ORIGINAL

IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER, OR A SIMILAR NEURODEVELOPMENTAL DISORDER,	*	
Various Petitioner(s),	*	
v.	*	Autism Master File
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

MERCK & CO., INC.'S RESPONSE TO PETITIONERS' MOTION TO ISSUE THIRD PARTY SUBPOENA

Dated: April 23, 2004

Paul F. Strain
Dino S. Sangiamo
Venable, LLP
1800 Mercantile Bank & Trust Building
2 Hopkins Plaza
Baltimore, Maryland 21201-2978
(410) 244-7400

Attorneys for Merck & Co., Inc.

TABLE OF CONTENTS

IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER, OR A SIMILAR NEURODEVELOPMENTAL DISORDER,	*	Autism Master File
Various Petitioner(s),	*	**MERCK & CO., INC.'S RESPONSE TO PETITIONERS' MOTION TO ISSUE THIRD PARTY SUBPOENA**
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Merck & Co., Inc. ("Merck") files this Memorandum in Opposition to Petitioners' Motion to Issue Subpoena to Merck & Co., Inc., regarding the "MMR" Vaccine (the "Motion").

INTRODUCTION

Petitioners have requested that the Special Master approve issuance of a subpoena directing Merck to produce various categories of documents pertaining to its M-M-R®II vaccine. The motion should be denied.

Issuance of the subpoena requested by Petitioners would contravene the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-10 *et seq.* (1991 & Supp. 2002) (the "Vaccine Act" or "Act"), in terms of both the Act's objectives and its specific terms. Congress has mandated that a precondition for Vaccine Court discovery is that the Special Master find the requested information "reasonable ***and*** necessary" to him or her. This limitation should apply with special force when the discovery sweeps broadly and is

directed at a vaccine manufacturer, the very entity that the Vaccine Act intended to insulate from litigation in order to help ensure the nation's supply of life-saving vaccines such as M-M-R®II. For the Special Master to find that he "needs" the requested discovery based on Petitioners' showing here would violate that congressional mandate.

Moreover, denial of the Motion would not impair the Special Master's ability to make a fair and informed determination of Petitioners' contention that M-M-R®II causes autism. This issue has been the subject of exhaustive, careful, published analysis. In the past several years, articles directly addressing this claim of a causal relationship have appeared in the world's top medical journals including The British Medical Journal, The Journal of the American Medical Association, The Lancet, The New England Journal of Medicine, Pediatrics and Vaccine. The peer-reviewed literature convincingly establishes the safety of M-M-R®II , but the important point for purposes of this Motion is that the literature provides an authoritative information source to guide the experts who testify, and ultimately, the Special Master's causation ruling. Petitioners, who can make no claim to the contrary, ignore this critical part of the record.

Further, by refusing to provide any insight into their experts' analysis, Petitioners have rebuffed Merck's reasonable requests for an explanation of what the missing piece of information is that prevents Petitioners' experts from proving their claim and that ostensibly prevents the Special Master from making a scientifically sound finding for the families that have filed claims.

Based on these considerations and others set forth below, Merck submits that denial of the Motion is not only required by law, but is also fully consonant with the best interests of the parties and the vaccine program.

ARGUMENT

I. A manufacturer subpoena may issue in Vaccine Court only under limited circumstances.

A. Broad discovery and the creation of new vaccine manufacturer litigation burdens are contrary to the general objectives of the Vaccine Act.

The role of the Vaccine Act in the nation's public health program is well-established. Aware of the importance of vaccination programs, Congress saw that public health was being put at risk because the burdens of litigation were driving manufacturers out of the business of producing vaccines. See Lowry v. Secretary of the Dep't of Health & Human Servs., 189 F.3d 1378, 1381 (Fed. Cir. 1999) (noting that "Congress instituted [the vaccine] compensatory program because the traditional civil tort actions against vaccine manufacturers were producing undesirable results . . ."). Congress recognized that the cost of vaccine-related litigation had reduced significantly the number of manufacturers willing to sell childhood vaccines, "making the threat of vaccine shortages a real possibility." H.R. 99-908 (P.L. 99-660), at 5, reprinted in 1986 U.S.C.C.A.N. 6344, 6346. Therefore, because "the high cost of litigation and difficulty of obtaining insurance was undermining incentives for vaccine manufacturers to remain in the vaccine market," Congress afforded the manufacturers relief by enacting the Vaccine Act, which protected the manufacturers from litigation while providing a forum for recovery for those claiming to have been harmed by vaccines. Lowry, 189 F.3d at 1381; see also Subcommittee on Health and the Environment, 99th Cong., Childhood Immunizations 1, 87 (Comm. Print 1986) (expressing congressional concern for "the annual defense costs of vaccine injury litigation that was not reimbursed by insurance").

Through the Vaccine Act, Congress established the Vaccine Court, which is a unique forum, with unique rules, serving a unique public interest. In addition to providing that vaccine manufacturers would not be a party to this vaccine injury remedial process, Congress also sought to streamline procedures. For example, Congress directed that the rules for Vaccine Court were to: "provide for a less-adversarial, expeditious, and informal proceeding," 42 U.S.C. § 300aa-12(d)(2)(A); "include flexible and informal standards for the admissibility of evidence," 42 U.S.C. § 300aa-12(d)(2)B); and "include the opportunity for parties to submit arguments and evidence on the record without requiring routine use of oral presentations, oral examinations, or hearings." 42 U.S.C. § 300aa-12(d)(E).

Congress' desire for streamlining applied specifically to the determination of causation, the only matter at issue in this Omnibus Proceeding. Congress expressed a preference for use of independent medical experts, not unfettered non-party discovery, as the most efficient method for conducting this inquiry. The House Report explains:

> [T]he Masters may, in some cases, be well-advised to retain independent medical experts to assist in the evaluation of medical issues associated with eligibility for compensation and the amounts of compensation to be awarded. In cases where petitioners assert a theory of vaccine causation of injury and respondents claim other causation, the Master may find it most expeditious to receive outside advice rather than attempt a full adversarial proceeding on the questions of causation. The Act authorizes such action by the Master and the Committee would encourage its use as appropriate.

H.R. 101-247 (P.L. 101-239), at 513 (1989), reprinted in 1989 U.S.C.C.A.N. 1906, 2239.

Thus, when Congress established the Vaccine Court, it explicitly sought to "replace the usual rules of discovery in civil actions in Federal courts" (H.R. 99-908 (P.L. 99-660), at 16-17 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6357-58), and expressed the goal of "encourag[ing] the continued availability of important childhood vaccines by

relieving the manufacturers of these vaccines from the burdensome costs of litigation imposed by vaccine-related negligence actions." Thomas v. Secretary of the Dep't of Health & Human Servs., 27 Fed. Cl. 384, 387 (Fed. Cl. Ct. 1992).

