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May 14, 2003

Office of Communications  
ATTN: Information Quality  
National Heart, Lung, and Blood Institute  
Bldg. 31, Rm. 4A-21  
Bethesda, MD 20892

Dear NHLBI Office of Communications:

The U.S. Chamber of Commerce and the Salt Institute jointly file the following petition pursuant to Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001<sup>1</sup>, the OMB Information Quality Guidelines (“the OMB Guidelines”)<sup>2</sup>, the Department of Health and Human Services Information Quality Guidelines (“the HHS Guidelines”)<sup>3</sup>, and the National Institute of Health Information Quality Guidelines (“the NIH Guidelines”)<sup>4</sup>.

The U.S. Chamber of Commerce is the world’s largest business federation, representing three million businesses of all sectors, sizes and regions. Those represented by the U.S. Chamber include numerous producers, distributors, retailers, and users of salt and salt products. The Salt Institute is a non-profit association of salt producers, consisting of companies that both produce and market sodium chloride. The Salt Institute is the world’s foremost source of authoritative information about salt. As such, both the U.S. Chamber and the Salt Institute have both direct and indirect interests in information disseminated by the National Heart, Lung, and Blood Institute (“NHLBI”) concerning the impact of sodium intake on blood pressure.

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<sup>1</sup> Section 515, Treasury and General Government Appropriations Act for Fiscal Year 2001; Public Law 106-554; see 44 U.S.C. §3516 (other provisions).

<sup>2</sup> 67 FR 8452.

<sup>3</sup> <http://www.dhhs.gov/infoquality/>

<sup>4</sup> <http://www.hhs.gov/infoquality/NIHinfo2.htm>

This petition seeks correction of information disseminated by NHLBI, which directly states and otherwise suggests that reduced sodium consumption will result in lower blood pressure in *all* individuals. Because these statements cannot be reproduced based on publicly-released study data, the statements are not in compliance with the Data Quality Act. The petitioning parties therefore request that NHLBI make additional data from the agency-funded DASH-Sodium study (discussed in detail below) publicly available.

## I. Generally Applicable Law

The Data Quality Act mandates that agencies “ensur[e] and maximiz[e] the quality, objectivity, utility, and integrity” of all disseminated information.<sup>5</sup> Under the act’s statutory language, OMB was required to develop government-wide guidelines and to oversee the creation of agency-specific guidelines within each federal agency. Each agency’s guidelines were required to establish an administrative mechanism allowing affected parties to seek correction of disseminated information that does not comply with *OMB’s* Guidelines.<sup>6</sup> In turn, the OMB Guidelines provide that the administrative mechanism must also allow correction of information that is inconsistent with the disseminating agency’s own guidelines.<sup>7</sup> Accordingly, information disseminated by an agency must be corrected if it is determined to be inconsistent with *either* the OMB Guidelines or the agency specific guidelines. In this particular case, the information is subject to one additional set of agency guidelines, as the Department of Health and Human Services and the National Institutes of Health promulgated separate guidelines.

## II. History and Contents of the DASH-Sodium Study

In recent years, scientists supported and funded by NIH have conducted two studies focusing on the relationship between improved diet quality and blood pressure control. The first clinical study, entitled Dietary Approaches to Stop Hypertension (“DASH”), focused on the blood pressure effects of an eating pattern rich in fruits, vegetables, and low-fat dairy products and reduced in saturated and total fat. Results of the DASH study were published in the *New England Journal of Medicine* (NEJM) on April 17, 1997.<sup>8</sup> As reported, researchers determined that the DASH diet was, by itself, highly effective in reducing blood pressure.

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<sup>5</sup> Section 515(b)(2)(A).

<sup>6</sup> Section 515(b)(2)(B).

<sup>7</sup> OMB Guidelines, §III.3 (67 FR 8452, 8459).

<sup>8</sup> A clinical trial of the effects of dietary patterns on blood pressure. *N Eng J Med* 1997; 336:1117-1124.

