

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. 04-CV-359 GBL

DECLARATION
OF DAVID MCCARRON, M.D.

This is my Declaration:

1. I am a Visiting Professor in The Department of Nutrition of the University of California at Davis and President of Academic Network, a healthcare communication and consulting firm in Portland, Oregon. From 1977-2002 I was a tenured Professor of Medicine at the Oregon Health Sciences University and the Head of its Division of Nephrology for the last 17 years of my tenure. In both my current academic capacity and previous one I have had primary responsibility for research projects that have spanned large scale human clinical trials and basic research investigations. This research career has had as its focus nutritional factors related to hypertensive cardiovascular disease. I have been the recipient of over \$30,000,000 of research funding over the past 25 years. I have received grants form the National Heart Lung Blood Institute (NHLBI), National Institute of Digestive, Diabetes and Kidney Disease (NIDDK), National Institute of Child Health and Human Development (NICHD), US Department of Agriculture

(USDA), National Aeronautical and Space Administration (NASA), American Heart Association and the National Kidney Foundation. In my capacity as a lead scientist on these grants I had responsibility for the submission of the original grants, the proper design of the planned studies to insure statistical power to test the hypothesis in question, the execution of the research, the direction of statistical staff to analyze data from the experiments and for being the primary author on the vast majority of the publications that ensued from this research. I have published over 250 original articles, editorials, reviews and book chapters, as well as over 500 abstracts submitted to scientific societies. Among my research initiatives is the largest set of human nutrition trials ever undertaken and reported in the medical literature that explored the effects of a comprehensive diet on risk factors for hypertensive cardiovascular disease. During that time period I have also served as a grant reviewer for the National Institutes of Health, USDA, the National Kidney Foundation, and the American Heart Association. I have been a frequent reviewer for over 20 different international biomedical research journals during the past 25 years. I have been an invited lecturer to over 100 medical institutions in 20 countries speaking principally on the effects of minerals including sodium and calcium on blood pressure control. I recently was selected as the recipient of the 2004 International Award in Modern Nutrition by a Swiss Foundation.

2. I received my undergraduate degree from Williams College with Highest Honors in Chemistry, Cum Laude and Phi Beta Kappa. I earned my M.D. from the

University of Pennsylvania. I completed my internal medicine training at Case – Western Reserve University Hospitals. I completed subspecialty training in Nephrology at Tufts – New England Medical Center where I was also chosen as the Chief Resident in Medicine. I am Board Certified in Internal Medicine and Nephrology, a Fellow of the American College of Physicians, a Fellow of the Council for High Blood Pressure Research of the American Heart Association and a Founding Member of the American Society of Hypertension.

3. In 1984 in the journal *Science*, I was the senior author on the paper that first described what has become known as the DASH Diet. I was a consultant to the Kaiser Center for Health Research in Portland, Oregon which was responsible for the development, execution and analysis of the first DASH Trial. The Editors of *Science* requested and published an editorial based upon the first DASH Trial results. The Editors of the American Journal of Hypertension requested and published two editorials by me on the data presentation and analysis of the DASH-Sodium Trial in 2003.

4. I have read the Plaintiffs earlier petitions to NHLBI as well as the recent complaint filed in federal court. I am familiar with the details of their request that NHLBI “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” used in the DASH Sodium Trial. Furthermore I understand the Plaintiffs

requested: “This data should include, but not necessarily be limited to, mean blood pressures, their standard deviations, and sample size for each of the subgroups ... A simple table for each subgroup comparing the blood pressure on the control diet versus the DASH Diet at each of the three levels of dietary sodium would likely address the petitioners initial concerns.”

5. I have reviewed the article by Bray *et al.* published in the July 15th, 2004 issue of the American J. of Cardiology entitled “Further Subgroup Analysis of the Effects of the DASH Diet and Three Dietary Sodium Levels on Blood Pressure: Results of the DASH-Sodium Trial.” (“Bray Paper”)

6. I have reviewed the affidavit of Nancy L. Geller, Ph.D., Director of the Biostatistics Research in the Division of Epidemiology and Clinical Applications of the NHLBI at the National Institutes of Health. In her affidavit she states that Table 2 “gives the *change* in both systolic and diastolic blood pressure for specific subgroups, defined by a single characteristic, across the three levels of dietary sodium intake....” Table 3 she states “gives *changes* in systolic and diastolic blood pressure, defined by two characteristics...”

For Table 2, she emphasizes these *changes* are provided for 10 subgroups defined according... Sample size is also included.” For a Table 3 she states “16 subgroups are defined Subgroups are also further broken down by age.”

