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September 22, 2003

Associate Director for Communications
Office of the Director
National Institutes of Health
Building 1, Room 344
1 Center Drive
Bethesda, Maryland 20892

Re: U.S. Chamber/Salt Institute Information Quality Appeal

Dear Mr./Mme. Associate Director:

This is an appeal of final agency action taken by the National Heart, Lung, and Blood Institute (NHLBI).

BACKGROUND

On May 15, 2003 the U.S. Chamber of Commerce (Chamber) and the Salt Institute (collectively the "Petitioners") filed a petition for correction of information pursuant to Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (the "Data Quality Act" or the "DQA"),[1] the OMB Information Quality Guidelines (the "OMB Guidelines"), the Department of Human Health and Human Services Information Quality Guidelines ("HHS Guidelines"), and the National Institute of Health Information Quality Guidelines ("NIH Guidelines")(collectively the "Guidelines").

NHLBI had cited and relied on the results of the Dietary Approaches to Stop Hypertension ("DASH") Sodium Trial (completed in January 2001) to issue multiple news releases, articles, documents, reports, and web site statements touting the alleged

[1] Section 515, Treasury and General Government Appropriations Act for Fiscal Year 2001; Public Law 106-554; see 44 O.K. §3516 (other provisions).

benefits of a diet containing less than 2,400 mg of sodium daily for *all Americans,* regardless of race, age, weight, or sex. *See* Petition at 5-6. However, NHLBI failed and refused to make available critical DASH-Sodium Trial data, data needed to independently verify both the methodological soundness and substantive accuracy of the DASH-Sodium Trial data. *See* Petition at 3-4. Petitioners, relying on the plain language of Section 515 and the OMB, HHS, and NIH Guidelines, formally requested the missing DASH data (the "Petition")(attached as Exhibit A and fully incorporated by reference hereto).

ARGUMENT

NHLBI did not find that Petitioners lacked standing. It did not assert that the claim was unripe, or that the agency lacked jurisdiction. NHLBI admitted that the disseminated information could not be reproduced, or tested, without the requested data. Nevertheless, NHLBI arbitrarily, capriciously, and in excess of its statutory authority, rejected the Petition, asserting that it will not now, nor at any time in the future, release the requested data. *See* Letter from Carl A. Roth to William L. Kovacs and Richard L. Henneman dated August 19, 2003 (the "Denial")(attached as Exhibit B).

The Denial is not a model of clarity. However, it appears that NHLBI rejected the Petition for the following reasons.

- NHLBI claimed the challenged information was not "influential" as defined by the NIH Guidelines, because NHLBI could not reasonably determine whether such information "will have or does have a *clear and substantial impact* on important public health policies or important private sector decisions, or will have important consequences for specific health practices, technologies, substances, products, or firms." *Id.* at fn.5. Therefore, the information was not required to be transparent or reproducible. Furthermore, it claimed that the NIH Guidelines allegedly applied only to "analytic results, and not to the original and supporting data used to produce the analytic results." *Id.* Finally, NHLBI claimed that no data had been excluded in the publications at issue, or that, if excluded, the data was excluded for editorial purposes, and that, even if excluding the full set of data for editorial reasons was wrong, because NHLBI might produce it in a future publication, it had no duty to do so at this point. *Id.* at 4-5.

- NHLBI reasoned that because the DASH-Sodium Trial results had been subject to formal, independent external peer review, published in JAMA, and because the investigators' methodology had been approved by a National Institute of Health

("NIH") peer review group, among others, the conclusions of the study were reliable. *See* Denial at 3-4. Therefore, it met the applicable data quality guidelines. *Id.*

- NHLBI argued the challenged disseminated information was not based on the DASH-Sodium Trial alone, but on "the totality of the available scientific evidence." *See id.* at 5

- NHLBI asserted the Petitioners were seeking information access, not correction, and that the appropriate mechanism for disclosure was the Freedom of Information Act ("FOIA"). See Denial at 2, 5. NHLBI then *sua sponte* deemed the Petition a FOIA request, assigned it FOIA Case No. 2003-059/29148, and denied same on the grounds that the agency did not have the requested data. *See* Letter from Suzanne A. Freeman to William L. Kovacs and Richard L. Hanneman dated September 3, 2003 (attached as Exhibit C).

NHLBI's arguments, assertions, and claims are unavailing. It must comply with the law, and release the requested information.

