ORIGINAL

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

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

Various Petitioners,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

AUTISM MASTER FILE
Special Master Hastings

RESPONDENT'S REPLY TO THE PSC'S REPLY RE MOTION TO COMPEL

Respondent herein replies to the Petitioners' Steering Committee's ("PSC") Reply Re Motion to Compel. For the reasons set forth below and in respondent's Response to Petitioners' Second Motion to Compel and Motion for Issuance of Third-Party Subpoenas, the PSC's Motion must be denied.

Quite tellingly, in neither the PSC's Motion nor in its Reply is there a single reference to any case law or other legal support for its contention that the Omnibus Autism Proceeding is the proper forum to conduct new epidemiologic research. Instead of providing the court with factual and legal support for its proposition, the PSC offers mere rhetoric.

The PSC argues that its proposed study is "reasonable and necessary" to the Special Masters' resolution of the factual issues presented in the Omnibus Autism Proceeding because further epidemiologic research concerning the relationship between receipt of thimerosal and MMR vaccine and the development of neurodevelopmental disorders is needed. The PSC, in so

arguing, would have the Special Masters believe that it is necessary for this court to insert itself into the milieu of scientific exploration and sanction litigation-driven research rather than allow the medical community to conduct its own independent research unrelated to any litigation. In fact, the PSC acknowledges that further studies into the effect of thimerosal or MMR vaccine on neurodevelopment are currently ongoing within the scientific community:

> The contention that [thimerosal containing vaccines], the MMR vaccine, or a combination of the two might have caused [neurodevelopmental] injuries is now the subject of intensive study and investigation by public and private researchers, including various of [the Department of Health and Human Services'] own subdivisions.

PSC Reply Re Motion to Compel ("PSC Reply") at 5.

That further studies into the effects of thimerosal and MMR vaccine may be warranted is not evidence that a study designed at the behest of a litigant, and performed for purposes of litigation only, is "reasonable and necessary" to the Special Masters' resolution of the issues in the Omnibus Autism Proceeding. This is particularly true when additional, independent studies are already underway.

The PSC further argues that respondent "ignores the fact record developed since March 2004. . . ." PSC Reply at 2. Yet, the PSC provides no citations whatsoever to the "fact record" upon which it relies. The PSC contends that it sought access to the VSD data in its March 2004 Motion to Compel, and, as such, the issue has been before the court for over three years. PSC Reply at 3. A review of the "fact record," however, reveals that the VSD data sought by the PSC in 2004 is markedly different from, and far more narrow than, what it now seeks. In March 2004, the PSC sought VSD data pertaining to the Thimerosal Screening Analysis only. The following is the PSC's 2004 request pertaining to VSD data:

5. Documents relating to the Thimerosal Screening Analysis (TSA), and access to Vaccine Safety Datalink (VSD) datasets.

   a) To the extent that any study relying on analyses or interpretations of the VSD is published, petitioners seek discovery of documents as described [in an earlier request].

   b) To the extent not covered by those requests, petitioners specifically request access to the diagnostic coding of the VSD health maintenance organizations used by the TSA investigators, up to and including the year 2003, and as far into 2004 as the data are available, for the **same children already included in the TSA**.

   c) Petitioners additionally request that their expert(s) be given access to designated VSD datasets as needed to validate and expand upon the epidemiological VSD analysis conduced [sic] by the Drs. Geier [sic], with the data updated to include diagnoses through the present.[1]

Petitioners' Motion to Compel Discovery in the Autism Omnibus Proceeding, March 9, 2004, at 4 (emphasis added).

The PSC further contends that respondent is ignoring the "expert testimony," which, according to the PSC, supports the new Motion. PSC Reply at 3. Once again, a review of the "fact record" belies the PSC's contention. At a hearing to address the PSC's March 2004 Motion to Compel, the PSC offered expert testimony from Dr. Harland Austin, an epidemiologist. Dr. Austin testified that he wanted to conduct two separate analyses using VSD data, which he termed Proposal I and Proposal II. See Petitioners' Exhibit 82 at 19, 21, attached hereto as Tab A. Dr. Austin testified, however, that he sought access to VSD data pertaining only to the extant

[1] As discussed in respondent's earlier Response to the PSC's current Motion, the 2004 Motion to Compel never articulated what data it sought with regard to the Geiers' projects. Nor did the PSC ever describe what analyses the Geiers intended to do. In any event, the Geiers' alleged projects are not the subject of the PSC's current Motion.

cohort (i.e., the same children) of the Thimerosal Screening Analysis:

> What I would like to do is this: I would like to use the methodology used in the unpublished version [of the TSA], the 2000 version, on the updated cohort [Proposal I] . . . The other proposal I have is: Update the follow-up experience of the extant cohort members [Proposal II].