7. Nowhere in her Affidavit does Dr. Geller acknowledge that the *mean and standard deviations* of the systolic and diastolic blood pressure for the three levels of dietary sodium for the subjects on the control and the DASH diet were not provided. This is the precise data which Dr. Geller noted were requested by the Plaintiffs.

8. My review of the Bray Paper unequivocally reveals that the data requested by the Plaintiffs is not provided by that Paper. Further my review of the Paper indicates that Dr. Geller's statement "It appears to me that the data Plaintiffs requested, and more, is available in the Subgroup Analysis Paper," is not substantiated by the data presented and thus is incorrect and inaccurate. That conclusion actually is supported by Dr. Geller's specific comment that "*changes*" in blood pressure are included, but she never references the presence of the "mean blood pressure" except at baseline (Bray, Table 1) which in no ways fulfills the requirement of the Plaintiffs request as noted above.

9. The authors of the Bray Paper acknowledge a critical limitation of the "change" in blood pressure data in Tables 2 and 3, the tables noted by Dr. Geller in her affidavit. The authors describe the "change in blood pressure" data as an "estimate" derived from a "statistical model" of the DASH Sodium data. The Bray authors provide no information on the "model" used to generate these "estimates" of the changes in blood pressure. Nowhere in her statement, does Dr. Geller acknowledge that the presentation of the data by the Bray Paper authors is

an “estimate” of the blood pressure effect of sodium on either the control or DASH diet rather than the actual measures of the mean blood pressures and their standard deviations as requested by the Plaintiffs. Further my reading of the Bray Paper in conjunction with the previous publications of the DASH-Sodium investigators indicates the authors have consistently employed this unusual presentation format of the data. This data presentation is not consistent with the FDA standard for data presentation from either a public or private entity seeking FDA approval for a consumer focused health claim.

10. Dr. Geller’s statement is not only incorrect, but also is misleading given the fundamental difference between the appropriate “mean blood pressure” as Plaintiffs requested and the irrelevant “changes in blood pressure” the Paper actually provides. These are not subtle or semantic differences in interpretation, but a gross difference that a statistician at the NIH should acknowledge.

11. Dr. Geller’s affidavit statements that the requested data could not be derived from the databases available to NHLBI is clearly wrong. In order for Dr. Geller’s colleagues at NHLBI, who are authors on the Bray Paper, to have signed the required disclosure statement of the American J. of Cardiology they must have had available to them the means and standard deviations requested from which they derived the “*changes*” in blood pressure reported in the Paper.

12. It is my unequivocal opinion that the Bray Paper fails completely in providing the Plaintiffs requested data in a useable form. Furthermore the Bray Paper and Dr. Geller's statements, in my opinion, overlook appropriate statistical standards for publishing basic data from either a federally or privately funded human study.

I declare, under penalty of perjury, that the foregoing is true and correct.

Executed on: August 19, 2004


DAVID MCCARRON, M.D.

CERTIFICATE OF SERVICE

I hereby certify that on August 27, 2004, a copy of Plaintiffs' Sur-Response to Defendant's Reply in Support of His Motion to Dismiss was served on the following parties by first-class mail, postage prepaid:

Dennis C. Barghaan, Jr.
Assistant United States Attorney
2100 Jamieson Avenue
Alexandria, Virginia 22314

Edward H. White
United States Department of Justice
Civil Division, Federal Programs Branch
20 Massachusetts Avenue, N.W., Room 7107
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2004 AUG 27 P 1:19
CLERK US DISTRICT COURT
ALEXANDRIA, VIRGINIA

August 27, 2004

VIA HAND DELIVERY

Clerk
United States District Court
Eastern District of Virginia
U.S. Courthouse
401 Courthouse Square
Alexandria, Virginia 22314

Re: Case No. 04-CV-359 GBL
Salt Institute, et al. v. Tommy G. Thompson

Dear Clerk of the Court:

Enclosed for filing in the above-referenced case on behalf of Salt Institute and the Chamber of Commerce of the United States of America ("Plaintiffs"), please find the original and one copy of Plaintiffs' Sur-Response to Defendant's Reply in Support of His Motion to Dismiss.

All questions or correspondence regarding this filing should be directed to the undersigned.

Sincerely,



Mark E. Solomons

Enclosure

cc: Dennis C. Barghann, Jr., Esquire
Edward H. White, Esquire

ALBANY
AMSTERDAM
ATLANTA
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