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

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CLERK US DISTRICT COURT
ALEXANDRIA, 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 NANCY L. GELLER

This is my DECLARATION:

1. I am the Director of the Office of Biostatistics Research in the Division of Epidemiology and Clinical Applications, of the National Heart Lung and Blood Institute (NHLBI) at the National Institutes of Health. The Division of Epidemiology and Clinical Applications plans and directs programs in epidemiologic studies, basic and applied behavioral research, demonstration and education research, and projects for disease prevention and health promotion, including large scale clinical trials. The Office of Biostatistics Research (OBR) provides statistical expertise to members of all Divisions of NHLBI and performs diverse functions in the planning, design, implementation and analysis of research studies. In these activities, the OBR has primary responsibility for providing objective, statistically sound, and medically relevant solutions to research

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problems. I have served in this position since September 1990.

2. I obtained a Ph.D. in mathematics from Case Western Reserve University in 1972 and have over 20 years of experience in clinical trials. I am the editor of one book and over 150 papers in the areas biostatistics and clinical research.

3. I have had no involvement in the planning, design, implementation or review of the NHLBI grant-funded DASH Trial or the DASH-Sodium Trial, other than general oversight, in my capacity as Director of OBR, of one of my senior colleagues who worked on this project.

4. As I understand it, the Plaintiffs in this case have asked that the 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." First Am. Compl., Relief Req., § C. They previously described their data request as follows: "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 [sic] 2400 mg/day intake level, on both the control diet and DASH diet." First Am. Compl. Ex. 1, pp.14-15. Furthermore, Plaintiffs stated: "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 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." First Am. Compl. Ex. 1, p.15.

5. Additionally, as I understand it, Plaintiffs have criticized the DASH researchers for failing to publish the "race, existing hypertension status, sex, age, and body-mass index values" of the research subjects and for failing to "usefully" report the "mean blood pressure, standard deviation, and sample size for each relevant subgroup... at each level of sodium intake on both the control and the DASH Diet." First Am. Compl. ¶¶ 20-21.

6. I have reviewed the article entitled "A Further Subgroup Analysis of the Effects of the DASH Diet and Three Dietary Sodium Levels on Blood Pressure: Results of the DASH-Sodium Trial" published in The American Journal of Cardiology on July 15, 2004. ("Subgroup Analysis Paper")

7. In the Subgroup Analysis Paper, Table 1 gives the mean blood pressures, standard deviations of systolic and diastolic blood pressure, and sample sizes, for many (22) subgroups at each of the three levels of dietary sodium intake (high, intermediate and low sodium groups) for subjects on the DASH diet and those on the control diet. The intermediate sodium level corresponds to the 2400 mg diet.

8. The subgroups variables described in Table 1 include race, existing hypertension status, sex, age and body-mass index. The subgroups defined in the paper were decided on at the time the DASH-Sodium protocol was written.

9. Table 2 gives the changes in both systolic and diastolic blood pressure for specific subgroups, defined by a single characteristic, across the three levels of dietary sodium intake, e.g., "lower vs. higher," "lower vs. intermediate," and "intermediate vs. higher." The 10 subgroups are defined according to race, existing hypertension status, sex, age and body-mass index. Sample size is also included.

10. Table 3 gives changes in both systolic and diastolic blood pressure for specific subgroups, defined by two characteristics, across the three levels of dietary sodium intake, e.g., "lower vs. higher," "lower vs. intermediate," and "intermediate vs. higher." The 16 subgroups are defined according to race and hypertension status, race and sex, age and hypertension status. Subgroups are also further broken out by age.

11. It appears to me that the data Plaintiffs requested, and more, is available in the Subgroup Analysis Paper.

12. Furthermore, while NHLBI maintains a copy of the DASH-investigators' raw data in its Limited Access Data Set (LADS) web site, with which I am familiar, this raw

data, alone, would not provide Plaintiffs with the mean blood pressures and standard deviations, both of which would need to be calculated based upon a particular researcher's study design, e.g., comparing blood pressures in non-African American males in different age quartiles.

13. In my view, the Subgroup Analysis Paper provides the data Plaintiffs have requested in a "useable" form. The raw data set that the NHLBI maintains, and releases, as a government record through the LADS site would require substantial effort to obtain these results.

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

Executed on: 7/30/04

Nancy L Geller

NANCY L. GELLER