In the United States Court of Federal Claims

ORIGINAL

OFFICE OF SPECIAL MASTERS

(Filed: July 16, 2004)

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

RULING CONCERNING MOTION FOR DISCOVERY FROM MERCK RE MMR VACCINE

HASTINGS, ***Special Master.***

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 by numerous families, filed under the Program, alleging that their children's neurodevelopmental disorders were caused by certain childhood vaccines. This ruling constitutes my ruling concerning a motion by the petitioners seeking discovery from a vaccine manufacturer, Merck and Co.

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

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[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.). I 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-acellar pertussis ("DTaP"), hepatitis type B, and hemophilus influenza type B ("HIB") vaccinations; or by some combination of the two. To date, more than 4,000 such cases have been filed with this court, and additional cases continue to be filed each week.

To deal with this large group of cases involving a common factual issue--*i.e.*, whether these types of vaccinations can cause autism--during the early summer of 2002 the Office of Special Masters (OSM) conducted a number of informal meetings 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 outcome of 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 general causation conclusions, reached 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). I 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." Most of that file may be viewed on this court's Internet website at www.uscfc.uscourts.gov/osm/osmautism.htm.

That Order set up a proceeding known as the Omnibus Autism Proceeding (hereinafter sometimes "the Proceeding"). In that Proceeding, 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 results of that general inquiry will then be applied to the individual cases. (2002 WL 31696785 at *3; 2002 U.S. Claims LEXIS 365 at *8.[3])

The *Autism General Order #1* assigned the responsibility for presiding over the Omnibus Autism Proceeding to the undersigned special master. In addition, I have also been assigned responsibility for all of the individual Program petitions in which it is 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 have requested that, in general, no proceedings with respect to the *individual petitions* be conducted until after the conclusion of the Omnibus Autism Proceeding concerning the *general* causation issue.[4] The OSM will then deal specifically with the individual cases.

B. Initial discovery process in the Omnibus Autism Proceeding

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 banded together to form the "Petitioners' Steering Committee" (hereinafter "PSC" or "the Committee") 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 this issue, in which the

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[3]As noted in the *Autism General Order #1* (2002 WL 31696785 at *2; 2002 U.S. Claims LEXIS 365 at *6-7) during the meetings of the informal advisory group, the respondent's representatives did not oppose the petitioners' general plan, as set forth above, that the OSM first conduct a general inquiry into the causation question, then apply the conclusions reached in that inquiry to the individual cases.

[4]I note that it is 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.

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, Exhibits A through KK, or a total of 37 exhibits, have been filed in *Taylor*. Many of those exhibits consist of multiple volumes, containing thousands of pages of documents. By my count, these exhibits have totaled about 132,000 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 has made several agency officials available to the PSC for depositions. Deposed thus far have been officials of the CDC, the FDA, and the ATSDR.

C. Requests for discovery from Merck

During the fall of 2003, the PSC indicated that, in addition to the discovery sought from the government, the committee would also be seeking discovery from vaccine manufacturers. On October 29, 2003, the PSC filed a request for authorization to issue a subpoena to the vaccine manufacturer, Merck and Company, for certain documents pertaining to that company's vaccine against the disease hepatitis type B, known as "Recombivax." That request was discussed at a series of status conferences, with participation by counsel from Merck. The PSC also indicated that it intends in the future to request subpoenas pertaining to other vaccine manufacturers, and therefore counsel for four other manufacturers--*i.e.*, Wyeth, Baxter, GlaxoSmithKline, and Aventis Pasteur--requested to participate in the proceedings pertaining to Merck, and, without opposition from the Committee, I permitted those counsel also to participate in the status conferences and briefing. The PSC, Merck, and the other vaccine manufacturers filed a number of briefs in November and December of 2003 relating to the Committee's request. Oral argument concerning that matter was originally scheduled for January 6, 2004, then rescheduled for March 2, 2004.

In February, however, the Committee announced that it intended to redirect its initial effort to obtain discovery from Merck. The Committee noted that while production of the FDA file concerning the Merck *Recombivax* vaccine was still ongoing, the government's production of the

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

FDA files concerning the Merck *MMR* and *measles* vaccines had already been completed. Therefore, the PSC withdrew its discovery request concerning the Merck *Recombivax* vaccine (reserving the right to reinstate that request in the future), and instead submitted a request for documents from Merck concerning its *MMR* and *measles* vaccines. The PSC and Merck filed briefs relating to the new discovery request, and oral argument was held on May 26, 2004.

The PSC's original request for documents concerning the MMR and measles vaccines was subsequently narrowed via the Committee's reply brief and at oral argument. After that narrowing process, the PSC now seeks the following documents:

> **B. Product Safety Research**. Produce documents relating to:
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> 1. Any research, survey, study, test or other investigation, whether published or not, conducted by Merck or any of its subdivisions or predecessor corporations, or any entity employed by Merck, under contract to Merck, or funded by Merck, regarding the human * * * health effects of MMR or the single-antigen measles component thereof.
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> 2. Any research, survey, study, test or other investigation, whether published or not, conducted by Merck or any of its subdivisions or predecessor corporations, or any entity employed by Merck, under contract to Merck, or funded by Merck, regarding the neurological or neurodevelopmental human * * * health effects of the MMR or the single-antigen measles component thereof.
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> 3. Any research, survey, study, test or other investigation, whether published or not, that was **not** conducted by Merck or any of its subdivisions or predecessor corporations, or any entity employed by Merck, under contract to Merck, or funded by Merck, but that Merck was aware of, regarding the neurological or neurodevelopmental human * * * health effects of the MMR or the single-antigen measles component thereof.

