In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

(Filed: May 25, 2007)
FOR PUBLICATION

IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER OR A SIMILAR NEURODEVELOPMENTAL DISORDER	*	**AUTISM MASTER FILE**
VARIOUS PETITIONERS,	*	
v.	*	Ruling Concerning Discovery Motion.
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

RULING CONCERNING PETITIONERS' "SECOND MOTION TO COMPEL"

The above-captioned proceeding is a special proceeding conducted pursuant to the National Vaccine Injury Compensation Program (hereinafter "the Program").[1] As will be detailed below, this proceeding involves claims filed under the Program by numerous families, alleging that their children's neurodevelopmental disorders were caused by certain childhood vaccines. This ruling constitutes our ruling concerning a discovery motion by the petitioners that has been described as the petitioners' "Second Motion to Compel."

For the reasons set forth below, we hereby deny that motion.

[1]The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 *et seq*. (2000 ed.). Hereinafter, for ease of citation, all "§" references will be to 42 U.S.C. (2000 ed.). We will also at times refer to the statute that governs the Program as the "Vaccine Act."

I

BACKGROUND

A. The "Omnibus Autism Proceeding"

The discovery dispute that is the subject of this opinion arises in the context of an unusual situation involving multiple cases filed under the Program that share a common issue of medical causation. Each of these cases involves an individual who suffers from a neurodevelopmental disorder known as an "autism spectrum disorder"--"autism" for short--or a similar neurodevelopmental disorder. In each case, it is alleged that such disorder was causally related to one or more vaccinations received by that individual--*i.e.*, it is alleged that the disorder was caused by measles-mumps-rubella ("MMR") vaccinations; by the "thimerosal" ingredient contained in certain diphtheria-tetanus-pertussis ("DTP"), diphtheria-tetanus-acellular pertussis ("DTaP"), hepatitis type B, and hemophilus influenza type B ("HIB") vaccinations; or by some combination of the two. To date, more than 5,100 such cases have been filed with this court, and more than 4,800 remain pending.

To deal with this large group of cases involving a common factual issue--*i.e.*, whether these types of vaccinations can cause autism--the Office of Special Masters (OSM) conducted a number of informal meetings in 2002 with attorneys who represent many of the autism petitioners and with counsel for the Secretary of Health and Human Services, who is the respondent in each of these cases. At these meetings the petitioners' representatives proposed a special procedure by which the OSM could process the autism claims as a group. They proposed that the OSM utilize a two-step procedure: first, conduct an inquiry into the *general causation issue* involved in these cases-- *i.e.*, whether the vaccinations in question can cause autism and/or similar disorders, and if so in what circumstances-- and then, second, apply the evidence obtained in that general inquiry to the individual cases. They proposed that a team of petitioners' lawyers be selected to represent the interests of the autism petitioners during the course of the general causation inquiry. They proposed that the proceeding begin with a lengthy period of discovery concerning the general causation issue, followed by a designation of experts for each side, an evidentiary hearing, and finally a ruling on the general causation issue by a special master. Then, the evidence concerning the general causation issue, obtained as a result of the general proceeding, would be applied to the individual cases.

As a result of the meetings discussed above, the OSM adopted a procedure generally following the format proposed by the petitioners' counsel. On July 3, 2002, the Chief Special Master, acting on behalf of the OSM, issued a document entitled the *Autism General Order #1*.[2]

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[2]The *Autism General Order #1* is published at 2002 WL 31696785, 2002 U.S. Claims LEXIS 365 (Fed. Cl. Spec. Mstr. July 3, 2002). We also note that the documents filed in the Omnibus Autism Proceeding are contained in a special file kept by the Clerk of this court, known as the "Autism Master File." An electronic version of that File is maintained on this court's website. This electronic version contains a "docket sheet" listing all of the items in the File, and also contains the

That Order set up a proceeding known as the Omnibus Autism Proceeding (hereinafter sometimes the "OAP"). In the OAP, a group of counsel selected from attorneys representing petitioners in the autism cases are in the process of obtaining and presenting evidence concerning the *general issue* of whether these vaccines can cause autism, and, if so, in what circumstances. The evidence obtained in that general inquiry will then be applied to the individual cases. (2002 WL 31696785 at *3; 2002 U.S. Claims LEXIS 365 at *8.)

The *Autism General Order #1* assigned the initial responsibility for presiding over the Omnibus Autism Proceeding to Special Master George Hastings. In addition, Special Master Hastings was also assigned responsibility for all of the individual Program petitions in which it was alleged that an individual suffered autism or an autistic-like disorder as a result of MMR vaccines and/or thimerosal-containing vaccines. The individual petitioners in the vast majority of those cases requested that, in general, no proceedings with respect to the *individual petitions* be conducted until after the conclusion of the OAP concerning the *general* causation issue.[3] The plan has been that the Office of Special Masters will deal specifically with the *individual* cases, once the OAP concerning the *general* causation issue has concluded.

In a document filed into the Autism Master File on January 11, 2007, the Chief Special Master made procedural alterations to the Omnibus Autism Proceeding. He added two additional Special Masters, Denise Vowell and Patricia Campbell-Smith, to preside over the OAP along with Special Master Hastings. Since that time, the three undersigned special masters have jointly resolved procedural issues in the OAP, such as the instant discovery motion.[4]

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complete text of most of the items in the File, with the exception of some documents that are withheld from the website due to copyright considerations or due to § 300aa-12(d)(4)(A). To access this electronic version of the Autism Master File, visit this court's website at www.uscfc.uscourts.gov. Click on the "Office of Special Masters" page, then on the "Autism Proceeding" page.

[3]We note that it has always been up to each individual petitioner to determine whether to defer proceedings concerning his or her own case pending the completion of the Omnibus Autism Proceeding. If an individual petitioner has proof of causation in his own case that he wishes to put before a special master at any time, that petitioner will be allowed to do so.

[4]Under the statutory scheme, a "decision" in an individual Vaccine Act case is to be filed by a *single* special master. However, the Omnibus Autism Proceeding is a special proceeding designed to efficiently deal with procedural issues that affect *many* different autism cases, and to allow for the efficient accumulation of evidence concerning "general causation" issues, so that such evidence can then be applied to individual cases. Accordingly, in resolving important procedural issues in the OAP, such as the instant PSC motion, we find it appropriate, and not inconsistent with the statutory scheme, that three special masters jointly address such issues.

