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),	*	**NON-PARTY MERCK & CO.'S RESPONSE TO PETITIONER'S MOTION TO ISSUE REVISED THIRD PARTY SUBPOENA**
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

* *

INTRODUCTION

Merck & Co., Inc. ("Merck") files this Memorandum in Opposition to Petitioners' Motion to Issue Revised Third Party Subpoena (the "Motion"). In their Motion, Petitioners have asked the Special Master to authorize the issuance of a subpoena that would direct Merck to produce the Product License Application ("PLA") for Merck's Recombivax HB vaccine, as well as numerous other categories of documents.[1]

As shown below, the requested subpoena should not issue because it 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

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[1] In addition to the PLA for Recombivax HB, the subpoena seeks production of 1) documents related to a) "the human or animal health effects" of thimerosal and ethyl mercury; b) "the neurological or neurodevelopmental human or animal health effects of the Recombivax HB vaccine or of any of its components, including all formulations of the product;" c) "the human and animal health effects of any preservatives, biocides, fungicides, adjuvants, stabilizing agents, and diluents used in any formulation of Recombivax HB;" and 2) documents involving communications between any persons at Merck and government agencies or employees. See Petitioners' Revised Request for the Production of Documents ("Subpoena").

Court discovery is that the Special Master find it "reasonable ***and*** necessary" to him or her. This limitation should apply with special force when the requested discovery sweeps broadly and is directed at a vaccine manufacturer, the very entity that the Vaccine Act intended to insulate from litigation. For the Special Master to find that he "needs" the requested discovery here would violate that congressional mandate. Accordingly, Petitioners' Motion should be denied.

ARGUMENT

No court has ever adjudicated whether Congress has granted the Special Master power to approve issuance of a subpoena to a vaccine manufacturer. Even assuming such authority does exist in limited circumstances, it clearly is absent here.

I. Issuance of the Subpoena Would Violate the Vaccine Act's Objectives of Reducing Litigation Burden for Vaccine Manufacturers and Streamlining Procedures.

Issuance of the subpoena requested in Petitioners' Motion would be contrary to Congress' desire, as expressed in the Vaccine Act, to safeguard the nation's vaccine supply by protecting vaccine manufacturers. One of Congress' primary goals in enacting the Vaccine Act was to alleviate vaccine manufacturers from the burdens of litigation, which Congress found to be driving those manufacturers out of the business of producing vaccines. See Lowery 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. Lowery, 189 F.3d at 1381.

Through the Vaccine Act, Congress established the Vaccine Court, which is a unique forum, with unique rules, serving a unique public interest. One of Congress' objectives for the Vaccine Court was 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 what Congress intended the Vaccine Act to accomplish. 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. In short, by creating more, rather than fewer, burdens on vaccine manufacturers, issuance of the subpoena would turn the Vaccine Act on its head.

II. Issuance Of The Subpoena Would Violate The Discovery Restrictions That Congress Put Into The Vaccine Act.

Consistent with its objectives, Congress made clear that discovery in the Vaccine Court was available only under limited circumstances. As shown below, those circumstances are not present here.

A. To the extent that the Special Master may ever approve issuance of a subpoena to a vaccine manufacturer, the circumstances under which he may exercise such authority are severely limited.

Petitioners admit that they are not entitled to "discovery as a matter of right [as] in civil litigation under the federal or state rules of procedure." Motion at 7.

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.)

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); see also H.R. 99-908 (P.L. 99-660), at 17 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6357-58 ("Other than the discovery specifically described as the prerogative of the Master, there is to be no other discovery in a compensation proceeding"). 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).

By insisting that the Vaccine Court rules include "limitations" on discovery (42 U.S.C. § 300aa-12(d)(2)(E)) and that discovery be allowed only where "necessary" (42 U.S.C. § 300aa-12(d)(3)(B)(iii)), Congress clearly intended that discovery was not to proceed in the usual permissive fashion under, for example, the

Federal Rules of Civil Procedure, which allow discovery of "any matter, not privileged that is reasonably likely to lead to the discovery of admissible evidence." This discovery limitation follows naturally from Congress' desire for a simplified, non-adversarial approach to fact development. In short, the standard for discovery in the Vaccine Court is much more rigorous.

In order to approve issuance of a subpoena, therefore, 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, would find it insufficient for purposes of the informal approach to Vaccine Court decisionmaking, and conclude that further discovery is "necessary." Accordingly, Petitioners should have to explain what they have available to them to prove causation, what the gaps are in their case, 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. [2]

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[2] Petitioners offer no standard for the Special Master to apply in determining necessity. Although Petitioners cite authorities in their Motion, none of them arises in the Vaccine Act setting and therefore none of them interprets the discovery standard of the Vaccine Court.

Obviously, Petitioners would prefer to pursue all sources, without any regard for the cost to those sources, and gather all potentially relevant documents. But that is precisely what Congress sought to prevent when it established the Vaccine Court. Notably, Congress provided that a Vaccine Court determination was not binding and gave petitioners the right to reject a Special Master's finding and pursue their claims in state and federal courts of general jurisdiction, where the rules of those fora would apply. In this forum, however, Congress rejected the no-stone-unturned approach to discovery, by providing for a streamlined process and not a costly fishing expedition.[3]

B. Petitioners have not shown that issuance of the subpoena is "necessary."

As set forth above, the burden on Petitioners to make a showing of necessity, as that term should be interpreted under the Vaccine Act, is very high. Here, measured against that standard, Petitioners' showing falls far short.

