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 DEVELOPMENTAL DISORDER,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

AUTISM MASTER FILE
Special Master George Hasting

PETITIONERS' REPLY IN SUPPORT OF THEIR MOTION TO COMPEL DISCOVERY FROM RESPONDENT

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TABLE OF CONTENTS

I. INTRODUCTION 1

II. POINTS AND AUTHORITIES 2

A. The Special Master is Authorized to Compel the Requested Discovery. 2

B. Respondent's Position is Contrary to Autism General Order #1 that Authorizes Discovery before Petitioners Present their Causation Case. 3

C. The Requested Discovery is Reasonable and Necessary. 4

1.) The Requested Discovery is Relevant 5

2.) Petitioners and the Special Master have a Need for the Requested Information 6

3.) The Relevance and Need for the Requested Discovery far Outweighs any Potential Hardship to Respondent or its Client Agencies. 8

D. Petitioners' Request for Documents Relating to Ongoing and Completed Government Studies is Consistent with the Permissible Scope of Discovery in Vaccine Court 10

E. Petitioners Request for Thimerosal Screening Analysis Data Should be Granted. 11

III. CONCLUSION 14

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TABLE OF AUTHORITIES

Cases

Autism General Order #1, 2002 WL 31696785 (July 3, 2002) 3, 4

Daubert v. Merrell Dow Phramaceuticals, 509 U.S. 579 (1993) 5, 13

Heat and Control, Inc. v. Hester Industries, Inc., 785 F.2d 1017, 1024 (Fed.Cir. 1986) 5, 9, 13

Speller v. U.S., 14 Cl. Ct. 170, 172 (Cl. Ct. 1988) 5, 13

Statutes

42 U.S.C. §242m(d) 13

42 U.S.C. §300aa-12 2

42 U.S.C. §300aa-12(d)(3)(B) 3, 4

42 U.S.C. 300aa-12(d)(3)(B)(i), (iii) 2

Rules

Rules of Court of Federal Claims 26-37 ..... 2, 10

Rules of Court of Federal Claims, Rule 26(b)(1) 5

Rules of Court of Federal Claims 45 ..... 2, 10

Vaccine Rule 7 ..... 2, 5

Vaccine Rule 7(b) 2, 4

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I. INTRODUCTION

Respondent's arguments against petitioners' Motion to Compel are unavailing and the Motion should be granted for several reasons. First, the Special Master is explicitly authorized by the Vaccine Act, the rules of the U.S. Court of Federal Claims, the Vaccine Court rules, and the relevant case law to conduct formal discovery of the sort requested in petitioners' Motion. In addition, the discovery sought by petitioners is reasonably necessary to the Special Master's inquiry into the issues of general causation in the Omnibus proceeding. The requested discovery is necessary to the Special Master's evaluation of the general causation evidence, regardless of the specific theories of causation the petitioners will ultimately present, because the requested discovery will provide the Special Master with information needed to evaluate and weigh the scientific evidence.

In addition, respondent incorrectly attempts to argue that the requested discovery can be "reasonable and necessary" only if petitioners first present some or all of their case for general causation, a position finding no support in legal authority and an argument directly at odds with the General Order that initiated this Omnibus Proceeding. Respondent completely ignores the balancing test that the Special Master is obliged to consider when deciding whether to conduct discovery, and respondent's argument fails when measured against the relevant legal standards.

Respondent's argument also fails because it overstates the scope of the petitioners' request for information relating to completed and ongoing studies, and in so doing overstates the alleged burden placed on the federal client entities in complying with the request. The respondent incorrectly attempts to make it appear that the petitioners' requests are nonspecific or unfocused, while the requests are in fact very narrowly drawn and directed with particularity to a finite set of completed and ongoing studies, and to specific government entities.

As will be described below, petitioners' discovery requests are reasonably necessary to the Special Master's completion of the general causation inquiry, the requests are appropriately specific, the burdens of compliance are low, and granting the discovery requests is squarely

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within the Special Master's authority under 42 U.S.C. §300aa-12. For all of these reasons, the Motion to Compel should be granted.

