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.

PSC REPLY RE MOTION TO COMPEL

AUTISM MASTER FILE

Special Master George Hastings

PSC REPLY RE MOTION TO COMPEL

This filing will serve as the PSC's Reply brief in support of the Motion to Compel filed on December 8, 2006. This filing will also address issues raised by a brief filed by the Managed Care Organizations at the invitation of the Special Masters.

A. The Special Masters are Authorized to Conduct the Requested Discovery

The requested discovery is within the ambit of authority granted to the Office of Special Masters by Congress, and may be exercised in this instance at the discretion of the three Special Masters now assigned to the Omnibus Autism Proceeding. The basis for discovery in the NVICP is first that it must seek relevant information from among existing evidence. *Schneider v. HHS,* 64 Fed.Cl. 742, 746 (2005). On its face, it can hardly be argued that the information the PSC urges the Special Masters to obtain is not relevant. The requested discovery would allow the Special Masters to examine a rich source of data using a large, powerful study, one of the central causation questions in this proceeding: whether there is an association between exposure to thimerosal-containing vaccines (TCVs), or the MMR vaccine, and neurological injuries of the sort at issue in these claims.

The relevance of the information has been detailed in the PSC's first Motion to Compel filed on March 9, 2004, as well in the PSC's Second Motion of December 2006. To the extent

that population studies may be informative in the Special Masters' causation inquiry, the PSC has developed an extensive fact record, including expert testimony, supporting the proposition that a VSD-based study expanding the scope (i.e., increasing the number of children, over a longer period of time, applying fewer exclusions) of the oft-cited 2003 *Pediatrics* investigation by Verstraeten, et al. (the Thimerosal Screening Analysis, or TSA) would be extremely important. It defies any fair reading of the record developed on this issue over the past two years for respondent to argue that the requested information is not relevant to the general causation issues in this proceeding.

Petitioners recognize that their burden goes beyond showing that the requested discovery is relevant; that is, the discovery must also be "reasonable and necessary" to the Special Masters' inquiry. 42 U.S.C. 300aa-12(d)(3)(B). Again, respondent apparently ignores the fact record developed since March 2004, including expert testimony, describing the limitations of the existing epidemiology regarding this issue, the need for additional studies generally, the need for "outcome" or diagnostic data after December 2000 for the Verstraeten study cohort, the need for data examining exposures and outcomes after thimerosal was gradually phased out of pediatric vaccines from 2000 to the present, and statements by respondent's own client agencies that additional population studies are required to fully investigate the possible association between TCVs and adverse health outcomes. As petitioners have argued for three years, those facts support a conclusion that the requested discovery is "reasonable and necessary" and that the discovery is authorized by §12(d)(3)(B).

For these same reasons the MCOs' contention that the requested discovery is not "necessary" misses the mark and ignores the fact record developed over the course of three years in the Omnibus Proceeding. That record also establishes the importance of the requested evidence to the conduct of the proceedings, the unavailability of the evidence or access to the evidence to anyone other than the MCOs and the CDC, and the inability of the Special Masters or petitioners to obtain the evidence, all supporting the use of injunctive relief in the form of the requested subpoenas.

B. The PSC has Raised Issues Relating to the Need for Such a Study for More than Two Years.

It is simply disingenuous for respondent to claim that the instant motion is an "eleventh hour" attempt designed to create delay, or that the issues raised in the motion are some sort of surprise to the Special Masters and the DOJ. Let there be no doubt—respondent and respondent's client agencies have acted at every turn to create delay on this issue. First, the VSD was "outsourced" and turned over to private parties at roughly the same time this litigation began in the NVICP, conveniently allowing respondent to argue that the VSD was no longer in the government's "possession or control" for purposes of discovery in this litigation.

Second, petitioners sought VSD access via a Motion to Compel in March 2004, raising essentially the same "necessity" arguments as the present motion. The 2004 motion involved extensive briefing, two hearings, and expert testimony on many of the same points at issue in the present motion—it completely defies that extensive record to contend that anything here is new or last-minute. Respondent resisted that 2004 motion 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. Petitioners also sought information about the Verstraeten TSA study, moving to compel access to raw data, datasets, analytical files, notes, and other materials generated and relied upon by the study investigators. That evidence might have provided information limiting the scope, at least, of the PSC's proposed study, but DOJ again resisted producing the evidence and some of it was apparently destroyed or lost by the government agencies.

Further, respondent argues that because the motion seeking VSD access was not filed at the inception of discovery proceedings in the Omnibus Proceeding in 2002 the motion is untimely. That position completely ignores that the Verstraeten paper was not even published until November 2003, and petitioners could not have known before then how flawed and limited the TSA would be—so flawed and limited that additional VSD analysis is necessary.

C. The Proposed Study is Feasible and Scientifically Sound

Petitioners' experts are fully prepared to modify the methodology and protocol of the proposed study to accommodate unique features of the VSD. Respondent again plays hide-the-ball, keeping the VSD under wraps while simultaneously criticizing the study design for not anticipating specific features of the database that can only be discovered by gaining access to the VSD itself. That certain data fields are sometimes unreliable within the VSD, or that the data is organized in ways that might create problems for implementing the proposed study are not reasons to deny the study to proceed; instead, they are reasons to allow access to the VSD so that the study can be adapted to the database.