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[3] The approach to discovery that Petitioners advocate carries the potential for abuse. Many of the attorneys for Petitioners are actively pursuing litigation against Merck and other vaccine manufacturers in civil court. By extracting discovery from a vaccine manufacturer here, Petitioners' counsel can use the Vaccine Court as a vehicle for the ulterior purpose of preparing themselves for that other litigation. The Special Master should not lose sight of the fact that, as originally drafted, the proposed subpoena contained requests that were patently irrelevant to any issue in this omnibus proceeding and, perhaps not coincidentally, mirrored themes that the plaintiffs' bar has suggested that it may pursue in the courts of general jurisdiction. For example, the requested subpoena at first sought information about:

> product packaging, . . . [including documents about] the relative costs, expenses or any other financial factor relating to a) the use of multi-dose vials versus single-dose vials, b) the use of single-dose pre-filled syringes, c) the use of preservatives . . . .

(Request for Production of Documents: Merck & Company, Incorporated, attached to Motion to Issue Third Party Subpoena, filed October 7, 2003, at 4, attached as Exhibit D.) Although that request for costing and other financial information now has been excised from the subpoena under consideration, the fact that it was ever included at all, despite the absence of even a pretense of a relationship to causation, reveals that the desire for discovery in this forum may be motivated not by "necessity" for purposes of the causation determination, but by the desire of Petitioners'/Plaintiffs' counsel to get a jump on manufacturer discovery for use in subsequent civil litigation.

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

To determine if an additional piece of information is necessary, logic dictates that consideration be given to what is already available. Petitioners and the Special Master have access to information provided by Respondent through the discovery process. 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 unfairly disadvantaged in defending its interests in this motion. Similarly, Merck needs to know in more detail how the discovery process has unfolded in order to assess and address Petitioners' complaints regarding delays in discovery. By separate Motion, Merck asks for more information on these subjects. 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.

Merck has reason to believe that this information would be relevant to the question of the necessity of the materials sought from Merck. At the inception of this Omnibus Proceeding, Petitioners issued document requests to Respondent that were extremely broad in nature. Among the fifteen categories of documents that Petitioners requested were "all documents that . . . relate to DPT, DtaP, HIB, Hepatitis B, and MMR vaccines, as well as Rhogam (a thimerosal containing product) and other thimerosal-containing products, as they relate to the development of autism spectrum disorder, PDD, gastrointestinal and neurological problems." (Document Request 2, Petitioners' Interrogatories and Requests for Production of Documents, filed August 2, 2002, at 18, attached as Exhibit A.) Petitioners also sought access to data from VAERS, the Vaccine

Safety Datalink, MEDWATCH, and the National Health Interview Surveys. (Requests No. 4-7.) In his November 7, 2003 Autism Update and Order (attached as Exhibit B), the Special Master noted that "the respondent has now essentially finished compliance with all of the petitioners' initial set of Requests for Production" (except for the PLAs and unpublished study data).

Petitioners also apparently have access to something called the Thimerosal Screening Analysis. (November 7, 2003 Autism Update and Order at 2.) In addition, Merck knows that Petitioners have requested a deposition of a CDC representative and are seeking to obtain documents from the CDC concerning the so-called "Stehr-Green study." (Id. at 2-3.) In other words, Petitioners have received and reviewed (and continue to receive and review) great quantities of documents ("many thousands of pages" according to the September 24, 2003 Autism Update and Order, attached as Exhibit C), all of them presumably relating to causation.

Thus, it is obvious that substantial information has been made available to Petitioners and the Special Master. Given the very limited circumstances under which Congress made non-party discovery available in the Vaccine Court, and the ignorance under which non-party Merck is operating with respect to what discovery Petitioners already have received, it would be grossly unfair to ask Merck to address Petitioners' motion without giving Merck access to information that will allow it to argue why the ***additional*** information Petitioners seek is not necessary.

2. The discovery Petitioners seek is not necessary even without regard for the other information available to the Special Master.

Although Merck is entitled to buttress its case by reference to discovery already made available to the Petitioners and the Special Master, Petitioners' showing of necessity is deficient even without regard for that material.

The documents that Petitioners ask the Special Master to deem necessary can be described as falling into one of two categories: 1) PLA documents, for which Petitioners have at least attempted to articulate a need; and 2) other documents, for which Petitioners have not made such an attempt. Merck addresses these two categories in turn.

(a) PLA documents.

Petitioners seek to subpoena from Merck the identical PLA documents that the FDA has been in the process of making available to them for the past eleven months. (Subpoena at A ("This request is intended to encompass all documents responsive to petitioners' earlier discovery request to the FDA . . .")). This is the only category of documents for which Petitioners attempt to show a need. With respect to them, Petitioners complain that getting the PLA documents from the FDA is a slow and cumbersome process and they attribute that sluggishness to Respondent's need to redact trade secret information from the PLA documents prior to producing them. Petitioners say nothing more about their "need" to obtain the PLA documents from Merck. Petitioners' theory has multiple flaws.

