

FILED

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.)

2004 AUG 27 P 1:19

CLERK US DISTRICT COURT
ALEXANDRIA, VIRGINIA

Case No. 04-CV-359 GBL

PLAINTIFFS SUR-RESPONSE TO DEFENDANT'S
REPLY IN SUPPORT OF HIS MOTION TO DISMISS

I. INTRODUCTION

This is an action to enforce Plaintiffs' rights arising under the Information Quality Act, 44 U.S.C. § 3516 note ("IQA"), and the Shelby Amendment, Pub. L. No. 105-277 1998 HR 4328 (1998). In accordance with these rights, Plaintiffs seek the disclosure of certain data relied upon by the Defendant ("DHHS") in support of health information disseminated to the general public, and the correction of that information to the extent it is not reasonably supported by the data relied upon, and disclosed to Plaintiffs. The Defendant filed a motion to dismiss this action under Rule 12(b)(1) and (6) of the Federal Rules of Civil Procedure alleging numerous jurisdictional, statutory and jurisprudential grounds in support of the motion.

Among the grounds asserted is the allegation made for the first time in Defendant's Reply Memorandum, that the Court has no jurisdiction over the subject matter because Plaintiffs' data request is moot, having been fulfilled by an article authored by several DHHS-sponsored researchers and published on July 15, 2004. Bray, et al., 94 Amer. J. of Cardiology 222, (2004) ("Bray"). The Bray Paper is accompanied by a declaration executed by Nancy L. Geller, Ph.D., an employee of DHHS, asserting, in summary, "It appears to me that the data plaintiffs

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requested, and more, is available in the Subgroup Analysis [Bray] Paper." Geller Declaration ¶ 11. Dr. Geller does not state that the data reported in the Bray Paper support the information disseminated to the public thus making any correction unnecessary. The Geller Declaration also supports the fairly obvious conclusion that DHHS was in violation of the IQA before the Bray Paper was published because the information it contains was not previously disclosed in accordance with Plaintiffs' request.¹

Plaintiffs were granted this opportunity to respond to Defendant's new Reply arguments based upon the Bray Paper and Geller Declaration.

II. ARGUMENT

A. The Bray Paper Does Not Provide The Data Requested

A principal objective of the IQA and perhaps the most important right it confers, is the expectation that valid data supports health and science information disseminated to the public by federal agencies. And that same data can be evaluated by knowledgeable people who are not affiliated with the agency and the statistical conclusions reached by the agency will be confirmed by the public reviewers as well. This process embodies the core principles of the IQA – transparency, reproducibility, objectivity and integrity. Congress gave meaning the these important values in scientific research and reporting by enacting the IQA. This Court should do so as well.

In order to evaluate agency conclusions, data must be presented to the public reviewer in a format that allows re-analysis. Plaintiffs' data requests seek the relevant information in a format that allows them to conduct a meaningful analysis that, in the end, should clearly show that the public information disseminated by the agency is either solidly based in scientific

¹ The admission that the Bray Paper fulfills Plaintiffs' request for data by disclosing "subgroup" information "across three levels of dietary sodium intake," Geller Declaration ¶ 7-10, suggests that Defendant's original mootness argument based upon other disclosures was never supported or was improvidently made. Plaintiffs requested subgroup data across the relevant levels of sodium intake and that was not provided in any format in the course of administrative proceedings although it was, apparently, available.

research or too flawed to warrant public dissemination. This is the disclosure obligation imposed by the OMB Guidelines. See 67. Fed. Reg. 8452, 8459-60 (2002).

In seeking data in a "meaningful" format, Plaintiffs have, since the beginning, specified that "this data should include, but not necessarily be limited to mean blood pressures, the 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." Geller Declaration ¶ 4 citing First Am. Compl. Ex 1 p.15.

David McCarron, M.D. is an expert consultant to Plaintiffs, and is well qualified to evaluate the degree to which the information contained in the Bray Paper complies with Plaintiffs' disclosure request. McCarron Declaration ¶¶ 1-3. Following a review of the Bray Paper and Geller Declaration, Dr. McCarron rejected Dr. Geller's conclusion that Plaintiffs now have all they asked for "and more". Id. ¶ 8 ("My review of the Bray Paper unequivocally reveals that the data requested by the Plaintiff's is not provided by that Paper").

