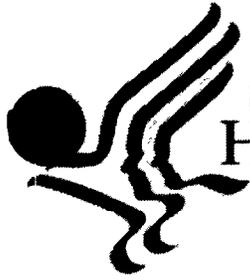


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Information Requests for Corrections and HHS' Responses

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August 19, 2003

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
 Salt Institute
 Fairfax Plaza, Suite 600
 700 North Fairfax Street
 Alexandria, VA 22314-2040

Dear Messrs. Kovaks and Hanneman:

This letter is in response to your May 14, 2003 request for correction filed under the National Institutes of Health "Guidelines for Ensuring the Quality of Information Disseminated to the Public" (NIH Guidelines). ⁽¹⁾ Your request challenges information that is contained in six documents discussing the effect of salt intake on human blood pressure and that, you assert, "directly states and otherwise suggests that reduced sodium consumption will result in lower blood pressure in *all* individuals." Two of these documents are clinical practice guidelines released by the National High Blood Pressure Education Program (NHBPEP). ⁽²⁾ and four are press releases and other consumer-oriented materials developed by NHBPEP. ⁽³⁾ Rather than asking the National Heart, Lung, and Blood Institute (NHLBI) to change or remove the challenged information, however, you have asked only that the agency produce copies of underlying data from the NHLBI grant-funded DASH-Sodium trial, the results of which NHLBI considered in the development of the challenged information.

Because you are not seeking the correction of any agency-disseminated information, but are instead seeking access to data produced in grant-funded research, the appropriate administrative mechanism is the Freedom of Information Act (FOIA), which specifically governs requests from the public for government records. Under the Office of Management and Budget revisions to Circular A110, individual requests for data produced under grants awarded by the NIH are handled through FOIA. More information regarding access to NIH grantees' data may be found at: <http://www.nih.gov/icd/od/foia/> and at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm. Accordingly, we will forward your request for data to the appropriate agency FOIA officials and you should expect a response from them shortly.

While your request for underlying grantee data is properly handled under FOIA, we note that the challenged documents in this case satisfy NTH's information quality standards. ⁽⁵⁾ Information dissemination is an important

part of the NIH's mission and the agency takes seriously its responsibility to ensure that the information it disseminates is accurate, reliable, clear, complete, unbiased, and useful. For example, the NHLBI strives to ensure that research findings related to the prevention, detection, and management of heart, lung, and blood diseases and of sleep disorders will benefit the public health. The Institute fulfills this goal by developing clinical practice guidelines for health professionals and educational messages for patients and the general population that reflect the latest science.

The NIH Guidelines presume that analytic information that is "subject to formal, independent external peer review" is of "reasonable quality" and sufficiently objective. NIH Guidelines, Section V(1). "For scientific and technical documents," the NIH Guidelines explain, "the scientific community recognizes peer review as the primary means of quality control" and NIH follows this standard also. NIH Guidelines, Section V(2)(a). In this case, NHLBI published the practice guidelines in *JAMA* and, thereby, subjected them to rigorous and independent peer review in accord with the *JAMA* editorial board's established requirements. In addition, all of the challenged documents were prepared and reviewed in accord with existing NHLBI procedures for publications. This process involves review and approval through multiple channels, including: (1) the National Education Program Coordinator; (2) the Senior Manager for Health Communications and Information Science in the NHLBI's Office of Prevention, Education and Control (OPEC); (3) relevant involved scientists; (4) the OPEC Director; (5) the NHLBI Director; and (6) the DHHS Public Affairs Office. ⁽⁶⁾

You should also know that neither the NHLBI nor the DASH-Sodium Steering Committee has made any attempt to hide data or to report results in ways that are manipulative or otherwise inconsistent with standard statistical practice. In particular, we would like to point out that the results you claim were not reported, i.e., those relating to the 2400 mg per day intake level and to the subgroups, were, in fact, 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).