II. POINTS AND AUTHORITIES

A. The Special Master is Authorized to Compel the Requested Discovery.

Respondent incorrectly claims, absent any supporting legal authority, that ordering the government to produce the requested discovery would be "unlawful." Resp. Memo., p. 8. The express terms of the Vaccine Act, however, give the Special Master the authority to " require the testimony of *any person* and the production of *any documents* as may be reasonable and necessary." 42 U.S.C. 300aa-12(d)(3)(B)(i), (iii) (emphasis added). Congress, by giving the Special Master the authority to conduct discovery as to "any" people and "any" documents, expressly allowed the Special Master to conduct discovery of parties and non-parties to Vaccine Act claims. Respondent's implication that only *petitioners* are subject to discovery in NVIC proceedings (Resp. Memo., p. 8, fn. 8) completely ignores the terms of the controlling statute.

Similarly, the rules of the Vaccine Court recognize Congress' grant of discretionary discovery authority to the Special Master, specifically authorizing the Special Master to conduct any of the discovery that is within the power of the Court of Claims under the Rules of the Court of Federal Claims. VR 7(b) (authorizing the use of the "discovery procedures provided by RCFC 26-37" in proceedings before the Special Masters). Vaccine Rule 7 therefore incorporates the discovery and subpoena rules of the Court of Claims, giving the Special Master discretion to conduct discovery as permitted under RCFC 26-37 and RCFC 45. The rules of the Court of Claims and the relevant case law authorize the Court to require discovery from any person without excluding the respondent, the Vaccine Rules expressly incorporate the discovery provisions of the RCFC, and nothing in the statute or in the rules exempts respondent from the Special Master's authority to conduct discovery.

The Special Master has the authority to order the discovery sought by petitioners' Motion if he decides that the discovery is reasonable and necessary to resolving the general causation

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inquiry in the Omnibus Proceeding. There is nothing "unlawful" about compelling the requested discovery.

B. Respondent's Position is Contrary to Autism General Order #1 that Authorizes Discovery before Petitioners Present their Causation Case.

Respondent consistently and mistakenly attempts to treat this Omnibus Proceeding as if it was, in a practical sense, a series of proceedings on individual "causation in fact" petitions for compensation, arguing that the government is not subject to any discovery until petitioners put on their cases for causation and compensation, that no discovery should go forward until petitioners have presented their cases, and insisting on a front-loaded proffer of evidence for every petition. Resp. Memo, pp. 4-8.

That argument has already been rejected by Chief Special Master Golkiewicz in Autism General Order #1, which recognized that these autism cases "present far different issues" than are presented in traditional Program claims. Autism General Order #1, 2002 WL 31696785 (July 3, 2002), at p. 5-6. Rather than "relatively few" cases alleging "actual causation" as initially anticipated by Congress, the Program here confronts approximately 4000 causation cases that place extraordinary demands on the Program. *Id.*, at 6. Respondent completely misses the mark in attempting to say that Congress "expressly prohibited" the discovery anticipated by General Order #1 (see, Resp. Memo., p. 7, fn.7) for the simple reason that the Chief Special Master decided that the discovery was required, and ordered it to proceed, pursuant to 42 U.S.C. §300aa-12 (d)(3)(B).

In creating the Omnibus Proceeding, the Chief Special Master specifically decided that discovery would proceed *before* expert reports are filed, and that "it will not be known whether one or more causation theories are at issue" until discovery is completed and reports filed. *Id.* Respondent's position urging that the petitioners first put on their causation case before discovery takes place is completely at odds with the sequence of events described in General Order #1. In addition, the General Order generally authorized discovery as part of the Omnibus

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causation inquiry, a decision directly at odds with respondent's ill-founded claims that discovery of the sort requested is somehow foreign to the NVICP.