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D. Materials Created for, or Produced in, Litigation in the United Kingdom Involving the MMR Vaccine and its Alleged Link to Gastrointestinal Disease and Autism Spectrum Disorders.

It is petitioners' understanding that Merck's MMR vaccine product was the subject of litigation in Great Britain, that Merck was a party to that litigation, and that the gravamen of the litigation was that the MMR, or the measles component thereof, caused gastrointestinal disease and autism spectrum disorders. Based on that knowledge and understanding, petitioners request that Merck produce the following categories of documents related to the British litigation:

1. A copy of the entire set of documents that Merck produced pursuant to discovery requests from the plaintiffs, limited to those documents relating to issues of causation;

2. Copies of any expert reports, summaries, witness statements, and depositions prepared by or on behalf of Merck in that litigation, limited to those documents relating to issues of causation.

(See PSC's "Request for the Production of Documents: Merck and Company," filed Feb. 26, 2004, as modified by concessions made in the PSC's reply brief filed on May 10, 2004 (pp. 6-7, 9), and at oral argument (Tr. 122-23[6]).)

II

DISCUSSION

A. The standard for my ruling

1. The statute and court rules

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

> 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–

> may require the testimony of any person and the production of any documents as may be reasonable and necessary.

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

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[6]"Tr."references are to the pages of the transcript of the oral argument held on May 26, 2004.

[7]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).

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 and document production, whenever that master deems such testimony or document production to be "reasonable and necessary" for the master's resolution of the case. And Vaccine Rule 7 appears to implement that statutory authority, by authorizing a special master, when that master deems it "necessary," to (1) utilize the formal discovery procedures of RCFC 26-37, and (2) to authorize a party to issue subpoenas, utilizing the procedures of RCFC 45, which includes provisions for subpoena enforcement.

In addition, the statute plainly extends the special master's authority to "require" testimony and document production 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 * * *." (§ 300aa-12(d)(3)(B)(iii), emphasis added.) And 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.

Some of the filings of the vaccine manufacturers have argued that special masters should be especially reluctant to require document production from *vaccine manufacturers*, as opposed to other non-parties. The manufacturers point to the legislative history indicating that one of the primary purposes of the Vaccine Act was to encourage the vaccine manufacturers to remain in the business of producing vaccines, by shielding them from the burden of tort suits by persons who believe they have been injured by vaccinations. (See, *e.g.*, H.R. Rept. No. 99-908, pp. 6-7 (1986) (*reprinted in* 1986 U.S.C.C.A.N. 6345-47).) Further, certain parts of the legislative history indicate, as the manufacturers argue, that Congress had in mind the goal of protecting the manufacturers from not only the cost of paying out *judgments* in tort suits, but also the significant costs involved in the

process of *litigating* tort suits, which can be exceedingly costly even if no actual judgment or settlement is ever paid.[8]

In light of the legislative history that shows clearly that one purpose of the Vaccine Act was to shield the vaccine manufacturers from the burden of tort suits by vaccinees, I agree that a special master considering whether to require testimony or document production from such a manufacturer should consider, among other factors to be weighed, whether placing such a burden on such a manufacturer would be contrary to the purposes of the Vaccine Act. However, that does not mean that a vaccine manufacturer should automatically be exempted from the possibility of being required to provide testimony or documents. As noted above, the statutory language plainly does not exempt *anyone* from being potentially required to provide testimony or documents, stating that a special master may "require the testimony of *any person* and the production of *any* documents." (§ 300aa-12(d)(3)(B)(iii), emphasis added.)

Moreover, one statutory provision that may be of some relevance here is § 300aa-12(d)(4)(B), which states as follows:

> A decision of a special master or the court in a proceeding shall be disclosed, except that if the decision is to include information–
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> > (i) which is trade secret or commercial or financial information which is privileged and confidential, or
> >
> > (ii) which are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy,
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> and if the person who submitted such information objects to the inclusion of such information in the decision, the decision shall be disclosed without such information.

This provision is obviously intended to protect the medical privacy of Vaccine Act petitioners. But in addition to subparagraph (ii) regarding medical privacy, Congress also included subparagraph (i), which protects the confidentiality of "trade secret or commercial or financial information" that may have been submitted to a special master by a "person" in the course of a Vaccine Act proceeding. I have found no legislative history explaining the purpose of this statutory provision. But one reasonable explanation of the provision is that Congress may have anticipated that in some situations a *vaccine manufacturer* might submit to a special master information regarding a vaccine, which information might fall within the category of "trade secret" information. In the absence of legislative history, this surmise admittedly amounts to little more than speculation, but it is hard to imagine what entity or person might possess "trade secret" information that might be relevant to a Vaccine

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[8] *See* Subcommittee on Health and the Environment, 99th Cong., 2d Sess., *Childhood Immunizations* (Committee Print 99-LL, 1986), at p. 87, expressing Congressional acknowledgment of the " defense costs of vaccine injury litigation" borne by the vaccine manufacturers.

Act proceeding, *other* than a vaccine manufacturer. Thus, this statutory provision may provide at least some support to the supposition that Congress anticipated that in certain instances a vaccine manufacturer might be called upon to provide information to a Vaccine Act special master.

2. 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 different respects.

The first difference is that 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 his or her authority to require testimony or document production, the master's task is apparently 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, more stringent standard.

