.(1) According to its web site, the Arnold Foundation provided $4,000 to the *BMJ* Publishing Group "To produce a report that analyzes the scientific research used to inform the recommendations produced by the Dietary Guidelines Advisory Committee."(13)

G. The BMJ described the article it published as a "BMJ Investigation." (1) The article begins

> "The expert report underpinning the next set of US Dietary Guidelines for Americans fails to reflect much relevant scientific literature in its reviews of crucial topics and therefore risks giving a misleading picture, an investigation by *the BMJ* has found."

The byline, which states "reported by Nina Teicholz," also represents that the article is a work of investigative journalism.

H. However, compared with other *BMJ* investigations and most investigative journalism, this article is poorly researched and poorly documented. The author did not say whether she interviewed DGAC members, Federal government staff members, or others who could describe the actual decision-making and conduct of the panel. She did not cite anyone who had firsthand knowledge of the actual decision-making and conduct of the DGAC, such as DGAC members or Federal government staff members, or uncover any information about their processes other than what was described in their report. Online resources that provide information about the DGAC's systematic review and guideline development process, such as video of public meetings of the DGAC (6,7), are not mentioned. No experts in systematic review methods or guideline development methods, who might have commented on whether they agreed with her criticisms, are cited. The author has written that she showed the *BMJ* manuscript to experts and to two DGAC members, but the article provides no information about what they may have said, either on or off the record.

I. The basic argument of the CSPI letter (3) requesting a retraction was that the article is "riddled with errors." The CSPI letter listed 11 points. My findings regarding each point are summarized in the Table and discussed in detail below.

| Points | Topic | My Finding |
|---|---|---|

[1] I could not find a record of this grant on the Arnold Foundation web site when searching on March 11, 2016. The author disclosed the funding source in *The BMJ.* I have not been able to find the amount of the grant.

| | | |
|---|---|---|
| 1, 2, 7,8 | Selection of systematic reviews was ad hoc. | Error. |
| 3 | The AHA/ACC guideline may be biased. | Matter of opinion. |
| 4 | The studies of saturated fats included in the Nutrition Evidence Library (NEL) review do not support its conclusion. | Matter of opinion. |
| 5 | Relevant studies were "never systematically reviewed" | Error. |
| 6 | Two important studies funded by the US National Institutes of Health "showing that a diet low in fat and saturated fat is ineffective for fighting heart disease, obesity, diabetes, or cancer" were omitted from the NEL review. | Error: the two studies evaluated the effect on serum lipids, not disease. |
| 9 | The NEL has not isolated red meat in their reviews. | Error. |
| 10 | The foundation of {the Nutrition Guidelines} has been to recommend eating less fat and fewer animal products (meat, dairy, eggs) | Not in error. |
| 11 | "… early critical reviews, including one by the National Academy of Sciences… were dismissed by the USDA." | Not in error. |

J. Of the 11 points, four (#1,#2,#7,#8) refute Teicholz' assertion that the DGAC selected systematic reviews in an *ad hoc* manner. On the contrary, chapter 2 of Appendix E-2 of the DGAC report (2) includes 23 "Evidence Portfolios" which describe in detail the searches and inclusion criteria for systematic reviews and provide a list excluded reviews along with the reasons for exclusion. Appendices E-2.26 through E2.28 of the DGAC report do this for reviews of dietary patterns and cardiovascular disease, measures of body weight, and risk of type 2 diabetes, respectively. Appendix E-2.43 does so for the topic of saturated fats and risk hrof cardiovascular disease.[2] In most cases, the evidence portfolio documents are structured as a report, followed by "supplemental information" that show the search strategy, eligibility criteria, and results of applying the criteria.