Respondent should not be permitted to turn the procedural sequence of General Order #1 on its head by requiring petitioners to present their causation case as a prerequisite for discovery. Just as there is nothing in the Vaccine Act, the rules of the Court, or the rules of the NVICP that limits reasonable and necessary discovery directed to respondent, there is no legal support for the proposition that the Chief Special Master was acting beyond his authority in directing the parties to proceed under the terms Autism General Order #1 in handling these claims. The Order directs that discovery be complete before the causation case is presented, and petitioners' instant Motion is consistent with that Order.

C. <u>The Requested Discovery is Reasonable and Necessary.</u>

Respondent erroneously assumes that discovery can be reasonable and necessary only if petitioners first present their causation case to the Special Master. As described above, that argument is not supported by any legal authority and is at odds with the General Order that controls this proceeding. Respondent further cannot point to any authority for the proposition that an expert affidavit or some other evidentiary showing is a prerequisite to the Special Master's exercise of his authority under the Vaccine Act to conduct or compel discovery. Rather, as the Special Master in this case wrote in an draft Order[1] regarding non-party discovery in this proceeding, the Special Master has "extremely broad authority to determine when to authorize a subpoena or other formal discovery procedures" pursuant to 42 U.S.C. §300aa-12 (d)(3)(B) and Appendix B of Vaccine Rule 7. Draft Order Authorizing Issuance of Subpoena, October 2003, p. 3. The decision to conduct discovery is governed by the "circumstances of the case," and the Special Master is guided by the same factors that any trial court would use under the applicable rules of civil procedure. *Id.* The decision is essentially a balancing test that

[1] Petitioners cite to the draft Order not as precedent, since the Order appeared in draft form only and was not signed or filed, but merely to acknowledge the source of petitioners' argument on this point.

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weighs the "relevance of the discovery sought, the requesting party's need, and the potential hardship to the party subject to the subpoena." *Heat and Control, Inc. v. Hester Industries, Inc.*, 785 F.2d 1017, 1024 (Fed.Cir. 1986).

Rather than addressing the balancing test outlined in *Hester,* respondent persists in the misguided argument that discovery should not proceed against the government at all, and that any further discovery requires the presentation of petitioners' causation case in order to establish "necessity." Under the relevant law, however, petitioners Motion satisfies the criteria that the Special Master should use in deciding whether the requested discovery is reasonable and necessary.

1.) The Requested Discovery is Relevant

Petitioners seek information reasonably calculated to lead to the discovery of admissible evidence, and information that is facially relevant. Under the rules of the Court of Federal Claims that are adopted by Vaccine Rule 7, relevance in discovery is broadly construed, and "where there is doubt over relevance, Rule 26(b)(1) indicates that the court should be permissive." *Speller v. U.S.,* 14 Cl. Ct. 170, 172 (Cl. Ct. 1988) (internal citations and quotes omitted). The requested discovery in petitioners' Motion is clearly relevant under this standard. Petitioners seek scientific and medical information related to causation, they seek information reasonably calculated to lead to the discovery of relevant scientific and medical evidence, and they seek information that will allow the Special Master and the parties to evaluate and weigh scientific evidence presented by experts from both sides of the general causation inquiry. Respondents note (Resp. Memo., p. 5, fn. 4) that petitioners must present scientific or medical evidence of causation that "meets standards of reliability comparable to those enunciated in *Daubert v. Merrell Dow Pharmaceuticals,* 509 U.S. 579 (1993)."[2] If that is the case, then the

[2] The *Daubert* standards relate to the admissibility of evidence and not only to its reliability—reliability is but one of the factors a court may consider under the *Daubert* analysis. The same standards of admissibility will of course apply to any scientific evidence proffered by respondent, as *Daubert* and its progeny apply to defendants and respondents as well as to plaintiffs and claimants.