First, Petitioners ignore the fundamental principle -- more applicable in this Vaccine Court setting even than it is in the regular civil courts -- that non-party discovery is not necessary when the requesting party has an available alternative for obtaining the desired documents that it has not exhausted, but merely wants to avoid.

See, e.g., Haworth, Inc. v. Hermana Miller, Inc., 998 F.2d 975, 978 (Fed. Cir. 1993) (holding that the district court properly denied a motion to compel non-party production of documents where the requesting party had not sought discovery from a party before burdening the non-party); Carl Zeiss Stiftung v. V.E.B. Carl Zeiss, Jena, 40 F.R.D. 318, 328 (D. D.C. 1966) (refusing to order non-party production where the documents were available from other sources). See also Anker v. G.D. Searle & Co., 126 F.R.D. 515, 522 (M.D.N.C. 1989) (party must show more than "general relevancy" in order to compel discovery from a non-party); Westinghouse Electric Corporation v. Carolina Power and Light Co., No. 91-4288, 1992 WL 370097, at *3 (E.D. La. Nov. 30, 1992) (same). Here, Petitioners' ability to obtain the PLA documents from Respondent shows that the subpoena is not necessary.

Second, that the current process is slow and ungainly does not make discovery from non-party manufacturers -- who, again, are the very entities whom Congress sought to protect when it enacted the Vaccine Act -- necessary, and Petitioners can cite no authority to the contrary.

Finally, Petitioners' complaints about delay from trade secret redaction fail to account for the likely utter irrelevance of the information being redacted. Petitioners have not explained what information they need from the PLAs that is even relevant -- let alone "necessary" -- to the causation issue in this proceeding; whatever it may be, it surely is not in the PLA documents that contain trade secrets, require redaction and, therefore, cause the "delays" of which Petitioners complain. In contrast, the clinical data in the PLAs relating to safety of the vaccines in humans typically require little redaction. Thus, Petitioners could propose that Respondent first make available to them the clinical documents in the relevant PLAs, which would substantially minimize the

"slow and cumbersome" features of which they complain. In fact, Merck understands that Respondent is beginning to do this with Recombivax, the PLA at issue in this subpoena, and shortly will begin producing to Petitioners those portions of the Recombivax PLA as to which there is no redaction dispute, rather than awaiting completion of the redaction process for the entire PLA.

Alternatively, Petitioners could simply agree to allow Respondent to produce the documents with the redactions that Merck has presented to the FDA. In the extremely unlikely event that a piece of information relevant to the proceedings appears to have been redacted, Merck, Petitioners and Respondent could examine the material in question and work toward a solution. Moreover, in any production that Merck would make pursuant to a subpoena, Merck would redact its trade secrets and other confidential information anyway. (See Part IV, infra.) As far as speed and access to information are concerned, therefore, the alternative of allowing Respondent to produce the documents with Merck's proposed redactions would put Petitioners in essentially the same position they would be in if they obtained the PLA documents directly from Merck.[4]

(b) Other documents.

In addition to the PLA documents, Petitioners seek (1) documents relating to Merck's communications with various government agencies (Subpoena at C) and (2) what Petitioners call "product safety research" documents. (Id. at B).

Petitioners do not even attempt to articulate why this discovery is "necessary." Instead, they just state that "[i]t is also likely that the vaccine manufacturers have information about the health and safety attributes of their products, that the

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[4] Merck has already provided the FDA with its redactions for the Recombivax PLA at issue in the requested subpoena. Those two alternatives -- production of undisputed pages (which is likely to

respondent does not have." (Motion at 3.) As shown above, Petitioners must show much more than the potential for relevance. Here, they have made no attempt to provide a basis upon which the Special Master could find that these documents are necessary to him.

Even if Petitioners had tried to carry their burden, they would not be able to do so. 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.

With respect to "product safety research" documents (Subpoena at B), Petitioners fail to even attempt a showing of necessity. Again, it is difficult to imagine how they could make such a showing, since ***all*** relevant information accessible by the Special Master for purposes of his determination is part of the necessity calculus. A great deal of data in the public record addresses the causation issue. For instance, the following epidemiological data is readily available:

- Hviid, A., et al., Association Between Thimerosal-Containing Vaccine and Autism. *JAMA* (2003); 290; 13: 1763-1766.

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exclude only irrelevant information) and production with Merck's supplied redactions -- therefore are readily available and, in fact, the first alternative may already be under way .

- Madsen, K., et al., Thimerosal and the Occurrence of Autism: Negative Ecological Evidence From Danish Population-Based Data. *Pediatrics* (2003); 112; 3: 604-606;

- Stehr-Green, P., et al., Autism and Thimerosal-Containing Vaccines. *Am J. Prev. Med.* (2003); 25(2): 101 - 106.

- Verstraeten, T., et al., Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized Health Maintenance Organization Databases. *Pediatrics* (2003); 112; 5: 1039 - 1048.

- Fombonne, E., The Prevalence of Autism. *JAMA* (2003); 289; 1: 87-89.

- Yeargin-Allsopp, M., et al., Prevalence of Autism in a U.S. Metropolitan Area. *JAMA* (2003); 289; 1: 49 - 55.