Transcript of September 23, 2004 Hearing at 80, 82, attached hereto as Tab B. Proposal I sought data through December 31, 2000 from the same children studied in the Thimerosal Screening Analysis – 140,887 children. Proposal II sought post-2000 data on those same 140,887 children. As is clear from Dr. Austin's testimony and his written outlines, neither Proposal I nor Proposal II sought access to the far more extensive VSD data – two million children – to which the PSC now requests. And neither of Dr. Austin's two proposals resembles the PSC's current study proposal, which would follow a much larger study population over a longer period of time, and explore health conditions beyond neurodevelopmental disorders. The PSC cannot credibly argue that the evidence it submitted in 2004 supports its new Motion.

Equally unavailing is the PSC's attempt to create the impression that respondent is responsible for the "delay on this issue." PSC Reply at 3. The PSC asserts inexplicably that its eleventh hour, new discovery request comes so late because of the "government's obstructionism." PSC Reply at 4. Again, the PSC misrepresents the "fact record."

Following an agreement between the parties, and by Discovery Order of this court, dated April 14, 2005, Dr. Austin was granted access to pre-December 31, 2000 VSD data to conduct a reanalysis of the Thimerosal Screening Analysis, as set forth in Proposal I. Contrary to the PSC's contention that respondent has been the dilatory party, the CDC made the data available in April, 2005, but the PSC did not have its expert review the data until August, 2006, over one year

later. The PSC now argues that "[r]espondent resisted [the] 2004 [Motion to Compel] and it took some eight months to resolve, eight months that petitioners would rather have spent obtaining and analyzing the data for the Special Masters' use." PSC Reply at 3. Significantly, when Dr. Austin did complete the reanalysis of the Thimerosal Screening Analysis, he concluded that "the methodology employed by the CDC was generally sound and that their findings are valid." Pet. Ex. 91 at 9. It is thus unclear how the PSC's perceived eight month delay of the resolution of this issue has prejudiced the Special Masters' consideration of the evidence.

With regard to the post-2000 VSD data applicable to Dr. Austin's Proposal II, on April 8, 2005, the PSC filed an Amended Motion to Compel, acknowledging that the CDC does not possess or control post-2000 VSD data, removing its request for such data, and stating that the PSC would apply directly to the MCOs for access to the post-2000 data:

> In the nearly one year since [the] Motion was filed, some of the requested discovery has occurred; that is, in some instances documents have been produced, and in other instances **it has been established that the respondent neither possesses nor controls documents**. . . . [P]etitioners withdraw Requests 5(b) and 5(c) of the original Motion based on discovery to date, reserving the right to renew this discovery request in the future. **Petitioners are applying for access to the data at issue directly to the entities that possess or control the data, or that control access to that data**.

Petitioners' Amended Motion to Compel Discovery in the Autism Omnibus Proceeding, April 8, 2005, at 1-2 (emphasis added). In the nearly two years since the PSC filed its Amended Motion to Compel and acknowledged that the CDC does not possess or control post-2000 VSD data, the PSC has offered no evidence to contradict that fact. The PSC said it would apply directly to the MCOs for access to post-2000 data, but the PSC has offered no evidence that it ever did so.[2]

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[2] In its Reply, the PSC states that its experts are willing to collaborate with the MCOs' investigators to conduct the proposed study, yet the PSC refuses to adhere to the MCOs' Institutional Review Board process.

Respondent has done nothing to "create delay on this issue."

Finally, the PSC threatens that if the Special Masters deny the new Motion to Compel, the PSC will move to exclude "any evidence proffered by respondent that relies on, or that is derived from, the VSD." PSC Reply at 6. The PSC further "reserves the right to raise the issue by motion before or during the general causation hearings beginning in June 2007." Id. If the PSC makes such a motion, it is imperative that the motion be raised, briefed by the parties, and ruled on by the court before the first test case is tried in June, 2007. It would be extremely prejudicial to respondent's preparation of his case, and the preparation of his witnesses, for respondent not to know, in advance, what evidence can and cannot be relied upon during the hearing. There is absolutely no reason why this issue cannot be fully resolved before trial. Indeed, the court's interest in a fair and efficient presentation of the evidence requires resolution of this threatened evidentiary challenge before the hearing commences.