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information sought in the Motion is particularly relevant because it will permit the Special Master to evaluate the scientific evidence and assess the evidence of both sides. The requested information is facially relevant, and contrary to respondent's unsupported claim, there is no requirement of an expert affidavit or the presentation of any part of petitioners' case that is required to establish relevance.[3]

2.) Petitioners and the Special Master have a Need for the Requested Information

The "background" materials regarding the completed and ongoing studies that are the subject of petitioners' Motion are, as far as petitioners can establish through discovery to date, in the exclusive possession of respondent's client federal agencies—there is no other source for the documents. The unavailability of the facially relevant information through any source other than respondent supports a finding that the formal discovery directed by the Special Master is needed in order to obtain the information. Petitioners have identified those specific studies—completed and ongoing—that are subject to the document discovery requests made in petitioners' Motion to Compel. The Motion is attached as Exhibit A (without its accompanying memorandum of law).

Request No. 3 seeks background documents relating to completed, published studies concerning possible links between thimerosal, the MMR vaccine, or a combination of the two, and the neurological injuries, including autism spectrum disorders, at issue in this proceeding.[4] There are five completed studies that petitioners believe are subject to this request. The studies were described in the depositions of Melinda Wharton, MD and Coleen Boyle, Ph.D., witnesses

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[3] Respondent mischaracterizes the requested discovery as an effort to examine the "mental processes" of the investigators involved in the subject studies. That simply is not the case—petitioners instead seek information regarding the *scientific* processes involved in generating each of the studies at issue, as the Special Master ought to have the benefit of knowing how a study was conducted and why it was conducted in one way as opposed to other ways. There is nothing "chilling" about an inquiry into the methodology of a scientific project when one must ultimately weigh the results of that project against other evidence.

[4] Request No. 1 makes essentially the same requests directed specifically to the Stehr-Green study, a study included in the list of completed studies.

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provided for deposition by respondent. The completed studies at issue are summarized at Exhibit B, and they are described in more detail in the depositions and documents produced at the depositions. (Dr. Wharton's deposition transcript and accompanying exhibits are attached as Exhibit D, and the transcript and exhibits of Dr. Boyle's deposition are attached as Exhibit E). As is apparent from the depositions, the background materials relating to the five completed and relevant published studies are available only from the respondent's client agencies, respondent has declined to provide the materials informally, so there is a need to compel their production through the formal discovery process available to the Special Master.

Similarly, Request No. 4 seeks background documents relating to ongoing, unpublished studies concerning possible links between thimerosal, the MMR vaccine, or a combination of the two, and the neurological injuries, including autism spectrum disorders, at issue in this proceeding. The eight ongoing studies at issue are summarized at Exhibit C, and they are described in more detail in the depositions and documents produced at the depositions. As is the case with the completed studies subject to Request No. 3, the materials relating to ongoing studies in Request No. 4 are available only from the respondent's client agencies, respondent has declined to provide the materials informally, so there is a need to compel their production through the formal discovery process available to the Special Master.

Finally, petitioners need the Special Master to compel the production of a representative of the NIH to appear as an organizational witness for deposition as requested in the Motion to Compel at No. 2 because respondent has refused to make such a witness available.

Because the facially relevant documents and witness are not available through any source but the respondent's client agencies, the Special Master needs to compel the production of the requested discovery.

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3.) The Relevance and Need for the Requested Discovery far Outweighs any Potential Hardship to Respondent or its Client Agencies.

Respondent makes much—too much, in fact—of the supposed burden and hardship that complying with petitioners' discovery requests would entail, leading off by inaccurately describing the discovery request as a "fishing expedition." Rather than a "fishing expedition," however, petitioners have targeted specific documents from specific studies (completed and ongoing), appropriately narrowing the scope of the requested discovery based on an evaluation of the discovery already produced. By taking the depositions of Ms. Boyle and Dr. Wharton, for example, petitioners narrowed the scope of studies subject to the Motion to Compel to two discrete lists. The requested organizational deposition of the NIH is also specifically described in the Notice of Deposition and, like the four depositions that have already taken place, the scope of the NIH deposition would be narrowly focused on the issue areas and subjects described in the Notice.