The DASH study was followed by the DASH-Sodium Trial, which considered whether sodium restriction had additional benefits beyond those that could be achieved by consuming the DASH diet alone. Results of the DASH-Sodium trial were published in NEJM on January 4, 2001.<sup>9</sup> DASH-Sodium tested three different levels of daily sodium consumption with both a DASH diet and a typical American control diet. The tested sodium levels were 3300 mg/day, 2400 mg/day, and 1500 mg/day. In the January 4, 2001 NEJM article, the authors concluded that the DASH diet “was associated with a significantly lower systolic blood pressure at each sodium level” and that the “reduction of sodium intake to levels below the current recommendation of [2,400 mg] per day and the DASH diet both lower blood pressure substantially....”<sup>10</sup> The publication also stated that the “results should be applicable to most people in the United States.”

Despite these broad statements, the data released by the authors did not address study results specific to subpopulations within the 412 participants, such as race, existing (or lack of existing) hypertension, sex, age, body-mass index, education level, etc. This is true despite the fact that, as the authors note, the study was designed intentionally to allow for such subgroup analyses. It would follow that the data and its presentation should have included the mean blood pressure, the standard deviation, and sample size of each of the relevant subgroups. As part of the peer review and editorial exchange process, NEJM published a letter to the editor in May 2001 in which a member of the Salt Institute’s Medical Advisory Board challenged the authors’ failure to produce the subgroup analysis. The Board member asserted that only through such a presentation of the data might it be determined that the Trial’s purported findings were indeed applicable to most people, including subjects with normal blood pressure.<sup>11</sup> That interpretation of what the DASH-Sodium authors intended to convey to readers was in fact emphasized strongly in an editorial that accompanied the Trial’s initial publication in NEJM.<sup>12</sup> No data, however, were provided by the study’s authors directly in response to this initial request. Instead, the authors referred to an anticipated publication in which the DASH-Sodium authors “wished to assure the readers of *Journal*” that the findings from the subgroup analyses were broadly applicable to all subjects.

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<sup>9</sup> Effects on blood pressure of reduced dietary sodium and the Dietary Approaches to Stop Hypertension (DASH) diet. *N Engl J Med* 2001; 344:3-10.

<sup>10</sup> *N Engl J Med* 2001;344:3.

<sup>11</sup> *N Engl J Med* 2001;344:1716-1717.

<sup>12</sup> *N Engl J Med* 2001;344:54 (“The combined dietary approaches studied in the DASH-Sodium trial were effective even in subgroups that have traditionally been thought not to benefit greatly from a reduction in dietary sodium (younger adults, persons without hypertension, and whites”).

On December 18, 2001, an *Annals of Internal Medicine* article was published that purported to analyze the subgroups of the DASH-Sodium study.<sup>13</sup> However, that analysis is based on a model that eliminates the data from the 2400 mg/day sodium intervention limb of the trial.<sup>14</sup> Instead, the authors “focused our comparisons on the maximum contrasts (higher versus lower sodium intake with the control diet, DASH diet versus control diet at the higher sodium intake, and the combined effect of DASH diet and lower sodium intake versus control diet and higher sodium intake).”<sup>15</sup>

Despite this limitation, the authors concluded that “decreases in blood pressure associated with reduced sodium intake were present in all subgroups and were clinically relevant.”<sup>16</sup> The authors further stated that, because both the DASH diet and sodium reduction interventions “decreased blood pressure in all subgroups studied ... the beneficial effects of the DASH diet and reduction of dietary sodium intake are broadly generalized across groups.” In reiterating these statements, the authors fail to acknowledge and emphasize that even with this modeling of the data, which would serve to increase the likelihood of supporting their statements, blood pressure is not changed in normal subjects under 45 years of age by reducing sodium intake from 3300 mg/day once they are placed on the DASH diet.<sup>17</sup>

As explained below, NHLBI has subsequently disseminated a considerable amount of information that is consistent with the author’s representations quoted above. However, because this highly influential information cannot be reproduced without a release of and access to the all blood pressure data for each of the subgroups at all three levels of sodium intake, including the absent data on the 2400 mg/day level, the agency is in violation of the Data Quality Act.

