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Information Requests for Corrections and HHS' Responses

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February 11, 2004

William L. Kovaks
Vice President
Environment, Technology, & Regulatory Affairs
Chamber of Commerce of the United States of America
1615 H. Street, N.W.
Washington, D.C. 20062

Richard L. Hanneman
President
The Salt Institute
Fairfax Plaza, Suite 600
700 North Fairfax Street
Alexandria, VA 22314-2040

Re: Request for Reconsideration submitted September 22, 2003

Dear Messrs. Kovaks and Hanneman:

I am responding, on behalf of the National Heart, Lung and Blood Institute (NHLBI), to your request for reconsideration (Appeal) under the National Institutes Health "Guidelines for Ensuring the Quality of Information Disseminated to the Public" (NIH Guidelines). The Appeal concerns NHLBI's denial of your May 14, 2003 request for correction (Correction Request) seeking copies of NHLBI grantee data.⁽¹⁾ The Appeal asks that NHLBI: (1) "correct the disseminating information by removing it from its publications and website" and (2) "be ordered to cease disseminating the subject information until the requested data is produced."⁽²⁾ The data at issue is from the NHLBI grant-funded DASH-Sodium trial and, as described in the Correction Request, concerns "DASH-Sodium blood pressure data for each subgroup... at each of the three levels of dietary sodium intake, including the missing 2,400 mg/day intake level, on both the control diet and the DASH diet."⁽³⁾ The Appeal claims that NHLBI, in failing to supply you with copies of the requested data, has violated the NIH Guidelines. Upon review of the relevant documents and consideration of all the issues and arguments raised, I affirm the agency's denial of your Correction Request.

As a preliminary matter, please understand that NHLBI supports NIH's long-standing policy to share and make available to the public the results and accomplishments of the activities that it funds. But, data sharing is sometimes complicated and limited by institutional policies, local rules to protect human subjects, and other local, state and Federal laws and regulations. In this case, NHLBI does not possess or control the data in question, which was prepared by NHLBI grantees. Public requests for access to grantee data, as detailed in the agency's initial response to your Correction Request, are evaluated under the terms of the Freedom of Information Act.⁽⁴⁾

Additionally, as noted in the agency's initial response to your Correction Request, you can request copies of the data directly from the Steering Committee of the DASH-Sodium study. The investigators have already honored two requests from others for access to data and are currently preparing a public access data set of the study for release in January 2004.⁽⁵⁾ To facilitate your request, I am pleased to provide you with the following contact information:

Frank Sacks, MD
Professor
Harvard School of Public Health
Department of Nutrition
665 Huntington Avenue
Boston, MA 02115

Nevertheless, I reviewed the government-disseminated information at issue here under the NIH Guidelines and affirm that it satisfies them. The Appeal seems to assert that the data on which certain agency-disseminated information is based are either incomplete or presented in a biased fashion and, thereby, the information fails to satisfy the "objectivity" and "integrity" provisions of the NIH Guidelines.⁽⁶⁾ The agency-disseminated "information" you are challenging appears to be information that "directly states and otherwise suggests that reduced sodium consumption will result in lower blood pressure in *all* individuals" that, you assert, is contained in the six documents you originally cited. With respect to each these documents, the NIH Guidelines, insofar as they are applicable, are satisfied.

First, I affirm the agency's prior finding that the two press releases are outside the scope of the NIH Guidelines.⁽⁷⁾ The remaining documents are: (a) two clinical practice guidelines released by the National High Blood Pressure Education Program (NHBPEP), both of which were published in the *Journal of the American Medical Association* (JAMA); and (b) two consumer-oriented materials that NHLBI developed from the practice guidelines.⁽⁸⁾ After careful review and consideration of these documents, the information contained therein, and the agency's process in developing and disseminating the information, I affirm that the documents and the information satisfy the NIH Guidelines.