B. Discovery from government files pursuant to PSC's initial discovery request

As noted above, at the outset of the Autism Omnibus Proceeding, the petitioners' counsel requested a significant period of time in which to conduct discovery before presenting the petitioners' case concerning the general causation issue. The original schedule called for a discovery period of 410 days--*i.e.*, about 14 months. (See 2002 U.S. Claims LEXIS 365 at *27-28.) A number of petitioners' counsel in the autism cases formed the "Petitioners' Steering Committee" (hereinafter the "PSC") in order to conduct the discovery and to otherwise represent the interests of the autism petitioners in the Omnibus Autism Proceeding. The PSC filed its initial, extensive discovery request on August 2, 2002. That document requested that the respondent provide many different sets of documents from the files of a number of different government agencies. The PSC and respondent's counsel began immediately to work together cooperatively in order to provide the PSC with the requested documents. An early complication to these cooperative efforts developed concerning the issue of whether the documents provided to the PSC would be covered by the Vaccine Act's "nondisclosure" provision contained at § 300aa-12(d)(4)(A). However, the parties worked out a compromise concerning that issue, in which the documents produced by respondent in response to the PSC's discovery requests are filed into the record of an individual autism case, *Taylor v. Secretary of HHS*, No. 02-699V, but those documents can be shared by the PSC with any petitioner or counsel having a pending autism case.[5] With that agreement in place, members of the PSC and respondent's counsel have continued to work together to provide a massive amount of documentation to the PSC.

The first information responsive to the PSC discovery request was provided to the PSC attorneys by directing them to various government websites, where certain material responsive to the PSC requests appeared. In addition, a large number of documents from several government agencies have been provided to the PSC and filed into the record of the *Taylor* case. To date, a total of 106 exhibits have been filed in *Taylor*, many consisting of multiple volumes. By our count, these exhibits have totaled about 218,000 pages of information. The federal agencies providing such information include the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the Centers for Disease Control (CDC), and the Agency for Toxic Substances and Disease Registry (ATSDR).

In addition, at the PSC's request, respondent made several agency officials available to the PSC for depositions. Officials of the CDC, the FDA, and the ATSDR were deposed.

C. Petitioners' second round of discovery from government files

On March 9, 2004, the PSC filed a "Motion to Compel Discovery." In this motion, the PSC requested that Special Master Hastings issue an order compelling the respondent to produce certain documents and make certain witnesses available for deposition. The issue was briefed, and the PSC

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[5]This compromise was formalized in Special Master Hastings' Order filed on December 19, 2002, in the Autism Master File.

filed an extensive set of exhibits relevant to this discovery request on October 7, 2004. An evidentiary hearing was held concerning the issue on September 23, 2004, the transcript of which was filed into the Autism Master File on September 29, 2004. Immediately following that hearing, the parties entered into an attempt to settle the dispute, and, after several months of effort, those talks proved successful. On April 8, 2005, the PSC filed an "Amended Motion to Compel Discovery," and the parties also submitted a proposed "Discovery Order" to settle the dispute. After his review, Special Master Hastings signed and filed that Discovery Order, as drafted by the parties, on April 14, 2005. As reflected in those two documents filed on April 8 and April 14, 2005, pursuant to the settlement the respondent provided some of the discovery requested, the PSC withdrew some of its discovery requests, and certain depositions were scheduled. Further, under that Discovery Order, the parties agreed that the PSC's two experts would be afforded access to certain material from the Vaccine Safety Datalink Project (that Project is described in detail below on this page).

After the filing of the Discovery Order on April 14, 2005, the parties went through the steps to execute the agreement. The parties regularly reported their progress concerning this matter during the regular, unrecorded status conferences held in the Omnibus Autism Proceeding, and Special Master Hastings at various times reported concerning that progress in his Autism Updates, issued over the following months. Eventually, the PSC's two experts did obtain access to the data specified in the agreement with respondent, and completed their analysis thereof. On December 13, 2006, the PSC filed the resulting report of those experts, as the Petitioners' Exhibit 91 in the Autism Master File.

D. Request for documents from vaccine manufacturers

On October 7, 2003, the PSC filed a motion requesting that a vaccine manufacturer, Merck & Co., be ordered to provide certain documents from its files. Extensive briefing followed, and on May 26, 2004, an evidentiary hearing was held concerning the request. On July 16, 2004, Special Master Hastings filed a Ruling denying the PSC's request.

E. The current discovery request

On December 8, 2006, the PSC filed its "Motion to Compel and For Issuing Third-Party Subpoenas" (hereinafter "Motion"). In the Motion, the PSC seeks to obtain access to certain data from the Vaccine Safety DataLink Project (hereinafter "VSD Project"). The VSD Project is a mechanism for conducting research on vaccine safety issues, established in 1990. The VSD Project is a collaborative effort of the Centers for Disease Control ("CDC"), a governmental agency, and eight large non-governmental organizations that provide health care, known as "managed care organizations" (hereinafter "MCOs"). (See Resp. Ex. A, filed 1-19-07.) The PSC's motion itself is vague as to the exact discovery desired, stating only that the PSC should be given "access to the VSD for purposes of an investigation into potential associations between thimerosal and MMR-exposure and adverse neurological or developmental outcomes in children." (Motion at 1.) However, along with the motion, the PSC filed Exhibit 86, which is entitled "Plan to Investigate Potential Vaccine Risk Factors for Autism and other Neurological and Neurodevelopmental

Disorders using the Vaccine Safety DataLink" (hereinafter the "Proposal"). This Proposal was authored by four medical experts. On its face, therefore, the PSC's request seemed to be that we order the CDC and the MCOs to allow the PSC's experts sufficient "access" to VSD Project "data" to enable those experts to carry out the proposed study described in Ex. 86.

Under the Proposal, the PSC's experts seek access to data concerning all children enrolled in all of the eight participating MCOs, apparently about 2.3 million children, pertaining to the years 1992 through at least 2004. The desired information includes, *inter alia*, data concerning: all vaccinations received by those children; all diagnoses of those children that fit within one of 35 specific diagnostic codes; the thimerosal content of all lots of vaccine administered after 1999; and all immunoglobulin vaccines or injections administered to the pregnant mothers of those children. (Ex. 86, pp. 2-3.)

F. Position of respondent and the MCOs

Both the respondent and the MCOs have filed briefs[6] and evidence opposing the PSC's request. They argue that the PSC has failed to show a need for the proposed discovery. They also argue that it would be unreasonable to grant the request, because, they contend, such an order would impose an unreasonable burden on both the CDC and the MCOs, and would be contrary to the contractual obligations governing the VSD Project.

II

THE STANDARD FOR OUR RULING

In this section II of this Ruling, we set forth and discuss the *standard* upon which we will base our ruling. We will divide our discussion into four parts, below.

A. The relevant statutory provisions and court rules

The Vaccine Act contains provisions with respect to discovery[7] in Program cases. The statute states that this court shall adopt rules that–

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[6]Our Autism Update filed on January 19, 2007, discussed the PSC's current "Motion to Compel." It indicated that the MCOs might be permitted to present their own case in opposition to the proposed subpoenas. In view of the time constraints imposed by the June 2007 hearing date, we determined that permitting the MCOs to interpose their written objections to the PSC discovery request would be more efficient, and lead to a more informed decision, rather than hearing their objections after issuing subpoenas.