### **III. A Description of the Information for Which Correction is Sought**

As discussed, the specific information at issue in this petition relates to the effect of sodium intake on human blood pressure.<sup>18</sup> Specifically, NHLBI has disseminated information in which the agency suggests that “all Americans” can experience a reduction in blood pressure by reducing daily sodium intake to no more

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<sup>13</sup> Effects of Diet and Sodium Intake on Blood Pressure: Subgroup Analysis of the DASH-Sodium Trial. *Ann Intern Med* 2001;135:1019-1028.

<sup>14</sup> Currently, NIH recommends that Americans consume less than 2400 mg/day, the level omitted from the subgroup analysis.

<sup>15</sup> *Ann Intern Med* 2001;135:1021.

<sup>16</sup> *Ann Intern Med* 2001;135:1025.

<sup>17</sup> *Ann Intern Med* 2001;135:1025 (Table 4).

<sup>18</sup> The terms “salt” and “sodium” are often used interchangeably. More accurately, salt is sodium chloride, made up of 40% sodium and 60% chloride by weight. However, because human consumption of sodium comes exclusively from salt (i.e., when NHLBI recommends reduced sodium intake, it is necessarily recommending reduced salt intake), we continue to use these terms interchangeably in this petition.

than 100 mmol/day, which equates to approximately 6 grams of sodium chloride or 2.4 grams of sodium per day.

Following the publication of the DASH-Sodium study in January 2001, NHLBI made multiple statements concerning the effect of salt intake on human blood pressure. These statements form the basis of this petition and constitute the specific information being challenged as a violation of the Data Quality Act:

- In an October 15, 2002, News Release, NHLBI stated, *without qualification*, that “limiting daily dietary sodium intake to less than 2,400 mg of sodium (about 1 teaspoon of salt) per day helps lower or control blood pressure.”
- In an October 16, 2002, *Journal of the American Medical Association* article entitled “Primary Prevention of Hypertension” (a product of the National High Blood Pressure Education Program)<sup>19</sup>, various results of the DASH-Sodium study were set forth, with a conclusion that the “findings are consistent with current national recommendations for a moderately low intake of dietary sodium (no more than 100 mmol/d; approximately 6 g of sodium chloride or 2.4 g of sodium per day) by *all* Americans and suggest that an even lower level of dietary sodium intake may result in a greater reduction in blood pressure.”<sup>20</sup> The article also includes a box stating that reducing dietary sodium intake to no more than 100 mmol per day is a proper lifestyle modification for primary prevention of hypertension.<sup>21</sup>
- In a December 17, 2001, News Release, NHLBI stated that the “DASH diet plus reduced dietary sodium lowers blood pressure for *all* persons.” In the release, NHLBI Director Dr. Claude Lenfant stated that “we can say that cutting back on dietary sodium will benefit Americans generally and not just those with high blood pressure.”<sup>22</sup>
- In a document entitled “Facts About the DASH Diet” currently available on NHLBI’s website,<sup>23</sup> the agency states, *without qualification*,

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<sup>19</sup> JAMA 2002; 288:1882-1888 (October 16, 2002).

<sup>20</sup> JAMA 2002; 288:1885 (emphasis added).

<sup>21</sup> Primary prevention specifically implies reduces blood pressure even in those subjects whose blood pressure is normal.

<sup>22</sup> <http://www.nhlbi.nih.gov/new/press/01-12-17.htm> (emphasis added).