Similarly, the following toxicological reports are publicly available:

- Clarkson, T., et al., The Toxicology of Mercury -- Current Exposures and Clinical Manifestations. *New England Journal of Medicine* (2003); 349; 18: 1731 - 1737.

- Magos, L., Reviewing on the Toxicity of Ethylmercury, Including its Presence as a Preservative in Biological and Pharmaceutical Products. *Journal of Applied Toxicology* (2001); 21: 1-5.

- Magos, L., The comparative toxicology of ethyl- and methylmercury. *Arch Toxicol* (1985); 57: 260-267.

- Pichichero, M., et al. Mercury concentrations and metabolism in infants receiving vaccines containing thimerosal: a descriptive study. *The Lancet* (2002); 360: 1737-1741.

- Myers, G., et al., Secondary Analysis from the Seychelles Child Development Study: The Child Behavior Checklist. *Environmental Research* (2000); 84; 12 - 19.

Petitioners have not even alluded to any of this information, which is only a portion of the scientific data that is in the public record. To satisfy their burden, Petitioners would have to explain why the Special Master might conclude 1) that the literature cited above (in addition to materials produced to date) are insufficient to make the non-binding, non-adversarial determination contemplated by the Vaccine Act; 2) that

an indispensable and specific piece of the causation puzzle necessary for that determination is missing from this data; 3) that further discovery for that carefully identified missing puzzle piece is "necessary;" and 4) that the puzzle piece is so indispensable that to ask Merck – a company that employs over 50,000 people and has made many vaccines over many years – to search its files for that missing piece would not violate Congress' intent to protect the vaccine supply by sparing vaccine manufacturers the burdens of litigation. In short, Petitioners must do much more than make the casual and general observation that it is "likely that the vaccine manufacturers have information about the health and safety attributes of their products." Their failure to do so here is fatal to their motion.

III. It is Unreasonable To Single Out Merck For Discovery.

Petitioners have not proffered any rational basis upon which the Special Master could conclude that he "needs" the requested categories of documents from Merck, but not from the other vaccine manufacturers whose products are at issue in this proceeding. Nonetheless, Petitioners have singled out Merck and have moved for an order authorizing issuance of a subpoena directed only to Merck. In the absence of any reasonable basis for imposing only on Merck the expense and burden of complying with a subpoena, the Special Master would be acting arbitrarily and without a reasoned basis in granting Petitioners' Motion. See, e.g., Rupert v. Secretary of the Dep't of Health & Human Servs., 55 Fed. Cl. 293, 299 (Fed. Cir. 2003) (stating that the special master's failure to articulate a reasonable basis for the master's decision rendered the decision arbitrary and capricious).[5]

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[5] Moreover, while Petitioners claim that "the discovery delays created by interposing respondent and its client agencies as an intermediary between the vaccine manufacturers and the petitioners"

IV. Merck Has A Right to Redact Trade Secret Information From Its Documents.

Petitioners argue that the current process by which PLA documents are produced to them by the FDA is "slow, cumbersome and costly." (Motion at 3).[6] Therefore, Petitioners seek both (1) to eliminate the middle-man, as it were, by by-passing Respondent and obtaining the PLA documents directly from Merck, and (2) to force Merck to turn over the documents without redacting its trade secrets, and with only a confidentiality order in place to protect it. As set forth above, Merck objects to producing the documents at all, and believes that the availability of the PLA documents from a party, even following a "cumbersome" process, makes issuance of a subpoena not necessary. Even more importantly, however, Merck maintains that it should not be forced to divulge its trade secrets, even with a protective order in place, and that if it has to produce the PLA documents, it is entitled to redact trade secret information from the documents prior to doing so.

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

As noted earlier, the vast majority (if not all) of the trade secret information contained in the PLAs is irrelevant to Petitioners. Under no authority or circumstance (even outside the Vaccine Court setting) is a party entitled to production of irrelevant 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").

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are the reason that they seek discovery from Merck (Motion at 4), they are further delaying the discovery process by taking this seriatim approach to the issuance of subpoenas.

[6] Contrary to Petitioners' assertions, the FDA and Merck have not conducted "collateral litigation over the legitimacy of the non-disclosure designations." (Motion at 4.) Merck and the FDA have

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.

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. Now, Petitioners want Merck to put those assets at risk and divulge its trade secrets without a showing that they are in any way "necessary" to this proceeding. Notably, the trade secrets that might be in jeopardy here belong to vaccine manufacturers, whom Congress, for reasons of public health, has expressed a desire to protect, and seen a need to provide with incentives to remain in the market.

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 – 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?

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collaborated in identifying those portions of the PLAs that require redaction and, to this point, have resolved any disagreements regarding the redactions.

Petitioners do not dispute that all of the information that Merck seeks to redact from the PLA documents is protected trade secret information. Neither do Petitioners dispute that the trade secret information in the PLAs is irrelevant to determining causation. Since Petitioners have not even attempted to argue that the Special Master has some need for the trade secret information, the only benefit to production of the PLA documents in unredacted form is a hastening of the discovery process.[7] Petitioners argue that their interest in hurrying up the discovery process trumps Merck's interest in protecting its trade secrets. Petitioners are wrong. Because the trade secret information that Merck seeks to redact is irrelevant to the issues here, a balancing test requires that the information be redacted prior to production.