[7]The term "discovery" is often used, in the context of litigation, to refer only to requests by a litigant for information from *another party* to the litigation. Here, however, we will use that term in a more expansive sense, to refer to requests for information from *either* a party *or* a non-party.

provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions in the United States Court of Federal Claims.

§ 300aa-12(d)(2)(E). That Act further provides that a special master–

(i) may require such evidence as may be reasonable and necessary,
(ii) may require the submission of such information as may be reasonable and necessary, [and]
(iii) may require the testimony of any person and the production of any documents as may be reasonable and necessary * * *.

§ 300aa-12(d)(3)(B). In turn, the "Vaccine Rules"[8] of this Court contain Rule 7 regarding discovery, which reads as follows:

Rule 7. Discovery.

There shall be no discovery as a matter of right.

(a) Informal Discovery Preferred. The informal and cooperative exchange of information is the ordinary and preferred practice.

(b) Formal Discovery. If a party considers that informal discovery is not sufficient, that party may seek to utilize the discovery procedures provided by RCFC 26-37 by filing a motion indicating the discovery sought and stating with particularity the reasons therefor, including an explanation why informal techniques have not been sufficient. Such a motion may also be made orally at a status conference.

(c) Subpoena. When necessary, the special master upon request by a party may approve the issuance of a subpoena. In so doing, the procedures of RCFC 45 shall apply. * * *

Accordingly, the statutory language plainly provides a special master with the authority to "require" testimony, or "require" the submission of "evidence" or "information" or "documents," whenever that master deems such testimony, evidence, information, or documents to be "reasonable and necessary" for the master's resolution of a Vaccine Act case. And Vaccine Rule 7 implements that statutory authority, by authorizing a special master, when that master deems it "necessary," to

[8]In actions before the special masters of the U.S. Court of Federal Claims, the special masters follow two sets of rules. The "Vaccine Rules of the United States Court of Federal Claims" (*hereinafter* "Vaccine Rules") are found in Appendix B of the Rules of the Court of Federal Claims (*hereinafter* "RCFC"). At the same time, special masters are bound by the other portions of the RCFC to the extent that such additional parts of the RCFC are referenced in the Vaccine Rules. Vaccine Rule 1; *Patton v. DHHS*, 25 F.3d 1021, 1026 (Fed. Cir. 1994).

(1) utilize the formal discovery procedures of RCFC 26-37, and (2) authorize a party to issue subpoenas, utilizing the procedures of RCFC 45.

In addition, the statute plainly extends the special master's authority to "require" testimony and submission of evidence to *non-parties* as well as the parties to a Program proceeding, stating that the master may "require the testimony of *any* person and the production of *any* documents * * *," and, in general, failing to limit the master's authority to Vaccine Act parties. (§ 300aa-12(d)(3)(B)(iii), emphasis added.) Once again, this court's rules confirm that authority. That is, Vaccine Rule 7(c) authorizes special masters to approve the use of subpoenas under the procedures of RCFC 45, and RCFC 45(c) provides for the service of subpoenas on "persons," not just parties.

B. Difference from other litigation

It is important to note that the statute provides this "discovery" authority to a special master in a context *quite distinct* from discovery in most legal proceedings. This context differs from most other litigation in two respects.

The first difference is that under the Vaccine Act there is a distinctly different orientation concerning the basic purpose of discovery. That is, in the context of most litigation, in discovery a *party* is seeking information that it hopes to later present before a factfinder; the judge's role in such discovery proceedings is merely to *referee disputes* concerning whether the discovery requested is appropriate within the prescribed discovery rules and precedents. In the Vaccine Act context, however, the special master is not only the referee of procedural disputes, but also the *ultimate factfinder* on all disputed factual issues; thus, when a master decides whether to use his or her discovery authority, the test is whether the master concludes that the production of the material in question is "reasonable and necessary" to the *master's own resolution* of the factual issues to be resolved. In other words, when a special master contemplates whether to utilize the authority to require testimony or submission of evidence, the master's task is to evaluate the importance and relevance of the material in question in light of the *overall context of the factual issues to be decided* by the master, determining whether the master reasonably needs that material in order to reach a well-informed decision concerning those factual issues.

The second crucial difference is that in Vaccine Act cases the *standard* for determining whether to require testimony or document production is quite different from the standard utilized in most litigation discovery disputes. Both RCFC 26(b)(1) and its counterpart in the Federal Rules of Civil Procedure, FRCP 26(b)(1), provide that "[p]arties may obtain discovery regarding any matter, not privileged, that is *relevant to the claim or defense* of any party * * *." Thus, the test is simply whether the material being sought is *relevant* to the issues in the case. In Vaccine Act cases, in contrast, the test, as noted above, is whether the special master finds that the material being sought is *reasonable and necessary* to the master's resolution of contested issues. Obviously, given the ordinary meanings of the words "relevant" and "necessary," material could be "relevant" to an issue without being "necessary" to the resolution of that issue. Therefore, it seems clear that the Vaccine Act sets a substantially higher standard.

C. The standard that we will utilize here

As noted above, the Vaccine Act's use of the phrase "reasonable and necessary" clearly indicates that the special master, in deciding when to "require" testimony or document production, is to use a standard that is higher than the "relevance" test generally used in other litigation. But, *how much* higher is the standard? That is not completely clear. The statute does not provide further guidance beyond the words "reasonable and necessary," and the legislative history offers no assistance. Certainly, the statute seems to afford the special master broad *discretion* in determining whether material is "necessary" or not, in the overall context of the case.

One might argue that the word "necessary" implies that the special master should require production only when it would be *absolutely impossible* to decide the factual issues in the case *without* the requested material. After consideration of this possibility, however, we conclude that the "reasonable and necessary" standard cannot be that strict. Such an interpretation would illogically set up a standard that could *never* be met, since a factfinder in a legal case can *always* rule on a factual issue no matter how scanty the evidence, even in the absence of *any* evidence. That is, in legal factfinding, if there is no evidence, the factual issue simply is resolved against the party having the "burden of proof." The "absolutely impossible" standard, therefore, plainly seems to be too strict, since under such a standard a special master would *never* require production, even of a petitioner's own medical records, and the master's statutory power to "require" testimony and the submission of evidence would amount to a nullity.