<sup>23</sup> [http://www.nhlbi.nih.gov/health/public/heart/hbp/dash/new\\_dash.pdf](http://www.nhlbi.nih.gov/health/public/heart/hbp/dash/new_dash.pdf).

that results of the DASH-Sodium study “showed that reducing dietary sodium lowered blood pressure ... at each sodium level.” The document then provides substantial information designed to allow a person to reduce sodium intake to 2,400 or 1,500 milligrams per day.

- In a document entitled “Facts about Lowering Blood Pressure,” currently available on NHLBI’s website<sup>24</sup>, the agency summarizes the results of the DASH-Sodium trial by stating that “the less sodium consumed, the lower the blood pressure” and that “the effects of sodium reduction were seen in all study participants – those with and without high blood pressure, men and women, and African Americans and others.”
- NHLBI’s *Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure*, which was released on May 14, 2003 and is currently posted on NHLBI’s website<sup>25</sup>, states that adoption “of healthy lifestyles by *all persons* is critical for the prevention of high [blood pressure] and is an indispensable part of the management of those with hyper-tension.” Among the major lifestyle changes recommended to achieve such “healthy lifestyles” is “dietary sodium reduction” to no more than 2400 mg/day.<sup>26</sup> In making this recommendation, NHLBI cites to both the January 2001 NEJM and the December 2001 *Annals of Internal Medicine* publications concerning the DASH-Sodium Study.<sup>27</sup> The report, including the reduced salt recommendation, has received substantial attention in the national press.

Taken both separately and collectively, the cited references, quotes, documents, and studies make a single unqualified representation, i.e., all Americans, regardless of race, lack of existing hypertension, sex, age, body-mass index, education level, etc., can reduce blood pressure by limiting dietary sodium intake to 2,400 milligrams or less per day. As explained below, however, the data that have been released from the DASH-Sodium study are not sufficient to support these statements or this message under the exacting standards of the Data Quality Act.

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<sup>24</sup> [http://www.nhlbi.nih.gov/health/public/heart/hbp/hbp\\_low/hbp\\_low.pdf](http://www.nhlbi.nih.gov/health/public/heart/hbp/hbp_low/hbp_low.pdf).

<sup>25</sup> <http://www.nhlbi.nih.gov/guidelines/hypertension/express.pdf>.

<sup>26</sup> <http://www.nhlbi.nih.gov/guidelines/hypertension/express.pdf> (table 5).

<sup>27</sup> <http://www.nhlbi.nih.gov/guidelines/hypertension/express.pdf> (see footnotes 25 and 26).

#### **IV. The Disseminated Information is Covered by the Data Quality Act**

In order for the Data Quality Act's standards to apply, certain threshold requirements must be met. Specifically, the challenged data must constitute (1) a "dissemination" of (2) "information" that (3) occurred on or after October 1, 2002 (the effective date of the Data Quality Act). In this case, all three requirements are easily attained.

The requirement that can be most quickly disposed of is the mandate that any dissemination occurred on or after October 1, 2002. The first two items (the NHLBI press release and the JAMA article) and the last item (the Joint National Committee report on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure) listed above were all issued for the first time after October 1, 2002. The remaining three items are currently available on the NIH website, and are therefore being continuously disseminated to this day.

The term "dissemination" is broadly defined in the HHS Guidelines as meaning "agency initiated or sponsored distribution of information to the public."<sup>28</sup> This same language defines "dissemination" under the OMB Guidelines.<sup>29</sup> The term "information" is similarly broad, defined by both HHS and OMB to mean "any communication or representation of knowledge such as facts or data, in any medium or form...."<sup>30</sup>

The NIH Guidelines more expansively discuss both information and dissemination, with particular attention to the types of information the agency releases. NIH's Guidelines expressly state that "scientific research papers, books, journal articles, and similar authoritative materials" are covered by the OMB guidelines.<sup>31</sup> The NIH Guidelines also list several other categories of information that, absent exclusions not found here, are subject to the guidelines, including "Scientific Reports"<sup>32</sup>, "Guidelines or Authoritative Health Information"<sup>33</sup>, and "Consumer Information"<sup>34</sup>. NIH also explicitly states that information "disseminated at the request of NIH or with specific NIH approval" is subject to the guidelines.<sup>35</sup> Whereas all of the NIH information cited above falls into one or more of these categories, the cited references constitute "information" that has been "disseminated"

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<sup>28</sup> HHS Guidelines, §D.2.h.