To permit broad discovery from a vaccine manufacturer would be exactly contrary to Congress' desires for vaccine manufacturer protection and streamlined procedures. If Petitioners are allowed to conduct such discovery, not only will vaccine manufacturers not be spared the burden that Congress intended to spare them, the Act will become a vehicle for increasing burdens on vaccine manufacturers, who would have to participate in discovery not just in the civil courts, but in this forum as well. Moreover, as borne out by the record to date, the pursuit of such discovery poses a substantial risk of complicating and stalling the proceedings. In short, issuance of subpoenas of the type requested here would turn the Vaccine Act on its head.

B. The specific discovery provisions of the Vaccine Act establish a demanding standard for the issuance of non-party subpoenas.

Consistent with the Act's objectives, Congress made clear that discovery in the Vaccine Court was available only under limited circumstances. The closest the Act comes to authorizing non-party subpoenas appears at § 300aa-12(d)(3)(B), which simultaneously limits such discovery by providing that:

> In conducting a proceeding on a petition, a special master . . . (iii) may require . . . the production of any documents as may be reasonable ***and necessary***.

(Emphasis added.) Congress also specified that the Vaccine Court rules were to "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." 42 U.S.C. § 300aa-12(d)(2)(E). Vaccine Rule 7(c), in turn, states that "[w]hen ***necessary***, the

special master upon request by a party may approve the issuance of a subpoena." (Emphasis added.)

Of critical importance in the proceedings to date, Congress made clear that "necessary" as used in the Vaccine Act and in Vaccine Rule 7 means necessary to the Special Master: "The Act provides the Master with powers to require such evidence ***as he or she may need*** to determine whether compensation should be awarded . . . ." H.R. 101-247 (P.L. 101-239), at 512-13 (1989), reprinted in 1989 U.S.C.C.A.N. 1906, 2238-39 (emphasis added). The statute provides: "There may be no discovery in a proceeding on a petition other than the discovery required by the special master." 42 U.S.C. § 300aa-12(d)(2)(B). Petitioners themselves admit that discovery in Vaccine Court is based on the "'inquisitional' model." (Motion at 9.)

Thus, for a subpoena to issue, the Special Master, not the requesting party, must conclude that discovery is necessary for a fair resolution of the claims at issue. Where, as here, the impetus for the subpoena originates with a party, that party must provide the particulars that would support a finding that the Special Master needs the information, not just that the party wants it. For a medically complex and well-studied technical question such as whether M-M-R®II causes autism, that showing almost certainly would require expert support, something that Petitioners have decided to withhold.

C. This Court should apply a demanding standard to Petitioners' subpoena request here.

Based on the foregoing principles, in order to approve issuance of a subpoena, the Special Master must do more than conclude that the requested subpoena describes documents that, if searched for and found, could be relevant or useful to

Petitioners. Instead, for each aspect of the discovery sought, the Special Master must find a specific reason why the discovery is "necessary" to his ability to adjudicate the causation issue and why the requested discovery should be had from Merck. Petitioners must articulate why the Special Master, after duly considering and weighing the available data such as the numerous studies in the peer-reviewed medical journals, would find that data insufficient for purposes of the informal approach to Vaccine Court decision-making, and conclude that further discovery is "necessary." Experts for Petitioners should have to explain what they have available to them to prove causation, what the gaps are in their analysis, why they need the requested materials, and why they have to get those materials from a non-party. In the special case of a non-party vaccine manufacturer, an important next step follows: the Special Master must weigh Petitioners' showing against the congressional purpose of sparing the manufacturers the burdens of litigation.

As shown below, Petitioners' necessity submission here falls far short of the appropriate standard.

II. Petitioners have not met their burden to show necessity.

In their Motion, Petitioners seek from Merck the Product License Application ("PLA") for Merck's M-M-R®II vaccine for the time period of 1990 to 2003, documents pertaining to research about M-M-R®II or its measles component, certain communications between Merck and the United States government, and expert reports and other documents produced in litigation in the United Kingdom. None of these materials is necessary.

A. PLA documents

Petitioners contend that a subpoena for the M-M-R®II PLA is necessary because they need to see certain information that is redacted in that same PLA as produced by Respondent. The premise of this argument is that Merck would not redact its trade secrets if it produced documents in response to a subpoena. This premise is wrong. (See Argument, § II.A.2., infra.) Even if not for its faulty legal basis, however, Petitioners' evidentiary showing to support necessity would still be wholly inadequate.

1. Petitioners have not shown that it is necessary for the Special Master to see Merck's PLA unredacted.

a. The Motion, by its own terms, narrows dramatically the portion of the PLA that Petitioners claim it is necessary for the Special Master to see unredacted.

Petitioners attempt to satisfy their burden of showing why the Special Master needs to see the PLA in unredacted form by providing two lists of documents, apparently prepared by counsel. One list is entitled "blank pages that might contain relevant information that is reasonably necessary to the causation inquiry" and one list is entitled "redacted pages that might contain relevant information that is reasonably necessary to the causation inquiry."

Before considering these lists, it is important to note that Petitioners have expressly disavowed any interest in seeking by subpoena any part of the PLA other than the documents that the lists identify. In Exhibit B to their Motion, Petitioners state:

> [P]etitioners do not [emphasis in original] seek disclosure or production of material that is obviously not relevant, where the irrelevance can be inferred from accompanying pages of the text. For this reason there are blank or redacted pages that are not listed in this Exhibit, and petitioners do not seek disclosure or production of any pages in the Merck MMR PLA unless specified herein. [Emphasis added].

Exhibit B, n.1. Therefore, although the proposed subpoena seeks the entire PLA from 1990 to 2003, the portion of the PLA that Petitioners in fact claim the Special Master needs to get by subpoena is limited to the documents on their two lists, which Merck now addresses.[1]

b. Petitioners have not shown that it is necessary for the Special Master to see unredacted the portions of the PLA that they have identified on their lists.