K. I am aware that, in the *Rapid Response* to the article (16), Teicholz presented a rebuttal to these four points. I reviewed the rebuttal. I do not agree that each appendix DGAC report presents "two contrasting methodologies." My interpretation is that the first description of the methodology provides a brief overview and the second provides the details. In systematic review, or supplementary file is used commonly to present additional details of the search strategy, inclusion criteria, and excluded studies. I found that the dates for the literature reviews in the appendices are stated clearly (e.g., January 2009 to August 2014 for the saturated fats evidence portfolio, Appendix E-2.43), and hand searching is a widely used and encouraged method to supplement electronic searches (17). The aim is to find all the relevant studies. Relying exclusively on electronic searches of bibliographic databases cannot do this.

L. In any case, the author's rebuttal is not a plausible rationale for what appeared in the *BMJ* article. The article in *The BMJ* does not mention that there were two methodologies, it implies there was none.

[2] The search and selection strategies are included in the evidence portfolios for all topics except for school-based and worksite-based issues topics, where they are in separate documents (Appendices E-2.29b and E 2.33b), and physical activity, which relied entirely on previously published US Government guidelines (Appendix E 2.49).

M. The CSPI letter (point #3) disputes Teicholz' statement that "use of external reviews by professional associations is problematic because these groups conduct literature reviews according to different standards and are supported by food and drug companies." She notes that the American Heart Association and the American College of Cardiology accept funding from industry. The CSPI letter responds that the guidelines in question were developed in collaboration with the US National Heart, Lung, and Blood Institute, a governmental body, and refer to the NHLBI's policies for Disclosing and Managing Conflicts of Interest. However, it is not a factual error to express the opinion that the AHA/ACC/NHLBI guideline could be influenced by funding from industry. The independence of professional society guidelines (18) and the effectiveness of the NHLBI's policies in protecting against bias are open questions.

N. The CSPI letter disputes Teicholz' argument that, based on her interpretation, none of the original studies included in the 2010 review support the hypothesis that saturated fats cause heart disease (Point #4). The issue here is not one of "error" but rather a disagreement over the interpretation of the research.

O. The CSPI letter notes that Teicholz concluded that the 2010 NEL review is substandard but also criticized the 2015 report because it did not rely sufficiently on NEL reviews. It is not an error to make both points in the same article.

P. The CSPI letter (Point #5) refutes Teicholz's statement that several important studies about saturated fat "…have never been systematically reviewed by any of the dietary guideline committees." Teicholz provides a list of these studies. The DGAC used a Cochrane review and another systematic review that included most of these studies.(19, 20) Teicholz responded "The *BMJ* statement is meant to imply that no committee has directly reviewed these trials." This response is inadequate. The statement "…have never been systematically reviewed by any of the dietary guideline committees" is ambiguous: it could mean "these studies were not included in any systematic review" or it could mean the DGAC did not conduct its own systematic review of these studies. Considering the context, however, only the first meaning is natural. Throughout the article Teicholz criticizes the DGAC for its selection and interpretation of systematic reviews; she never argues that the DGAC should rely on its own direct review of trials. The statement is in error.

Q. Similarly, the CPSI letter (Point #6) disputed Teicholz' assertion that the NEL review omitted two important studies "showing that a diet low in fat and saturated fat is ineffective for fighting heart disease, obesity, diabetes, or cancer." Teicholz is correct that the NEL review omitted these studies, but did not mention that they were included in the Cochrane review the committee used. Also, the studies evaluated effects on serum lipids, not disease. In response, Teicholz asserts "Regarding the other complaint: it is standard to interpret serum cholesterol measures as markers for heart disease." (14) This explanation is inadequate and unscientific. Cholesterol is a risk factor for heart disease, not a marker for it. Even if it were a marker, the original statement was not limited to heart disease. The original statement is in error.