In Westinghouse, 1992 WL 370097 at *3, 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

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[7] If Petitioners want to argue that a redaction is in some way relevant, they can, for example, submit an expert affidavit explaining why that is the case.

because potential for harm caused by disclosure of trade secret information outweighed the relevancy of the information and requesting party's need for it).

Forcing a non-party manufacturer to reveal valuable trade secrets that are irrelevant to the issue in dispute may be expedient, but it is an incorrect application of the relevant balancing test and wrong as a matter of law.

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 by law 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 the manufacturers 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.[8] 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." Id. 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").[9]

V. The Special Master Lacks Authority To Issue A Subpoena.

Only the Court of Federal Claims, and not the Special Master, has authority to issue a subpoena in a Vaccine Court proceeding. Vaccine Rule 7(c) states that "[w]hen necessary, the special master shall authorize issuance of a subpoena" and that "in so doing, the procedures of RCFC 45 shall apply." Rule of Court of Federal Claims 45, in turn, provides that the clerk of the court may issue a subpoena and that "[an] attorney as officer of the court, authorized to sign filings under RCFC 83.1, may also issue and sign a subpoena on behalf of the Court of Federal Claims." RCFC 45((a)(3). Petitioners do not point to any authority that allows the Special Master either to issue a subpoena himself, or to authorize counsel for a Vaccine Court petitioner to issue a subpoena. Thus, Merck understands that if the Special Master were to conclude that the requested subpoena is reasonable and necessary, he then would approve a

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[8] 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.

[9] 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.

subpoena that the Court of Federal Claims would issue. To the extent that Petitioners intend for a different procedure to apply, they should so state.

CONCLUSION

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

Date: November 14, 2003

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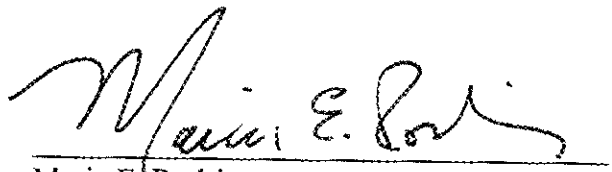
CERTIFICATE OF SERVICE

I hereby certify that on November 14, 2003, I served the foregoing **MOTION FOR LEAVE TO PROCEED AS AN INTERESTED PARTY; NON-PARTY MERCK & CO.'S RESPONSE TO PETITIONER'S MOTION TO ISSUE REVISED THIRD PARTY SUBPOENA,** plus **EXHIBITS;** and **NON-PARTY MERCK & CO.'S MOTION FOR INFORMATION RE DISCOVERY TO DATE** on the following individuals:

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

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

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



Maria E. Rodriguez
VENABLE LLP
Attorneys to Non-Party Merck & Co.

EXHIBIT A

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF THE SPECIAL MASTERS

IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER, OR A SIMILAR NEURODEVELOPMENTAL DISORDER, Petitioner, v. **SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,** Respondent.	No. Special Master Hastings

INTERROGATORIES AND REQUESTS FOR PRODUCTION OF DOCUMENTS

Petitioners, by counsel, propound the following Interrogatories to the Respondent. These discovery requests shall be deemed continuing in nature so as to require supplementation if further information becomes available that would be responsive to any of the discovery requests.

DEFINITIONS/INSTRUCTIONS

A. "Person" shall mean the plural as well as the singular and shall include any nature of person, corporation, partnership, joint venture, association, government agency, and every other form of entity cognizable at law.

B. "Identity" and "identify" when used in reference to an individual person means to state the full name, relationship to you, present or last known home and business addresses, home and business telephone numbers, and the present or last known position and business affiliation of such person. "Identify" when used in reference to documents, studies and other such items means to state the complete details surrounding such matters, including, but not limited to, the identity of anyone having custody of such materials, the authors, investigators, publication references, and other information designed to provide details about the nature of all such studies, documents or other matters referred to.

C. Unless otherwise indicated, these Interrogatories refer to the time, place, and circumstances of the design, manufacture and distribution of any MMR vaccines and any vaccines containing thimerosal, aluminum or any other heavy metals.

D. "You" and "your" means the defendant, her agents, employees, representatives, experts, investigators, attorneys, or anyone acting on behalf of the defendant.

E. The phrase "state the facts" with respect to a specified matter shall mean to state each and every fact, incident, event, condition, or circumstance pertinent to the matter.

F. All Interrogatories should be answered on the basis of the Respondent's knowledge or information and belief, including that learned through hearsay, and including the persons mentioned above in paragraph D.

G. If you cannot answer an Interrogatory after conducting a reasonable investigation, you should so state and answer to the extent that you can, stating what information that you do have, what information you cannot provide, and what efforts you have made to obtain the unknown requested information.

