

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF VIRGINIA

SALT INSTITUTE and the CHAMBER OF
COMMERCE OF THE UNITED STATES OF
AMERICA

Plaintiffs,

v.

TOMMY G. THOMPSON, Secretary, U.S.
Department of Health and Human Services,
Defendant

Case No.

Judge:

lat...
2004-01-20-16
04cv359 *gj*

COMPLAINT

Introduction

1. The National Heart, Lung, and Blood Institute (“NHLBI”), an agency of the Department of Health and Human Services (“HHS”), has wrongfully withheld important and readily available scientific information from the public and interested researchers, inappropriately used incomplete and potentially unsound scientific data, and disseminated inaccurate influential health risk information in violation of controlling legal standards and good scientific practice. These actions violate the Information Quality Act (the “IQA”), Section 515 of Public Law 106-554, 44 U.S.C. § 3516, note; the information quality guidelines issued by the Office of Management and Budget (“OMB”), HHS, and the National Institutes of Health (“NIH”); and Public Law 105-277 (the “Shelby Amendment”), which guarantees public access to all federally-funded research data.

2. This is an action for declaratory and injunctive relief.

3. Plaintiffs request this Court review and invalidate NHLBI's ongoing violations of the IQA, and order Defendant to: (a) comply with all applicable information quality principles, including those mandated by Congress for risk information under the Safe Drinking Water Act, 42 U.S.C. 300g-1(b)(3)(A),(B), (b) disclose the scientific data previously requested by the Plaintiffs, including mean blood pressures, standard deviations, and sample sizes of the relevant subgroups, in a useful form, and (c) correct the wrongfully disseminated influential information, as more particularly set forth below.

4. In the alternative, Plaintiffs ask this Court to review and invalidate the restrictions placed by Defendant on their right of access to federally-funded data in excess of the Shelby Amendment. Plaintiffs also seek a declaration of their right to data access as Congress has mandated.

Jurisdiction and Venue

5. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. § 1331. It has authority to grant the relief requested under 5 U.S.C. §§ 701 - 706, and under 28 U.S.C. §§ 2201 and 2202.

6. Venue is proper under 28 U.S.C. § 1391(e). Salt Institute is principally located in this District, and no real property is involved in this action.

The Parties

7. Salt Institute (the "Institute") is a non-profit association of companies, founded in 1914, that produce and market salt for food and other uses. It is incorporated in Illinois, and maintains its principal place of business in Alexandria, Virginia. It engages in a number of activities for the benefit of its members, including public policy education and advocacy, engineering and medical research, field studies, and laboratory

investigations on salt use. This research has included investigations into the genetic and nutritional factors that contribute to human hypertension (high blood pressure) and identification of a simple and inexpensive test to identify “salt-sensitive” individuals who might benefit from low-salt therapeutic diets. The Institute and its members are adversely affected or aggrieved by NHLBI’s final agency action. The Institute’s net worth is less than \$7 million.

8. The Chamber of Commerce of the United States of America (the “U.S. Chamber”) is the world’s largest business federation with an underlying membership of approximately three million businesses from across the United States, nearly 3,000 state and local chambers, 830 associations, and over 90 American Chambers of Commerce abroad. The U.S. Chamber is incorporated and maintains its principal place of business in the District of Columbia. Its members include companies that use, market, and/or sell food products containing salt. The U.S. Chamber and certain of its members are adversely affected or aggrieved by NHLBI’s final agency action.

9. Salt Institute and U.S. Chamber members include companies that manufacture or sell salt for use in food, or that market and sell food containing salt. These companies have standing to sue in their own right, for they have suffered actual or threatened injury due to the Defendant’s conduct. This injury, however, is likely to be redressed by a favorable decision in this case. Furthermore, the interests Plaintiffs seek to protect are germane to their organizational purpose, and neither the claims asserted, nor the relief requested, requires the individual participation of these companies in this action.

10. Tommy G. Thompson is the Secretary of Health and Human Services, a Department within the Executive Branch of the federal government. Secretary Thompson is charged with overseeing HHS, NHLBI and NIH, and for funding scientific studies, including the DASH-Sodium Trial (the “Sodium Trial”) that is at issue in this case. He is sued in his official capacity.

Facts

Background

11. There is only a limited amount of published data on the relationship between salt intake and human health outcomes, or “hard endpoints,” such as heart attacks, strokes, and other cardiovascular events. This data suggests a diet with too little salt does not improve human health, and may in fact increase the risk of dangerous cardiovascular and other ailments. Otherwise healthy persons over the age of 65, who follow generalized government exhortations to reduce salt intake, in fact appear to face an increased risk of suffering health ailments associated with salt deficiency.