<sup>29</sup> OMB Guidelines, §V.8.

<sup>30</sup> HHS Guidelines, §D.2.e; OMB Guidelines §V.5.

<sup>31</sup> NIH Guidelines, §II.1.

<sup>32</sup> NIH Guidelines, §III.3.

<sup>33</sup> NIH Guidelines, §III.5.

<sup>34</sup> NIH Guidelines, §III.7.

<sup>35</sup> NIH Guidelines, §II.

by the agency and the Data Quality Act and its implementing guidelines therefore apply.

## **V. The Disseminated Information was Subject to Pre-Dissemination Review**

The NIH Guidelines contain extensive provisions concerning internal procedures that are to be followed to accomplish compliance with the Data Quality Act. In terms of scientific research papers, brochures, documents, and similar materials, the procedures are summarized by the guidelines' provision that "[i]n general, any writing by an NIH employee on a work-related subject, whether intended for electronic or print publication, or for oral delivery, must be prepared according to accepted NIH standards of quality, reviewed for substantive content, and administratively approved."<sup>36</sup> This mandate is consistent with the requirement contained in the OMB Guidelines that – for any information that was first disseminated on or after October 1, 2002 – agencies develop and utilize a “process for reviewing the quality ... of information before it is disseminated.”<sup>37</sup>

Because at least some of the enumerated information was first released after October 1, 2002, NIH's pre-dissemination procedures were applicable to such information. However, the petitioning parties do not presently question whether the agency complied with its required internal procedures before disseminating any of the challenged information, as we are not at this time directly challenging the substantive accuracy of the enumerated statements. Rather, this petition addresses the failure on the part of NIH to make publicly available underlying data that would allow affected parties, such as petitioners, to validate whether the agency's statements substantively comply with the Data Quality Act mandate of reproducibility. Although this petition is not based on the agency's pre-dissemination requirements, petitioners raise the issue to demonstrate that following such procedures may have led the agency to correct its violation of the Data Quality Act without petitioners having to resort to the present undertaking.

## **VI. The Enumerated Information Does Not Meet the “Objectivity” Standards of the Data Quality Act**

Under the OMB and HHS Guidelines, the “objectivity” requirement of the Data Quality Act involves two distinct elements: presentation and substance. The disseminated information being challenged by this petition is in violation of both the presentation and substance prongs of the objectivity standard.

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<sup>36</sup> NIH Guidelines, §V.2.a.

<sup>37</sup> OMB Guidelines, §§III.2, III.4.



## **A. Presentation Objectivity**

With regard to the “presentation” aspect of objectivity, the OMB Guidelines require that information be presented in an “accurate, clear, complete, and unbiased manner.” To achieve this mandate, the information must be “presented within a proper context.” The OMB guidelines specifically provide that “[s]ometimes, in disseminating certain types of information to the public, other information must also be disseminated to ensure an accurate, clear, complete, and unbiased presentation.”<sup>38</sup>

The OMB Guidelines further state that, to meet the objectivity standard with regard to presentation, agencies must identify “in a scientific, financial, or statistical context, 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.”<sup>39</sup> In its guidelines, the Department of Health and Human Services adopted OMB’s definition of presentation objectivity.<sup>40</sup>

The information being challenged by this petition, in combination with the lack of publicly available data on the DASH-Sodium study, has resulted in a clear public message being presented by NHLBI, i.e., all individuals can reduce their blood pressure by reducing sodium intake. But, because vital study information is being withheld, the public cannot “assess for itself whether there is some reason to question the objectivity of the sources.” The public cannot, that is, determine whether the agency has accurately stated or reflected the effect, within subgroups that were included in the DASH-Sodium study, of a daily sodium intake of 2,400 mg vis-à-vis a daily intake of 3,500 mg or 1,500 mg.