H. "Documents" is meant in the broadest sense. It is intended to include the original and/or any copy regardless of its origin or location, or any contract, agreement, invoice, book, pamphlet, periodical, letter, memorandum, telegram, report, record, study, handwritten note, map, drawing, working paper, chart, paper, graph, index, tape, data sheet, data processing card, e-mail, electronically stored information such as on computer disk or hard drive, file server, or other computer backup storage system, or any other written, recorded, computer generated, transcribed, punched, taped, filmed, photographic or graphic matter, however produced or reproduced to which defendant has had access. The term "document" also includes all tangible things, including products, devices, samples or models. It shall also mean any written, recorded or graphic matter however produced or reproduced and whether or not claimed to be privileged against discovery on any grounds, including, but not limited to, statements, reports, records, lists, memoranda, telegrams, correspondence, schedules, photographs, videotapes, sound recordings, microfilm, microfiche, files, and information stored in computers or other data or word processing equipment.

Interrogatories

1. Identify each and every person who has provided information used in answering these interrogatories and providing the documents requested, specifying what information that person provided.

ANSWER:

2. Please identify all studies, reports and other documents of which the Respondent is aware which report or discuss a possible relationship between vaccinations, thimerosal, ethyl mercury, methyl mercury, aluminum, and/or MMR vaccination and the development of neurodevelopmental disorders, autistic spectrum disorders, gastrointestinal disorders, or neurological injuries of any kind.

ANSWER:

3. Please identify all studies or investigations that have been or are in the process of being performed which the Respondent is aware of and which are directed toward looking at any possible relationship between vaccinations, thimerosal, ethyl mercury, methyl mercury, aluminum, MMR vaccination and the development of neurodevelopmental disorders, autistic spectrum disorders, gastrointestinal disorders, or neurological injuries of any kind.

ANSWER:

4. Please provide information concerning any animal studies of which Respondent is aware which have addressed any of the issues referred to above or which are being planned to address any such issues. Also, specifically describe in full and complete detail any animal models Respondent is aware of, which may be models for mercury toxicity, aluminum toxicity, or vaccine induced autism, vaccine induced gastrointestinal disorders, or vaccine induced neurological injury.

ANSWER:

5. Please identify any and all studies of which the Respondent is aware which have been or are being conducted by any HMO, military, manufacturers of vaccines, associations or other organizations outside of the government that are designed to look at any of the issues referred to above.

ANSWER:

6. Please identify any and all studies concerning the safety and efficacy of MMR vaccines or any other vaccinations containing mercury, mercury-containing compounds, or aluminum that have been relied upon in the licensing and evaluation process by federal agencies.

ANSWER:

7. Please provide any and all information concerning any analyses that have looked at the composition of the vaccines referred to above. Included in this request would be any tests or studies that have looked at the actual materials which are contained in the vaccines, including not only the various antigens, but also things like thimerosal, formalin, or any other antigens, preservatives, contaminants, or chemicals, as well as any tests or analyses that have looked at the synergistic effects of such contents of vaccines.

ANSWER:

8. Please provide any and all protocols for manufacturing and testing any of the above referenced vaccines (either by the manufacturers or the Respondent) and any documents that might exist concerning changes that have been made and/or are contemplated.

ANSWER:

9. Please provide the numbers of doses of each of the MMR vaccinations and thimerosal-containing vaccinations distributed annually from 1990 through 2001, broken down by adult doses versus children's doses. What percentage of doses distributed each year are for adults and what percentage are for children?

ANSWER:

10. Please provide the numbers of doses of each of the above referenced vaccinations distributed annually from 1990 through 2001, designating the specific lot numbers and the numbers of doses manufactured and distributed in each such lot.

ANSWER:

11. Please give the names, positions, addresses and phone numbers of any government employees, including their department and institute information, who have knowledge or are working on the issues referred to in the above referenced interrogatories.

ANSWER:

12. What are the requirements necessary for a lot of vaccine to be defined as a "hot lot?"

ANSWER:

13. The Food and Drug Administration continually looks for lots that have received more serious reports that should be expected on the basis of such factors as size, time in use, and chance variation. When such a lot is detected, further investigations are initiated that could lead to recall of the lot under some circumstances. What is the number of serious adverse reports necessary for the FDA to consider that a lot has received more adverse reactions than would be expected based upon chance variation and what are the circumstances that could lead to the FDA's recall of a vaccine?

ANSWER:

14. Why was hepatitis B vaccine (containing thimerosal) to be given to newborns withdrawn? Please identify and produce all documents related to this decision.

ANSWER:

15. Supply any information that the government or manufacturers have concerning the presence of unintended viral contaminants in the MMR vaccines and any thimerosal containing vaccines. This should include the presence of whole viruses and viral sequences including but not limited to diarrhea virus, bacteriophages, chicken viruses, monkey viruses, human viruses or other viruses.

ANSWER:

16. Please supply any information the government or the manufacturers have on the levels of endotoxins or other toxins in any of the above referenced vaccines.

ANSWER:

17. Has the government ever recalled any lots of MMR vaccine or any thimerosal containing vaccine, and has any manufacturer ever voluntarily recalled any lot of these vaccines. Please supply any information and documents concerning such incidents.

ANSWER:

18. Has any government agency ever criticized or demanded changes in the package inserts of any manufacturer of MMR vaccine or thimerosal containing vaccines? If so please document these incidents.

ANSWER:

19. Has any government agency ever criticized the manufacturing processes regarding MMR vaccines or any thimerosal containing vaccines? If so please document all such incidences.