12. In October 2002, NHLBI began disseminating articles, press releases, and website postings that advised *all* Americans, including persons with healthy diets and normal blood pressure, to severely restrict salt intake to avoid the risk of high blood pressure. Plaintiffs believe this directive was based in large part on two scientific publications that selectively reported data from the government-funded Sodium Trial, resulting in inaccurate and misleading data interpretation. NHLBI, however, has refused to make available full, accurate, useful, and transparent documentation of the Sodium Trial data, much less identify all of the scientific studies it relied upon in issuing its important health risk claim.

13. Because key data are being withheld in violation of the law, Plaintiffs are unable to undertake an independent reanalysis of the science, and cannot test or verify NHLBI's risk claims. Verification and testing is particularly important in this case because the limited amount of scientifically sound Sodium Trial data that is in the public realm suggests, that for most Americans, normal consumption of dietary salt in a healthy diet has no statistically verifiable adverse effect on blood pressure levels. In other words, it seems NHLBI's claim that all persons should limit salt intake regardless of their pre-existing cardiovascular risk is unsupported by sound science, the product of a statistically invalid interpolation of clinical data, and, quite simply, wrong.

14. Additional scientific investigation into this important issue has been materially impaired due to NHLBI's refusal to provide data access and disclose the relevant information in accordance with applicable information quality requirements.

The DASH Study And Sodium Trial

15. High blood pressure increases the risk of heart disease and stroke, and may cause heart failure, kidney disease, and blindness.

16. For over thirty years, the Defendants have considered high blood pressure a major public health problem.

17. In 1997, researchers supported and funded by the Defendants published a clinical study (the Dietary Approaches to Stop Hypertension or "DASH Study") in the New England Journal of Medicine ("NEJM") suggesting that a diet rich in fruits, vegetables, low-fat dairy products, coupled with reduced saturated and total fat intake, could reduce blood pressure (the "DASH Diet"). The DASH Diet did not severely restrict dietary salt intake.

18. The DASH Study was followed in 2000 by the Sodium Trial, which involved a total of 412 participants. The Sodium Trial was designed to determine whether modifying the DASH Diet by severely restricting dietary salt intake would further reduce blood pressure.

19. In a January 4, 2001 NEJM article, the Sodium Trial's investigators claimed that the data derived from the 412 participants, some of whom ingested 3,300 milligrams of salt per day, some of whom ingested 2,400 milligrams of salt per day, and some of whom ingested 1,500 milligrams of salt per day, demonstrated that limiting salt intake to below-normal levels would reduce the blood pressure of "most people in the United States."

Flaws In The Disclosed Data

20. The study cohort reported in the NEJM article, however, appeared to be greatly skewed toward persons with salt sensitivity, and was not a representative sample of adult Americans. Furthermore, the investigators failed to provide specific data on the different population subgroups needed to support an independent reanalysis and confirmation of the critical finding that all Americans, without exception, should reduce salt intake. Among other things, the investigators should have, but did not, report the race, existing hypertension status, sex, age, and body-mass index values of each person in the study.

21. Additionally, the mean blood pressure, standard deviation, and sample size data for each relevant subgroup for which the study was powered in advance of the Sodium Trial should have been usefully reported at each level of sodium intake on both the control diet and the DASH Diet.

22. As part of the peer review and editorial exchange process, the NEJM published letters challenging the failure to provide subgroup data needed to verify the authors' claims, noting that from a clinical application standpoint the effect of salt restriction on blood pressure was limited to black women with hypertension, and making the point that studies had shown an inverse relation between salt intake and cardiovascular morbidity. Thus, NHLBI was on notice that the Sodium Trial was methodologically suspect no later than May 31, 2001.

23. In response to the concerns expressed about the quality of the NEJM article's conclusion, the Sodium Trial investigators assured NEJM readers that a full exposition of the relevant data would be forthcoming. Yet, to this day, these data have never been reported in full by the NEJM article's authors, for the appropriate subgroups.

24. On December 18, 2001, an *Annals of Internal Medicine* ("Annals") article was published by the Sodium Trial investigators purporting to present the subgroup data needed to determine whether the claims made in the NEJM article were based on sound science.

25. In this article, however, the Sodium Trial investigators breached accepted scientific methodological norms by dropping the middle data set from the analysis, arbitrarily assuming a linear relationship, and then "modeling" accordingly. Without the middle data set, which to this day has yet to be reported in a useable form, qualified members of the public could neither reproduce the investigators' results, nor test their conclusions.