I. NHLBI'S DISSEMINATED, INFLUENTIAL INFORMATION WAS NEITHER REPRODUCIBLE NOR OBJECTIVE.

The law requires disseminated, influential information to be useful, reproducible and objective. *See* Section 515; 67 Fed. Reg. 8453. Because NHLBI has refused to make available the requested data, the disseminated information cannot meet the legal test.

A. The Information Is Influential

1. NHLBI treated the information as if it were "influential."

NHLBI asserts that the challenged information is not "influential." Thus, it is not subject to the OMB Guidelines that require an agency disseminating "influential" data to apply a "high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties."[2] As a matter of law, "influential information" is information the agency can "reasonably determine…will or does have a clear

[2]OMB Guidelines, §V.3.b.ii; HHS Guidelines, §D.2.c.ii.

and substantial impact on important public policies or important private sector decisions.[3]

The NHLBI's claim that the disseminated information is not influential is simply disingenuous. As a threshold matter, the information was posted on NHLBI's website with the intention of influencing the public's dietary choices, which brings it to a level of having a "clear and substantial impact" on public policy.[4] Further evidence that the agency considered the disseminated information "influential" can be found in its own external press releases. At least one major trade publication took the agency at its word regarding the importance of the information; a recent article appearing in *Science* described the study as: "…an influential [emphasis added] study of sodium intake and hypertension."[5] Finally, the information was part of the Joint National Committee report on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, which is designed to be one of the foremost points of reference for American medical professionals.[6] Notwithstanding the agency's *post hoc* rationalizations for refusing to follow the law, it is difficult to imagine NHLBI disseminating any information more "influential" than the DASH-Sodium Trial.

2. <u>There are no disclosure exceptions</u>.

NHLBI claims that even if influential, the requested information need not be reproduced. It asserts that the NIH Guidelines require only that the analytic data be reproducible, and not necessarily to the original and supporting data used to produce the analytic results." *See* Denial at 3, fn.5. Again, NHLBI is simply wrong on the law. The NIH Guidelines specifically provide that "the research data…and any supporting data that form the basis of the communication in question should be available promptly and completely to all responsible scientists seeking further information." NIH Guidelines at sec. V(1). NIH further states that exceptions to this policy "may be necessary to maintain the

[3] OMB Guidelines, §III.C.9.

[4] The OMB Guidelines specifically mention the internet as a prime example of a method of information dissemination that requires a high degree of attention to data quality requirements, due to factors such as speedy dissemination and widespread availability of the information to the public.

[5] Industry Groups Petition for Data on Salt and Hypertension. *Science Magazine* 2003; 300; 1350.

[6] In addition, NHLBI noted that it might, in the future, commend the findings of the DASH-Sodium Trial to the newly-appointed Dietary Guidelines Advisory Committee. If NHLBI did so, the data would be even more influential in directly shaping public policy during discussion and revision of the Dietary Guidelines for Americans.

confidentiality of clinical data or if unique materials were obtained under agreements that preclude their dissemination." *Id.* NHLBI has never asserted either of these exceptions applies; the information must be produced, and is subject to the reproducibility standard.

B. The Disseminated Information Is Not Reproducible.

The DQA mandates that disseminated information must be both useful to and useable by the public.[7] Congress recognized that scientific information is useful only if it can be substantially reproduced; thus, the law requires that if an agency disseminates influential scientific information, there must be a high degree of transparency about the data and methods to facilitate the reproducibility of such information by qualified third parties. *See* OMB Guidelines sec. V.10; HHS Guidelines sec. D.2.i. Under the OMB Guidelines: "'reproducibility' means that the information is capable of being substantially reproduced, subject to an acceptable degree of imprecision."[8]

In this case, it is impossible to reproduce or test NHLBI's disseminated information, because the agency has refused to provide a complete body of data and provide the requisite scientific transparency. This transparency in an agency's presentation of underlying data is necessary in order to determine DQA compliance:

> Making the data and models publicly available will assist in determining whether analytic results are reproducible…Agency guidelines **shall** [emphasis added], however, in all cases, require a disclosure of the specific data sources that have been used and the specific quantitative methods and assumptions that have been employed.[9]

Agencies must apply the transparency requirement to influential data, unless there is a "compelling interest," such as trade secrets or other confidentiality issue, which trump the disclosure obligation.[10] NHLBI has not claimed that there is such a compelling interest in this case. Therefore, there is

[7] OMB Guidelines, Summary of OMB Guidelines at 8453.

[8] OMB Guidelines, §V.C.10.

[9] OMB Guidelines, §V.B.i-ii.