Although Merck will address certain aspects of Petitioners' lists, the short answer to their attempt to establish necessity through these lists is much more general. Petitioners' decision not to submit an expert affidavit has foreclosed any prospect of a finding of, or even dialogue about, necessity. Petitioners could have submitted an affidavit in which their expert explained his or her theory of causation. The affidavit could have explained what the expert still needed to see in order to support that theory. It could then have explained the dubious proposition advance by Petitioners' counsel that the needed material included manufacturing process-type details (the kind of information redacted from the PLA). It then could have identified those details, at least by type, which could then have facilitated an analysis of whether such details had been redacted. In the instances in which Petitioners say the necessity of redacted content can be deduced

[1] On the issue of burden, Merck asks the Special Master to consider the import of Petitioners' statement of PLA irrelevance from Merck's perspective and perhaps that of the Food and Drug Administration (the "FDA") as well. Respondent appropriately asked Merck to provide input regarding Merck trade secrets before producing the M-M-R®II PLA. Diverting time from the difficult and important business of managing the production of licensed vaccines and attempting to license new ones, a Merck manufacturing official spent considerable time reviewing the PLA for trade secrets and educating counsel, who in turn spent considerable time implementing redactions and negotiating them with the FDA. It was tremendously detailed and technical work. Merck has experienced the same resource drain with the PLA for its hepatis B vaccine Recombivax HB® and is in the process of experiencing it with the PLA for its haemophilus B vaccine Pedvax®. Even without regard to the subpoena, therefore, Merck has already had to commit substantial resources to this process, notwithstanding what Merck now learns to be the irrelevance of the vast majority of the laboriously redacted information in the PLAs from Petitioners' perspective. Moreover, as shown in the analysis that follows, there is no reason to believe that the pages identified by Petitioners will be any more relevant.

from information on surrounding PLA pages, the expert could have identified and explained that information and its relevance to the alleged causation theory. Having done none of these things, Petitioners have asked the Special Master to guess as to why the redacted technical manufacturing material is supposedly necessary to his analysis of Petitioners' claim that M-M-R®II causes autism. This approach cannot support a finding of necessity.[2]

(i) Pages described by Petitioners as: "Blank pages that might contain relevant information that is reasonably necessary to the causation inquiry."

Petitioners identify 57 documents that they say show the necessity of a subpoena on the basis that the pages in those documents are "blank." Merck vehemently disputes the assertion that the absence of information on a page as received by Petitioners equates with necessity. A simple analysis of those "blank" documents is nevertheless instructive:

- Fully 43 of these 57 documents cited by Petitioners in fact have no redaction at all. (The bates numbers for these documents are identified on Exhibit 1 hereto at ¶ A.) The majority of those 43 documents consist of a page with a date-received stamp that the FDA apparently routinely puts on the back of a cover letter when received. A handful of others are unredacted file titles. Petitioners therefore already have the "blank" pages in 43 of the 57 documents in unredacted form.

- Another two documents are internal FDA memos that Merck presumably does not have in its files, and were apparently redacted by Respondent based on the FDA's deliberative process privilege, not Merck trade secret concerns. (Id. at ¶ B.)

- Another document is actually several documents, consisting of a file title, a date stamp and FDA redactions. (Id. at ¶ C.)

---

[2] As noted above, Merck will also show that it would in any event be entitled to redact these trade secrets even if it were subpoenaed to produce the PLA.

- Thus, 46 of these 57 documents -- 81% -- were never redacted by Merck. It is also worth noting that all but one of these 46 documents pre-date 1990 and therefore are not within the scope of the 1990 to 2003 time frame of the subpoena anyway.

- Of the remaining 11 documents, five pre-date 1990 and therefore would not be called for by the subpoena. (Id. at ¶ D.)

The foregoing analysis shows that there are six documents with so-called "blank" pages at issue, not 57. With respect to these six documents, Petitioners' statement that "one cannot tell from the surrounding pages or other context what, if anything, might be on the [blank] pages" (Petitioners' Exhibit B at 1) is largely inaccurate. Each of the documents is part of a submission that is described in an unredacted or only partially redacted cover letter that was also part of the production to Petitioners. In addition, for several, Petitioners have omitted from their Exhibit B the first page of the document, which provides additional guidance regarding relevance. Although these additional content indicators should have been apparent to Petitioners, Exhibit 1 hereto identifies them. (Exhibit 1 hereto at ¶ E.)

It seems facially obvious from the unredacted information provided in the accompanying cover letters and first pages that production of the redacted information is not necessary. For purposes of deciding this Motion, however, the Special Master need look no further than Petitioners' decision not to produce an expert affidavit. As described above, an affidavit could have supplied various forms of information bearing on the necessity inquiry. Had such an expert presentation been made by Petitioners, Merck could have responded; because it was not made, there is nothing to which Merck can respond. More importantly, Petitioners have deprived the Special Master of information he would need to conclude that Petitioners have met their burden of showing necessity.

(ii) Pages described by Petitioners as: "Redacted pages that might contain relevant information that is reasonably necessary to the causation inquiry."

Petitioners describe the other 32 PLA documents that they would like to have subpoenaed as follows: "In addition, there are pages containing subject headings or other text indicating that the document might contain relevant information necessary to the causation inquiry, and where portions of those pages are redacted." Nothing in these pages shows the necessity of a subpoena of Merck.

Many of these documents can quickly be excluded from consideration. Eleven are internal FDA memos, which presumably are not in Merck's files and which were not redacted by Merck. (The bates numbers for these documents are identified on Exhibit 2 hereto, at ¶ A.) Another document has no redaction at all. (Id. at ¶ B.) Another has only redactions to protect the privacy interests of individuals. (Id.) Two more pre-date 1990. (Id. at ¶ C.)

That leaves 17 documents in this category at issue, not 32. (Id. at ¶ D.) Although Petitioners state that there are "subject headings or other text" supporting their necessity showing for these documents, they do not identify these headings or the text upon which they rely. Here, their decision not to submit an expert affidavit is especially unhelpful. The expert could have explained what those indications were and how they connect to his or her theory of causation. Having failed to come forward with this information, Petitioners have prevented Merck from responding meaningfully. Again, more importantly, Petitioners have left the Special Master to guess as to why the requested information is necessary.

Petitioners have not shown that it is necessary for the Special Master to see any of the redacted information.

2. Petitioners' showing of necessity for the M-M-R®II PLA rests on the faulty premise that Merck would not redact the PLA if produced in response to a subpoena.

Though flawed in its particulars, Petitioners' selection of "blank" and partially redacted documents is, in the end, beside the point: if a subpoena were to issue, Merck would have the right to redact the information in question anyway. As a result, a subpoena would not yield production of the redacted material that Petitioners say the Special Master needs.

a. Petitioners have no right to receive irrelevant trade secret information.