Instead, it seems to us that the "reasonable and necessary" standard means that the special master should require production if the master concludes that, given the overall context of the factual issues to be decided by the master, he or she could not make a *fair and well-informed* ruling on those factual issues without the requested material. Requiring production must also be "reasonable" under all the circumstances, meaning that the special master must consider the *burden* on the party who would be required to testify or submit evidence. That is, the importance of the requested material for purposes of the special master's ruling must be *balanced* against the burden on the producing party. This is the interpretation of the "reasonable and necessary" standard that we will utilize here.[9]

D. Vaccine Act precedent supports the use of this standard.

There is relatively little case law relating to discovery questions during the 18-year history of the Vaccine Act. This is not to say that the special masters during that time period have not utilized their statutory authority to require testimony and the submission of evidence. To the contrary, special masters have routinely employed such authority in order to obtain *medical records* pertaining to a particular vaccinee seeking compensation, by authorizing the parties to serve

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[9]As noted above, Vaccine Rule 7 states that the "procedures" of RCFC 26-37 and RCFC 45 are applicable to Vaccine Act discovery issues. Therefore, in applying the "reasonable and necessary" standard in Vaccine Act discovery disputes, a special master may also look to guidance provided in the Court of Federal Claims case law developed in interpreting those rules of the RCFC.

subpoenas to hospitals, physicians, etc. We have found virtually no case law concerning this use of subpoenas, however, probably because such use is so plainly appropriate under the statutory language that it has never been challenged.[10]

We have, however, identified several Vaccine Act opinions relevant to this dispute, which, in our view, support the standard that we have adopted here. The first such opinion concerned an earlier discovery dispute in this Omnibus Autism Proceeding. At that time, the PSC was seeking certain documents from a vaccine manufacturer, and, in a ruling that denied the requested discovery, Special Master Hastings adopted and applied the same "fair and well-informed ruling" standard that we have adopted here. See *In re: Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder*, 2004 WL 1660351, at * 8-9 (Fed. Cl. Spec. Mstr. July 16, 2004). Second, the same standard was endorsed by Special Master Margaret Sweeney[11] in *Werderitsh v. HHS*, 2005 WL 3320041 (Fed. Cl. Spec. Mstr. Nov. 10, 2005). A third relevant decision is *Golub v. Secretary of HHS*, 44 Fed. Cl. 604 (1999), *rev'd on other grounds*, 243 F. 3d 561 (Fed. Cir. 2000). In *Golub*, a special master denied the petitioners' claim that their daughter's injury was vaccine-caused, and, on appeal, the petitioners argued that the master had erred in failing to grant their discovery request that a government agency be required to divulge certain information. Judge Andewelt of this Court denied the appeal, noting that there existed "extensive available information" upon which the petitioners could argue their causation claim, and upon which the special master could evaluate that claim. *Id*. at 609. Given this existence of available information, the judge found that it was "not necessary for the special master to require the Department of Health and Human Services to search for additional unpublished materials, the existence of which is uncertain." *Id*. *Golub*, thus, provides additional support for the standard that we have adopted here. That is, the ruling indicates that the special master should evaluate a request for production of material by considering the *overall context of what other evidence is available* to the master, compelling production only when the other available evidence seems insufficient upon which to evaluate the relevant issues.

III

DISCUSSION

We have evaluated the PSC's request for discovery here at issue under the standard set forth above. After careful consideration, we conclude that the request must be denied. Based upon the record before us, we do *not* find that the requested material is "necessary" to the resolution of the factual issues in the Omnibus Autism Proceeding. We also conclude that, under the circumstances,

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[10]We have identified one case in which it is merely mentioned, without discussion, that a special master had authorized the issuance of a subpoena to obtain medical records. *Vant Erve v. Secretary of HHS*, No. 92-341V, 1997 WL 383144 at *3 (Fed. Cl. Spec. Mstr. June 26, 1997), *rev'd on other grounds*, 39 Fed. Cl. 607 (1997).

[11]Then a special master of this court, Margaret Sweeney has since been appointed a judge of this court.

it would not be "reasonable" to order the requested discovery. We will explain these conclusions in detail below.

A. The PSC request amounts to a request that we order that a study be performed.

Initially, we note that the PSC states that it is merely seeking "access" to "data," so that the *PSC's experts* can utilize that data to conduct a study. In reality, however, the request is much more complex than that. The respondent and the MCOs each filed a number of exhibits to their respective initial responses to the PSC's motion. Those exhibits make it clear that the "data" that the PSC seeks does *not* exist in a format in which it could simply be "copied," either by copying machine or by electronic copying or otherwise, and handed over to the PSC. Moreover, those exhibits also make it clear that under the contracts that govern the VSD Project, "data" of the type that the PSC seeks may *never* simply be handed over to an outside party to utilize in a study. To the contrary, it is clear that any study involving VSD Project data *must* involve *substantial participation* by personnel of the CDC and by personnel of any HMOs involved in the study. The PSC does *not* dispute that the relevant contracts so require.

Accordingly, it is clear that what the PSC seeks in its current discovery request is more than mere "access" to "data." In actuality, the PSC seeks that we order that a *study be performed*, involving work by personnel of both the CDC and the MCOs as well as by the PSC's experts.[12]

B. We do not find that the requested study is "necessary."

The first issue that we will address is whether the requested discovery is "necessary." After carefully considering the materials filed concerning this issue by the PSC, the respondent, and the MCOs, and also considering the *entire record* developed in the course of the Omnibus Autism Proceeding, we do *not* find that the requested study is "necessary" to the resolution of the factual issues in the OAP. We conclude, rather, that we can make a *fair and well-informed ruling* concerning those factual issues without the requested study. We detail several reasons for this conclusion below.

1. The PSC's proposed study seeks much irrelevant data.

One very important point, concerning the issue of whether the proposed study is "necessary" to the resolution of the OAP causation issues, is that certain major aspects of the proposed study do not appear even to be *relevant*, much less *necessary*, to the factual issues in the OAP. For example,

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[12]The opposing parties have sparred over the issue of whether the data from each of the MCOs should be considered to be under the "control" of the CDC or the MCO itself. While our initial impression, based upon the exhibits filed concerning this dispute, is that the post-2000 VSD Project data appears to be under the MCOs' control, we find it to be unnecessary to make a formal finding concerning the issue. Regardless of who "controls" the data, we do not see that it would be necessary or reasonable to order the performance of the study requested by the PSC.

the Proposal seems to seek much data concerning heart, hypertensive, and renal conditions. (Ex. 86, p. 5.) Based on the record before us, we cannot understand how a study of such data would relate to the issues of whether MMR vaccines and/or thimerosal-containing vaccines can cause *neurodevelopmental* disorders such as *autism*. The PSC certainly has made no attempt to explain why this data might be relevant.

Accordingly, this factor, that much of the data involved in the proposed study does not seem to be relevant to the OAP causation issues, is an extremely strong reason to conclude that the proposed study is not "necessary" to our resolution of those OAP causation issues.