3. Vaccine Act precedent concerning discovery

There is extremely little case law relating to discovery questions during the 15-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 document production. To the contrary, I have routinely utilized such authority in order to obtain *medical records* pertaining to a particular

vaccinee seeking compensation. Specifically, I have routinely authorized the parties to utilize *subpoenas* to hospitals, physicians, and other keepers of medical records, requiring such non-parties to make such records available for my use in resolving a case. I understand that similar use of subpoena authority to obtain records from non-party record-keepers has also been routine for all of the Vaccine Act special masters. I have found virtually no case law concerning this use of subpoenas, probably because such use is so plainly appropriate under the statutory language that it has never been challenged.[9] That is, this exercise of authority seems to flow naturally from the statutory provision that a special master "may require the testimony of *any person* and the production of *any* documents." (§ 300aa-12(d)(3)(B)(iii), emphasis added.) And it seems obvious that such exercise of authority to obtain medical records pertaining to a particular Vaccine Act petitioner is appropriate under the "reasonable and necessary" standard, since it is hard to imagine what could be more "necessary" to the resolution of a dispute concerning what caused a person's injury, than the medical records pertaining to that person.

The only Vaccine Act case law of which I am aware that is relevant[10] to the dispute here 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 caused by several vaccines, including the pertussis vaccine. On appeal to a judge of the Court of Federal Claims, the petitioners argued that the master had abused her discretion by failing to grant their discovery request that a government agency be required to divulge information concerning the removal of a certain ingredient from the pertussis vaccine at some point after their daughter's vaccination. Judge Andewelt of this Court denied the appeal, concluding that the special master had not abused her discretion. (*Id.* at 609.) The judge noted 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. 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

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[9]I 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).

[10]I have identified four other published Vaccine Act opinions which include discussion of a special master's "discovery" authority. *McNerney v. Secretary of HHS*, No. 90-1689V, 1992 WL 120345 (Cl. Ct. Spec. Mstr. May 5, 1992) (special master ordered petitioner to provide a release authorizing the vaccinee's physician to be interviewed by respondent's counsel); *Crossett v. Secretary of HHS*, No. 89-73V, 1990 WL 608690 (Cl. Ct. Spec. Mstr. May 4, 1990) (special master denied respondent's request that he order vaccinee to undergo testing); *Baggott v. Secretary of HHS*, No. 90-2214V, 1992 WL 79987 (Cl. Ct. Spec. Mstr. April 2, 1992) (special master ordered respondent to produce certain records from government files, but did not discuss the "reasonable and necessary" standard); and *DeRoche v. Secretary of HHS*, No. 97-643V, 2002 WL 603087 (Fed. Cl. Spec. Mstr. March 28, 2002) (special master indicated willingness to subpoena treating physician to testify). However, none of those decisions seem relevant here.

Human Services to search for additional unpublished materials, the existence of which is uncertain." (*Id*). This precedent seems to indicate 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.

4. The standard that I 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 contains 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.

The arguments of some of the vaccine manufacturers seem to imply 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 suggestion, I 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 * * * production" would amount to a nullity.

Instead, it seems to me 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 the requested testimony or document production 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 testify or produce documents. 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 I will utilize here.

B. The requested material is not "necessary" to my resolution of the factual question here.

The question as to the Committee's request for document production here at issue is, therefore, whether I find the requested material to be "reasonable and necessary" to my resolution of factual issues to be resolved in the Omnibus Autism Proceeding. Based upon the record before

me at this time, I do *not* find that the requested material is "necessary" to the resolution of factual issues in the Omnibus Autism Proceeding.

I will explain this conclusion in detail below, as to each of the two general categories of documents that the petitioners seek. First, however, I will describe the factual issues that I must resolve in the Omnibus Autism Proceeding. In the *Autism General Order #1*, the Chief Special Master stated that the issues to be addressed in the Omnibus Autism Proceeding are whether–

> cases of autism, or neurodevelopmental disorders similar to autism, may be caused by Measles-Mumps-Rubella ("MMR") vaccinations; by the "thimerosal" ingredient contained in certain Diphtheria-Tetanus-Pertussis ("DTP"), Diphtheria-Tetanus-acellar Pertussis ("DTaP"), Hepatitis B, and Hemophilus Influenza Type B ("HIB") vaccinations; or by some combination of the two.

(2002 WL 31696785 at *1; 2002 U.S. Claims LEXIS 365 at *1.) The document requests here, however, pertain specifically to the *MMR* vaccine and its measles component. Thus, the factual issue relevant here is whether the *MMR vaccine* can cause autism or similar neurodevelopmental disorders, alone or in conjunction with the thimerosal-containing vaccines.

I must also comment as to the information currently available to me concerning that factual issue. At this point in the Omnibus Autism Proceeding, neither the Petitioners' Steering Committee nor the respondent have yet supplied evidence concerning that issue. The plan for the Proceeding has been that only after the PSC completed the discovery process--*i.e.*, the process of obtaining documents from government files and perhaps vaccine manufacturer files--would that Committee and the respondent submit expert reports, and later present oral expert testimony at an evidentiary hearing. (*See, e.g., Autism General Order #1*, 2002 WL 31696785 at *3-5; 2002 U.S. Claims LEXIS 365 at *7-8. Therefore, it is difficult for me to determine *at this time* what is "necessary" for my resolution of the relevant factual issue, when I have not yet even heard the *petitioners' theory* as to exactly how the MMR vaccine allegedly causes autism, nor the government's rebuttal thereto. However, the Committee wants me to *now* compel document production from Merck, so that I simply must make an evaluation of the "necessity" issue *at this time* as best I can, even though the two parties to the Omnibus Autism Proceeding have as yet not submitted to me their views concerning the relevant factual issue.