Under no authority or circumstance (even outside the Vaccine Court setting) is a party entitled to production of irrelevant trade secret material. See Duplan Corporation v. Deering Milhiken, Inc., 397 F. Supp. 1146, 1185 (D.S.C. 1974) (parties seeking production of trade secret information must establish its relevancy and "[i]n doubtful situations, production will not be ordered"). Therefore, unless and until Petitioners can articulate a reasoned argument why Merck's trade secrets are relevant to the narrow causation issue in this proceeding, Merck has no obligation to produce its trade secrets, which means that it has the right to redact trade secret information from the PLA and/or withhold certain portions of it. The Federal Circuit cases make clear that Petitioners' offer to stipulate to a protective order (Motion at n.5) does not suffice as a basis for denying Merck's right to redact. See Katz v. Batavia, 984 F.2d 422, 424 (Fed. Cir. 1993) (denying request for subpoena and noting that a protective order "'does not eliminate the requirements of relevance and need for the information'") (quoting Micro

Motion, Inc. v. Kane Steel Co., Inc., 894 F.2d 1318, 1325 (Fed. Cir. 1990) (purpose of protective order "is to prevent harm by limiting disclosure of relevant and necessary information") (emphasis in original)).

b. Only redaction, and not mere entry of a protective order, is sufficient to safeguard Merck's interests.

Merck's trade secrets are among its most valuable assets. By imposing on government agencies the requirement that they purge trade secret information from PLAs prior to making them public, Congress has recognized as much and acknowledged the importance of safeguarding the fruits of manufacturers' research and development efforts. Notably, the trade secrets that might be in jeopardy here relate to the manufacture of vaccines, the continuing supply of which Congress has appropriately recognized to be a national public health imperative. A significant purpose of the Vaccine Act was to protect against erosion of financial incentives for vaccine manufacturers to remain in the market to supply their vaccines; that same legislation should not become the vehicle for casual release of the bedrock intellectual property assets that are instrumental to those financial incentives.

Like the proverbial bell that once rung cannot be unrung, a trade secret loses value once it is no longer secret. Even as a result of simple and excusable inadvertence, confidential information that has been produced pursuant to a protective order can be -- and too often is -- divulged. That parties to a protective order are subject to the contempt powers of a court offers little comfort. What good is it to a manufacturer whose prized trade secrets become known to its competitors that someone might be held in contempt, or a fine imposed?

In Westinghouse Electric Corporation v. Carolina Power and Light Co., No. 91-4288, 1992 WL 370097 (E.D. La. Nov. 30, 1992), the court refused to compel production of trade secret information when it determined that, although the information was "generally relevant" to the issues in the case, the requesting party had "failed to persuade this court that there is a substantial need which outweighs the burden and prejudice to the non-party" of divulging its trade secrets. Here, where the trade secret information is not even "generally relevant," there is nothing to weigh against the potential harm to Merck. See also American Standard, Inc. v. Pfizer, Inc., 828 F.2d 734, 743 (Fed. Cir. 1987) (affirming district court's denial of motion to compel non-party discovery where subpoenaed party claimed information at issue was trade secret and requesting party "failed to show a need for the information sought"); Allen v. Howmedica Leibinger, 190 F.R.D. 518, 526 (W.D. Tenn. 1999) (denying discovery because potential for harm caused by disclosure of trade secret information outweighed the relevancy of the information and requesting party's need for it).

c. Petitioners cannot be permitted to do an end run around the statutory and court-imposed requirement that the FDA produce the PLA documents in redacted form.

Prior to disclosing a PLA, the FDA is required to redact trade secret information that vaccine manufacturers provided to it in connection with the licensing process. See 18 U.S.C. § 1905; 21 U.S.C. § 331(j); 5 U.S.C. § 552(b)(4); 21 C.F.R. §§ 20.61(c) & 314.430; Chrysler Corp. v. Brown, 441 U.S. 281, 285, 318 (1979) (holding that an agency's disclosure of trade secret information constitutes an unlawful agency action). Congress imposed that requirement on the FDA in order to provide an incentive for manufacturers to divulge all relevant information to the licensing entity, secure in the

knowledge that they would not lose their trade secrets as a result. See Critical Mass Energy Project v. Nuclear Regulatory Comm'n, 975 F.2d 871, 872 (D.C. Cir. 1992).

Courts have interpreted the FDA's statutory duty to redact trade secret information from PLAs strictly, and have held that even a litigant's interest in having access to a full administrative record does not trump a manufacturer's interest in protecting its trade secrets. See MD Pharmaceutical, Inc. v. DEA, 133 F.3d 8, 13-15 (D.C. Cir. 1998) (holding that a third-party's interest in a complete administrative record provides "no support for the proposition that [the] party . . . must have unfettered access to all information considered by the agency"); Zeneca v. Shalala, No. WMN99-307, 1999 WL 167139, at **3-4 (D. Md. March 4, 1999) (refusing to order the production of trade secrets under a protective order); Serono Labs., Inc. v. Shalala, 35 F. Supp. 2d 1, 4 (D.D.C. 1999) (even when FDA was willing to produce PLA pursuant to a protective order, i.e., without redaction of trade secret information, court did not allow because such action on the FDA's part would have been "arbitrary, capricious and unreasonable and contrary to law").

Consistent with these holdings, the Special Master has implicitly found that the requirement to redact trade secret information applies in the context of producing documents to the Vaccine Court petitioners. It would be nonsensical, then, to allow claimants to do an end-run around the Special Master's determination by requiring Merck to produce the documents in unredacted form, with only a protective order in place as security.

In Serono Labs, the court ruled that the FDA could not produce a full administrative record that contained drug manufacturers' trade secrets pursuant to a

protective order, but had to "create three versions of the administrative record, an unexpurgated record which contains the entire record and a version from which Ferring's trade secrets have been removed to give to Serono, and a version from which Serono's trade secrets have been removed to be given to Ferring." The court noted that such an obligation was "unquestionably onerous" and suggested that if the process seemed to take too long, Serono (who argued for production of the administrative record without trade secret redaction) could invoke the court's power to "expedite agency action." Notably, the court said nothing about Serono's circumventing the law altogether by issuing a non-party subpoena to Ferring for documents provided to the FDA.[3] To the contrary, the court ruled that "a party . . . is under no obligation to accept less than the absolute protection the statute creates for its trade secrets." 35 F. Supp. 2d at 3; see also MD Pharmaceutical, 133 F.3d at 15 (holding that protective order was insufficient and requiring redaction of trade secrets from PLA); Zeneca, 1999 WL 167139, at *4 ("the Court does not believe that the disclosure of trade secrets is appropriate, even subject to a protective order").[4]

In sum, there is no necessity for the Special Master to see redacted information and issuance of a subpoena would serve no purpose.

---

[3] Note that Serono was litigated under the liberal standards for discovery applicable in the federal courts of general jurisdiction, and not in vaccine court, where discovery is ***not*** available as of right and the standard for discovery is much higher.

