

**Order Re: Motion To Quash Subpoenas Re Yale Study's
Hospital Records**

08/19/2002

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLEIN RE: PHENYLPROPANOLAMINE (PPA)
PRODUCTS LIABILITY
LITIGATION,MDL NO. 1407
ORDER RE: MOTION TO
QUASH SUBPOENAS RE YALE
STUDY'S HOSPITAL RECORDSThis document relates to
all actions

I. INTRODUCTION

Plaintiffs filed an Emergency Motion to Quash Subpoena[s] Re: Yale Study's Hospital Records. Having reviewed pleadings filed in support of and in opposition to the motion, along with the remainder of the record, and, being fully advised, the court finds and concludes as follows:

II. BACKGROUND

Plaintiffs seek to quash a series of subpoenas duces tecum served on hospitals possessing medical records for participants in the Yale Hemorrhagic Stroke Project ("HSP"). Yale provided defendants with all of the documentation relating to the HSP in their possession and joins plaintiffs in their objection to the hospital subpoenas.

Defendants served subpoenas on thirty two hospitals seeking medical records on twenty seven different patients, all participants in the HSP identified as consuming PPA-containing products prior to suffering strokes. The subpoenas appear to seek copies of all medical records, reports, and/or documents pertaining to the patients at issue. As discussed below, however, defendants argue that the subpoenas seek only the medical records to which the HSP investigators had access. They request redactions generally mirroring those conducted on the documents received from Yale (i. e., name; social security number; street address; last four digits of telephone number; family member names; birthday; doctors' names; etc.) To reduce the redaction burden, the hospitals are advised to contact defendants as to the volume of documents affected by the subpoena, so that any necessary adjustments can be made, and defendants offer reimbursement for redaction and copying costs.

At the time defendants filed their opposition, seven hospitals had produced documents, and three hospitals had objected based on confidentiality.²² Plaintiffs assert without further detail that four hospitals have indicated no record of service of a subpoena, but intend to move to quash such a subpoena should they be served.

III. DISCUSSION

Plaintiffs first argue that the documents are not discoverable because they are neither relevant nor reasonably calculated to lead to the discovery of admissible evidence. They assert that Yale has already produced the records they utilized in conducting the HSP. They further argue that the defendants cannot show that their need for the records outweighs the burden placed on participating hospitals. See, e.g., Deitchman v. E.R. Squibb & Sons, Inc., 740 F.2d 556, 560-61 (7th Cir. 1984).

Both plaintiffs and Yale argue that the documents are privileged based on their confidential nature. In particular, Yale points to the Confidentiality Certificate issued by the Department of Health and Human Services in connection with the HSP. That certificate "requires that there be no disclosures of identifying characteristics of research subjects in any Federal . . . proceedings." See Yale University's Submission re Plaintiffs' Motion to Quash Subpoena Re Yale Study's Hospital Records, at 1. Yale is not confident the general redaction indication in the subpoenas suffices or that the redaction would be completed thoroughly and properly. They also aver that the production of unrelated medical records would violate the confidentiality expectations of the patients. To the extent the subpoenas are enforced, Yale strongly suggests the requirement of compliance with a uniform redaction protocol.

Finally, both plaintiffs and Yale assert the "chilling effect" resulting from these types of subpoenas. That is, the idea that parties may in the future obtain *all* of one's medical records may dissuade individuals from participating in important medical research, particularly those individuals with rare or stigmatizing medical conditions, mental health problems, and/or those who engage in the use of illegal drugs or alcohol.

Defendants concede their desire to verify the accuracy of the data underlying the HSP and to clarify the extent to which the HSP participants were scrutinized for "potential stroke risk confounders." See MDL Defendants' Opposition to MDL Plaintiffs' Emergency Motion to Quash Subpoena Regarding Hospitals' Records, at

12. They assert a strong likelihood of, among other flaws, bias in the HSP.³³ See, e.g., Deitchman, 740 F.2d at 562-63 (allowing defendant drug company to review the data underlying a study key to the case; stating that "a study of this sort may have a number of different, but inadvertent, biases present" and that "if the conclusions or end product of a research effort is to be fairly tested, the underlying data must be available to others equally skilled and perceptive.")

Defendants reject the assertion that all of the participants' medical records have been produced by Yale. Specifically, they point to two patients for whom no medical records were produced, and aver only a limited production of records for many others. Defendants concede that Yale may have never received these records and may have instead received only research forms containing summaries of the information contained within the records. Defendants also assert that the subpoenas seek only the medical records to which the HSP investigators had access.

Federal Rule of Civil Procedure 26 allows discovery, for good cause, of "any matter relevant to the subject matter involved in the action." Fed. R. Civ. P. 26(b)(1). To the extent documents were reviewed and/or utilized by the HSP investigators, but not produced by Yale, they are unquestionably relevant. Moreover, even where records relevant to the study were never released to Yale in other than summary form, those records would still be relevant to this litigation and discoverable pursuant to Rule 26.

Moreover, the confidentiality agreements already associated with those relevant documents, taken together with defendants' requests for redaction, mitigates any concern with respect to issues of confidentiality. The parameters of the subpoena redaction indication appear to be modeled on the Yale redaction agreement. However, as suggested by Yale, the parties should agree as to a uniform redaction protocol to apply to these documents. The court also does not find that the subpoenas as they relate to documents relevant to the HSP impose an undue burden on the hospitals. The letters accompanying the subpoenas clarify that defendants will work with the hospitals to narrow requests if necessary and will pay for redaction and copying costs. Nor does the argument as to a chilling effect succeed with respect to these documents. The HSP has been concluded for some time, many thousands of HSP-related documents have been produced to date, and the patients involved in the HSP agreed to the disclosure of their relevant medical records, so long as any identifying information

was redacted.

However, contrary to defendants' assertion, the court reads the plain language of the subpoenas as seeking *all* of the patients' medical records. As such, the requests incorporate a multitude of documents entirely irrelevant to the HSP and the issues before this court. Moreover, in agreeing to disclose medical records to Yale for the HSP, patients presumably did not believe such records would include entirely unrelated documents, and particularly those unrelated documents associated with matters of a more personal nature.

As such, the court believes the documents appropriately produced in response to these subpoenas should include only those documents relevant to the HSP. The court orders the defendants to work with the hospitals from whom they have not yet received any documents to ensure that the productions will include only such relevant documents. As described above, the parties should also agree to a uniform redaction protocol applying to these document productions.

IV. CONCLUSION

For the reasons stated above, the court hereby DENIES Plaintiffs' Emergency Motion to Quash Subpoena[s] Re: Yale Study's Hospital Records. The parties are ordered to meet and confer as to an appropriate uniform redaction protocol. Defendants are ordered to work with the hospitals to ensure that the document productions are conducted in accordance with the parameters of this order.

DATED at Seattle, Washington this 16th day of August, 2002.

/s/

BARBARA JACOBS ROTHSTEIN
UNITED STATES DISTRICT JUDGE