R. Teicholz also criticizes the NEL because its reviews have not isolated the effect of red meat on health. *The BMJ* article states:

> Consulting the NEL for a review on this topic turns up a surprising fact: a systematic review on health and red meat has not been done. Although several analyses look at "animal protein products," these reviews include eggs, fish, and dairy and therefore do not isolate the health effects of red meat, or meat of any kind.[37]

The citation (#37 in the article) is a link to a web page listing questions about meat addressed by NEL

reviews.[3] The CSPI letter (Point #9) asserts that these reviews "do examine the results on red meat and processed meats." In response, Teicholz states

> "These are all reviews of "animal protein products," as stated, which includes eggs, fish, and dairy, along with meat. The effect of red meat is not separated out for specific analysis. This can be confirmed by looking at the reviews."

The NEC reviews used this search string:

> (Animal protein* OR meat[mh] OR "Egg Proteins, Dietary"[mh] OR "Fish Proteins"[mh])

This search string would identify a primary study that isolated red meat. In fact, many of the primary studies included in the reviews isolated red meat. The NEL reviews summarizing the primary studies included a column labelled "Red Meat Association (Pos, Neg, None)" which isolated the effect of red meat. The Figure shows an example from the NEL review of animal protein products and cardiovascular disease.(21)

| Author, Year, Study Design, Class, Rating | Name of Study/Location | Total Meat Association (Pos, Neg, None) | Red Meat Association (Pos, Neg, None) | Processed Meat Association (Pos, Neg, None) | Poultry Association (Pos, Neg, None) |
|---|---|---|---|---|---|
| Djousse et al 2008<br><br>Study Design: Prospective Cohort Study<br><br>Class: B<br><br>Rating: | Physicians' Health Study.<br>Location: US. | Not examined. | Not examined. | Not examined. | Eggs: Ø MI, stroke or type of stroke. |

S. The CSPI letter disputes two of Teicholz' statements that can be characterized as comments on the history of the Dietary Guidelines (Points #10, #11). The first is "The foundation of *{the Guidelines'}* advice has been to recommend eating less fat and fewer animal products (meat, dairy, eggs) while shifting calorie intake towards more plant foods (fruits, vegetables, grains, and vegetable oils) for good health." The second is that, in 1980, the USDA "dismissed" early critical reviews, including the National Academy of Sciences report, *Toward Healthy Diets.*(22) As argued below, the author's assertions are not errors.

T. The CSPI letter points out that the 2015 DGAC did not recommend eating less fat—in fact, it

[3] Teicholz is not saying that no systematic reviews of red meat have been done, only that the NEL has not done one. A systematic review of red meat and cardiovascular disease and diabetes was published in 2010 (R. Micha, S.K. Wallace, D. Mozaffarian Red and processed meat consumption and risk of incident coronary heart disease, stroke, and diabetes mellitus: A systematic review and meta-analysis Circulation, 121 (2010), pp. 2271–2283). Several dozen meta-analyses of red meat and cancer risk have also been published.

recommends substituting preferred fats for others, not reducing total fats. The CSPI is correct, but the author's point is about the historical foundations of the guidance and is an historical interpretation, not an "error." Previous versions of the guidance (for example, 1990 and 1995) advise Americans to "Choose a diet low in fat".(23,24) The recommendations regarding fats have not changed very much even though, since 2000, the guidelines do not specifically say to eat less fat.

U. In Point #11, the CSPI letter argues that the 1980 Dietary Guidelines were published before the National Academy of Sciences report. However, it is possible that the USDA "dismissed" the NAS report after the guidelines were published, and it is also possible that, before the guidelines were published, the USDA/HHS panel was aware of the findings later published in the NAS report. More information could provide a definitive answer to this historical question.

*CONCLUSION*

V. Many of the author's arguments in the *BMJ* article and in her rebuttal to the CSPI letter reflect a lack of knowledge of current practice in guideline development and systematic review methods, and it does not appear that she consulted any experts or published works on these topics.

W. The decision to publish the article as a BMJ Investigation is regrettable. The article is better described as an opinion piece, editorial, or even an example of lobbying literature than an independent investigation. Within the article, the phrases "an investigation by the BMJ" and "The BMJ has also found that the committee's report used weak scientific standards…" obscure the fact that all of the assessments of the DGAC process and findings are the author's, and that the investigation consisted entirely of a "critical review" of the report by the author.

