

IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

FILED

JUN 28 2004

U.S. COURT OF
FEDERAL CLAIMS

IN RE: CLAIMS FOR VACCINE
INJURIES RESULTING IN AUTISM
SPECTRUM DISORDER, OR A SIMILAR
DEVELOPMENTAL DISORDER,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

AUTISM MASTER FILE
Special Master George Hasting

**PETITIONERS' REPLY TO "RESPONDENT'S SUPPLEMENTAL RESPONSE TO
PETITIONERS' STEERING COMMITTEE'S MOTION TO COMPEL DISCOVERY"**

I. INTRODUCTION

Respondent was granted leave to file a supplemental response to petitioners' motion to compel discovery, based on the argument that respondent needed the opportunity to describe why petitioners' discovery requests were allegedly ambiguous and non-specific. The supplemental response, however, consists largely of a reiteration of respondent's arguments already raised and briefed in great detail in the government's original response to the motion to compel; that is, that the petitioners have supposedly not shown that the requested discovery is necessary to the Special Master's inquiry, and that petitioners are allegedly obliged to present some or all of their causation case in order to support a showing of "necessity." In other parts, the brief does nothing more than set out respondent's interpretation of some of petitioners' discovery requests, interpretations that could simply have been confirmed or clarified by a telephone call to petitioners' counsel.

To the extent that respondent's instant brief merely repeats the "necessity" arguments already raised, petitioners reply by incorporating by reference the legal arguments and supporting points and authorities as articulated in petitioners' original motion to compel and the subsequent reply in support of that motion. Petitioners will not burden the Special Master with repeating those arguments in the following text, as they've been exhaustively addressed in the earlier briefs of both parties.

In those instances where the supplemental brief raises new issues that actually bear on the specificity of the petitioners' discovery requests, the petitioners reply as set forth below.

II. SPECIFIC REQUESTS FOR CLARIFICATION

A. NIH Deposition

Respondent correctly surmises (Supp. Resp., p. 5) that the scope of the petitioners' requested deposition of a representative of the National Institutes of Health is identical to the scope of depositions of CDC, ATSDR and FDA officials already deposed. The subject matter of the requested deposition is described by the notices of deposition served to each of the previous government entities, and reproduced in the supplemental response at pages 5 – 10. The scope of the requested deposition as described in the notice of deposition, therefore, is unambiguous and is specific enough that the respondent and its client entities can offer a substantive response to the request.

B. Documents Related to Completed Studies

Respondent accurately reports that petitioners narrowed the scope of their Request for Production No. 3, directing it solely to the discrete list of five completed and published studies that are described in Exhibit B of petitioners' Reply Memorandum. (Supp. Resp., p. 11). Respondent then seeks clarification of what petitioners meant by five of the seven subparts of petitioners' Request No. 3; that is, subparts (a), (b), (c), (d) and (g). Respondent repeats virtually

identical requests for clarification on these subparts of request No. 3 for each of the five completed studies.

As applied to *all five* completed studies, petitioners intend that each subpart of Request No. 3 have the following meanings:

Subpart (a): The request for datasets or compilations of data is meant to include, as respondent surmises, the final dataset upon which the conclusions of a study were based. In addition, the request seeks discovery of any other dataset or compilation of data that a study's authors relied upon in the course of that study, not limited solely to the "final dataset" that a published study was based on. A study investigator, for example, may have generated datasets to test a hypothesis that was ultimately rejected and not included in the published study. Investigators may also have generated a series of datasets during the course of a study using different inclusion or exclusion criteria before creating the final dataset that the study ultimately relied on. Different datasets or compilations of data may have been generated and relied upon in preparing drafts or interim reports during the course of a study, and those datasets or compilations might not necessarily have been the "final" dataset relied upon in any of the published studies.

Petitioners therefore mean the request for datasets and compilations of data to include datasets and compilations created or generated during the course of the study, and not limited to the "final dataset" upon which the conclusions of a study were based.