[10] OMB Guidelines, §V.b.ii.B

no viable justification for shirking its obligation to disclose, in a transparent manner, the influential data.

C. The Information Was Not Complete And Was Not Objective.

NHLBI's assertion that it has met legal "objectivity" requirements is contrary to the facts. The relevant law defines "objectivity" to mean that the information is:

> [P]resented in an accurate, clear, complete, and unbiased manner. This involves whether the information is presented **within a proper context** [emphasis added]. Sometimes, in disseminating certain types of information to the public, **other information must also be disseminated** [emphasis added]…[11]

The OMB Guidelines specifically require agencies to disseminate only complete information.[12] The OMB Guidelines also require that agencies ensure and maximize the "integrity" of all disseminated information,[13] which highlights the importance of completeness in data presentation. In simple terms, a partial release of data can never be "complete" and can never be objective.

NHLBI claims it had no obligation to provide complete information because the requested data were not reported in the New England Journal of Medicine article due to "an editorial choice made, in part, to focus on some of the original hypotheses relating to the linear and additive effects of sodium reduction…"[14] In essence, the agency's legal claim is that a journal editor's decision is dispositive of its Section 515 obligations.

This claim is ill-founded. Nothing in Section 515, or in any of the Guidelines, can be relied upon to fashion a data transparency exemption out of a journal editor's judgment. For DQA compliance purposes, a decision which affects the context of a study, in such a significant way as to alter the ability of the public to objectively interpret disseminated data, amounts to more than a mere "editorial choice." If NHLBI is allowed to disseminate information, and

[11] OMB Guidelines, §V.3.a.
[12] OMB Guidelines, §V.3.a.

[13] Section 515(b)(2)(A).
[14] Denial letter at 4.

then hide behind the façade of "editorial choice," the public's right to transparency will be gutted, and the DQA would have little or no meaning.

As a practical matter, the agency has had ample opportunity to publish the full set of data on the agency website, among other places. Had the agency done so, the Petition and this appeal would never have been necessary. NHLBI, however, for its own undisclosed reasons, elected to conceal data, rather than follow the law, and provide transparency.

II. PEER REVIEW IS NOT DISPOSITIVE OF DATA QUALITY

NHLBI claims that peer review is dispositive of DQA reliability. This is not the law. As a threshold matter, the agency must demonstrate that the relevant peer review process meets the general criteria for competent and credible peer review recommended by OMB-OIRA to the President's Management Council (9/20/01). OMB Guidelines Sec. V(3)(b)(i). This NHLBI has not done.

Moreover, even OMB-OIRA peer review, and even peer review by NIH or by JAMA, is not dispositive of data quality. To the contrary, OMB specifically rejected the notion that peer review is adequate to demonstrate quality. 67 Fed. Reg. 8455. OMB stated: "The fact that the use of original and supporting data and analytic results have been deemed 'defensible' by peer-review (sic) procedures *does not necessarily imply that the results are transparent and reproducible*." *Id.* (emphasis added). Instead, peer review creates a mere rebuttable presumption of objectivity, satisfying at most one of the three DQA requirements (e.g., utility, objectivity, and integrity). *See* OMB Guidelines Sec. V(3)(b)(i); NIH Guidelines Sec. D(2)(c)(1).

This "rebuttable presumption" of objectivity strengthens Petitioners' claim to the requested data. Without the requested data, the public cannot evaluate the sufficiency of the peer review. If the public cannot evaluate the sufficiency of the peer review, then Petitioners' right to rebut the presumption of objectivity is effectively (and improperly) frustrated. NHLBI may not, as it attempts to do, invoke a non-existent "peer review" bar to limit Petitioners' legal rights.

III. NHLBI CANNOT RELY ON THE "TOTALITY OF SCIENTIFIC EVIDENCE"

NHLBI asserts that it did not rely solely on the DASH-Sodium study in disseminating the subject information. Instead: "The NHLBI recommendations on public health issues…are based on the totality of the available scientific evidence." *See* Denial at 5. If true, then NHLBI has admitted it routinely violates the DQA. The

OMB Guidelines specifically state: "With regard to analytic results…agency guidelines shall generally require sufficient transparency…[so] that an independent reanalysis could be undertaken by a qualified member of the public. *These transparency standards apply to agency analysis of data from a single study as well as to analyses that combine information from multiple studies.*" 67 Fed. Reg. 8456. Without knowing specifically what constitutes "the totality of the available scientific evidence" NHLBI purportedly relied on in disseminating the information, the public cannot possibly test the quality of that "evidence." Every time NHLBI disseminates information based on a "totality of the evidence" standard, without ensuring the relevant transparency standards are respected and met, it violates the law.