26. Good science required the Sodium Trial's reported results be supported by a properly controlled multivariate statistical analysis for each subgroup studied.

Although the Sodium Trial was purportedly designed to allow for subgroup analysis by age, ethnicity, gender, and preexisting blood pressure category, the data needed to determine statistical significance – means, standard deviations, and sample size – were not, and have not been, reported in useful form.

27. Finally, Table 4 of the Annals article, in which an appropriate multivariate analysis *was* used, demonstrated that the DASH Diet actually eliminated sodium's effect on blood pressure in all but hypertensive individuals over 45 years of age. In other words, the verifiable data showed that in most cases, it was the overall quality of a person's diet, and not the amount of dietary salt consumed, that determined blood pressure levels.

28. Nevertheless, the Annals article authors concluded that “decreases in blood pressure associated with reduced sodium intake were present in all subgroups and were clinically relevant,” and that “the beneficial effects...of the reduction of dietary sodium intake are broadly generalized across groups.”

Dissemination Of Unsound Science

29. Ignoring both the methodological flaws and the unverifiable claims made in the NEJM and Annals articles, NHLBI disseminated influential information, as defined in the IQA Guidelines, concerning the human health effects of dietary salt. This information included:

- (a) An October 15, 2002, NHLBI News Release stating 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”.

(b) An October 16, 2002, NEJM article entitled “Primary Prevention of Hypertension (a product of the National High Blood Pressure Education Program),” stating that the DASH Sodium Trial findings “are consistent with current national recommendations for a moderately low intake of dietary sodium...by *all* Americans and suggest that an even lower level of dietary sodium intake may result in a greater reduction in blood pressure.” (emphasis added) This article also includes a box stating that reducing dietary sodium intake to no more than 1,000 milligrams per day is a proper lifestyle modification for “primary prevention” of hypertension. “Primary prevention” specifically implies reduction in blood pressure even in those subjects whose blood pressure is normal.

(c) A December 17, 2001, NHLBI News Release stated “reduced dietary sodium lowers blood pressure for *all* persons.” (emphasis added) In this document, 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.”

(d) A document titled “Facts About the DASH Diet” currently available on NHLBI’s website, states, without qualification, that the results of the Sodium Trial “showed that reducing dietary sodium lowered blood pressure ... at each sodium level.”

(e) A document titled “Facts about Lowering Blood Pressure,” currently available on NHLBI’s website, states “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.”

(f) 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, recommends that *everyone* limit “dietary sodium” to no more than 2,400 milligrams per day. In making this recommendation, NHLBI cited both the January 2001 NEJM and the December 2001 Annals articles.

30. The disseminated influential information, including the cited references, quotes, documents, and studies, stand for a single unqualified representation: *all* Americans can and should reduce blood pressure by limiting dietary sodium intake to 2,400 milligrams or less per day.

31. NHLBI disseminated this influential human health risk information with the expectation this information would have a clear and substantial impact on important public health policy, and on important private sector decisions, by consumers and others.

32. The dissemination of this information violated the IQA in that:

(a) The disseminated information was not comprehensive, nor objective, nor useful, as required by the IQA, HHS Guidelines §4 and OMB Guidelines § V.

(b) NHLBI refused to make available or apparently consider data showing the specific populations addressed in the Sodium Trial, the expected risk or central estimate of risk for each, the appropriate upper or lower bound estimate of risk, all significant uncertainties, peer reviewed studies regarding the claimed

effect, and the methodologies used to reconcile inconsistencies in the scientific data as required by the IQA, HHS Guidelines §4(g) and OMB Guidelines §V(3)(b)(ii)(C).

(c) NHLBI refused to make available the information necessary for the public to determine whether the peer review of the Sodium Trial met the general criteria for competent and credible peer review as recommended by OMB to the President's Management Council (9/20/01), as required by the IQA, HHS Guidelines §D(2)(c)(1) and OMB Guidelines §V(3)(b)(i).

(d) NHLBI refused to make available in a scientifically valid and useful form the data and methods necessary for a reanalysis to be undertaken by a qualified third party as required by the IQA, HHS Guidelines §D(2)(c)(2) and OMB Guidelines §V(3)(b)(ii).

(e) NHLBI refused to make available full, accurate, useful, and transparent documentation regarding the data supporting the disseminated information as required by the IQA, HHS Guidelines §D(2)(c) and OMB Guidelines §V(3)(a).