[4] In Zeneca, the court noted the argument made by one drug manufacturer party that even if its competitor's trade secrets were protected from disclosure by the FDA, those same secrets were discoverable directly from the competitor manufacturer. The court's response: "That may or may not be so." The court said nothing more on the issue, which it stated was not before it at the time. Merck knows of no other decision that has addressed this question.

B. Product safety research

With respect to "product safety research" documents (Subpoena at B), Petitioners have again thwarted a meaningful necessity analysis by their decision not to submit an affidavit from their expert explaining what data is missing from his or her theory of causation. It seems doubtful that such an affidavit could be prepared. The medical literature concerning the alleged link between autism and M-M-R®II is extensive and precludes a finding of product research necessity.

1. A rich supply of published peer-reviewed literature is available to experts and the Special Master.

The hypothesis of a link between the measles, mumps and rubella vaccine and autism began with an article published in The Lancet in 1998 by Dr. Andrew Wakefield.[5] In this publication, the authors reported that the parents or physicians of eight of the 12 children examined associated the onset of behavioral symptoms with MMR vaccinations. The article went on to explain: "We did not prove an association between measles, mumps and rubella vaccine and the syndrome described. . . . Further investigations are needed to examine this syndrome and its possible relation to this vaccine." (p. 641)[6]

---

5 A. J. Wakefield, et al., Ileal lymphoid, Nodular hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children. Lancet. 1998; 351:637-641.

6 In March 2004, ten of the thirteen authors of this article retracted the suggestion of a link with MMR in the following statement: "We wish to make it clear that in this paper no causal link was established between MMR vaccine and autism as the data were insufficient. However, the possibility of such a link was raised and consequent events have had major implications for public health. In view of this, we consider now is the appropriate time that we should together formally retract the interpretation placed upon these findings in the paper, according to precedent." S.H. Murch, et al. "Retraction of an Interpretation", Lancet. 2004; 363:750; see also A.J. Wakefield, et al. "MMR-responding to retraction," Lancet. 2004; 1327-28 (letter from remaining three authors, reaffirming that "no claim of a causal association with MMR was ever made").

Although the number of study subjects was too small to form the basis for scientific conclusions and the study results have not been replicated by others, the suggestion by Dr. Wakefield and his colleagues of a possible link between the MMR vaccine and autism led to further research on the subject. To date, the following peer reviewed articles have been published:

> Peltola H., Patja A., Leinikki P., et al., No Evidence for Measles, Mumps and Rubella Vaccine-Associated Inflammatory Bowel Disease or Autism in a 14-year Prospective Study. Lancet. 1998; 351:1327-1328. ("Over a decade's effort to detect all severe adverse events associated with MMR vaccine could find no data supporting the hypothesis that it would cause pervasive developmental disorder or inflammatory bowel disease.")
>
> Taylor B., Miller E., Farrington C.P., et al., Autism and Measles, Mumps and Rubella Vaccine: No Epidemiological Evidence for a Causal Association. Lancet. 1999; 353:2026-2029. ("Our analyses do not support a causal association between MMR vaccine and autism. If such an association occurs, it is so rare that it could not be identified in this large regional sample.")
>
> Farrington C.P., Miller E., Taylor B., MMR and Autism: Further Evidence Against a Causal Association. Vaccine. 2001; 19:3632-3635. ("In conclusion, the results presented here, combined with those we obtained earlier, provide powerful evidence against the hypothesis that MMR vaccine, or indeed any measles-containing vaccine, causes autism at any time after vaccination.")
>
> Kaye J.A., Melers–Moutes M., Jick H., Mumps, Measles and Rubella Vaccine and the Incidence of Autism Recorded by General Practitioners: A Time Trend Analysis. British Medical Journal. 2001; 322:460-463. ("Because the incidence of autism among 2-5 year olds increased markedly among boys born in each year separately from 1988 to 1993 while MMR vaccine coverage was over 95% for successive annual birth cohorts, the data provide evidence that no correlation exists between the prevalence of MMR vaccination and the rapid increase in the risk of autism over time.")
>
> Dales L., Hammer S.J., Smith N.J., Time Trends in Autism and in MMR Immunization Coverage in California. Journal of the American Medical Association. 2001; 285:1183-1185. ("These data do not suggest an association between MMR immunization among young children and an increase in autism occurrence.")

Madsen K.M., Hvid A., Vestergaard M., et al., A Population Based Study of Measles, Mumps and Rubella Vaccination and Autism. New England Journal of Medicine. 2002; 347:1477-1482. ("This study provides strong evidence against the hypothesis that MMR vaccination causes autism.")

Taylor B., Miller E., Lingam R., et al., Measles, Mumps and Rubella Vaccination and Bowel Problems or Developmental Regression in Children with Autism: Population Based Study. British Medical Journal. 2002; 324:393-396. ("These findings provide no support for an MMR associated 'new variant' form of autism with developmental regression and bowel problems, and further evidence against involvement of MMR vaccine in the initiation of autism.")

Fombonne E., Chakrabarti S., No Evidence for a New Variant of Measles-Mumps-Rubella Induced Autism. Pediatrics. 2001; 108: E58. ("No evidence was found to support a distinct syndrome of MMR-induced autism or of 'autistic enterocolitis.' These results add to the recent accumulation of large-scale epidemiologic studies that all failed to support an association between MMR and autism at population level.")

Makela A., Nuorti J.P., Peltola H., Neurologic Disorders After Measles, Mumps Rubella Vaccination. Pediatrics. 2002; 110:957-963. ("We did not identify any association between MMR vaccine and encephalitis, aseptic meningitis, or autism.")

These articles will provide the Special Master and any experts who testify with the assistance of the careful, peer-reviewed analysis of preeminent medical doctors and scientists publishing in preeminent medical journals. Petitioners themselves have elsewhere told the Special Master that "[d]ecisions on causation in . . . this program [the Autism Omnibus Proceeding] will depend heavily on expert testimony, which will in turn rely on analyses of published, relevant studies." Petitioners' Motion to Compel Discovery in the Autism Omnibus Proceeding at 12 (filed March 9, 2004) (emphasis added). Yet, in their necessity submission for the Merck subpoena, Petitioners omit any reference to this literature. Petitioners have accordingly failed to identify deficiencies in

the literature, why they are likely to be filled by information to be found at Merck, and, ultimately, why a subpoena should issue to fill them.