The study was designed with appropriate statistical power to permit formal analyses in subgroups defined by 3 factors, namely, hypertension status (hypertensives and non-hypertensives), ethnicity (African American and other), and sex (men and women), and Figure 1 of the paper shows mean changes in both systolic and diastolic blood pressures for both the control and DASH diets at all 3 levels of sodium intake addressed in the study, including the 2400 mg per day level. Figure 2 shows the corresponding changes in mean blood pressures for each of the subgroups defined by hypertension status, ethnicity, and sex. It is true that the text focused on the effects on systolic blood pressure of sodium reduction from "high" (3300 mg per day) to "low" (1500 mg per day). This was an editorial choice made, in part, to conform to the strict word limits of the NEJM and, in part, to focus on some of the original hypotheses relating to the linear and additive effects of sodium reduction. For example, the investigators had hypothesized, and judged that the data did ultimately show, sodium reduction to have significantly greater blood pressure lowering effects when going from intermediate to low sodium levels than from high to intermediate sodium levels. It, therefore, made sense to highlight the full blood pressure reduction achieved, since most of the effect occurred between the intermediate and low levels of intake.

A second paper containing subgroup analyses was also published. That paper, which appeared in the December 18, 2001 issue of the *Annals of Internal Medicine* (AIM), provided results relating to the effects of sodium reduction on blood pressure for the subgroups, defined by hypertension status, ethnicity, and sex, along with those for other subgroups of clinical interest such as age, body mass index, physical activity level, and alcohol use. The unadjusted data presented in Table 2 of the paper showed that mean systolic blood pressure decreased in response to lower sodium in all subgroups examined, with a striking consistency among the responses - all subgroups benefited from sodium reduction. However, since the study was only designed to ensure appropriate statistical power to detect true effects between the subgroups defined by hypertension status, ethnicity, and sex further dividing those subgroups into additional subgroups would likely result in very small sample sizes and consequently unacceptably low power. For example, a sub-sub group of 19 white nonhypertensive men, ages 45 and younger, would almost certainly be too small to permit conclusions to be drawn about mean blood pressure response to sodium intake.

Please note that the investigators' approach to subgroup analysis and reporting was carefully evaluated and approved by many experts in statistics, clinical trials, and hypertension, through their participation in an NIH peer review group, an independent Protocol Review Committee, an independent Data and Safety Monitoring Committee, the NEJM review process, and the AIM review process. None of those groups requested additional post-hoc subgroup analysis.

The NHLBI recommendations on public health issues, including sodium intake, are based on the totality of the

available scientific evidence. In the case of the NHBPEP recommendations on sodium intake, a substantial body of evidence developed over more than a decade shows a clear causal relationship between sodium intake and blood pressure. (7) (8) The DASH-Sodium study is but one piece of evidence that, along with studies in laboratory animals, observational studies in humans, and clinical trials together support the conclusion that the population can benefit from reducing its sodium intake to no more than 2400 mg of sodium per day. (9) (10) Indeed, the recommendation of a goal of consuming not more than 2400 mg of sodium per day is the same as the sodium goal in the current U.S. Dietary Guidelines, (9) which, in turn, is consistent with the 1989 statement of the independent National Academy of Sciences that affirmed the efficacy and safety of a dietary sodium intake of 2400 mg per day or less. (10)

Additionally, you may be interested to know that the Steering Committee of the DASH-Sodium study has already honored two requests for access to data. Each of those requests was made directly to a member of the Steering Committee for the study. In addition, the DASH-Sodium investigators are currently preparing a public access data set of the study for release in January 2004. They are doing this even though they are under no obligation to do so according to the terms and conditions of their grant awards.

In summary, your request for underlying data generated by NIH grantees as part of the DASH-Sodium trial is properly handled under the existing mechanism for grantee data access set forth in FOIA. Although the NIH Guidelines are inapplicable to your request, we note that the challenged information satisfies the NIH's information quality standards. Moreover, in this case, the grantee is preparing a data set for public distribution shortly that may alleviate your concerns.

I would like to let you know that you may appeal the agency's decisions either in writing or electronically within 30 days of receiving this response. Your request should state the reasons for your appeal. It does not need to reference a tracking number. The request may be sent electronically to InfoQuality@od.nih.gov or in hard copy to the Associate Director for Communications, Office of the Director, National Institutes of Health, Building 1, Room 344, 1 Center Drive, Bethesda, Maryland 20892. If the appeal is sent in hard copy, please clearly mark the appeal and outside envelope with the phrase "Information Quality Appeal."