As the various Data Quality Act guidelines make clear, an agency is not entitled to simply highlight selected information that favors its stated position. With the advent of the Data Quality Act, agencies must “present” all relevant data whenever disseminating information. Here, NIH has failed to do so, withholding from public view the essential subgroup data not simply related to the 2,400 mg/day intake level removed from the Annals analysis<sup>41</sup>, but, as noted above, the mean blood pressures, standard errors and sample sizes for each subgroup at each sodium intervention level. NIH is therefore in violation of this aspect of the Data Quality Act.

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<sup>38</sup> OMB Guidelines, §V.3.a.

<sup>39</sup> OMB Guidelines, §V.3.a.

<sup>40</sup> HHS Guidelines, §D.2.c.

<sup>41</sup> See footnote 13.

## **B. Substantive Objectivity**

Substantive objectivity involves two standards: (1) a basic standard applied to all information disseminated by an agency, and (2) a heightened standard of reproducibility that applies to “influential” scientific, financial, and statistical data. In the case of the widely followed and distributed DASH-Sodium data, both standards were required to have been, but in fact have not been, met by NHLBI.

### **1. Basic Substantive Objectivity Standard**

The substance of all information disseminated by federal agencies must meet a basic standard, defined as a “focus on ensuring accurate, reliable, and unbiased information.” In addition, in scientific and statistical contexts, “the original and supporting data shall be generated, and the analytical results shall be developed, using sound statistical and research methods.”<sup>42</sup>

This basic level of objectivity is generally “presumed” if “data and analytic results have been subjected to formal, independent, external peer review.”<sup>43</sup> In this case, the DASH-Sodium study itself underwent an adequate peer review, and the study therefore can be presumed to meet the basic level of substantive objectivity. However, it is not the outcome of the study that is the subject of this petition – it is the agency’s public representation of that outcome, along with the agency’s failure to release vital data from the study even though, through the “Letters to the Editor” process, the authors were specifically asked to release the data. The authors’ failed to meet that component of the peer review process. This raises the question of whether the agency’s presentation is “accurate, reliable, and unbiased.” There is simply no way to know – absent public release of all subgroup blood pressure data including, but not limited to, the 2400 mg/day intake level – whether NHLBI’s presentation is in fact accurate and free of bias. Accordingly, the agency’s release of the information for which correction is being sought is inconsistent with the agency’s obligations under the Data Quality Act’s basic substantive objectivity standard.

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<sup>42</sup> OMB Guidelines, §V.3.b; HHS Guidelines, §D.2.c.

<sup>43</sup> OMB Guidelines, §V.3.b.i; HHS Guidelines, §D.2.c.i.

## 2. Substantive Objectivity Standard for “Influential” Information

When an agency disseminates “influential” scientific, financial, or statistical information, the OMB Guidelines requires that the agency include “a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties.”<sup>44</sup> More specifically, with “regard to analytic results” relating to influential information, agencies must provide “sufficient transparency about data and methods that an independent reanalysis could be undertaken by a qualified member of the public.”<sup>45</sup>

The term “influential” is defined to mean that an agency “can reasonably determine the dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions.”<sup>46</sup> In the present case, it is clear that NIH has released the data in question for the express purpose of influencing both public policies and private sector decisions. For instance, NHLBI studies can heavily influence the Food and Drug Administration when that agency establishes labeling mandates on businesses. Moreover, NHLBI’s conclusions concerning the DASH-Sodium study have been widely – and favorably – distributed by many others.<sup>47</sup> This information, in turn, affects the dietary decisions of hundreds of millions of individuals.