ANSWER:

20. Has the government ever found a manufacturer in violation of the regulations in regard to the manufacture, testing, packaging, advertising practices, storage or distribution of any MMR vaccines or any thimerosal containing vaccines? If so pleases document all such incidences.

ANSWER:

21. Does the government have any knowledge of the levels of P2 protein, myelin basic protein (MBP) or other potentially dangerous proteins or other potentially dangerous substances in MMR vaccines or any thimerosal containing vaccines? If so please supply all documents related to the levels and effects of such contamination.

ANSWER:

22. Does the government have any knowledge of any other contaminants that are or were contained in MMR vaccines or any thimerosal containing vaccines? If so please document these fully.

ANSWER:

23. Has any government agency or employee ever made recommendations concerning improving MMR vaccines or any thimerosal containing vaccines? If so please document fully.

ANSWER:

24. Has any government laboratory or any government funded laboratory or any other laboratory that the government knows about done any studies indicating any kind of problem with MMR vaccines or any thimerosal containing vaccines? If so please document these fully.

ANSWER:

25. Supply any information the government or the manufacturers have on adjuvants and preservatives used in MMR vaccines or any thimerosal-containing vaccines and supply any studies or other information they may have on the safety of the substances.

ANSWER:

26. In the case of *Sharkey v. HHS*, No. 99-699V, the Chief Special Master requested a report on planned and ongoing studies examining the safety of Hepatitis B vaccines. In response to that request, the Respondent filed Exhibit A, which is a report by Dr. Vito Caserta. Please update that report (since Hepatitis B vaccine contained thimerosal), and also please provide the same information for MMR vaccines and any thimerosal containing vaccines. Specifically, Exhibit A referenced the following studies, but this question is not limited to those studies. This question includes all studies, including the following:

A. "Another VAERS study is in press and will be published in the Journal of Clinical Epidemiology in the next few months. This study has developed and applied standardized case definitions for acute encephalopathy, encephalitis, and multiple sclerosis (MS). Although this study will not address causation, it is relevant to Hepatitis B vaccine because many claims allege MS.

B. A review was recently initiated in VAERS describing a case series of Hepatitis B vaccine recipients with reported allergy to yeast or latex. This review is a low priority in VAERS and it is not known if it will be completed.

C. A VAERS study is in the early planning stages to look at a comparison of disability after

Hepatitis B vaccine compared to other vaccines. It has not been decided whether this study should begin.

D. A VSD infant mortality study manuscript has been written and it is currently undergoing early revisions. This study will probably be published within the next 3 years.

E. The manuscript for a neonatal mortality study is currently being written. This study will probably be published within the next 4 years.

F. The VSD report on the thimerosal screening analysis has been written and is currently undergoing clearance. It will probably be published in the next 2 years.

G. A descriptive manuscript on anaphylaxis has been written and is undergoing early revisions. It will probably be published in the next 3 years.

H. The data collection is complete and the analysis is currently underway for an encephalopathy study.

I. The data collection is complete and the analysis is currently underway for a study on gender based differences in adverse events.

J. NIH, DoD, and USAID are not currently sponsoring any ongoing Hepatitis B vaccine safety research.

K. In Europe, the Cochrane Collaboration has prepared a protocol for a project that is partially funded by the World Health Organization (WHO). The Collaboration is searching for additional funding to complete the project. This project will perform systematic review of the evidence relating to the safety of Hepatitis B vaccine. The final report will include a review of all the available comparative studies on the vaccine and the hypothesized adverse events. The studies will be examined against a set of inclusion criteria, data will be extracted in a standardized way, and the quality of the different study designs will be assessed. The final product will be a competed database containing validated data extracted from the identified studies. The timeline for this study is very uncertain because of incomplete funding.

L. The NIH, the University of Rochester and the National Naval Medical Center are studying the levels of mercury in serum, hair and possibly other tissues after vaccination. This is a clinical study where infants are tested within a few weeks after routine immunizations. Data analysis is currently underway and follow-up studies are planned. Time to publication is unknown.

M. Another study from Sweden performed a randomized trial of pertussis vaccines, with and without thimerosal, given in the first year of life. Approximately 179 trial participants

were given an IQ and other cognitive tests at 5.5 years of age. The results should be available soon.

N. Another thimerosal study involves the WHO and the Public Health Laboratory Service in England. This is a cohort study of infants who received up to 150 mcg of Hg by 6 months of age. The study analyzed the UK General Practitioner Research Database between 1988 and 1996 (178,000 births). The results should be available soon.

O. Another NIH pilot study looking at infant macaques will evaluate whether the distribution of thimerosal and methyl mercury is the same. A parallel rodent study may also be done."

With regard to each study referenced above and with regard to any other studies identified, please provide any related documents.

With regard to each study referenced above and with regard to any other studies that are identified, please provide the following:

a. The name, address and phone number of the principal investigator(s);
b. The source of funding for each study, including any additional funding that is being contemplated for current or future studies;
c. The expected date of completion of the data gathering phase of the study;
d. The expected date of the completion of the analysis phase of the study;
e. The expected date of publication of any results from the study;
f. The custodian of the study data;
g. The stated purpose of the study;
h. The methodology of the study, including the level of sensitivity anticipated, using standard epidemiological principles; and
i. Who made the decisions to conduct the study and who decided upon the methodology?