As you know, the NIH Guidelines presume that analytic information that is "subject to formal, independent external peer review" is of "reasonable quality" and sufficiently objective.⁽⁹⁾ In this case, both sets of practice guidelines received such review through the JAMA publication and peer review process. I am aware of no evidence to suggest that this external review process was in any way

insufficient. Nor have you provided any evidence to rebut the presumption that it was adequate. Furthermore, as the agency detailed throughout the Response, ample and varied scientific evidence supports the information contained in these publications. (10)

The information contained in the two remaining documents, the NHLBI consumer-oriented materials, is based on the JAMA peer reviewed practice guidelines and a wide array of other scientific research, all of which is cited therein. They too satisfy the objectivity requirements of the NIH Guidelines.

The NHLBI documents were designed to translate the results of clinical research into public health messages. Hypertension is a public health problem. The Framingham studies show that people who do not have high blood pressure at 55 face a 90% chance of developing hypertension during their lifetimes. (11) Consistent with this research, NHLBI's public health messages concerning the effects of salt intake, as set forth in the challenged documents, are clearly and carefully supported by a broad base of scientific and medical research. (12)

Results of the DASH-Sodium trial relating to the 2400 mg per day intake level and to the subgroups were included in the primary outcomes paper of the DASH-Sodium study, which appeared in the January 4, 2001 issue of the *New England Journal of Medicine* (NEJM). In the NEJM paper, Figure 2 shows clearly a decrease in systolic blood pressure when those on a controlled diet reduce sodium intake from 3.39 g daily to 2.4 g daily. The decrease is even greater if sodium intake is reduced to 1.5 g/day for participants on a regular diet. This decrease is statistically significant for all groups listed except for non-black participants with hypertension who undergo a reduction in sodium to 2.4 g/day. However, for this group, statistical significance is achieved when the sodium is reduced to 1500 mg/day. The reduction in systolic pressure is less pronounced in those on the DASH diet, since blood pressure is already decreased (Figure 1).

In addition, the results of the study are clearly outlined in information available on the Internet; the study is described on page 4 of the DASH Eating Plan. (13) and in the October 16, 2002 JAMA article. (14) In the NHLBI publication, *Your Guide to Lowering High Blood Pressure*, the following statement is made: "Most Americans consume more salt than they need. The current recommendation is to consume less than 2.4 grams (2,400 milligrams [mg]) of sodium a day. That equals 6 grams (about 1 teaspoon) of table salt a day. The 6 grams include *all* salt and sodium consumed, including that used in cooking and at the table." (15) This information is also available on the Internet at <http://www.nhlbi.nih.gov/hbp/prevent/sodium/sodium.htm>. In my view, the NHLBI statements concerning salt intake satisfy the objectivity and integrity requirements of the NIH Guidelines.

The NIH Guidelines' provisions to ensure that agency-disseminated information is sufficiently "objective" do not require the agency to obtain and release grantee data developed as part of the DASH-Sodium Trial. Even if the documents at issue are considered "influential" as that term is used in the NIH Guidelines -- and I do not think that they are -- the "reproducibility" standard contained in the NIH Guidelines does not require the agency to obtain and release grantee data. Rather, the concept of "reproducibility," as it is contemplated in the NIH Guidelines, requires the agency to ensure that information is "*capable of being reproduced*," subject to an acceptable degree of imprecision." (16)

Consistent with long-standing notions of reproducibility in the scientific community, the NIH Guidelines apply this standard to "analytic results and not necessarily to the original and supporting data used to produce the analytic results." (17) Thus, the methodology employed to develop data and reach research conclusions should be readily ascertainable. Qualified scientists reviewing particular studies should be able to reproduce the research results without needing additional information about study design or conduct. In this case, the JAMA published guidelines, the NHBPEP publications based upon them, and the other publications related to the DASH-Sodium Trial fully explain the methodology and study design used to develop the data. Looking at these publications, qualified scientists are capable of reproducing the studies and able, therefore, to test whether the conclusions are supported by the research. Thus, the NIH Guidelines' requirement for reproducibility, though inapplicable, is satisfied in this case.