2. Petitioners' showing of necessity for more research data is inadequate.

Ignoring all of the available literature cited above, Petitioners instead cite to the report of the Institute of Medicine ("IOM") from April 2001. Petitioners acknowledge that "the report concluded that existing epidemiological studies [did] not support a causal connection between [M-M-R®II] and [Autism Spectrum Disorders]" (Motion at 10-11.) Petitioners assert, however, that a case for necessity can be made from other statements in the report.

First, Petitioners point to the fact that the IOM noted limitations inherent in epidemiological data and in an attempt to base a theory of causation on Vaccine Adverse Event Reporting System data. These are unremarkable observations that fail to identify what is missing from the theory of causation that Petitioners' experts will proffer and why it must be obtained from Merck.

Next, Petitioners point to the IOM's reference to the Wakefield hypothesis and suggest that the IOM found the data in this area generally to be "fragmentary." In fact, it was the proposed causation model that the IOM found to be "incomplete and fragmentary," and to "have not been supported by validated and replicated controlled studies." (IOM Report at 5-6.) In any event, Petitioners have not said whether their experts plan to advance the Wakefield hypothesis, what kind of data their experts need in order to support it, or why that data must be obtained from Merck. Nor have Petitioners tailored the proposed subpoena to request only this needed data.

Finally, Petitioners point to the IOM's observation that "all possible etiologies" should be considered because Autism Spectrum Disorders are serious. Again, this general statement does not identify what Petitioners need or why they need to get it from Merck.

In short, Petitioners' citation to the IOM report changes nothing. The fact remains that they have not shown what is missing from their theory of causation, or even what that theory is. Even had they done so and crafted an appropriately narrowed request for research of the type they needed, they would still have to show why Merck should be burdened with its production. Petitioners in essence ask the Special Master to hold that anytime an unrecognized theory of causation is presented in Vaccine Court, a subpoena for a vaccine manufacturer to search its files should issue without any additional showing of need. That is not the law. Petitioners decided not to make the forthright showing required to support a finding of necessity. The request for Product Safety Data should therefore be denied.

C. Communications with the federal government

Documents related to Merck's communications with federal agencies (Subpoena at C) are available from and, presumably, have already been provided by, Respondent. (See Request 13 of Petitioners' Requests to Respondent at 22, "all correspondence of any kind, emails, memos, letters, reports, etc., exchanged between the government and any vaccine manufacturer, any health and/or medical agency, or international organization in any country related to MMR, thimerosal, or any other preservative in any vaccine.") Given that the Special Master already has these documents, it is difficult to imagine how it might be "necessary" that the Special Master

get them again from Merck. Moreover, even if those documents were not already available to the Special Master, Petitioners have not explained why the documents might be necessary for the Special Master to render a decision regarding causation.

D. United Kingdom litigation documents

The subpoena seeks production of documents produced in litigation currently pending in the United Kingdom involving M-M-R®II, as well as measles, mumps and rubella vaccines sold by other manufacturers. Petitioners request (1) all of the documents "produced pursuant to discovery requests from the plaintiffs, limited to those documents relating to issues of causation," and (2) expert reports and similar documents relating to causation either prepared by Merck or served on Merck. A subpoena for these documents should not issue.

1. Petitioners have not even tried to show necessity for the "causation" documents produced by Merck in the United Kingdom litigation.

Petitioners' Motion does not even attempt to justify why Merck should be subpoenaed to produce here the "causation" documents that it produced in the United Kingdom "pursuant to discovery requests from the plaintiffs." Because Petitioners have not addressed this category of documents in their necessity showing, Merck assumes that they do not intend to pursue that discovery.[7]

[7] Merck reserves the right to file an additional submission should Petitioners subsequently attempt to show necessity for these documents.

2. Petitioners have not shown necessity for the expert reports produced in the United Kingdom litigation and have not accounted for the tremendous burden and legal complexity that their production would entail.

a. A subpoena for the expert reports is not necessary.

To establish the necessity of the expert reports, Petitioners state: "Reports of this type are essential elements of discovery in the U.S. federal court system and in the civil justice system of the vast majority of states." (Motion at 15.) That statement misses the mark for several reasons.

First, as Petitioners have elsewhere acknowledged, the rules of discovery in Vaccine Court differ from those in other United States jurisdictions. Here, a party seeking discovery must show necessity, not mere relevance. To point out that a document being sought in this Court is of a type that is often produced in other courts does not show why a subpoena should issue. Two different standards apply.

Second, discovery of this type would not be permitted in most United States jurisdictions. While parties often turn over reports for the experts whom they intend to call as witnesses in that litigation, Petitioners have not cited any case from any jurisdiction in which a non-party has been ordered to turn over expert reports. Such discovery would be barred by Fed. R. Civ. P. 45(C)(3)(B), which provides that a District Court "shall quash or modify" a subpoena if it "requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party." (Emphasis added) ; accord RCFC 45(C)(3)(B). In fact, even as to parties, Petitioners' request exceeds the bounds of the rules applicable in most jurisdictions. If, contrary to fact, this was a case in a United States District Court and Merck was a party, Fed. R. Civ. P.

26(b)(4)(B) would preclude Petitioners from getting discovery about experts Merck did not intend to call as witnesses at trial, unless Petitioners could show "exceptional circumstances under which it is impracticable for [Petitioners] to obtain facts or opinions on the same subject by other means." See also RCFC 26(b)(4)(B) (same). Petitioners have not tried to make such a showing, nor could they given the breadth of attention this causation issue has received in the medical journals and the many years Petitioners' experts have had to refine their theories. Further, even if one were to make the above-referenced counter-factual assumptions and were to further assume counterfactually that Merck intended to call at this trial the experts who authored the United Kingdom reports, Petitioners' request would still go beyond the rules because there is no requirement that a party produce reports that its testifying experts have written in other cases. See Fed. R. Civ. P. 26(a)(2)(B); see also RCFC 26(a)(2)(B); Surles v. Air France, 2001 WL 815522, at *7 (S.D.N.Y. Jul. 19, 2001) ("By implication, because [Rule 26(a)(2)(B)] requires only the production of a list of the expert's cases, Surles is not entitled to disclosure of the reports in those cases, regardless of their subject matter" (emphasis in original)), aff'd, 2001 WL 1142231 (S.D.N.Y. Sep. 27, 2001). Petitioners' request would therefore be improper even in courts of general jurisdiction and even under circumstances much more conducive to their request.

Petitioners do not even attempt to satisfy the governing necessity standard. They do not say why it is necessary that expert reports from other litigation be provided to the Special Master here in order for the Special Master to adjudicate the issues before him. Presumably, Petitioners' experts are capable of presenting the Petitioners' causation theories. If that is not so, it was incumbent upon Petitioners to provide affidavits from

their experts explaining why they were unable, after study of the abundant literature, to determine whether M-M-R®II causes autism. Petitioners elected not to do so.