In the course of preparing for and testifying at deposition, Ms. Boyle and Dr. Wharton prepared and presented exhibits describing what "background" documents existed relevant to each completed or ongoing study, who prepared the documents, and where the documents are located. While those lists are not necessarily exhaustive of Requests Nos. 1, 3 and 4 in petitioners Motion, they are at least a good start, and those exhibits demonstrate that respondent's client agencies can, in fact, identify responsive documents and the exhibits describe with some particularity where the documents are located. It simply is not true that petitioners' request somehow seek to canvass every government agency or that petitioners seek to impose an ongoing document production burden that would impede the scientific functions of the relevant client agencies. The list of studies subject to the discovery request is finite and specific; the categories of documents requested is finite and specific; the list of agencies or entities in possession of the requested documents is finite and specific; and it appears from the depositions

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of government witnesses so far that the existence of relevant documents, and their contents and location, can be described with some particularity.

Respondent's overblown claims of "burden" or "hardship" fail in the context of what petitioners are actually seeking based on the discovery already conducted in this proceeding. Respondent also fails to satisfy the legal burden of demonstrating that the alleged hardship is so oppressive as to bar discovery. As described by the Federal Circuit, the burden of showing that requested discovery is oppressive or unduly burdensome is on the party resisting the request, and the burden is "a heavy one." *Heat and Control, Inc. v. Hester Industries, Inc.*, 785 F.2d at 1025.[5] Respondent unsuccessfully attempts to meet its heavy burden by making vague and abstract claims of burden based on mischaracterizing the requests as a non-specific "fishing expedition," with no effort to identify any oppression or undue burden that would result from complying with the specific requests made in the Motion to Compel. Respondent fails to even discuss the relevant legal standard, respondent's showing of hardship fails to meet the heavy burden imposed by the law, and any alleged hardship is outweighed by the relevance of the requested discovery and the need to obtain it through an order of the Special Master.[6]

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[5] The requested discovery went forward in *Hester* despite the existence of privileged and confidential material that was subject to the discovery request. Respondent in this instance is not asserting any privilege or claiming that any of the requested discovery is confidential, having temporarily dropped (while "reserving") their deliberative process objections.

[6] Petitioners withdraw their request for unredacted PLAs (Request No. 6 in their Motion). The request is withdrawn based on telephone conference calls and correspondence with respondent indicating that complying with the request would involve respondent and /or its client agencies in protracted collateral litigation with the vaccine manufacturers. Moreover, it was made clear in related discovery proceedings directed to the vaccine manufacturers that the manufacturers would indeed resist any production of unredacted PLAs, whether the requests were directed to the manufacturers or to the respondent. Petitioners have weighed the burden and hardship that such collateral litigation would impose on the parties and the impact such collateral litigation would have on the progress of the Omnibus Proceeding against the relevance and need for the unredacted PLAs in deciding to withdraw the request.

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D. Petitioners' Request for Documents Relating to Ongoing and Completed Government Studies is Consistent with the Permissible Scope of Discovery in Vaccine Court.

Respondent erroneously argues that discovery of "background documents" relating to relevant studies of the sort permitted in civil litigation is not analogous to this Omnibus Proceeding in Vaccine Court. That premise is wrong in the first instance because the Vaccine Rules, particularly Rule 7 and its subparts, explicitly incorporate the rules of discovery of the U.S. Court of Federal Claims into vaccine compensation proceedings, and the Special Master (as discussed extensively above) is authorized by statute to take advantage of those discovery rules if he finds it reasonable and necessary. Those rules—RCFC 26-37, and 45—are of course virtually identical to the Federal Rules of Civil Procedure governing discovery in the civil justice system. Respondent's position that the civil discovery rules and discovery rules in Vaccine Court are not parallel is unavailing in light of the specific adoption in the Vaccine Rules of the discovery rules that govern civil proceedings of the sort described by petitioners' Motion.