There are, in fact, a number of medical journal articles and studies available to me concerning this issue. I will not attempt to discuss or even enumerate all of them in this document, but I note that a comprehensive evaluation of the available studies was recently prepared by a committee of medical experts on behalf of the Institute of Medicine (IOM). On May 18, 2004, the IOM published a report entitled *Immunization Safety Review: Vaccines and Autism* (National Academies Press, 2004) (hereinafter "2004 IOM Report"). That report was authored by a committee of 11 experts chosen by the IOM to review the evidence concerning the possibility of a causal link between vaccines and autism. The IOM committee reviewed that evidence, and concluded that the evidence "favors rejection of a causal relationship" between the MMR vaccine and autism and between

thimerosal-containing vaccines and autism. (2004 IOM at 51.[11]) However, what is most relevant here is not the IOM committee's *conclusions*, but, rather, its (1) *discussion of the arguments*, pro and con, concerning the possibility of a causal relationship between vaccines and autism, and (2) its *enumeration and description of the articles and studies* that the IOM committee found to be relevant to the causation questions that it studied. As to the issue of the potential causal relationship between the *MMR vaccine* and autism, the IOM committee discussed in detail the arguments and evidence on both sides of that issue, and also listed and described the relevant articles and studies. (2004 IOM at 37-56.) Concerning the latter, the IOM examined and described 16 epidemiological studies relevant to the issue, in addition to the original "case series" study by Wakefield and colleagues that initiated the public interest in the possible causal relationship. (2004 IOM at 37-51.)

Utilizing these discussions available in the 2004 IOM Report, I have been able to examine the Wakefield article and the sixteen subsequently-published studies, as a way of generally informing myself concerning the factual issue of whether the MMR vaccine causes autism. This has given me background information concerning the issue, a general understanding of the arguments on both sides, and an understanding of the evidence that is already publicly available concerning that issue. I have applied this knowledge concerning that factual issue to my determination whether the documents now sought by petitioners are "necessary" to my ultimate resolution of that factual issue.[12]

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[11]As of this date, the only copy of the 2004 IOM Report that I have seen is the "advance copy." "2004 IOM" citations are to the pages of that copy.

[12]I find it quite appropriate to utilize the 2004 IOM Report as a tool for identifying the items of evidence the are available concerning the general issue of whether MMR vaccines cause autism. First of all, the parties to the Omnibus Autism Proceeding have as yet not provided any analysis, or even any bibliographies, concerning that causation issue, so I am left to find expert assistance as best I can. Moreover, the Institute of Medicine seems clearly to be an appropriate source of expert assistance for a special master in a Vaccine Act proceeding. The National Academy of Sciences ("NAS") was created by Congress in 1863 to be an advisor to the federal government on scientific and technical matters (See *An Act to Incorporate the National Academy of Sciences*, Ch. 111, 12 Stat. 806 (1863)), and the Institute of Medicine ("IOM") is an offshoot of the NAS established in 1970 to provide advice concerning medical issues. Further, when it enacted the Vaccine Act in 1986, Congress *specifically directed* that the Institute of Medicine be requested to conduct studies concerning potential causal relationships between vaccines and illnesses. See the *National Childhood Vaccine Injury Act of 1986*, Pub. L. No. 99-660, 100 Stat. 3755 (1986), section 312(e)(2)(A), and section 313(a)(2)(A). In the intervening years, the IOM has formed committees which have prepared numerous reports concerning issues of possible relationships between vaccinations and injuries. (For a listing of those reports, *see* 2004 IOM at 77.)

In addition, I note that during the 15-year history of the Vaccine Act, special masters have consistently referred to and relied upon those reports of the Institute of Medicine. *See, e.g., Capizzano v. Secretary of HHS*, No. 00-759V, 2004 WL 1399178, at *2 & n. 6 (Fed. Cl. Spec. Mstr.

I will now discuss, in turn, the two categories of documents that the PSC now seeks from the files of Merck.

1. Merck's "Product Safety Research" documents

The first general category of documents sought by the PSC is entitled "Product Safety Research" documents. As noted above, the PSC seeks all documents from Merck files "relating to" the following:

> 1. Any research, survey, study, test or other investigation, whether published or not, conducted by Merck or any of its subdivisions or predecessor corporations, or any entity employed by Merck, under contract to Merck, or funded by Merck, regarding the human * * * health effects of MMR or the single-antigen measles component thereof.
>
> 2. Any research, survey, study, test or other investigation, whether published or not, conducted by Merck or any of its subdivisions or predecessor corporations, or any entity employed by Merck, under contract to Merck, or funded by Merck, regarding the neurological or neurodevelopmental human * * * health effects of the MMR or the single-antigen measles component thereof.
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> 3. Any research, survey, study, test or other investigation, whether published or not, that was **not** conducted by Merck or any of its subdivisions or predecessor corporations, or any entity employed by Merck, under contract to Merk, or funded by