Subpart (b): Each of the completed studies contains a description of the methodology used to complete the study, and discovery is not necessary to obtain this information as it is published. Petitioners, however, seek additional information if in the course of any study the investigators changed the methodology or employed any methodology not described in the published study. The request is self-evident—if the only methodology employed in a study is that described in the publication, then respondent can simply make that clear in a substantive response to the discovery request and the matter is resolved on its face. If other methodologies,

or calculations were employed in a study and are not described in the publication, then respondent can make that clear in a substantive response to the discovery request and the Special Master can focus his inquiry on whether those documents are subject to discovery.

Subpart (c): Petitioners intend to limit the discovery requests of this subsection to documents in the files of government employees, as respondent assumes. Frankly, petitioners are surprised that respondent would find this request ambiguous or confusing, as by definition a request for the production of documents can only include those documents in the possession or control of the party to whom the request is directed—in this case, the government. In any case, petitioners certainly are not asking that the Special Master compel the government to produce documents that are located outside the possession or control of respondent’s client entities.

Subpart (d): Respondent correctly assumes that the time frame for which petitioners seek documents relating to communications between the study investigators and other parties is limited to the design phase of the study, and from when the study began to when it was accepted for publication.

Subpart (g): As is the case with subpart (c) above, petitioners intend to limit the deposition requests of this subpart to depositions of government employees only. Petitioners certainly are not asking that the Special Master compel the government to produce non-government witnesses for any depositions. By “key” or “lead” investigator, the petitioners mean every investigator listed as an author in the published study. Respondent indicates that it is not prepared at this time to identify which, if any, of the completed studies it will rely on during the hearing on general causation. Petitioners therefore reserve this request until such time as respondent does identify the studies it will rely on.

C. Ongoing Studies

As a threshold issue, respondent incorrectly attempts to argue that discovery of the eight specific unpublished studies should not go ahead because the request is “premature” in the

absence of formal notices of deposition or document requests being served. The motion to compel, however, was explicitly intended to resolve all pending discovery disputes, including those disputes involving ongoing studies. In telephone status conferences it was agreed that an email from petitioners' counsel Mike Williams to Mr. Matanoski, summarizing the various discovery requests and identifying the areas of disagreement (See PSC's Motion to Compel, p. 6-7, and Exhibit D, March 8, 2004) would serve as a *de facto* discovery request by petitioners for the sake of the motion to compel. All of these issues have been raised, argued, briefed and debated—there is nothing premature about petitioner's request.

In addition, respondent claims that it cannot discern why petitioners seek discovery relating to ongoing studies. This argument completely misses the point that all of the extensively briefed arguments in support of discovery of the published studies expressly apply to the ongoing studies as well. Petitioners have been clear all along that the rationale for allowing discovery of the published studies and the ongoing studies are virtually identical, for the simple reason that the ongoing studies ultimately will be published and will thus become as necessary to the Special Master's inquiry as those studies already published. All of the arguments and rationale for conducting discovery of the published studies apply to the ongoing studies as well, as briefed in petitioners' motion and reply.

Further, as was the case with the completed studies, respondent raises "ambiguity" concerns about subparts (a) and (d) of petitioners' discovery Request No. 4, and raises those concerns as to all of the ongoing studies that are subjects of the motion to compel.

Subpart (a): Petitioners can confirm that the request for documents as it relates to all the ongoing studies is meant to include only those documents in the possession and control of government employees. Petitioners further clarify that the datasets sought include both the final

data relied upon in the conclusion of a study as published, as well as datasets and compilations created or generated during the course of the study, as described above in discussing Request No. 3(a) regarding completed studies.

Subpart (d): Petitioners confirm that they seek depositions only of government employees and petitioners do not seek an order compelling respondent to produce any non-government witnesses for depositions regarding ongoing studies. In addition, as described above, petitioners have stated the purpose for the depositions; that is, the reasons and rationale for these depositions are identical to those for the depositions requested regarding completed studies.