2. There is ample evidence available elsewhere.

Next, we note that there already exists a very large amount of material available concerning the issues of whether MMR vaccines and/or thimerosal-containing vaccines can cause autism. First, we note that a mass of relevant material has been filed into the record of the Omnibus Autism Proceeding and into the record of the first "test case" to be tried as part of the OAP. Between December 8 and December 13, 2006, the PSC filed the Petitioners' Exhibits 1 through 91, most of which are relevant to the "general causation" factual issues described above, into the Autism Master File. Moreover, an even greater mass of material has been filed into the record of the case of *Cedillo v. HHS*, No. 98-916V, the case which the PSC has designated as the first "test case" in the OAP.[13] In *Cedillo*, the petitioners have filed five expert reports concerning the general issue of whether the combined effect of MMR vaccines and thimerosal-containing vaccines can cause autism. (*Cedillo*, Exs. 55, 57, 59, and 61, 63.) The petitioners have also submitted 196 medical articles and medical text excerpts, filed as attachments to those expert reports. (*Cedillo*, tabs to Exs. 55, 57, 59, and 61, 63.) The respondent, in turn, has filed 11 expert reports in *Cedillo*. (*Cedillo*, Exhibits L, N, P, R, T, V, X, Z, BB, DD, FF.) The respondent has also filed 517 medical articles and medical text excerpts, as tabs to the respondent's expert reports. (*Cedillo*, tabs to Exhibits L, N, P, R, T, V, X, Z, BB, DD, FF.)

Each of the undersigned special masters have read the expert reports filed in *Cedillo*, along with many of the studies and other articles filed by both sides in *Cedillo*, and many of the studies and articles contained at the PSC's Exhibits 1 through 91 filed into the Autism Master File. While none of us has, as yet, read *all* of those materials, our ongoing study of these materials has certainly given each of us a general understanding of the arguments on both sides of the OAP causation issues, and

[13] An evidentiary hearing in the *Cedillo* case is scheduled for June 11 through June 29, 2007. At that hearing both the PSC and respondent will present testimony concerning both a "general causation issue"--*i.e.*, whether MMR vaccines and thimerosal-containing vaccines can *combine* to cause autism--and *also* the "specific causation issue" in the *Cedillo* case. All three of the undersigned special masters will preside over that hearing. Special Master Hastings alone will decide the *specific causation* issue in that *Cedillo* case, while the other two special masters will participate in order to hear the *general causation* evidence, which they can thereafter apply to individual autism cases assigned to them.

an understanding of the evidence that is already publicly available concerning those issues. We have applied that understanding to our determination whether the material now sought by petitioners is "necessary" to our ultimate resolution of those factual issues.

Accordingly, the existence of this huge amount of available literature, described above, strongly supports our conclusion that it is not "necessary" for us to have the study that the PSC proposes to conduct utilizing VSD Project data.

3. The PSC has failed to submit evidence showing a need for the requested study.

In addition, we note that the PSC simply has failed completely to *submit any evidence* that might cause us to believe that we need to see the study that the PSC wishes to conduct. The PSC did submit Exhibit 86, the Proposal itself, authored by four well-qualified experts. But the PSC did not submit any reports or statements from those experts, or any other experts, explaining *why* it might be "necessary" for us to see the results of the study that the PSC proposes.[14] In its initial motion, the PSC did point to certain expert testimony that had been provided by PSC expert Harland Austin in the Omnibus Autism Proceeding on September 23, 2004. (Motion at 7.) But the PSC did not bother even to suggest *how* Dr. Austin's 2004 testimony supports the PSC's current motion.

In his 2004 testimony, Dr. Austin, a professor of epidemiology, pointed out what he believed to be deficiencies in a study known as the "Verstraeten study," one of the existing epidemiological studies concerning the issue of a potential causal relationship between thimerosal-containing vaccines and autism.[15] (Transcript at 70-85.) The PSC's Motion, however, while referring (pp. 8-9) to the Verstraeten study, fails to explain the relevance of the testimony of Dr. Austin or the Verstraeten study to the instant request. Dr. Austin's 2004 testimony, moreover, was offered in support of a *much different* discovery request, part of which was granted in the Discovery Order filed on April 14, 2005. We do not find in that testimony of Dr. Austin any substantial support for the PSC's *current* discovery request.

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[14]Of course, we do not mean to suggest that a party need *always* produce expert testimony in order to persuade a special master to require testimony or the submission of evidence. If, based on the overall available evidence, it seemed to us to be "necessary" to require certain production, we would order such production regardless of whether an expert had specifically so advised.

[15]Verstraeten, T., et al, "Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized Health Maintenance Organization Databases," *Pediatrics*, 112(5): 1039-1048 (November 2003). A copy of this article was filed into the Autism Master File, as the Petitioners' Exhibit 22, on December 8, 2006.

The only other evidence which the PSC has cited, in support of its current request, is a quotation from a report issued by the National Institutes of Health (NIH) in October of 2006.[16] That NIH panel was tasked with examining how VSD Project data might be used to further evaluate the possibility of a causal relationship between thimerosal-containing vaccines and autistic disorders. (Ex. 88, pp. 8-9.) The panel noted that it had "considered," as one possible use of the VSD Project data in this regard, an "expansion" of the Verstraeten study. (*Id*. at 13.) The panel's report continued as follows:

> The panel recommended that further consideration be given to conducting an extension of the Verstraeten study that would include additional years for follow up, would add more MCOs and reexamine the criteria for exclusion of births and/or take a sensitivity analyses approach to examining the impact of various exclusion criteria.

(*Id*. at 14.) The PSC urges that the above-quoted recommendation of the NIH panel, concerning a possible "extension" of the Verstraeten study, "is almost exactly what [the PSC's] proposed study seeks to accomplish." (Motion at 9.)

We have paid careful attention to this statement in question by the NIH panel. After full consideration, however, we find that this NIH panel statement does *not* support a conclusion that the study now proposed by the PSC is "necessary" to allow us to reach a fair and well-informed resolution of the OAP causation issues. First, the NIH panel recommended only that an extension of the Verstraeten study be given "further consideration" (Ex. 88, p. 14), not necessarily that such an extension would be a *good* use of VSD Project resources, as opposed to *other* possible uses of those resources. Second, this recommendation was only *one* of *several* possible uses of VSD Project data that the panel thought worthy of consideration. (*Id*. at 12-15.) Most importantly, while the NIH panel did use the terms "expansion" and "extension" of the Verstraeten study, there is no evidence whatsoever that the NIH panel had in mind anything like the huge study, involving more than two million children, now proposed by the PSC. While there do appear to be certain general similarities between this particular recommendation of the NIH panel and the PSC's current Proposal, the PSC offers no evidence for its bald assertion that the PSC's proposed study would do "almost exactly" what the NIH panel proposed. While the NIH panel obviously envisioned a study at least *somewhat* greater in scope than the Verstraeten study, the panel's recommendation was vague. In contrast, the PSC's Proposal appears to us to propose a massive, time-consuming, and hugely-expensive undertaking, as we will detail below (p. 16). Thus, contrary to the PSC's suggestion, the NIH panel's quotation does not offer strong support to the proposition that the PSC's proposed study is "necessary" to our resolution of the OAP causation issues.