Specifically, Dr. McCarron details the shortcomings of the Bray Paper.

- "[T]he mean and standard deviations of the systolic and diastolic blood pressures for the three levels of dietary sodium for the subjects in the control and the DASH diet were not provided." Dr. McCarron notes further Dr. Geller's acknowledgment that these precise data were requested and that at no place in her declaration does she state that these data were provided by the Bray Paper or in any format. McCarron Declaration ¶ 7.
- Dr. Geller specifically comments that "'changes' in blood pressure are included, but never references the presence of the 'mean blood pressure' except at baseline (Bray Table 1) which in no way fulfills the requirement of the Plaintiffs' request ..." Id. ¶ 8.
- Tables 2 and 3 in the Bray Paper purportedly show the "change in blood pressure" reported are "estimates" derived from a "statistical model" yet no information concerning the "model" used to generate the "estimates" is provided. These "estimates" are not an adequate substitute for "the actual

measures of the mean blood pressures and their standard deviations as requested by the Plaintiffs." Id. ¶ 9.

- The statistical presentation of the data is "unusual" and "not consistent with FDA standards." Id.
- The data provided as described by Dr. Geller are "irrelevant" and "misleading". Id. ¶ 10.
- Dr. Geller's statement that the data requested could not be derived from the databases available to NHLBI, seems to be an admission of Defendant's non-compliance; the NHLBI colleagues who authored the Bray Paper "must have had available to them the means and standard deviations requested..." Id. ¶ 12.

B. Plaintiffs' Claims Are Not Moot

This Court has jurisdiction to consider a case in which there is an ongoing controversy. Mellen v. Bunting, 327 F.3d 355,364-5 (4th Cir. 2003). A case is moot if the plaintiff has obtained all the relief requested and there is nothing more for the court to offer. Friedman, Inc. v. Dunlap, 290 F.3d 191,197 (4th Cir. 2002). A defendant who voluntarily changes conduct after a suit is filed and then alleges the absence of a case or controversy, bears a "heavy burden to establish mootness." Lyons Partnership, L.P. v. Morris Costumes, Inc., 243 F.3d 789, 800 (4th Cir. 2001); see also Bunting, 327 F.3d at 364.

In a closely analogous setting, the D.C. Circuit, in a matter arising under the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA"), held that the partial disclosure of requested documents by a third party did not moot the controversy, even where the agency claimed that all the factual information requested was released as a result of the partial disclosure. Center For Auto Safety v. EPA, 731 F.2d 16, 19-20 (D.C. Cir. 1984). The court held that the release of four of nineteen documents requested did not deprive the court of jurisdiction to consider the merits of the FOIA request. Id.

Here, there is no viable argument that Plaintiffs IQA or Shelby Amendment claims are moot. Without considering the Bray Paper or Geller and McCarron Declarations, the mootness claim fails because Plaintiffs have a right not only to data but to a correction of disseminated

information not supported by the data. Neither the Bray Paper nor the Geller Declaration is dispositive of the correction claim. It is similarly clear that DHHS has not carried its heavy burden (or any burden) of showing that there is nothing more for Plaintiffs to get. Plaintiffs' claim and the McCarron Declaration emphasize the need for adequate data in a proper format to allow Plaintiffs to test DHHS public conclusions for objectivity, reliability, transparency, utility and integrity.² Plaintiffs' claim, and the McCarron Declaration emphasize that adequate data must include mean and standard deviations derived from research findings and something more than mere "estimates" of health affects allegedly documented by the study.

Nothing in the Geller Declaration states that these requests have been met, and therefore, nothing in these materials justifies a dismissal for mootness.

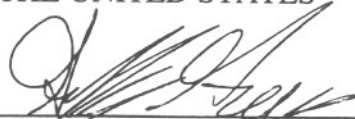
CONCLUSION

For these reasons, Defendant's Motion to Dismiss on account of mootness should be denied.

Respectfully submitted,

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² See OMB Guidelines, supra, 67 Fed. Reg. at 8458.