IV. FOIA IS NO SHIELD TO DQA COMPLIANCE OBLIGATIONS

The Petition falls squarely within the DQA's ambit, for it seeks to cure an agency's failure to provide the public with the information necessary to interpret influential, disseminated scientific information. NHLBI, however, attempts to use FOIA as a shield against its DQA obligations. It claims that OMB Circular A-110 mandates that data produced under grants awarded by NIH are to be handled through FOIA.[15]

NHLBI's attempted use of FOIA to limit its DQA obligations is unsupported by law. Even a cursory reading of the statute and OMB Guidelines demonstrates that the DQA obligations are both separate from, and more extensive than, FOIA obligations. The statute's plain language provides that "affected persons may seek and obtain correction of information…that does not comply with the guidelines…" Sec. 515(b)(2)(B). Disseminated information must be "objective." 67 Fed. Reg. 8453 (February 22, 2002). "Objectivity" means the disseminated information is accurate, clear, and complete. *Id.*; *see also* 67 Fed. Reg. 8459. In fact, OMB specifically admonishes agencies to "identify…the supporting data and models, so that the public can assess for itself whether there may be some reason to question the objectivity of the sources." *See* OMB Guidelines Sec. V(3)(a). If the supporting data is not made available, then, by definition, the public cannot assess for itself whether there may be some reason to question the objectivity of the sources.

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[15]*See* Denial at 2. Note that NHLBI *sua sponte* deemed the Petition a FOIA request, assigned it a FOIA Case Number, and then denied the request because the data required to sustain the conclusions being disseminated by NHLBI are ***not available*** within the agency. This admission is further evidence of a DQA violation, and it is further justification for ceasing dissemination of the information in question, pending the outcome of this appeal. Furthermore, NHLBI's action appears to be a direct violation of OMB Circular A-110, "Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations." The relevant statute and OMB Guidelines specifically require Federal awarding agencies to ensure that all data produced under an award be made available to the public through the procedures established under FOIA. NHLBI's FOIA violation is independently actionable.

NHLBI claims that the relevant guidelines support its reliance on FOIA as a mechanism for responding to DQA requests. "FOIA procedures provide well-established safeguards that allow affected persons to raise information quality concerns without imposing 'unnecessary administrative burdens' and creating 'new and potentially duplicative or contradictory processes' for agency information practices." *See* Denial at 2 (citation omitted) NHLBI distorts the applicable law. OMB specifically directs agencies "to incorporate the standards and procedures required by these guidelines into their existing information resources management and administrative practices…." 67 Fed. Red. 8453. Put another way, OMB recognizes that DQA imposes new obligations, and it suggests that agencies incorporate those additional obligations into its information resources management program, rather than creating separate DQA and FOIA response bureaucracies (as NHLBI has in fact done).

Moreover, there is nothing in the OMB Guidelines that precludes a Request for Correction of *incomplete* disseminated information, especially when such data is influential and must meet a reproducibility requirement, key Data Quality Act concepts. Simply because Petitioners seek to obtain the missing piece of data from a study used to support the dissemination of scientific information does not automatically render the Petition a FOIA request.

To divert attention from its responsibility to disclose the missing data under the Data Quality Act, NHLBI asserts that Petitioners should not be concerned about the missing data because the Steering Committee of the DASH-Sodium Trial plans to release this data "sometime in 2004."[16] NHLBI, however, has already disseminated information based on the DASH-Sodium Trial. As a matter of law, it is the agency's dissemination of information, not the plans of a study "Steering Committee," that triggers the public's data quality rights. If an agency can disseminate information, and then make the public wait an indefinite amount of time to receive influential data that is otherwise subject to a high transparency requirement, the public's ability to reproduce the data, and potentially mitigate the harm that could be caused by the agency's action, is substantially impaired. Under these circumstances, the Data Quality Act ceases to protect the public, and the mandates of the Congress are frustrated.

[16] Denial letter at 5.

CONCLUSION AND RELIEF REQUESTED

For the reasons stated above, Petitioners request that their Petition be granted. Petitioners further request: (1) that the NHLBI correct the disseminating information by removing it from its publications and website, and (2) that NHLBI be ordered to cease disseminating the subject information until the requested data is produced.

RESPECTFULLY,

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U.S. Chamber of Commerce
Petitioner

Richard Hanneman
Salt Institute
Petitioner

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Attachments