In sum, the challenged information satisfies the NIH Guidelines. Under the Guidelines, NHLBI is not required to produce the underlying grantee data that you assert are unavailable. Moreover, these data, relating to the 2400 mg per day intake level and to the subgroups, are available in the primary outcomes paper of the study appearing in the January 4, 2001 issue of the *New England Journal of Medicine*. In that article, and in other documents related to the study, the research design and methodology are fully reported and thus, the results are capable of being reproduced. Finally, I would like to reiterate that you may request copies of the data from the grantees. We understand, furthermore, that they are planning to disclose a public access data set in January 2004 that may facilitate your review.

Again, NHLBI appreciates your comments and hopes the information provided above helps to clarify the state of our work in the area of hypertension risks and our efforts to communicate it to the public.

Sincerely yours,

Barbara Alving, M.D.
Acting Director

1. See Letter from William L. Kovacs and Richard L. Hanneman dated May 14, 2003.

2. Appeal at 10.

3. See Correction Request, at 14-15. You also suggest: "This data should include, but not necessarily be limited to, mean blood pressures, their standard deviations, and sample size for each of the subgroups." *Id.* at 15.

4. I adopt and affirm the agency's views on the applicability of the Freedom of Information Act as the mechanism for obtaining grantee data. See Response at 2. Additionally, while I will not describe each here, I note that some allegations raised in the Appeal are not consistent with fact, e.g., the conclusion that NHLBI has "admitted that the disseminated information could not be reproduced, or tested, without the requested data." See Appeal at 2. To my knowledge, NHLBI has made no such admission.

5. See Letter from Carl A. Roth dated August 19, 2003 (Response), at 5.

6. See Appeal at 6.

7. See Response at 2.

8. I note some confusion about the identity of the first of the cited NHLBI materials. The Request for Correction discusses a document entitled "Facts about Lowering Blood Pressure" that is reportedly available at the following cite: http://www.nhlbi.nih.gov/health/public/heart/hbp/hbp_low/hbp_low.pdf. Following this link reaches a document entitled "Your Guide to Lowering Your Blood Pressure" (NIH Pub. No. 03-5232), which NHLBI produced in May 2003. It replaced a document called "Facts about Lowering Blood Pressure" (NIH Pub. No. 00-3281), which NHLBI originally produced in May 2000 and updated to include the language you quote in July 2001. The language you quote concerning the results of the DASH-Sodium trial satisfy the NIH Guidelines in my view, but, because NHLBI released the "Facts" document, and the information you quote from it, before October 1, 2002, that information falls outside the scope of the NIH Guidelines. See NIH Guidelines, Section II. However, because the link you provided is to the May 2003 publication, we have reviewed it. The May 2003 does not contain the language you quote from the "Facts" document.

9. NIH Guidelines, Section V(1).

10. See Response at 3-5.

11. Vasan, RS, Beiser, A, Seshadri, S, et al., *Residual Lifetime Risk for Developing Hypertension in Middle-aged Women and Men: The Framingham Heart Study* 287 JAMA (8) 1003-1010. See also *Your Guide to Lowering High Blood Pressure* at 2.

12. See Response at 3-5.

13. See *Facts About the DASH Eating Plan* (NIH Pub. No. 03-4082), available in the web at http://www.nhlbi.nih.gov/health/public/heart/hbp/dash/new_dash.pdf.

14. Whelton, PK, He J, Appel, LJ, et al., *Primary Prevention of Hypertension: Clinical and Public Health Advisory from the National High Blood Pressure Education Program* 288 JAMA (15) 1882-1888.

15. *Your Guide to Lowering High Blood Pressure* at 12.

16. OMB Guidelines at §V(10), 67 Fed. Reg. at 8460 (emphasis added).

17. NIH Guidelines, Section VII.

Last Revised: August, 2004

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