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[16]"Report: Thimerosal Exposure in Pediatric Vaccines," National Institutes of Health, of the Department of Health and Human Services, October, 2006. A copy of that report was filed into the Autism Master File, as the Petitioners' Ex. 88, on December 8, 2006.

4. Additional factor

Finally, we note that the PSC itself states that "the petitioners could very well establish general and individual causation in these Omnibus claims *without epidemiological evidence*." (Motion at 9, emphasis added.) This acknowledgment by the PSC casts further doubt on the assertion that the epidemiological study that the PSC seeks here is "necessary" for the resolution of the OAP causation issues.

5. Summary concerning "necessary" issue

In short, for all the reasons noted above, we do *not* find that the PSC's proposed study is "necessary" to our resolution of the OAP causation issues.

C. We find that it would not be "reasonable" to grant the PSC's request.

As explained above, under the standard that we have adopted for considering discovery requests in Vaccine Act proceedings, in addition to considering whether the requested discovery is "necessary" for the special master's resolution of the case or cases involved, a special master must also consider whether the request is "reasonable" under all the circumstances, which means that the special master must consider the *burden* on the party who would be required to testify or submit evidence. That is, the importance of the requested material for purposes of the special master's ruling must be balanced against the burden on the producing party. In this situation, considering all the circumstances, we conclude that it would *not* be "reasonable" to grant the PSC's request.

Initially, we note that, as indicated above, the respondent and the MCOs each filed a number of exhibits, which collectively make it clear that under the contracts that govern the VSD Project, "data" of the type that the PSC seeks may *never* simply be handed over to an outside party to utilize in a study. To the contrary, any study involving VSD Project data *must* involve *substantial participation* by personnel of the CDC and by personnel of any MCOs involved in the study.[17] Therefore, it is clear that what the PSC seeks in its current discovery request is that we order both the CDC and the MCOs to *conduct a study*, in conjunction with the PSC's experts. We do not find that it would be reasonable for us to issue such an order, for several reasons.

First, as shown by the exhibits filed by the respondent and the MCOs, the resources of both the CDC and the MCOs are finite. Any resources expended on the study that the PSC proposes would, of course, not be available for any other medical research. Medical scientists employed by the CDC and the MCOs are the ones who make the judgment as to how to use their resources, weighing the utility of one possible use against other potential uses. The PSC now asks us to, in effect, take over that function, of deciding how the resources of the CDC and the MCOs should be

[17]In the PSC's reply memorandum filed on March 19, 2007, the PSC did *not* dispute that the relevant contracts so require.

used. But we have no idea about the other potential uses, and, thus, are in no position to take over that weighing function. We do not find it reasonable that we do so.

Moreover, as also noted above, the VSD Project is governed by contractual arrangements between the MCOs, which are non-governmental entities, and the CDC. The PSC asks us to completely override those contractual provisions. The PSC, however, cites to us no precedent, or even argument, concerning *why* we might seriously consider taking the step of attempting to set aside those contractual provisions. We certainly see no basis for concluding that we would be acting "reasonably" if we attempted such an override.

In this regard, we note that there do exist, as the record shows, *established procedures* by which medical researchers can propose a study to the CDC and the MCOs. However, while the Verstraeten study was published in 2003, there is no indication that the PSC or its experts have, during the ensuing years, gone through the established procedures for proposing a study of the type that the PSC now seeks.[18] Accordingly, it seems particularly unreasonable to ask that the CDC/MCO contracts be overridden, by judicial fiat, when there is no indication that any attempt has been made to obtain anything like the PSC's proposed study through the established VSD Project procedures.

Moreover, the study that the PSC proposes appears to be a *massive*, *time-consuming*, *costly* one. The only estimates that appear in the record before us, undisputed by the PSC, are that such a study would take from three to five years to complete (Resp. Ex. A (Baggs Declaration) at para. 24), and would cost more than five million dollars (Resp. Ex. A at para. 23).[19] We do not see that it would be "reasonable" to order a study that would take so long, or to order such a costly study in the absence of a plan to pay for the study (the PSC states only that it "anticipates contributing to the cost of the study," without pledging any particular amount).[20]

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[18]The PSC's motion contained a footnote that stated that "petitioners sought access to the VSD by working directly with researchers" who had sought approval for studies through the ordinary VSD Project procedures. (Motion at 3, fn. 2.) The PSC states that those researchers had their research "terminated" by the CDC, and were "barred from any ongoing access to the VSD." (*Id*.) The PSC does not state who those "researchers" were, nor provide any further description of their research attempts. The PSC acknowledges, however, that those research attempts "were not explicitly designed to investigate an association between thimerosal exposure and pediatric neurological or developmental injuries, as is the case with the proposed study in this Motion." (*Id*.) The PSC's own footnote, thus, appears to confirm that the PSC has *not* attempted, since 2003, when the Verstraeten study was published, to go through established VSD Project procedures to obtain the study that they now seek.

[19]Again, the PSC, in its reply brief, did not take issue with those estimates as to time and cost provided by the respondent's exhibit in question.

[20]In its reply brief, the PSC suggests, in response to the arguments raised by the respondent and the MCOs, that it would be willing to "modify" the proposed study design. (Reply at 4, 5.) The

D. Summary concerning application of our standard to the PSC's current discovery request

As set forth above, it seems to us that the "reasonable and necessary" standard means that a special master should require discovery procedures if the master concludes that, given the overall context of the factual issues to be decided by the master, he or she could not make a *fair and well-informed* ruling on those factual issues without the requested material. Requiring the requested discovery must also be "reasonable" under all the circumstances, which means that the special master must consider the burden on the party who would be required to comply. That is, the importance of the requested material, for purposes of the special master's ruling, must be *balanced* against the burden on the producing party. In this case, we have noted above that we do not find *either* that the requested discovery is "necessary" to the resolution of the OAP issues, *or* that it would be "reasonable" to grant the request. Obviously, then, there is no need for any "balancing". We must, accordingly, deny the PSC's request.

E. The Vaccine Act case law is consistent with our ruling here.

We have already noted (p. 10) that certain case law regarding Vaccine Act discovery disputes supports our use of the *standard*, for evaluating discovery disputes, utilized in this case. Here, we note further that the Vaccine Act case law also is consistent with the *substance* of the ruling that we have reached in this case.

One relevant ruling is *In re: Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder*, 2004 WL 1660351 (Fed . Cl. Spec. Mstr. July 16, 2004). That opinion, as discussed above, described a ruling in a previous discovery dispute in the Omnibus Autism Proceeding. In that ruling, Special Master Hastings looked to the substantial amount of epidemiological evidence and similar evidence that already existed relevant to the issue of whether MMR vaccines and/or thimerosal-containing vaccines can cause autism. He concluded, as we do here, that in light of that existing evidence, it was not necessary, nor reasonable under the circumstances, to order the production of the material in question. Thus, while the material being sought here is quite different from that being requested in that earlier discovery dispute, the earlier ruling is consistent with our conclusion here that the requested production is neither necessary nor reasonable, in light of the existing evidence.