(f) Although NHLBI apparently relied on certain studies in addition to the Sodium Trial in developing the health risk directive and disseminating the information, it has refused to identify those studies, or sufficient transparency about the data obtained and methods used to allow for independent reanalysis, as required by the IQA, HHS Guidelines §D(2)(c)(2) and OMB Guidelines §V(3)(b)(ii).

(g) NHLBI refused to identify and disclose error sources affecting the Sodium Trial data quality to the public as required by the IQA, HHS Guidelines §D(2)(c) and OMB Guidelines §V(3)(b).

(h) NHLBI disseminated information that was based on data that was not generated or developed using sound statistical methods as required by HHS Guidelines Section D(2)(c) and OMB Guidelines Section V(3)(b).

Plaintiffs Seek Relief

33. On May 14, 2003, Plaintiffs filed an IQA petition, seeking data disclosure and information correction, as appropriate. (Exhibit 1.) Plaintiffs requested disclosure of the mean blood pressures, standard deviations, and sample sizes of the relevant subgroups on each of the three levels of sodium intake for both the control and the DASH Diet. Upon information and belief, these data were readily available in useful form at all times relevant.

34. Instead of producing the limited information requested, NHLBI denied Plaintiffs' petition by letter dated August 19, 2003. (Exhibit 2.) Petition page 2 stated: "This petition seeks correction of information disseminated by NHLBI". However, in its denial, NHLBI mistakenly asserted "Rather than asking (NHLBI) to change or remove the challenged information, you have asked only that the agency produce copies of underlying data," and then claimed that because Plaintiffs sought access to data produced in grant-funded research, the Freedom of Information Act and OMB Circular A-110, not IQA, controlled.

35. NHLBI then proceeded to deny Plaintiffs' IQA request for a variety of reasons. Among other things, NHLBI claimed the disseminated information was not

influential, and argued that external peer review was enough, without more, for IQA compliance. NHLBI then stated its claim that all Americans would benefit from sodium reduction was not based solely on the Sodium Trial, but rather on the “totality of the scientific evidence.” Prior to this time, NHLBI had specifically cited solely the Sodium Trial as scientific support. In violation of the IQA, it never identified the studies or cited the data it believed constituted the allegedly supportive “totality of the scientific evidence.”

36. On September 3, 2003, NHLBI advised Plaintiffs that it was, sua sponte, treating the IQA petition as a request for Freedom of Information Act disclosure. It then denied that request on the grounds that NHLBI did not have the requested data, and advised that it would not forward a request for access to third-party investigators unless the request concerned access to data that were first produced under a new or competing grant after April 17, 2000, and that were “Cited publicly and officially by the Federal Government in support of an agency action that has the force of law.” (Exhibit 3.)

37. Plaintiffs timely appealed NHLBI’s IQA denial on September 22, 2003. (Exhibit 4.)

38. In January 2004, NHLBI listed the Sodium Trial on NHLBI’s “Limited Access Data Set” (the “LADS”) website. The LADS website provides researchers with limited, and tightly controlled, access to raw data sets. Upon information and belief, NHLBI placed the raw data in LADS, in whole or in part, to frustrate Plaintiffs’ efforts to test, in a reasonable time and at reasonable cost, the scientific validity of NHLBI’s risk claim that all Americans should reduce sodium intake. This action by NHLBI violated the IQA’s transparency, utility, and objectivity requirements.

39. NHLBI denied Plaintiffs' appeal on or about February 11, 2004. (Exhibit 5.)

Causes of Action

COUNT I: VIOLATIONS OF THE ADMINISTRATIVE PROCEDURE ACT - IQA
(5 U.S.C. §§ 702, 704, 706)

40. Plaintiffs repeat paragraphs 1-39.,

41. The IQA, codified as part of the Paperwork Reduction Act, requires each federal agency to issue guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of the information (including scientific and statistical information) it disseminates, and to establish an administrative mechanism to allow interested persons to seek and obtain correction of disseminated information that does not meet quality standards.

42. The IQA was enacted to ensure that studies which form the basis of government information, policies and action are even-handed, free of bias, and reliable, that government conclusions based on these studies are objective and supported by scientifically sound data, and that the public has meaningful access to the data and methodological information needed to test and reproduce the government's results.

43. The IQA stands for the principle that the quality of government-disseminated scientific information is a direct function of the information's objectivity and reproducibility. The law also recognizes that the public's capacity to test the objectivity and reproducibility of government information depends entirely upon the quality of an agency's scientific data and research methods disclosure. Without scientifically sound disclosure, government information cannot be tested.