In addition, respondent mistakenly argues that treating the Omnibus Proceeding in a manner similar in some respects to a multi-district litigation in the federal courts would create unneeded complexity and impose overly litigious burdens on these compensation proceedings. That argument fails for several reasons. First, the Omnibus Proceeding that essentially coordinates approximately 4000 individual claims in one proceeding for purposes of addressing general causation issues is itself directly modeled on the MDLs involving pharmaceutical mass torts and other toxic exposures cases involving multiple plaintiffs. Second, the MDL model, to the extent that it is analogous to the Omnibus Proceeding, actually *reduces* the complexity of the overall caseload, avoiding duplicative discovery requests, saving the resources of the parties and the court by addressing general causation once instead of 4000 times, and reducing the burden on the Program that would otherwise be imposed by the processing of 4000 individual claims under the timelines imposed by the Vaccine Act. Third, as argued in petitioners' Motion, the type of discovery requested here is regularly conducted in the civil litigation system, particularly in

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MDLs involving complex issues of scientific evidence. Fourth, respondent incorrectly tries to distinguish and limit Judge Rothstein's rulings in the PPA cases described in petitioners' Motion, but that argument fails because the supposedly "limiting" aspects of Judge Rothstein's opinion were directed at the "deliberative process" objections which respondent has dropped in this case. That the PPA discovery sought was relevant to theories of liability rather than causation is of no matter—the point of the opinion and order is that a party is entitled to "background materials" necessary to proving a claim or defense in a case. That same premise supports discovery here, where the requested information is relevant to general causation.

Finally, respondent argues at length that petitioner's request is overly litigious, and that granting the Motion would inject a hitherto foreign element of adversarial litigation into the vaccine compensation proceedings. It is not petitioners' place here to describe whether, or how, or why a no-fault compensation program has apparently assumed many of the characteristics of adversarial litigation over time. There is no denying, however, that the program does appear to parallel the adversarial model of the civil litigation system in some respects. One cannot help but reach that conclusion when, for example, respondent's own Response Brief arrives via facsimile with a transmittal heading from "DOJ Vaccine Litigation." There is an element of litigation to these proceedings, but it does not emanate from petitioners' discovery requests or from the instant Motion. That the requested discovery resembles the type of discovery permitted in analogous proceedings in the civil justice system[7] is not a sufficient rationale to bar the requested discovery.

E. Petitioners Request for Thimerosal Screening Analysis Data Should be Granted.

Petitioners' Request No. 5 seeks access to datasets generated by the Vaccine Safety Datalink ("VSD") as part of the CDC's thimerosal screening analysis ("TSA"), Phase II of which

[7] One of the biggest differences between petitioners' requested discovery and the discovery that would occur in an analogous civil mass tort proceeding is that petitioners here seek no discovery of issues relating to liability, damages, or punitive damages. The requested discovery is therefore significantly more limited than discovery in the civil setting.

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was published in 2003. Petitioners' request is reasonable and necessary for two primary reasons. First, as explained in petitioners' original Motion, the requested documents are needed in order to completely assess and analyze the conclusions of the study, to examine the study for possible bias, to reach conclusions about the strengths and limitations of the studies' contributions to causality, to explain apparent differences in the conclusions reached by Phase I and Phase II, and to validate and analyze other research that is underway involving the VSD. In addition, the Request at No. 5(b) is particularly subject to discovery in this instance because of the very high relevance of the requested data and its unavailability from any other source.

Request 5(b) seeks data that would allow petitioners and the Special Master to determine whether any of the children included in the TSA's initial cohort who were not diagnosed as having autism or any other neurodevelopmental disorder by the cut-off date of the study in 2000 might have *later* received such a diagnosis. The median age at which autism spectrum disorders is diagnosed is approximately five years old, so those many members of the TSA cohort who were less than five years old at the time of the study's end-date would be excluded from a later, age-appropriate diagnosis. While the TSA tracked the relative thimerosal exposures of those younger members of the cohort, the published study provides no information as to whether those exposures ultimately led to a relevant injury. The data petitioners seek would allow the Special Master and the parties to determine the ultimate diagnostic fates of thousands of children included in the initial TSA cohort. The discovery sought is therefore extremely relevant, as it would allow the Special Master and the parties to measure the incidence of autism and other neurological injuries in a subset of the exposed TSA cohort, evidence directly relevant to the general causation inquiry in the Omnibus Proceeding.