Further, in two Vaccine Act cases, special masters have declined to grant discovery requests in which a party wanted the special master, in effect, to order a substantial medical study to be done. First, in *Schneider v. HHS*, 2005 WL 318697 (Fed. Cl. Spec. Mstr. Feb. 1, 2005), the petitioner urged Special Master Edwards to compel the production of numerous documents from the manufacturers

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PSC, however, does not propose any particular modifications. We have considered whether it might be appropriate for us to grant some sort of relief short of what the PSC proposes. However, we do see any "necessity" for *any* aspect of the proposed study, nor do we find it to be "reasonable" for us to try ourselves to design some smaller study and impose it on the CDC and one or more MCOs.

of hepatitis B vaccines, and to order testing of "all" hepatitis B vaccine lots for the presence of a certain substance known as "PMSF." (2005 WL 318697 at *5.) The special master declined to do so, opining as follows:

> Thus, in the special master's view, the Program is not the appropriate forum for--and a special master should not preside over--wide-ranging discovery, or should not devise unique procedures, aimed at developing original scientific or medical theses. [Footnote omitted.] Indeed, scientific or medical "research" conceived and conducted in the context of litigation poses an inherent danger: scientific or medical "research" conceived and conducted in the context of litigation is not subjected usually to the time-honored practices in the scientific and medical communities of peer-review and of publication--two of several, significant touchstones of evidentiary reliability. *See, e.g., Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593; 113 S.Ct. 2786, 2797 (1993). * * * Precedent and the Act supports wholly the special master's conservative--if not extremely narrow--construction of a special master's function. In *Knudsen*, the Federal Circuit announced that "research" regarding "how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others" is properly "for scientists, engineers, and doctors" working outside the judicial arena, "in hospitals, laboratories, medical institutes, pharmaceutical companies, and government agencies," and not for the Court of Federal Claims. *Knudsen*, 35 F. 3d at 549.

(*Id*.) In this regard, the special master added the following additional point, which we find to be quite insightful:

> Moreover, the Program is just one component of an intricate statutory structure establishing the Nation's policy on childhood vaccines. In the intricate statutory structure, Congress directed the formation of a National Vaccine Program in the Department of Health and Human Services, *see* § 300aa-1 & 2; the formation of the National Vaccine Advisory Committee, *see* § 300aa-5; and the formation of the Advisory Commission on Childhood Vaccines. *See* § 300aa-19. The Director of the National Vaccine Program is responsible for "coordinat[ing] and provid[ing] direction for research * * * to prevent adverse reactions to vaccines." § 300aa-2(a)(1). The National Vaccine Advisory Committee, comprised of "individuals who are engaged in vaccine research or the manufacture of vaccines or who are physicians, members of parent organizations concerned with immunizations, or representatives of State or local health agencies or public health organizations," supports the Director of the National Vaccine Program by "recommend[ing] research priorities and other measures the Director of the Program should take to enhance the safety and efficacy of vaccines." § 300aa-5(b)(2). The Advisory Commission on Childhood Vaccines, comprised of health professionals, legal representatives of vaccine-injured children, attorneys, and government officials, performs duties that are similar to the National Vaccine Advisory Committee. *See* § 300aa-19(f). In

> addition, in the intricate statutory structure, Congress directed the Secretary of the Department of Health and Human Services to contract with the Institute of Medicine (IOM)--the august division of the National Academy of Sciences (NAS) chartered in 1970--or with "other appropriate nonprofit private groups or associations" to canvass scientific and medical evidence regarding adverse consequences of routine childhood vaccines. National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, §§ 312-13, 100 Stat. 3779-82 (1986). [Footnote omitted.] Thus, in the intricate statutory structure, Congress has provided both a mechanism distinct from the Program to foster fitting scientific or medical research regarding vaccine safety, and a mechanism distinct from the Program to foster fitting review of scientific or medical research regarding vaccine safety.

(*Id*.) Similarly, Judge Wiese of this court, in affirming the special master's ruling in *Schneider*, indicated the same general view. He wrote as follows:

> The special master rejected petitioner's [discovery] request, and properly so. At its most basic level, discovery is concerned with the search for relevant information among existing evidence. Petitioner's request, however, involved the special master initiating a scientific study to examine the relationship between PMSF and the safety of the Hepatitis B vaccine. Such a request is beyond the authority of the special master to grant. As the special master pointed out, the task of ensuring the safety of the nation's vaccine program rests not with the courts but rather with the Secretary of the Department of Health and Human Services and the advisory bodies that the Secretary is authorized to appoint, specifically, the National Vaccine Advisory Committee and the Advisory Commission on Childhood Vaccines. *See*, respectively, 42 U.S.C. §§ 300aa-5, 19.

Schneider v. HHS, 64 Fed. Cl. 742, 746 (2005). We agree with this general point made by both Special Master Edwards and Judge Wiese in *Schneider*. That is, the fact that the Vaccine Act specifically provided *other mechanisms*, for vaccine-related *scientific research*, indicates that Congress likely did not envision that a Vaccine Act *special master* would order any such large research project in the course of resolving a compensation claim.

Also instructive is the ruling of Special Master Sweeney in *Werderitsh*, cited above (p. 10). In that case, the petitioner requested that the special master order that petitioner be afforded access to extensive data from a government-controlled database known as Vaccine Adverse Event Reporting System ("VAERS"), so that a study could be performed using that data. (2005 WL 3320041, at *1.) In denying the request, the special master specifically stated agreement with the point of Special Master Edwards in *Schneider*, set forth above. (*Id*. at *14.) She further noted that she "believes that it is inappropriate for [a special master] to direct scientific research within the framework of the Vaccine Program." (*Id*.) Thus, the *Werderitsh* ruling, we believe, is also consistent with our ruling in this case.

In sum, we note that the PSC has failed to point to any Vaccine Act precedent supporting the current discovery request. To the contrary, in our view, the Vaccine Act case law is completely consistent with our ruling concerning the instant discovery motion.

F. The cited non-Vaccine Act case law also supports our ruling.

The respondent and the MCOs have also cited a number of opinions concerning discovery requests in non-Vaccine Act settings. While not of directly precedential effect in this Vaccine Act setting, those opinions do cast some further doubt on the propriety of granting the PSC's request here.