The NIH Guidelines provide additional insight concerning what constitutes “influential” information in the present circumstances. As an initial matter, NIH states that, to “facilitate the replication of scientific and other influential information by qualified third parties, NIH continues to encourage the sharing of original data and methods where practicable.” The guidelines also mandate that research data “and supporting data that form the basis of any research communication should be made available promptly and completely to members of the public who seek further

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<sup>44</sup> OMB Guidelines, §V.3.b.ii; HHS Guidelines, §D.2.c.ii.

<sup>45</sup> OMB Guidelines, §V.3.b.ii.B; HHS Guidelines, §D.2.c.ii.

<sup>46</sup> OMB Guidelines, §V.9; HHS Guidelines, §D.2.i.

<sup>47</sup> See, e.g., <http://www.nyhwriter.com/SALTSALTSALT.htm>;  
<http://www.sciam.com/article.cfm?articleID=000ED49B-AC42-1C59-B882809EC588ED9E>;  
<http://nutrition.about.com/library/weekly/aa010401a.htm>; <http://www.mfitnutrition.com/eatingforbetterhealth-newsletters-detail.asp?newsletterID=8>; [www.americanheart.org](http://www.americanheart.org).

information.”<sup>48</sup> More centrally, the NIH Guidelines provide that the types of agency data that may be considered influential within the scope of the OMB Guidelines include NIH research reports and NIH recommendations about health practice.<sup>49</sup>

Therefore, based on NIH’s guidelines, it is essentially beyond debate that NHLBI’s statements and other disseminated information concerning DASH-Sodium and the effect of sodium intake on blood pressure are “influential” under the OMB and HHS Guidelines. The agency is, accordingly, obligated to meet the reproducibility/transparency requirement for such information. It has not.

The OMB and HHS information quality guidelines define “reproducibility” to mean that “information is capable of being substantially reproduced, subject to an acceptable degree of imprecision.”<sup>50</sup> As cited above, the guidelines anticipate agencies meeting this requirement by making data and methods publicly available.<sup>51</sup>

The DASH-Sodium findings as reported by NHLBI are neither transparent nor reproducible in the absence of subgroup data relating to the 2,400 mg/day level of sodium intake. In support of this statement, petitioners have attached an opinion letter from Dr. John H. Laragh, one of the nation’s foremost experts on hypertension. As explained in the letter, Dr. Laragh was a founder and was the first president of the American Society of Hypertension, and is a past-president of the International Society of Hypertension. Moreover, Dr. Laragh is currently editor-in-chief of the American Journal of Hypertension. Dr. Laragh summarizes his opinion as follows:

“In neither of the publications of the DASH-Sodium Trial was I able to identify a complete and objective presentation of the data that

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<sup>48</sup> NIH Guidelines, §VII.

<sup>49</sup> NIH Guidelines, §VII.

<sup>50</sup> OMB Guidelines, §V.10; HHS Guidelines, §D.2.i.

<sup>51</sup> The OMB and HHS Guidelines also provide that, where data and methods cannot be made public because of other compelling interests, agencies must apply “especially rigorous robustness checks.” In this case, there do not appear to be such “other compelling interests,” given that the data relating to sodium intake levels other than 2,400 mg/day has already been released.

would allow an appropriate independent expert or entity to determine the validity of NHLBI's interpretation. Specifically only a full presentation of the mean blood pressures, their [standard deviations] and sample size for each of the subgroups that NHLBI stated in the NEJM paper the study was 'powered' to test for, would suffice to confirm independently the validity of their public statements.... [O]nly a complete table of the blood pressures on the various combinations of the DASH Diet and dietary sodium level will allow interested parties to determine independently the validity of NHLBI's public posture on this important policy issue."