The discovery is highly relevant, and based on the respondent's brief the use of the Special Master's discovery power is needed in order to get the information. Respondent represents that the CDC "are able to access post-2000 data for the research they undertake in collaboration with principal investigators from the MCOs. However, *post-2000 data is not*

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available to external researchers as part of the Data Sharing Program," unless the data ultimately makes it way into a completed CDC study. Resp. Memo., p. 19, fn. 16 (emphasis added). It appears from this note that, contrary to respondent's general position that the petitioners can obtain the requested TSA data via the IRB process as "external researchers," the petitioners cannot get this requested data through that process. It appears that obtaining the data through the CDC is the only option available, and the only way to get the data from the CDC is to compel its production via an order of the Special Master.

Respondent's other objections to the release of the data subject to request No. 5 center largely on issues of privacy and confidentiality, and as such they are unfounded. The Public Health Service Act strictly limits access to data provided by the MCOs in order to protect individual patient information and to prevent the disclosure of proprietary information related to the participating MCOs. As petitioners have consistently maintained, however, the patient privacy concerns under 42 U.S.C. §242m(d) can be addressed by removing any identifying information form the requested datasets, and petitioners do not object to any reasonable protective order that allows access to the data while also preventing the release of information that could directly or indirectly identify any individual whose medical information is part of the database. Such a protective order could also protect the proprietary interests of the MCOs. Petitioners have no interest whatsoever in identifying either individual members of the TSA cohort or in discovering trade or business secrets of the MCOs.

Finally, respondent attempts to use the wrong legal standard in assessing this discovery request. Respondent mistakenly relies on *Daubert* to argue that discovery should not be compelled. Resp. Memo., p. 21. The criteria in *Daubert,* however, address the *admissibility* of evidence at trial—the case has nothing to do at all with the legal standards for *discovery*. The scope of permissible discovery is of course much broader than the scope of admissible evidence, a point made in *Speller v. U.S.,* 14 Cl.Ct. 170 and *Heat and Control, Inc. v. Hester Industries, Inc.,* 785 F.2d 1017 (discussed above), and obvious on the face of RCFC 26.

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The TSA data is highly relevant and available only through discovery directed to the respondent and its client agencies. Respondent makes no showing of hardship or burden, and the privacy concerns of the relevant federal statutes can be completely addressed by an appropriate protective order. Discovery of the requested TSA data is therefore reasonable and necessary, and the Special Master should compel its production.

III. CONCLUSION

For all of the reasons described above, petitioners' Motion to Compel Discovery, Requests Nos. 1-5, should be granted and the Special Master should issue an Order directing respondent to produce the documents and deponent requested in petitioners' Motion.

DATED this 4th day of June, 2004.

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CERTIFICATE OF SERVICE

I hereby certify that on June 4, 2004, I served the foregoing **PETITIONERS' REPLY IN SUPPORT OF THEIR MOTION TO COMPEL DISCOVERY FROM RESPONDENT** on the following individual(s):

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Alexandria, VA 22314

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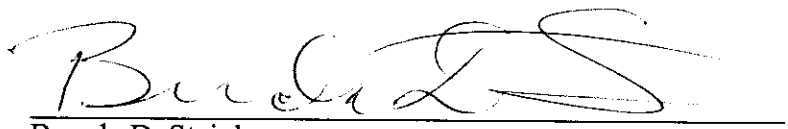

Brenda D. Steinle
WILLIAMS DAILEY O'LEARY CRAINE & LOVE, P.C.

cc: George Hastings, Special Master
U.S. Court of Federal Claims
Office of the Special Master
529 14th St. N.W. #302
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(Exhibits A through E, attached to the Petitioners' Reply, have been filed into the Master Autism File, but are not being placed on the website for the Omnibus Autism Proceeding due to the provisions of 42 U.S.C. § 300aa-12(d)(4)(A).)