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Golkiewicz, June 8, 2004) (due to the "IOM's statutory charge, the scope of its review, and the cross-section of experts making up the committee, the special masters have consistently accorded great weight to the IOM's findings"); *Larive v. Secretary of HHS*, No. 99-429V, 2004 WL 1212142, at *11 (Fed. Cl. Spec. Mstr. Millman May 12, 2004); *Falksen v. Secretary of HHS*, No. 01-0317V, 2004 WL 785056, at *13 (Fed. Cl. Spec. Mstr. Abell Mar. 30, 2004) ("the Court gives great deference to the findings of the Institute of Medicine on the issue of cause and effect between vaccines and discrete injuries"); *Malloy v. Secretary of HHS*, No. 99-0193V, 2003 WL 22424968 (Fed. Cl. Spec. Mstr. Edwards May 1, 2003); *Snyder v. Secretary of HHS*, No. 94-58V, 2002 WL 31965742, at *2 (Fed. Cl. Spec. Mstr. Hastings Dec. 13, 2002) (IOM's synthesis of available evidence was of "particular assistance"); *Hill v. Secretary of HHS*, No. 96-783V, 2001 WL 166639 at *3-4 & n. 2 (Fed. Cl. Spec. Mstr. French Dec. 13, 2000) (relying on criteria set out by IOM); *Castillo v. Secretary of HHS*, No. 95-0652V, 1999 WL 605690 (Fed. Cl. Spec. Mstr. Wright Jul. 19, 1999); *Schell v. Secretary of HHS*, No. 90-3243V, 1994 WL 71254, at *5 (Fed. Cl. Spec. Mstr. Baird Feb. 22, 1994); *Terran v. Secretary of HHS*, 41 Fed.Cl. 330, 337 (1998) (Judge Tidwell affirmed special master's reliance on conclusions of IOM), *aff'd*, 195 F.3d 1302 (Fed. Cir. 1999); *Ultimo v. Secretary of HHS*, 28 Fed.Cl. 148 (1993) (Judge Tidwell affirmed special master's reliance on IOM report); *Cucuras v. Secretary of HHS*, 26 Cl.Ct. 537, 540 (1992) (Judge Harkins affirmed decision of special master who "gave greater weight to the report" of the IOM).

> Merck, but that Merck was aware of, regarding the neurological or neurodevelopmental human * * * health effects of the MMR or the single-antigen measles component thereof.

After careful consideration of this request, I conclude that production of such documents is *not* "reasonable and necessary" to my resolution of the factual issues to be addressed in the Omnibus Autism Proceeding.

To begin with, I note, based on the representations of Merck's counsel at oral argument, that to comply with this request would appear to involve a substantial burden upon Merck. Merck has been licensed to produce MMR vaccines or measles-only vaccines since 1968, so the request covers documents spanning many years. (Tr. 36.) Moreover, the request for all documents relating to the "human health effects" of the relevant vaccines would appear likely to sweep in a vast amount of documents. I note, for example, that all company documents related even to the *intended effect* of MMR vaccines--*i.e.*, to produce immunity--would seem to fall within this request, since immunity is certainly a "human health effect." (*See also* Tr. 36, 63-64, 88-90.) Thus, under the "reasonableness" part of the statutory test, I would need to conclude that my need for these documents outweighs what would appear to be a substantial burden on Merck of searching for and retrieving a large number of documents from many years' worth of company files.

But it is not necessary for me even to consider this issue of the potential burden on Merck, since in the record before me here simply exists almost nothing to support a conclusion that production of these requested documents would be "*necessary*" to my resolution of the relevant factual issues. The PSC has supplied virtually no evidence in this regard. The PSC has not supplied the report or oral testimony of an expert to explain why I might need these documents. The PSC has not even articulated a *general theory* as to how the MMR vaccine might cause or contribute to autism, so that I might consider how the requested documents might potentially yield evidence relevant to that theory.

Instead, the PSC's presentation concerning this necessity issue has been confined to a few paragraphs of vague arguments of counsel in the Committee's two briefs (*see* Br. filed 3-23-04, pp. 10-13; Br. filed 5-10-04, pp. 7-9) and in oral argument at the hearing (Tr. 8-10, 20-21). These arguments have been less than persuasive. The PSC has suggested vaguely that "significant gaps" exist in the available scientific evidence concerning the relevant causation issue, and that the requested documents might help to plug those gaps. (Br. 3-23-04 at 11.) But the Committee has not explained exactly where those gaps exist, nor how the requested material could fill the gaps. For example, the PSC pointed out that a IOM committee report published in 2001 noted the "inherent methodological limitations" of the available epidemiologic studies--*i.e.*, the fact that such studies may not be able to rule out the possibility that the MMR vaccine might cause neurological injury in "very rare" instances. (Br. 3-23-04 at 11.) But this limitation of epidemiologic studies is, indeed, "inherent," and that fact is well known. More importantly, the PSC does not explain how the production of the requested material would yield significant information to supplement the epidemiologic studies.

Essentially, the PSC's argument boils down to repeated variations of the suggestion that a vaccine manufacturer "might have information about the properties and characteristics of its own product that is not generally available to others." (Br. 3-23-04 at 12.) The PSC argues that documents relating to the human health effects of MMR vaccines are "on their face" potentially relevant to the causation issues that I must eventually decide in the Omnibus Autism Proceeding. (Br. 5-10-04 at 7; Tr. 4.) In this regard, the PSC's argument does have at least some appeal. It is certainly conceivable that among Merck's documents relating to the "human health effects" of these vaccines, there are documents that *might be relevant* to the factual issues before me. Thus, in some other discovery context, in which the test was simply whether the request is reasonably calculated to lead to "relevant" evidence, the PSC might have a better argument. In this Vaccine Act proceeding, however, as explained above, the standard is a much higher one--*i.e.*, I must conclude that the requested material is not only relevant, but also "*necessary*" to my factual inquiry. And given the record before me, I simply see no grounds for concluding that it is "necessary" for me to see the documents requested here.