Moreover, the expert reports Petitioners seek were prepared in different litigation, involving different vaccinees, in a different jurisdiction, where reports are written in such a way that they can generally serve as direct examination. Facts specific to the claimants are therefore intertwined with the analysis in the majority of the reports making their relevance -- let alone necessity -- here even more marginal.

Petitioners have not shown that this most unusual use of the third party subpoena process is necessary.

b. Even if a subpoena for the expert reports was necessary, an order for their production would still be inappropriate due to the requirements of English procedural law.

(i) English court rules restrict Merck from producing the expert reports.

The Civil Procedure Rules ("CPR") of the English High Court create numerous obstacles to Merck's production of expert reports here. CPR 31.22(1) provides:

> A party to whom a document has been disclosed may use the document only for the purposes of the proceedings in which it is disclosed, except where –
>
> (a) the document has been read to or by the Court or referred to, at a hearing which has been held in public;
>
> (b) the Court gives permission; or
>
> (c) the party who disclosed the document and the person to whom the document belongs agree.

An order to produce the expert reports in the Vaccine Court would entangle Merck in the prohibitions of CPR 31-22(1).

(a) Reports produced by claimants.[8]

Senior English counsel acting in the English litigation have advised that the reports from the claimants' experts are documents disclosed to Merck. None of the events described in subparts (a), (b) and (c) of the rule has occurred. Merck cannot now produce those reports, because Merck may only "use" them "for the purposes of the proceedings in which [they] were disclosed."

Moreover, Merck should not be put to the burden of having to take steps to trigger the exceptions to the non-disclosure rule. For example, to seek approval for release from the English Court pursuant to §31.22(1)(b), Merck would have to pay counsel to make and pursue an application in that forum. Such an application also would make no sense. Merck does not advocate production of the claimants' expert reports here and thus is hardly in a position to persuade the English Court as to why disclosure should be allowed. Nor should Merck be required to chase down the claimants and ask them for permission to produce the reports pursuant to §31.22(1)(c). Besides the fact that Merck should not be put to this burden and expense, Merck should not be put in the position of having to ask the parents of the claimants to agree to disclosure of the medical information which is often embedded into the analysis in these reports, which the parents most certainly would consider private and which is protected by strict rules of confidentiality. Merck would also need the approval of the claimants' experts, if they are the people to whom the reports "belong" under §31.22(1)(c). Furthermore, production of the claimants' reports in these circumstances would require the consent of the owners of the clinical and other records on which the reports rely since these too are documents

---

[8] The term "claimants" in United Kingdom litigation is the equivalent of the United States term "plaintiffs."

caught by the provisions of CPR 31-22(1). Seeking the consent, which might well be refused, of the owners of the claimants' records would involve corresponding with numerous healthcare providers and might take many months.

An additional layer of complication applicable to both of these possible exceptions to the non-disclosure rule arises out of the claimants' representation status. The claimants in the United Kingdom litigation are currently not represented by counsel. This increases considerably the burden to Merck of securing consents or of seeking a court order for release of the reports. The English Court is not likely to waive readily the claimants' right to maintain confidentiality of the reports under these highly unusual circumstances, especially when the claimants lack legal representation.

(b) Reports produced by defendants.

Similar principles present an obstacle to production of the expert reports disclosed by the United Kingdom defendants.[9] Most of these reports either refer to facts about the claimants or refer to test results from the claimants. The facts and test results derive from documents disclosed to Merck in the litigation. Thus, absent occurrence of the events described in §31.22(1)(a),(b), or (c), these reports could not be disclosed.

Even the defense reports that do not contain information provided by the claimants are not so easily disclosed. When the experts undertook to assist in the English litigation, it was not suggested to them that their analysis was going to be entered into the record in another proceeding in another country. Legitimate concerns they have about such a use of their reports could be magnified by the fact that the reports will lack context

---

[9] Twenty-five of the 30 expert reports produced by the defendants were jointly produced by Merck and the two primary co-defendants. Three were produced only by Merck. The two reports produced individually by co-defendants would be documents disclosed to Merck, the production of which would be barred by a simple application of CPR 31.22(1).

given that they would be produced without the benefit of oral evidence, reports of the claimants' experts, the reports of most of the defense experts, the Particulars of Claim,[10] and other important documents from the English litigation. Nor would the experts have the opportunity they would have had at trial in England of giving supplementary or explanatory oral evidence, commenting on the evidence relied upon by the claimants and/or petitioners, or otherwise responding to challenges to their evidence. Entirely apart from consideration of the experts' intellectual property rights in their reports; out of fairness to the experts in this unusual circumstance, Merck would be obliged to contact each before production, which would no doubt prompt discussion and other follow-up. This exercise would complicate the production of even those few defense reports that do not contain claimant materials.

(ii) This Court should defer to the applicable English court rules.

Various tests have been applied by courts addressing the question of whether it is appropriate to order a party to produce documents in contravention of the laws of another nation. See, e.g., Cochran Consulting, Inc. v. Uwatec USA, Inc., 102 F.3d 1224, 1226-27 (Fed. Cir. 1996); Volkswagen, A.G. v. Valdez, 909 S.W.2d 900, 902 (Tex. 1995); Minpeco, S.A. v. Conticommodity Servs., Inc., 116 F.R.D. 517, 523 (S.D.N.Y. 1987); see also Restatement (Third), Foreign Relations Law of the United States, § 442 (1987). Although the particulars of the tests have varied, several general principles emerge. These principles militate strongly against issuance of a subpoena here.

---

[10] "Particulars of Claim" are, very generally, the United Kingdom equivalent of "complaints."

First, orders to compel violations of the laws of another country should be undertaken very reluctantly. As the D.C. Circuit stated in In re Sealed Case, 825 F.2d 494 (D.C. Cir. 1987):

> We do not here decide the general issue of whether a court may ever order action in violation of foreign laws, although we should say that it causes us considerable discomfort to think that a court of law should order a violation of law, particularly on the territory of the sovereign whose law is in question.

Id. at 498; see also Cochran, 102 F.3d 1224, 1230 (Fed. Cir. 1996) ("[I]t is inappropriate for the United States, a nation founded on the rule of law, to require that a person violate the criminal laws of a sovereign nation.").