Having outsourced the CDC to a third-party vendor during the pendency of this litigation, after opposing every discovery request relating to the VSD for over three years, having resisted every effort of the PSC to gain access to the VSD for the benefit of the Special Masters, respondent finally now complains that the study would take too long for the Special Masters' purposes. Again, the delay here was created by the relevant government agencies, and if, as a result, the proposed study might delay the conclusion of general causation proceedings, that is not a flaw of the study, it is the product of the government's obstructionism. The respondent should not be rewarded for its delay by depriving the Special Masters and the petitioners the benefits and important evidence that the proposed study would generate.

Respondent further attempts to argue that the motion should be denied because the study will not be "reliable." That position is remarkable in that the study is obviously not even started, and one cannot rationally determine whether evidence is reliable or not until the evidence exists to be evaluated. Respondent makes similar errors of logic in claiming, before the requested investigation is underway, that the results would be flawed, uninformative or otherwise not useful in the general causation inquiry. This position makes as much sense as reviewing a movie yet to be filmed, or critiquing a book yet to be written.

D. The Alleged Burden on the MCOs to Comply with Prospective Subpoenas is Outweighed by the Compelling Need for the Information

At issue here are the legal claims for compensation of some 4800 seriously injured children, as well as the scientific questions about causation that are the basis of those thousands of petitions. The contention that TCVs, the MMR vaccine, or a combination of the two might have caused these injuries is now the subject of intensive study and investigation by public and private researchers, including various of DHS' own subdivisions. As petitioners described in their motion, both the IOM and the NIEHS have recognized the limits of the relevant existing population studies, the need for additional studies, and the use of the VSD as perhaps the most powerful investigative resource available to inform those studies. There is no doubt that complying with the requested subpoenas would require a significant undertaking by the MCOs, but it is an undertaking proportional to the need. The MCOs are also compensated for their participation in the VSD, just as AHIP is compensated for its administrative role. In addition to that compensation, the PSC anticipates contributing to the cost of the study as a matter of equity and practicality.

The PSC's experts are no strangers to research and the challenges of conducting sophisticated, complicated studies and working with less than perfect data. The experts are willing and able to work collaboratively with the MCOs to modify the study design to accommodate the vagaries of the VSD and to accommodate the demands of the data storage and retrieval systems of the MCOs. The proposed study does not contemplate or anticipate that the study design be simply turned over to the MCOs for implementation. The PSC is not asking the MCOs to do petitioners' work for them, but rather is moving the Special Masters to give the PSC experts access to the data in order for the PSC experts to do the work themselves—the work of generating SAS computer programs to query the data sets, sorting, sifting, assembling and ultimately analyzing the data. This is not analogous to a civil litigant impermissibly asking its adversary to conduct tests on behalf of the opposing party; rather, it is the Special Masters requiring that the MCOs make existing data available to experts so that the experts can conduct

research for the benefit of the Special Masters. Again, the PSC motion does not request the creation of data that does not exist, it instead seeks access to existing data so that it may be organized and analyzed to provide necessary information to the Special Masters.

E. The Proposed Study Will Not Compromise Patient Privacy

The petitioners' experts have no intention of conducting research or using methodologies that would in any way compromise the medical confidentiality or patient privacy of any participant in the VSD. The experts, again, have all participated in many studies involving human subjects, sensitive medical information and personal data, and routinely employ study methodologies to avoid the discovery or disclosure of identifying information or confidential records. While the MCOs' concern for the integrity of confidential patient data is completely legitimate, their suggestion that such a study would compromise privacy is entirely speculative. Study designs and protocols as a matter of course include privacy safeguards, and that would certainly be the case in this instance.

F. Petitioners Reserve the Right to Seek Alternative relief if the Motion is Denied

If the motion to compel is denied, then the PSC reserves the right to move to exclude any evidence proffered by respondent that relies on, or that is derived from, the VSD. It appears that respondent transferred possession, if not control, of the VSD to a third party during the pendency of this litigation, perhaps placing the VSD beyond the scope of the discretionary discovery available to the Special masters in these proceedings. Respondent has also refused to produce requested documents relating to the TSA, and respondent might have lost or destroyed materials (including documents, datasets and datafiles) generated during the course of the TSA. Those actions have deprived the Special Masters and petitioners of the benefit of that discovery, and in equity the respondent should be estopped from introducing evidence relying on the VSD.

The PSC is not making such a motion at present, but reserves the right to raise the issue by motion before or during the general causation hearings beginning in June 2007.

CONCLUSION

The Special Masters are authorized to grant the relief requested against either the respondent or the third-party MCOs. Granting the Motion to Compel would provide the Special Masters with information about potential associations between TCVs and the MMR vaccine and neurological injuries that is necessary to resolving issues of general causation in the Omnibus Proceeding. The data exists, it is not available to the Special Masters or petitioners absent an Order granting the motion, it is in the possession or control of the CDC, the MCOs, or both, and the burdens of complying with such an Order are outweighed by the compelling need for the evidence. For all of these reasons, the petitioners' Motion to Compel should be granted.

DATED this 16th day of March, 2007.

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CERTIFICATE OF SERVICE

I hereby certify that on March 16, 2007, I served the foregoing **PSC REPLY RE MOTION TO COMPEL** on the following individual(s):

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By United Parcel Service, next day delivery.

Petitioners specifically authorize the Court and the Office of Special Masters to post this document, and any attachments or exhibits thereto, on the Court/OSM website, expressly waiving any confidentiality as to the contents of these materials. Petitioners expressly wish to publicly disclose this filing in any other forum designated by the Court or the OSM.

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