X. In 2014, before the DGAC had finished their report, Teicholz had urged beef producers to call their congressional representatives and demand an inquiry of the committee (25). She also criticized the DGAC report within days of its release in February, 2015. (26, 27) The BMJ article disclosed that Nina Teicholz was a member of the Nutrition-Coalition, but not that this organisation and its funder, Action Now Initiative, were actively lobbying the US Congress to question the science behind the DGAC report. Before the BMJ article was published, lobbyists arranged meetings between Teicholz and Congressional officials.(28)

Y. Despite these very concerning issues, I do not recommend that the article should be retracted on the grounds that it is "riddled with errors." While there are errors, the main problem is that the article contains interpretations, opinions, and poorly informed judgments about what is and isn't "standard" or "established methods" when it comes to systematic review and guideline development.

Z. Nothing in my report should be interpreted as a defense of the NEL systematic review process or of the DGAC guideline process. While I was not asked to comment on the validity of the USDA/HHS process, in the course of assessing the Teicholz article and the CSPI letter, I reviewed the DGAC report and the 2015-2020 guidelines as well as videos of the public meetings of the DGAC, documentation of the 2010 DGAC's methodology, and several NEL reviews. I found nothing to contradict Teicholz' central concern that the DGAC' processes to protect against bias are inadequate. It is clear that further investigation of the composition of the committee, as well as its conflict of interest policies and work group structure, are warranted. The NEL and DGAC do not appear to have incorporated key developments in methodology and governance of evidence-based guideline development since 2010. The DGAC's role in grading the evidence and the lack of an evidence to decision framework are examples of practices that may fall below the current international standard for conducting systematic reviews. An impartial, informed evaluation of their effectiveness in protecting against bias is needed.

**REFERENCES**


1. Teicholz, N. The scientific report guiding the US dietary guidelines: is it scientific? BMJ 2015;351:h4962. http://dx.doi.org/10.1136/bmj.h4962 (Published 23 September 2015). Also published 26 September 2015 as "How dietary guidelines are out of step with science." http://www.bmj.com/bmj/section-pdf/905904/5 \
2. Dietary Guidelines Advisory Committee. Scientific Report of the 2015 Dietary Guidelines Advisory Committee. First Print. February, 2015. Available at http://health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf
3. Bonnie Liebman. Letter Requesting BMJ to Retract "Investigation." *BMJ*, December 17, 2015. http://www.bmj.com/content/351/bmj.h4962/rr-36 First published November 5, 2015 at http://cspinet.org/bmj-retraction-letter.html
4. Marantz PR, Bird E, Alderman MH. A call for higher standards of evidence for dietary guidelines. *Am J Prev Med* 2008;34:234–40.
5. Nissen, SE. U.S. Dietary Guidelines: An Evidence-Free Zone. *Ann Intern Med*. Published online 19 January 2016 doi:10.7326/M16-0035
6. Topic selection criteria and approaches for examining evidence. - Dietary Guidelines Advisory Committee. DGAC Meetings. Materials and Presentations. http://web.health.gov/dietaryguidelines/2015-BINDER/meeting1/topicSelectionCriteria.aspx For video see http://health.gov/dietaryguidelines/2015-BINDER/meeting1/index.aspx
7. Millen, B. Introduction to Subcommittee Reports. In 2015 Dietary Guidelines Advisory Committee, Fifth Meeting (Day 1). Webcast. http://videocast.nih.gov/summary.asp?File=18613&bhcp=1 17:06ff.
8. IOM (Institute of Medicine). 2011. *Finding What Works in Health Care: Standards for Systematic Reviews*. Washington, DC: The National Academies Press.
9. Centre for Reviews and Dissemination. 2009. *Systematic Reviews. CRD's guidance for undertaking reviews in health care.* https://www.york.ac.uk/media/crd/Systematic_Reviews.pdf
10. IOM (Institute of Medicine). 2011. *Clinical Practice Guidelines We Can Trust.* Washington, DC: The National Academies Press.
11. Teicholz, N. Public Comment. 5/8/2015. http://health.gov/dietaryguidelines/dga2015/comments/readComments.aspx Comment ID #29540
12. Teicholz, N. A Critical Review of the Science for Key Recommendations in the 2015 Report by the USDA Dietary Guidelines Advisory Committee. September 20, 2015. Available at http://www.forbetterdietaryguidelines.org Accessed
13. Arnold Foundation Website. http://www.arnoldfoundation.org/grants/#grant-9659
14. Teicholz, N. Overview of BMJ Retraction Request (Dec 29, 2015; last updated Jan 27, 2016). https://thebigfatsurprise.com/overview-bmj-retraction-request-including-response-11-allegations/
15. *The BMJ*. Medical investigative journalism: staying on the cutting edge. http://www.bmj.com/content/medical-investigative-journalism-staying-cutting-edge 10.1136/bmj.i6511
16. Teicholz NE. Rapid response to: Teicholz, N. The scientific report guiding the US dietary guidelines: is it scientific? BMJ 2015. 22 October 2015. http://www.bmj.com/content/351/bmj.h4962/rapid-responses.
17. Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]*. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org .
18. Norris,SL, Holmer, HK, Ogden,LA, Burda, BU. Conflict of Interest in Clinical Practice Guideline Development: A Systematic Review. PLoS One. 2011; 6(10): e25153.