Dr. Laragh's inability to "reproduce" NHLBI's interpretation of the DASH-Sodium data should be determinative of this issue. His call for the release of all study data is also consistent with further provisions of NIH's guidelines:

"It is NIH policy to make available to the public the results and accomplishments derived from the activities that it funds. Therefore, NIH-funded intramural and extramural investigators are expected to make the results and accomplishments of their activities available to the research community and to the public at large, and to effect their timely transfer to industry for commercialization."<sup>52</sup>

Elsewhere, the NIH Guidelines similarly provide:

"NIH recognizes the scientific need for replication of findings, and encourages data sharing as appropriate. After publication, the research data, any unique reagents, and any supporting data that form the basis of the communication in question should be made

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<sup>52</sup> NIH Guidelines, §I.

available promptly and completely to all responsible scientists seeking further information.”<sup>53</sup>

NHLBI’s failure to make the 2400 mg/day data available has prevented qualified third parties from determining whether NHLBI’s conclusions are reproducible. As such, the agency is not in compliance with the Data Quality Act and its implementing guidelines, and the enumerated statements must be corrected.

## **VI. The Petitioners are “Affected Parties”**

In order to seek correction of agency information that is in violation of the Data Quality Act, a petitioner must be an “affected party.” The HHS and NIH Guidelines do not define the term “affected party,” but instead rely upon the petitioner to describe how it is affected by the information error.<sup>54</sup>

As described, the Salt Institute is an association of salt producers, consisting of member companies that both produce and market sodium chloride. These companies are, on a bottom line basis, directly affected by changes in the public’s use of salt and salted products. The public’s use of salt and salted products is, in turn, heavily influenced by scientific findings of the federal government, including NHLBI and NIH.

The U.S. Chamber is the world’s largest business federation, whose membership includes a substantial number of companies that use and/or market salt and salt products, including food manufacturers, grocers, restaurants, salt mining companies, and the Salt Institute itself. The Chamber’s member firms therefore constitute those who are both directly and indirectly affected by NHLBI’s information concerning the relationship between sodium and blood pressure.

## **VII. Proposed Corrective Action**

NIH’s Guidelines request that petitioning parties recommend corrective action concerning agency information that is not in compliance with the Data Quality Act. The petitioners’ proposed solution in this matter, at least initially, is quite simple. Petitioners recommend that NHLBI make publicly available all DASH-Sodium blood pressure data for each subgroup relating to those participants at each of the three levels of dietary sodium intake, including the missing the 2,400 mg/day intake level,

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<sup>53</sup> NIH Guidelines, §V.1.

<sup>54</sup> NIH Guidelines, §VI.1.

on both the control diet and DASH diet. This data should include, but not necessarily be limited to, mean blood pressures, their standard deviations, and sample size for each of the subgroups. Publicly available data relating to the 2,400 mg/day intake level should be, at a minimum, consistent with the information previously released in relation to the higher and lower sodium intake levels. A simple table for each subgroup comparing the blood pressures on the control diet versus the DASH Diet at each of the three levels of dietary sodium would likely address the petitioners initial concerns.

Because this petition is based solely on the agency's failure to make study data publicly available, petitioners do not at this time request or recommend that the challenged information be removed from public view. However, should petitioners determine, upon review of the complete subgroup blood pressure data, that NHLBI's interpretations still cannot be reproduced, petitioners reserve the right to pursue additional Data Quality Act challenges. These challenges could include a request to remove the information from agency websites and other public domains.

#### **VIII. Contact Information**

The following individuals serve as contact points for the petitioners for all purposes related to this petition:

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The U.S. Chamber and the Salt Institute consider compliance with the Data Quality Act to be a foremost responsibility of federal agencies and a chief manner in which agencies can improve the quality of regulations and other information. We therefore appreciate the opportunity to file this petition and thank NHLBI for its consideration of our proposed corrective action.

Sincerely,



William L. Kovacs  
U.S. Chamber of Commerce



Richard L. Hanneman  
Salt Institute