As noted above, it seems obvious from the statute itself that, as confirmed by Judge Andewelt's above-quoted analysis in *Golub*, a Vaccine Act special master must 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 production seems necessary in the overall context. Thus, with respect to the discovery request at issue here, it is significant that concerning the relevant causation issue, a significant amount of available evidence does exist. As noted above, the recent 2004 IOM Report details sixteen different published epidemiologic studies concerning the issue of the possible causal connection between the MMR vaccine and autism, in addition to the original Wakefield "case series" study. (*See* 2004 IOM at 37.) And in the course of dealing with medical causation issues in Vaccine Act cases for 15 years, I have been repeatedly advised by experts that in analyzing medical causation issues, the best form of evidence consists of epidemiologic studies.[13]

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[13]Numerous authorities confirm that in determining whether a certain agent causes harm to humans, epidemiologic studies are usually the best form of evidence available. *See, e.g., Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1198 (11th Cir. 2002) ("Epidemiology, a field that concerns itself with finding the causal nexus between external factors and disease, is generally considered to be the best evidence of causation in toxic tort actions."); *Brasher v. Sandoz Pharms. Corp.*, 160 F. Supp. 2d 1291, 1296 (N.D. Ala. 2001) ("epidemiological studies provide the best proof of the general association of a particular substance with particular effects"); Peter Goss et al., *Clearing Away the Junk: Court-Appointed Experts, Scientifically Marginal Evidence, and the Silicone Gel Breast Implant Litigation,* 56 Food Drug L.J. 227, 237 (2001) ("Because prospective clinical trial data were unavailable, epidemiological comparison of exposed and unexposed populations was the best available method for determining causation."); Joan Hodgman, *Apnea of Prematurity and Risk for SIDS*, 102 Pediatrics 969 (1998) ("The most reliable and reproducible information we have about SIDS comes from epidemiologic studies."); Michael C. Moore & Charles J. Mikhail, *The Fight Against Tobacco*, 111 Pub. Heath Rep. 192 (1996) ("Epidemiology and statistics, not individualized proof, are the most reliable and efficient modes for proving causation of disease in populations."); Jonathan M. Rhodes, *Unifying Hypothesis for Inflammatory Bowel Disease and Associated Colon*

Based on my experience, therefore, it would appear that the existence of all these epidemiologic studies does, indeed, constitute a wealth of information. Given this wealth of available epidemiologic evidence, it is unclear why I would also need the requested documents from Merck's files.

Moreover, if the epidemiologic evidence were not enough, it is also noteworthy that I, and the PSC, *already* have available a large number of "product safety" documents from Merck's files concerning the Merck MMR vaccine and its component parts. That is, the documents that the respondent has already filed in the *Taylor* case and supplied to the PSC (see discussion at p. 4 above) include documents provided by the Food and Drug Administration (FDA) from that agency's vaccine license application files. These documents include many pages of documents regarding vaccine safety issues that were provided by Merck to the FDA in order to gain approval for Merck to market its MMR vaccine and its three component vaccines. By my count, the PSC and I have already received about 8,700 pages of documents from these FDA files, including approximately 2,600 pages relating to the Merck MMR vaccine, 1700 pages relating to the Merck measles vaccine, 1400 pages relating to the Merck mumps vaccine, and 3,000 pages relating to the Merck rubella vaccine. Thus, given the availability of these documents relating to the development of these particular Merck vaccines, along with the available epidemiologic studies, again it is unclear why I would also need the *additional* "product safety research" documents from Merck's files now requested by the PSC. The PSC has simply failed to point to any persuasive indication that I would need such documents.

With respect to this failure of the PSC to point to a significant evidence supporting the assertion that I "need" the available documents, it is significant that no expert testimony was introduced concerning the issue. I agree with the PSC, to be sure, that in theory there is no absolute procedural requirement that a party produce expert testimony in order to persuade me to require production of testimony or documents. If, based on the overall available evidence, it seemed to me to be "necessary" to require certain production, I would order such production regardless of whether an expert had specifically so advised me. But it is worth noting that throughout our discussions at Omnibus Autism Proceeding status conferences over the last several months concerning the PSC's efforts to obtain documents from Merck, it has often been mentioned that one possible way to demonstrate the "need" for such document production would be for the PSC to produce an expert who could explain the importance of the requested documents in the overall context of the available evidence. For example, during an extended unrecorded telephonic status conference held on December 19, 2003, I discussed (with counsel for the PSC, respondent, and the vaccine manufacturers) the PSC's then-pending request for discovery from Merck, which at that time concerned Merck's Hepatitis B vaccine rather than its MMR vaccine. I specifically noted that to

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Cancer: Sticking the Pieces Together with Sugar, 347 Lancet 40 (1996) (epidemiological data is "easiest to verify and likely to be the most reliable"); Jesse R. Lee, *Medical Monitoring Damages: Issues Concerning the Administration of Medical Monitoring Programs*, 20 Am. J. L. and Med. 251, 256 (1994) ("An epidemiological study represents the best evidence of a toxin's capacity to induce a certain disease").

understand the alleged need to require production, it would be quite helpful if petitioners presented an expert who had analyzed all the available evidence concerning the relevant causation issue, and could explain the need for the additional material in light of the available evidence. Further, the briefs of the vaccine manufacturers filed in late 2003 through April of this year have also repeatedly argued that the PSC cannot demonstrate the need for production without producing expert testimony. Moreover, until the PSC filed its reply brief on May 10, 2004, the Committee's representatives continued to hold open the possibility that the Committee might indeed present an expert report and/or expert oral testimony in support of this discovery request. Of course, the PSC was under no strict procedural requirement to present such expert testimony, and I understand that for strategic reasons the Committee might be reluctant to do so at this time. However, the PSC's election not to offer expert support for the Committee's request has simply left me with virtually no evidence upon which I could reasonably base a decision to require production.

Another point worthy of note is that in the 2004 IOM Report, the IOM committee found itself able to reach a conclusion concerning the factual issue of whether the MMR vaccine causes autism, apparently *without* seeing any need to view documents from the files of Merck or any other manufacturer of MMR vaccine. Similarly, that same IOM committee and previous IOM committees have issued ten different reports over the last 14 years, examining whether many different vaccines cause many different illnesses or conditions.[14] In none of those reports is there any indication that any of the IOM committees, in addressing the various causation issues, saw a need to view documents from vaccine manufacturer files.