19. Hooper L, Summerbell CD, Thompson R, Sills D, Roberts FG, Moore HJ, Davey Smith G. Reduced or modified dietary fat for preventing cardiovascular disease. *Cochrane Database Syst Rev*. 2012;5:CD002137. doi:10.1002/14651858.CD002137.pub3.
20. Mozaffarian D, Micha R, Wallace S. Effects on coronary heart disease of increasing polyunsaturated fat in place of saturated fat: a systematic review and meta-analysis of randomized controlled trials. *PLoS Med*. 2010;7(3):e1000252. doi: 10.1371/journal.pmed.1000252.
21. NEL. What is the relationship between the intake of animal protein products and cardiovascular disease? (DGAC 2010) http://www.nel.gov/evidence.cfm?evidence_summary_id=250252
22. National Research Council, Food and Nutrition Board, National Academy of Sciences. Toward healthful diets. National Academy Press, 1980.
23. Dietary Guidelines for Americans. Third Edition. 1990. http://health.gov/dietaryguidelines/1990thin.pdf?_ga=1.122793931.1523549049.1456058698
24. Dietary Guidelines for Americans. Fourth Edition, 1995. U.S. Department of Agriculture. U.S. Department of Health and Human Services. http://health.gov/dietaryguidelines/dga95/?_ga=1.89172315.1523549049.1456058698
25. Radke, A. "Big Fat Surprise" author talks about the importance of beef in dietary guidelines. Beef Magazine. November 24, 2014. http://beefmagazine.com/beef-quality/big-fat-surprise-author-talks-about-importance-beef-dietary-guidelines
26. Teicholz, N. The Government's Bad Diet Advice. New York Times. FEB. 20, 2015. http://www.nytimes.com/2015/02/21/opinion/when-the-government-tells-you-what-to-eat.html
27. Roybal, Joe. Q&A: Nutrition author says dietary recommendations are "shockingly" unscientific. Beef Magazine. April 20, 2015. http://beefmagazine.com/beef-quality/qa-nutrition-author-says-dietary-recommendations-are-shockingly-unscientific
28. Purdy, C and Bottemiller Evich, H. The money behind the fight over healthy eating. Politico. 10/07/15. http://www.politico.com/story/2015/10/the-money-behind-the-fight-over-healthy-eating-214517