Second, the importance of the documents being sought and the ability of the requesting party to develop the pertinent facts by other means should figure prominently in the Court's analysis. E.g., Minpeco, 116 F.R.D. at 529-30; Volkswagen, 909 S.W.2d at 903. As shown above, Petitioners have not shown that the information they seek from the expert reports can be found only in those reports. This is a far cry from cases in which courts have been prepared to issue production orders notwithstanding inconsistency with foreign law, such as those involving United States grand jury investigations in which critical evidence can be obtained only from sources overseas. E.g., In re Grand Jury Subpoena Dated August 9, 2000, 218 F. Supp. 2d 544 (S.D.N.Y. 2002).

Third, orders directing violations of foreign law are especially inappropriate when directed at non-parties to the litigation. E.g., In re Sealed Case, 825 F.2d at 498; United States v. First Nat'l Bank, 699 F.2d 341, 346 (7th Cir. 1983); Minpeco, 116 F.R.D. at 530. That principle, based on basic fairness, should be especially applicable in the setting here. The Vaccine Act, designed to protect vaccine

manufacturers from litigation, should not become the vehicle by which a vaccine manufacturer is forced to choose between either failing to comply with a subpoena from a United States court in a proceeding to which it was not a party or violating the rules of another court in a proceeding in which it was a party.

Petitioners' Motion does not make the case for thrusting the Special Master into this thicket of requirements of international law and principles of international comity. As far as common sense and Petitioners' showing would suggest, the relevance of the expert reports is, at most, cumulative of what the experts for the parties here could do. Production of the reports would also entail violations of privacy interests of the English litigants and, quite possibly, the interests of experts who have committed themselves to assisting in the proceeding there. This simply is not a case in which Merck should be directed to make a production that would violate the rules a foreign court that is itself trying to manage an ongoing litigation involving important issues of public health.[11]

---

[11] There is authority for the proposition that where foreign law prohibits production of materials, a court "may require the person to whom the order to produce is directed to make a good faith effort to secure permission from the foreign authorities to make the information available." Restatement (Third) Foreign Relations Law of the United States, §442(2)(a) (1987). Based on the considerations described above, this is an inappropriate setting in which to make such an order. Moreover, the unrepresented status of the other parties in interest for any application by Merck to the English Court portends a slow and unwieldy process there.

III. Merck is entitled to information regarding other material made available to the Special Master.

A. Merck is entitled to access to the information that is already available to the Special Master because a determination of necessity must take that information into account.

Petitioners have built their argument in support of issuance of a subpoena around their contention that the Respondent's discovery responses are inadequate. Petitioners begin their necessity argument by stating:

> By the government's own admissions in various discovery documents and in the public record, there are significant gaps in the scientific picture that Merck should be able to fill by providing documents responsive to the petitioners' request. Given the gaps in the available scientific evidence produced by the government, the Special Master needs to look elsewhere for the information.

Motion at 10 (emphasis added.)

Merck is not privy to and has no way of ascertaining precisely what discovery Respondent has made available. Therefore, as a preliminary matter, Merck is deprived of the information it needs to respond to Petitioners' core argument that the "discovery documents" and "scientific evidence produced by the government" identify gaps and are otherwise insufficient. This is of particular concern because it is Merck's impression that, despite the inquisitional model that Petitioners admit applies here, it is Petitioners, not the Special Master, who have expressed an interest in obtaining Merck's documents by subpoena. The Special Master appears to be relying upon the traditional adversarial method for purposes of determining subpoena necessity, making it all the more important that Merck be granted access to Respondent's discovery to test Petitioners' contention that the inadequacy of that discovery is what compels the issuance of a subpoena here.

Accordingly, by separate Motion, Merck asks that it be granted access to Respondent's discovery. At this juncture, Merck requests that, before the Special Master rules on Petitioners' Motion, Merck be granted both (1) access to deposition transcripts, documents and interrogatory answers pertinent to this proceeding and (2) an opportunity to make any further arguments based on the information learned as a result.

B. To deprive Merck of access to information integral to the determination of necessity would violate Merck's right to a fair hearing.

In prior motions practice in connection with Petitioners' effort to obtain a subpoena related to thimerosal and Merck's Recombivax HB® vaccine, the Special Master denied Merck access to the information that Respondent had produced to date. In so doing, the Special Master stated:

> I note that Merck's argument in favor of its request is logical and persuasive. If I had discretion to disclose the information in question on my own, I would do so. Further I note at the status conference held on November 25, 2003, the representative of the Petitioners' Steering Committee stated that the Committee would also have no objection to sharing the requested information with Merck. The 'person who submitted the information,' however, is respondent. Thus, according to law, that information may not be disclosed to the non-party Merck without respondent's consent.

Order Re Merck's "Motion for Information Re Discovery," at 1-2 (November 26, 2003).

Although Merck acknowledges the statutory provision on which the Special Master's prior ruling was based, Merck respectfully disagrees that the solution is to rule on this matter affecting Merck's interests while Merck is denied access to the materials that it needs to defend itself. To proceed in this fashion would be to adjudicate Merck's rights while denying Merck access to information that is not only relevant to those rights, but, as noted above, has been given central prominence in Petitioners' argument. Merck submits that, especially in light of Petitioners' attempt to preclude

Merck from redacting its trade secrets in response to a subpoena, such an approach would deprive Merck of a fair hearing on this Motion. See generally Mathews v. Eldridge, 424 U.S. 319 (1976). The Vaccine Act simply is not suited for party-initiated requests for broadly sweeping subpoenas that seek to burden non-parties, especially vaccine manufacturers.

CONCLUSION

For the reasons set forth above, Petitioners' Motion should be denied.

Dated: April 23, 2004

Paul F. Strain
Dino S. Sangiamo
Venable, LLP
1800 Mercantile Bank & Trust Building
2 Hopkins Plaza
Baltimore, Maryland 21201-2978
(410) 244-7400

Attorneys for Merck & Co., Inc.

CERTIFICATE OF SERVICE

I hereby certify that on April 23, 2004, I served the foregoing Merck & Co. Inc.'s Response to Petitioners' Motion to Issue Third Party Subpoena by electronic mail and by first class mail on the following individuals:

Vincent Matanoski, Esquire
U.S. Department of Justice
Torts Branch, Civil Division
P.O. Box 146, Benjamin Franklin Station
Washington, D.C. 20044-0416

Ghada Anis, Esquire
Petitioner's Steering Committee
733 15th Street, N.W., Suite 700
Washington, D.C. 20005

Michael L. Williams, Esquire
Williams Dailey O'Leary Craine & Love, P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135

Dino S. Sangiamo
Venable LLP
Attorneys for Merck & Co., Inc.

(Exhibits 1 and 2 to Merck's Response have been filed into the Master Autism File, but are not being placed on the website for the Omnibus Autism Proceeding due to the provisions of 42 U.S.C. § 300aa-12(d)(4)(A).)