For example, courts have often denied discovery requests in which a party or non-party would be required to "create" or "prepare" documents that do not already exist. See, *e.g.*, *Alexander v. Federal Bureau of Investigation*, 194 F.R.D. 305, 310 (D.D.C. 2000) ("Rule 34 * * * only requires a party to produce documents that *are already in existence*"; a party "is not required to prepare, or cause to be prepared, new documents solely for their production") (emphasis added); *Insituform Technologies, Inc. v. Cat Contracting, Inc.*, 168 F.R.D. 630, 633 (N.D. Ill. 1996) ("Rule 45 * * * does not contemplate that a non-party will be forced to create documents that do not exist"); *Rockwell Int'l Corp. v. H. Wolfe Iron & Metal Co.*, 576 F. Supp. 511, 513 (W.D. Pa. 1983) ("Rule 34 cannot be used to require the adverse party to prepare, or cause to be prepared, a writing to be produced for inspection, but can be used only to require production of things in existence."), quoting *Soetaert v. Kansas City Coca Cola Bottling Co.*, 16 F.R.D. 1, 2 (W.D. Mo. 1954); *United States v. U.S. Alkali Export Ass'n*, 7 F.R.D. 256, 259 (S.D.N.Y. 1946) ("Rule 34 is to be used to call for the production of documents already in existence * * * and not to require an adverse party to prepare a written list to be produced for inspection."); *Gray v. Faulkner*, 148 F.R.D. 220, 223 (N.D. Ind. 1992) ("Of course, 'if a document or thing does not exist, it cannot be in the possession, custody, or control of a party and therefore cannot be produced for inspection.'"). Similarly, one court found it inappropriate to impose upon a party the duty of "sorting or analysis of data" or the "task of culling relevant [data] from a long list." *Sanders v. Levy*, 558 F. 2d 636, 642 n.7 (2d Cir. 1976), *rev'd on other grounds, sub nom. Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340 (1978).

We note that those opinions, cited by the MCOs in their briefs, should not be interpreted to establish a hard and fast rule that a court may *never* order a person to "create" or "prepare" documents or to sort through data. There may be instances when it may be reasonable to so order, especially in this era of computerized data. However, these case law pronouncements do seem to stand for the principle that courts should be *cautious* in ordering persons to engage in such activities. Such pronouncements, thus, would seem to be instructive concerning the situation here, in which the PSC seeks to place on the CDC and the MCOs the burden of *conducting a study*, which would seem to be even more onerous than the burdens of "creating documents" or "culling data" mentioned in the cited opinions.

Even more instructive are discovery rulings in which courts have refused to order a party to *conduct tests* or *conduct research* requested by another party. *See, e.g.*, *Sperberg v. Firestone Tire*

& Rubber Co., 61 F.R.D. 80, 83 (N.D. Ohio 1973) (while "each party is free to prepare and perform tests in the manner he deems best, * * * he cannot compel another party to perform the same tests"); *In re Air Crash Disaster*, 1991 WL 147365, *2 (N.D. Ill. July 26, 1991) ("Rule 34 does not require a party to conduct tests * * *."); *Sladen v. Girltown, Inc.*, 425 F.2d 24, 25 (7th Cir. 1979) (reversing district court order requiring plaintiffs to conduct tests). These rulings, too, seem quite supportive of our decision to deny the PSC's request here.

Finally, the MCOs have cited opinions in which courts have noted that a litigant's showing of need for evidence must be *especially strong* in order to outweigh a burden of production which that litigant wishes to place on a *non-party*. *Anker v. G.D. Searle & Co.*, 126 F.R.D. 515, 522 (M.D.N.C. 1989) (party "must show a *substantial need* which outweighs the burden and prejudice to the non-party") (emphasis added); *Bio-Vita, Ltd. v. BioPure Corp.*, 138 F.R.D. 13, 17 (D.Mass. 1991) ("To obtain discovery from nonparties, a party must establish that its need for discovery outweighs the nonparty's interest in nondisclosure."). Again, this principle seems applicable to the situation here, in which the MCOs are nonparties to this OAP litigation.

Again, we acknowledge that these cited rulings from non-Vaccine Act cases are certainly not *directly* applicable to Vaccine Act discovery requests, in which the presiding special master is afforded wide discretion under the "reasonable and necessary" test specified in the Vaccine Act itself. But, in our view, such non-Vaccine Act opinions can at least provide some *instruction* and *guidance* for special masters of this court, in our analyses of whether to grant Vaccine Act discovery requests. And we note that the PSC has not even *attempted* to respond to these cases cited by the respondent and the MCOs. Nor has the PSC cited to any non-Vaccine Act precedent in which any court in *any* type of litigation has *ever* issued a "discovery" order even remotely similar to the one which the PSC requests that we issue here.

Thus, the teachings of these non-Vaccine Act rulings, and the failure of the PSC to respond to them or to cite any non-Vaccine Act case law supporting the PSC's request here, adds at least some support to our ruling here.

IV

CONCLUSION

For all the reasons set forth above, we hereby DENY the instant motion of the PSC. However, we find it appropriate to add a few final comments.

First, we note that, in reaching this ruling, we are not unmindful of the stakes here. The Omnibus Autism Proceeding involves nearly 5,000 families with children who suffer from serious and often tragic neurodevelopmental disorders. We are exceedingly sympathetic to the plight of these families.

Second, we add that we are *not* inherently opposed to utilizing the discovery powers provided in the Vaccine Act to assist these petitioners in obtaining medical records or other materials that may assist them in presenting their cases. To the contrary, in many of these individual autism cases, we already have, at the request of the individual petitioners, authorized subpoenas so that the petitioners could more easily obtain copies of medical records or similar records pertaining to their injured children. Moreover, the record of the Omnibus Autism Proceeding demonstrates that, under the supervision of Special Master Hastings, a vast number of documents from governmental agencies (about 218,000 pages) have been supplied to the PSC pursuant to the PSC's *initial* discovery request. (See p. 4, above.) Then, pursuant to the PSC's *second* round of discovery, the PSC was given substantial access to certain data from the VSD Project, enabling experts chosen by the PSC to analyze that data. (See pp. 4-5, above.) Accordingly, on an overall basis, one cannot reasonably say that the PSC's discovery requests in the Omnibus Autism Proceeding have not met with substantial success.

However, after careful analysis of the *particular request* at issue here, we simply cannot find that the request has merit, for the reasons stated above. Therefore, we have no choice but to deny the request.[21]

Patricia Campbell-Smith	Denise Vowell	George L. Hastings, Jr.
Special Master	Special Master	Special Master

[21]In the original Motion, the PSC stated that, if the court elected not to order the PSC's proposed study, the PSC would "move in the alternative for an Order excluding any evidence proffered by respondent that relies in whole or in part on the VSD." (Motion at 14.) The PSC in its reply, however, changed that stance, stating that it is "not making such [an alternative] motion at present," but "reserves the right" to file such a motion in the future. (Reply at 6.) Accordingly, we will not address the PSC's potential alternative motion unless the PSC notifies us that it is making that alternative motion.