Finally, respondent raises several arguments relating exclusively to petitioners' request for information relating to the Thimerosal Screening Analysis (TSA) and access to Vaccine Safety Datalink (VSD) datasets. Petitioners note again that much of respondent's brief on this point repeats the "necessity" arguments already addressed in this proceeding. To the extent that the supplemental brief raises any new issues of specificity or ambiguity, however, petitioners reply first by noting that they cannot describe with particularity how many datasets might be at issue because petitioners do not know how many datasets or compilations of data the government has already created or generated, aside from those identified in the published HMO Study authored by Dr. Verstraeten. Not knowing the number of datasets or compilations that might already exist, petitioners cannot know the contents of those datasets and cannot therefore describe a specific protocol for access to, or use of, the datasets.

It also appears that respondent itself cannot determine whether the government has access to the requested data or not. While the footnote to the respondent's initial response to petitioners' motion to compel appears to say that the government has no responsive data and no

access to such data, the supplemental brief qualifies that footnote. Instead of simply saying that the government has no documents responsive to petitioners request, respondent writes that “the data sought in subpart (b) is not, *to a large extent*, within the possession, custody or control of the CDC,” and that it is “unlikely that a search pursuant to a suitably specific request would actually lead to the identification of a ‘document’ within the CDC’s custody or control.” Supp. Resp., p. 37 (emphasis added). Respondent therefore is demanding that petitioners provide details about documents that respondent itself cannot say with certainty even exist.

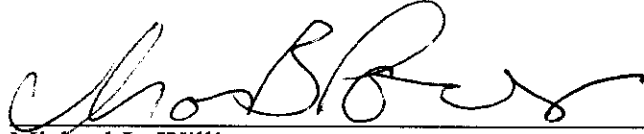
If these documents don’t exist then the respondent should make that clear and unambiguous. If the responsive documents do exist, then respondent ought to make that clear so that the parties and the Special Master can focus the inquiry on specific issues of the discovery inquiry; that is, how relevant the documents are, how much need there is for the documents, whether there is any hardship or burden associated with producing the documents, and whether there are issues of privilege and confidentiality.

III. CONCLUSION

Petitioners’ requests for production, as described in the Motion to Compel and supported in petitioners’ memoranda, are sufficiently clear, specific and unambiguous so that respondent can reply to them substantively and the Special Master can rule on the merits of the various discovery requests. Petitioners’ Motion to Compel should be granted, and an Order should issue directing respondent to comply with petitioners’ discovery requests.

DATED this 25th day of June, 2004.

WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.



Michael L. Williams
Thomas B. Powers

Counsel for Petitioners' Steering Committee
1001 S.W. Fifth Avenue, Suite 1900
Portland, OR 97204
Tel.: (503) 295-2924
Fax: (503) 295-3720

CERTIFICATE OF SERVICE

I hereby certify that on June 26, 2004, I served the foregoing **PETITIONERS' REPLY TO "RESPONDENT'S SUPPLEMENTAL RESPONSE TO PETITIONERS' STEERING COMMITTEE'S MOTION TO COMPEL DISCOVERY** on the following individual(s):

Vincent Matanoski
U.S. Department of Justice
Tort Branch, Civil Division
1425 New York Avenue, N.W., Room 3126
Washington, DC 20005

Mark Raby
U.S. Department of Justice
Tort Branch, Civil Division
1425 New York Avenue, N.W., Room 3126
Washington, DC 20005

Ghada Anis, Liaison Counsel,
Petitioners' Steering Committee
For the Omnibus Autism Proceeding
Miller & Associates
105 N. Alfred St.
Alexandria, VA 22314

by United Parcel Service, next business day delivery.



Brenda D. Steinle
WILLIAMS DAILEY O'LEARY CRAINE & LOVE, P.C.

cc: George Hastings, Special Master
U.S. Court of Federal Claims
Office of the Special Master
529 14th St. N.W. #302
Washington, D.C. 20045