We appreciate your comments and hope 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,

Carl A. Roth, Ph.D., LL.M.
Associate Director for Scientific Program Operation

1. These guidelines were issued pursuant to, and are consistent with: (1) the Department of Health and Human Services "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public" (HHS Guidelines); (2) the Office of Management and Budget "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies" (OMB Guidelines); and (3) section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001.

2. The guidelines are: (1) "Primary Prevention of Hypertension: Clinical and Public Health Advisory from the National High Blood Pressure Education Program," which appeared in the October 16, 2002 issue of the *Journal of the American Medical Association* (JAMA); and (2) the "Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7)," reported in the May 21, 2003 issue of JAMA.

The two press releases fall outside the scope of the NIH Guidelines. The guidelines apply only to information that is released on or after October 1, 2002 and, they explicitly exclude press releases "that support the announcement or give public notice of information that NIH has disseminated elsewhere." NIH Guidelines, Section II. NIH released the first of the challenged press releases on December 17, 2001, before the NIH Guidelines became effective. NIH issued the second press release to announce the release of the clinical practice

guidelines published in the October 16, 2002 JAMA. Thus, neither press release is subject to the NIH Guidelines.

4. The NIH Guidelines explicitly reference application of FOIA procedures to data quality complaints. NIH Guidelines, Section VI(3). FOIA procedures provide well-established safeguards that allow affected persons to address information quality concerns without imposing "unnecessary administrative burdens" and creating "new and potentially duplicative or contradictory processes" for agency information practices. See 67 Fed. Reg. 8453 (Feb. 22, 2002) (OMB agency guidance for preparing information quality standards).

5. The challenged information is not, however, "influential" as that term is used in the NIH Guidelines and subject to a requirement of "reproducibility." First, "influential" information under the NIH Guidelines is information that the agency can reasonably determine "will have or does have a *clear and substantial impact* on important public policies or important private sector decisions, or will have important consequences for specific health practices, technologies, substances, products or firms." NIH Guidelines, Section VII (emphasis added). While NIH intends the information it disseminates to be useful, it does not believe that the information rises to the level of having a "clear and substantial" impact in the listed areas. Second, the NIH Guidelines apply the "reproducibility" standard to "analytic results and not necessarily to the original and supporting data used to produce the analytic results." NIH Guidelines, Section VII. While NIH favors data archiving "where feasible to facilitate the reproducibility of influential information," the NIH Guidelines recognize that "[e]xceptions may be necessary" for example, to maintain the confidentiality of clinical data or satisfy existing research resource agreements. NIH Guidelines, Section VII. Therefore, even if the reproducibility standard applied in this case, it would not entitle you to copies of underlying grantee data.

6. Additional layers of review included: (a) for the fact sheets--the OPEC Coordinator, Program Operations and the Chief of the NIH Editorial Operations Branch; (b) for the JAMA publications--the 46 member organizations of the NHBPEP Coordinating Committee, the NHLBI Deputy Director, the OPEC Coordinator, Program Operations and the Chief of the NIH Editorial Operations Branch; and (c) for the press releases--the NIH Office of Communications.

7. Chobanian AV, Hill M. National Heart, Lung, and Blood Institute Workshop on Sodium and High Blood Pressure. A Critical Review of Current Scientific Evidence. Hypertension. 2000;35:858.

8. See also the numerous sources cited in the JAMA-published clinical practice guidances, found at: 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. JAMA 2002 Oct 16; 288 (15) 1882-8; and Chobanian AV, Bakris GI, Black HR, et al. The seventh report of the Joint National Committee on Prevention, Evaluation, and Treatment of High Blood Pressure. JAMA 2003 May 21; 2560-72.

9. United States Department of Agriculture and Department of Health and Human Services. Nutrition and Your Health. Dietary Guidelines for Americans, Fifth Edition, 2000. Home and Garden Bulletin No. 232.

10. Recommended Dietary Allowances 10th Edition Subcommittee on the Tenth Edition of the RDAs Food and Nutrition Board. Commission on Life Sciences, National Research Council. NATIONAL ACADEMY PRESS; Washington, D.C. 1989.

Last Revised: August, 2004

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