Respectfully submitted,

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Date: March 26, 2007

Proposal I

- Obtain the data set and the SAS programs from the VSD investigators.
- Use the methodology used in the unpublished report on the updated cohort
  - Do not require at least one clinic visit for comparison children.
  - Stop following children at time of first disenrollment.
  - Do not adjust for clinic at HMO B.
  - Report findings for combined categories of neurologic degenerative and neurodevelopmental disorders.
  - Combine the data for HMO A and HMO B.
- Do an analysis combining all 3 HMO's.
- Compare these findings to those in the published report.
- If different, find the explanation(s).

Proposal II

- Update the follow-up experience of the extant cohort members.
- Younger members of the cohort (i.e., those born after 1997) had less thimerosal exposures, but these children were only followed until age 3 (median age of an autism diagnosis is about 4 years).
- Access to the data and methodology should be made available to the general scientific community.

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

AUTISM-OMNIBUS,)
Petitioner,)
v.)
UNITED STATES,)
Respondent,)

Courtroom 9
National Courts Building
717 Madison Place, N.W.
Washington, D.C.
Thursday,
September 23, 2004

The parties met, pursuant to notice of the Court, at 9:30 a.m.

BEFORE: HONORABLE GEORGE HASTINGS
Special Master

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opposite of what we noticed in the U.K. In the U.K. early exposures protected. That implies that late exposures were bad. So this is the opposite. This type of bias is not supported by what happened in the U.K.

Another potential problem with this is that you have now restricted your comparison series to a group of kids who are going to be sicker. If you are in the emergency department, or you are at the clinic for some reason, now you have a group of sick kids. So I am not so sure why they made this exclusion; I am not so sure that is justified. I would like to see what would happen if you looked at the new data and you didn't make these exclusions.

Well, here is the proposal that I put together. I think it would be useful to obtain the data and the SAS programs. That is what Ms. Lally is going to talk about after my presentation. She is going to talk about the type of information that we would need to try to implement Proposal 1.

What I would like to do is: I would like to use the methodology used in the unpublished version, the 2000 version, on the updated cohort. For example, do not require at least one clinic visit for comparison children; stop following children at the

time of first disenrollment as they did in the unpublished version; do not adjust the clinic at HMO B; report findings of combined categories; combine the data for HMOs A and B. There is absolutely no reason not to do that.

In fact, I would take it a step; further and i would look at HMOs A and C because HMO C can not stand alone. Compare these findings, that is use the methodology of the unpublished version and compare these findings to the published report and try to see what happened. Try to see why some of these positive findings, in fact, disappeared and try to find an explanation for that. What is the rationale for this? Many of the positive findings from the unpublished report disappeared in the published report. there are important, very important methodological differences the two reports with no adequate explanation for why they made these changes. There is really only four follow-up for these thimerosal and autism which I have briefly discussed: the Hviid and CDC studies and the two U>K. studies. Of these studies, there is no argument that the CDC is the most important.

Why is it the most important? Because it was done in the United States by the Public Health Agency of the United States, the CDC, it had the

highest thimerosal exposures with the most variabilities. It was low in high levels of exposures and it comes from multiple vaccines. So I think that there is no issue that this is probably the most important of all of the studies of the issue.

What is another rationale for the proposal? Well, some of the statements that the CDC investigators, and Mr. Williams showed me some of those statements, have led to some general distrust of this published report and I think this distrust comes out of some of the statements that have been made.

The other proposal that I have is: Update the follow-up experience of the extant cohort members. As Mr. Williams pointed out some of the younger members of the cohort, well, none are old enough. They weren't old enough to have been diagnosed with autism, which has a mean age of diagnosis of about four years. Kids born after 1997 in this country had less thimerosal exposure, so we now have a group of kids who are on the low end of exposure so they might help us learn something about the association between thimerosal and autism.

I propose that access to the data and the methodology should be made available to the general scientific community. Why? Well, the last two slides

CERTIFICATE OF SERVICE

I certify that on this 26th day of March, 2007, a copy of the foregoing **RESPONDENT'S REPLY TO THE PSC'S REPLY RE MOTION TO COMPEL** was served by Federal Express Overnight upon:

Michael L. Williams
Williams Love, et al.
9755 SW Barnes Road
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Portland, OR 97225-6681

Respondent did not fax a copy of the foregoing **RESPONDENT'S REPLY TO THE PSC'S REPLY RE MOTION TO COMPEL** to Ghada Anis because respondent lacked a current facsimile number for Ms. Anis. At the conference call on March 16, 2007, it was revealed that Ms. Anis no longer worked at the law firm where she had previously directed that correspondence be sent. Ms. Anis has provided no new contact information.