Similarly, it is noteworthy that for more than 15 years Vaccine Act special masters have constantly considered allegations that various vaccines have caused various conditions or illnesses. Yet I am aware of no case in which a special master found it necessary to require that a vaccine manufacturer provide documents from its files. And I am aware of only a single previous instance in which a petitioner has even *requested* documents from a vaccine manufacturer.[15] This factor tends to support my conclusion that it is not "necessary" that I view the requested Merck files for purposes of this Omnibus Autism Proceeding.

Finally, I note that the logic of the PSC's argument in this proceeding would seem to apply to *every* Vaccine Act case in which a petitioner contends that an injury was "caused-in-fact" by a vaccination. That is, the PSC in support of its request here does not point to a *particular* gap in the

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[14]For a listing of those reports, see 2004 IOM at 77.

[15]In *Kantor v. Secretary of HHS*, No. 01-679V, the petitioners sought documents from Merck's files. The petitioners never asked the special master, however, to *require* such document production from Merck, because the parties and Merck reached agreement concerning the request. That is, on November 21, 2002, the petitioners, respondent, and Merck filed a Stipulation for Entry of a Protective Order, stipulating that Merck would provide certain documents to the petitioners, subject to a confidentiality agreement which specified that such documents could be utilized only for purposes of that Vaccine Act case.

petitioners' causation evidence, nor does the Committee focus on any *particular* documents from Merck files. Instead, the committee does no more than assert, without supplying evidence for the assertion, a causal relationship between MMR vaccines and autism, and then asks broadly for all documents from the files of an MMR vaccine manufacturer concerning the "human health effects" of the MMR vaccine. If this completely unspecific and unsupported assertion demonstrates a "need" for such documents for purposes of the Omnibus Autism Proceeding, why would that not be true for *every* causation allegation concerning *every* vaccine? Logically, why would the manufacturer documents concerning the "human health effects" of *every* vaccine not be "necessary" to *any* special master's inquiry into whether *any* vaccine caused *any* type of human injury? To be sure, this Omnibus Autism Proceeding context seems a bit different at first glance, since the documents would be potentially relevant to *thousands* of Vaccine Act cases, rather than a single case. But why would the same *logic* not apply in the case of *any* petitioner alleging *any* type of injury from a vaccine? Thus, this circumstance--*i.e.*, the fact that the PSC's argument would seem to logically support similar discovery from vaccine manufacturers in *every* Vaccine Act causation case--gives me further reason to doubt that the PSC's "Product Safety Research" request is the type of discovery envisioned by Congress when Congress granted to the special masters the authority to "require" the production of documents from non-parties to Vaccine Act cases.

In sum, having carefully considered the PSC's arguments, I conclude that it is *not* "necessary" that I require the production by Merck of the requested "Product Safety Research" documents.

2. The "United Kingdom litigation" documents

Secondly, the PSC also seeks documents arising from certain litigation involving Merck in the United Kingdom (Great Britain). Apparently a number of families with autistic children filed suit against Merck and other vaccine manufacturers, alleging that the children's autism disorders were caused by MMR vaccinations. Eight such lawsuits were designated as the lead cases, and moved towards a consolidated trial. Apparently certain documents were turned over by Merck to the plaintiffs during the course of the litigation, and also both sides prepared written expert reports concerning the causation issue. Those eight cases have not yet gone to trial, and it is not clear whether they ever will. The PSC, however, requests that I require Merck to produce the following documents from that litigation.

> 1. A copy of the entire set of documents that Merck produced pursuant to discovery requests from the plaintiffs, limited to those documents relating to issues of causation;
>
> 2. Copies of any expert reports, summaries, witness statements, and depositions prepared by or on behalf of Merck in that litigation, limited to those documents relating to issues of causation.

(See PSC's "Request for the Production of Documents: Merck and Company," filed Feb. 26, 2004, as modified by concessions made in the PSC's reply brief filed on May 10, 2004 (p. 9).)

As to this second request, concerning the "U.K. litigation" documents, once again, after careful consideration, I will not require that Merck produce such documents, because I see no significant reason to conclude that such documents are "necessary" to my resolution of the Omnibus Autism Proceeding.

To be sure, as to these "U.K. litigation documents," in contrast to the situation with respect to the "product safety" documents, there is no concern about whether an order to produce the documents would cause a large burden on Merck. Apparently, it would be a relatively simple matter for Merck to copy these documents and supply a copy.

The problem with the PSC's request, rather, is that there is virtually no support in the record before me that the requested documents are "*necessary*" to my resolution of the Omnibus Autism Proceeding. The PSC has not only failed to supply any *evidence*, such as expert testimony, that might indicate that I need these documents, but has also failed to provide even any serious *argument* by its counsel in this regard. For example, in its opening brief the PSC did not even *mention* the documents described in Category 1 above (*i.e.*, the "entire set of documents produced"). (See Br. 3-23-04 at 14-15.) And in its reply brief, that Committee offered only a single sentence cryptically suggesting (without saying why) that such Category 1 documents might have "importance" to the Omnibus Autism Proceeding. (See Br. 5-10-04, p. 10, last sentence of last full paragraph.)