44. The IQA encourages sound government decision-making, and promotes scientific discourse by deterring agencies from relying on flawed studies, drawing scientifically unwarranted conclusions, and disseminating inaccurate information.

45. The NHLBI disseminated influential information.

46. Due to the NHLBI's failure to comply with the IQA in the dissemination of this influential information, and to its wrongful denial of Plaintiffs' petition and appeal, Plaintiffs have suffered legal wrong and are adversely affected and aggrieved by final agency action for which there is no other adequate remedy at law, within the meaning of 5 U.S.C. §§ 702, 704.

47. NHLBI's wrongful agency action includes:

- (a) Disseminating influential information in violation of the IQA.
- (b) Denying Plaintiffs' petition and appeal for production of scientific data.
- (c) Failing to meet IQA objectivity requirements.
- (d) Failing to meet IQA utility requirements.
- (e) Failing to meet IQA transparency requirements.
- (f) Failing to disclose all of the studies and data NHLBI relied upon in disseminating the challenged information.
- (g) Failing to make available sufficient data from the Sodium Trial for the public to evaluate the sufficiency of the peer review.
- (h) Failing to comply with the information quality requirements mandated by Congress with regard to the Safe Drinking Water Act.
- (i) Denying Plaintiffs' petition and appeal for disclosure and correction.

48. Defendant's actions, as set forth in this Complaint are arbitrary and capricious, an abuse of discretion, in excess of statutory authority, and without observance of the procedure required by law.

49. The challenged agency action should be declared unlawful, and set aside.

COUNT II: VIOLATION OF THE IQA (44 U.S.C. § 3516, NOTE)

50. Plaintiffs repeat paragraphs 1-49.

51. NHLBI disseminated influential information in violation of applicable information quality requirements.

52. Plaintiffs requested disclosure of necessary data to undertake an independent reanalysis of the disseminated information, and for correction thereof, as appropriate.

53. NHLBI wrongfully denied Plaintiffs' petition and appeal, withheld the useful data necessary to test the scientific validity of the disseminated information, violated applicable information quality requirements, and refused to correct the challenged information, all in violation of the IQA.

54. NHLBI's actions, as set forth herein, should be declared unlawful. Additionally, Defendant should be ordered to disclose the information requested by Plaintiffs, and correct the challenged disseminated information, in accordance with the IQA.

COUNT III: VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT - SHELBY AMENDMENT (5 U.S.C. §§ 702, 704, 706)

55. Plaintiffs repeat paragraphs 1-54.

56. The Sodium Trial was funded by HHS, NIH, and/or NHLBI.

57. The scientific data developed through the Sodium Trial, and with government funding, was retained by the government-funded third-party investigators.

58. Congress intended, and through the Shelby Amendment, specifically directed, that the public be given access to *all* data generated by federally-funded studies, even when the data was retained by a third-party investigator. Defendant, in excess of his statutory discretion and contrary to law, instead restricted public access only to data from new studies funded after April 17, 2000 that was cited publicly and officially in support of an agency action with the force of law.

59. Therefore, NHLBI did not make available to Plaintiffs or the public a procedure through which the Sodium Trial data, or other similar data, could be obtained through the Freedom of Information Act.

60. Defendant thus violated the Shelby Amendment's plain language directing federal agencies to "ensure *all* data produced under an award (of funds) be made available to the public through the procedures established under the Freedom of Information Act."

61. Plaintiffs are adversely affected and aggrieved by this final agency action, and have no other adequate remedy at law.

Relief Requested

WHEREFORE Plaintiffs request this Court:

- A. Assume jurisdiction of this case.
- B. Declare Defendant has violated the IQA.
- C. Order Defendant to comply with the IQA, and to produce, in a useable and scientifically valid form, the mean blood pressures, standard deviations, and sample sizes

of the requested subgroups on each of the three levels of sodium intake for both the control and the DASH Diet.

D. Order Defendant to comply with all IQA requirements prior to disseminating any additional information pertaining to dietary salt.

E. Order Defendant to develop and make available procedures under the Shelby Amendment through which the public may be able to obtain *all* data funded by the Agencies, and through which Plaintiffs may request and obtain the Sodium Trial data.

F. Award Salt Institute its attorney fees and other expenses under the Equal Access to Justice Act, 28 U.S.C. §2412, and both Plaintiffs their costs, as authorized by 28 U.S.C. § 1920, as appropriate.

G. Grant such other and further relief as the Court deems just.

Respectfully submitted,
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