Of course, the PSC does argue persuasively that the Category 2 documents--*i.e.*, the expert reports--are *relevant* to the Omnibus Autism Proceeding, since they directly address the same general causation issue that I face in this Proceeding. And the Category 1 documents might also prove to be of some *relevance* to my inquiry here, since they, too, likely relate in some way to the causation issue that I face here. However, as explained above, *relevance* is not enough. The test is whether the requested documents appear to be "necessary" to my resolution of the Omnibus Autism Proceeding. And the record before me simply provides no support for a conclusion that either category of documents is "necessary" for my inquiry. As to the Category 1 documents, as noted above, the PSC has simply provided me with nothing at all upon which to base a "necessity" finding. And as to the Category 2 expert reports, while such reports do seem *relevant*, I certainly see no reason for finding them "necessary" to my resolution of the Omnibus Autism Proceeding. As explained above concerning the "Product Safety" document request, I have available no less than 16 epidemiologic studies in addition to the original Wakefield study, concerning the issue of whether MMR vaccines cause autism. In addition, both the parties to this Omnibus Autism Proceeding have indicated that they will eventually provide me with one or more expert reports, as well as oral expert testimony at a hearing. Therefore, while additional expert reports would likely be of at least some relevance and interest, I cannot say that for me to see such additional expert reports would be "necessary" to my inquiry.

I must, therefore, also deny the request that I order Merck to produce the "United Kingdom litigation documents."

III

CONCLUSION

In conclusion, I note several additional points. First, I stress that while I have utilized the 2004 IOM Report, for purposes of this Ruling, as a useful source for determining *what evidence is available* concerning the issue of whether the MMR vaccine causes autism, I have *not* endorsed or adopted that Report's *conclusion* concerning that causation issue. As noted above, the PSC has not yet even begun to present its evidence concerning that causation issue in this Omnibus Autism Proceeding. I will, of course, consider and address that causation issue in the Omnibus Autism Proceeding only *after* the parties to the proceeding have had their opportunity to fully present their evidence.

Second, while I have denied the PSC's particular pending motion for discovery from Merck, this ruling does *not* constitute a conclusion that no special master should *ever* require production of documents from a vaccine manufacturer. To the contrary, as set forth above at pp. 7-9, I have concluded that the statute and court rules clearly do provide a special master with the authority to "require" production of documents from *any* "person," including a vaccine manufacturer, *if* the master concludes that such document production is "necessary" to his or her resolution of a Vaccine Act case.

Third, I note that I am sympathetic to the statements of the PSC that it is difficult to demonstrate the "necessity" of documents, when the PSC has not yet seen the documents in question. Nevertheless, the statute clearly requires that the special master must find the proposed document production to be "reasonable and necessary" in light of the overall circumstances of the case, and in this instance I simply see no good reason to conclude that the requested production is "necessary" to my resolution of the Omnibus Autism Proceeding.

Finally, I note that in oral argument the counsel for the vaccine manufacturers seemed to imply that I should at this time declare an end to the time period in which the PSC may seek additional evidence concerning the causation issues in the Omnibus Autism Proceeding, and require that the PSC move immediately to present its causation evidence. I see no reason, however, to pursue such a course.

It is true, of course, that in the *Autism General Order #1*, the Chief Special Master set a time-table for the Omnibus Autism Proceeding under which the parties would by now have presented their evidence concerning the general causation issues. (2002 WL 31696785 at *4-5; 2002 U.S. Claims LEXIS 365 at *11-12.) It is also true that I myself would be happy to move those causation issues to a conclusion as soon as possible--not for the sake of the respondent, the vaccine manufacturers, or myself, but for the sake of the many *families* who have pending Vaccine Act claims, who need

help for their developmentally-impaired children, and who have voluntarily elected to stay proceedings concerning their own individual Vaccine Act petitions pending the completion of the Omnibus Autism Proceeding. For the sake of these families, I would *very much* like to reach a resolution of the Omnibus Autism Proceeding as soon as possible--and I absolutely *will* provide a *very prompt* resolution concerning the general causation issues, *after* the PSC has had its opportunity to present its evidence concerning those causation issues.

However, it must be kept in mind that the primary purpose of the Vaccine Act is to *benefit the petitioners*, and in these autism cases the petitioners are families with children suffering from devastating disorders. I believe that it is appropriate to give the petitioners' representatives the time that they need in order to develop their causation case to the greatest extent possible. All of us involved in the Omnibus Autism Proceeding would like to see it conclude soon, but it is also terribly important to give these families the chance to present the best case that they can. It is true that this process is taking longer than Congress ideally envisioned for most Vaccine Act cases, but the length of the process is simply the result of the fact that these cases involve novel and difficult scientific issues of medical causation. Congress clearly understood that *some* Vaccine Act cases *would* take longer than the ideal, as shown by the fact that Congress gave each petitioner the option under § 300aa-21(b) of staying in the Compensation Program even after the initial time period for decision had expired. The fact is that over the history of the Vaccine Act, many cases have taken longer to arrive at a final decision than the ideal 240-day period, usually because the *petitioners themselves* needed more time to present their cases. But in almost every such case, the petitioner has elected to stay in the Program for whatever time it took to present the petitioner's case and receive a decision. In the Omnibus Autism Proceeding, I am committed to promptly resolving the general causation issues as soon as petitioners are ready to present their proof. In the meantime, if any individual petitioner wishes to decouple his or her claim from the Omnibus Autism Proceeding and to request a prompt resolution of that claim based on whatever evidence that petitioner is able to present, then such a prompt resolution will be provided. However, at this time I do not see a reason to arbitrarily force the PSC to present its evidence in the Omnibus Autism Proceeding before that Committee deems itself ready to do so.

Accordingly, the instant motion having been denied, I will continue to work on the Omnibus Autism Proceeding along with counsel for both sides. The next status conference in that proceeding is currently scheduled for August 10, 2004.

George L. Hastings, Jr.
Special Master