ANSWER:

27. On October 1, 2001, the IOM report on *Thimerosal Containing Vaccines and Neurodevelopmental Disorders* (hereinafter "IOM Thimerosal Report") was published. In that report, reference is made on page 43 to evidence derived from the VAERS data. With regard to Table 4 on page 44, please specify for each case report exactly who "attributed" the adverse event to thimerosal.

ANSWER:

28. On page 45 of the IOM Thimerosal Report, the committee concludes that there are problems with the VAERS data. Problems include underreporting, lack of detail, inconsistent diagnostic criteria, and inadequate denominator data. Please provide information concerning any reports, communications, studies or other data that have addressed any or all of these problems. Also, please provide any evidence that these problems do or do not apply equally to all vaccines.

ANSWER:

29. Beginning on page 45 of the IOM Thimerosal Report, the committee discusses the VSD study (Verstraeton 2001). With regard to that study, please provide the following information:

a. The name, address and phone number of the principal investigator(s);
b. The source of funding for each study, including any additional funding that is being contemplated for current or future studies;
c. The expected date of completion of the data gathering phase of the study;
d. The expected date of the completion of the analysis phase of the study;
e. The expected date of publication of any results from the study;
f. The custodian of the study data;
g. The stated purpose of the study;
h. The methodology of the study, including the level of sensitivity anticipated, using standard epidemiological principles; and
i. Who made the decisions to conduct the study and who decided upon the methodology?

Also, please provide all information concerning the Simpsonwood panel, including but not limited to the following:

j. Names, affiliations, and contact information for all members;
k. The custodian of all minutes, correspondence and other documents generated by or as a result of the proceedings of that panel, before, during and after the meeting in June of 2000; and
l. Describe in full and complete detail the proceedings of that panel, or, in lieu thereof, produce all documents, such as minutes, memorandum, read-aheads, correspondence, emails, and other documents of any kind.

ANSWER:

30. The IOM issued a report in 2001 on Thimerosal-Containing Vaccines and Neurodevelopmental Disorders. In that report, the IOM made specific recommendations. What has the government done with regard to any of the following recommendations?

a. The use of the Thimerosal-free DTaP, Hib, hepatitis B vaccines in the United States, despite the fact that there might be remaining supplies of thimerosal-containing vaccine available. Did the government use the suggested mechanisms to accomplish this goal? Why or why not?
   i. "Dear Doctor" letters
   ii. Existing supplies bought back from providers by vaccine makers or the CDC.

b. Full consideration be given by appropriate professional societies and government agencies to removing thimerosal from vaccines administered to infants, children, or pregnant women in the United States.

c. Appropriate professional societies and governmental agencies review their policies about the non-vaccine biological and pharmaceutical products that contain thimerosal and are used by infants, children and pregnant women in the United States.

d. A review and assessment of how public health policy decisions are made under uncertainty in order to develop suggestions to improve the decision making process about vaccines in the future.

e. A review of the strategies used to communicate rapid changes in vaccine policy and research on how to improve those strategies.

f. A diverse public health and biomedical research portfolio that involves several different agencies.

g. Case-control studies examining the potential link between neurodevelopmental disorders and thimerosal-containing vaccines.

h. Further analysis of neurodevelopmental outcomes in the cohorts of children outside the United States who did not receive thimerosal-containing doses as part of a clinical trial of DTaP vaccine.

i. Conducting epidemiological studies that compare the incidence and prevalence of neurodevelopmental disorders before and after the removal of thimerosal from vaccines.

j. Increased efforts to identify the primary sources and levels of prenatal and postnatal background exposure to thimerosal (e.g., Rho (D) Immune Globulin) and other forms

of mercury (e.g., maternal consumption of fish) in infants, children, and pregnant women to identify populations at higher risk for mercury toxicity.

k. Incorporation of Phase III of the VSD studies as part of an overall package of research and geared to accurately identify neurodevelopmental conditions of concern.

l. Research on how children, including those diagnosed with neurodevelopmental disorders, metabolize and excrete metals—particularly mercury.

m. Continued research on theoretical modeling of ethylmercury exposures, including the incremental burden of thimerosal with background mercury exposure from other sources.

n. Careful, rigorous and scientific investigations of chelation when used in children with neurodevelopmental disorders, especially autism.

o. Research to identify a safe, effective and inexpensive alternative to thimerosal for countries that decide they need to switch.

p. Research in appropriate animal modes on neurodevelopmental effects of ethylmercury.

In answering this question please provide full and complete information, including the names of the people responsible for deciding what studies to perform and what not to perform and how to conduct such studies.

ANSWER:

31. The IOM issued a report in 2001 on Measles-Mumps-Rubella Vaccine and Autism. In that report, the IOM made specific recommendations. What has the government done with

regard to any of the following recommendations?

A. Currently, a number of research studies are in progress regarding the etiology, brain structure and/or function, developmental course, and epidemiology of ASD ("autistic spectrum disorders"). In order to evaluate and compare these current and future studies the IOM recommended use of accepted and consistent case definitions and assessment protocols for ASD in order to enhance the precision and comparability of results from surveillance, epidemiological, and biologic investigations.

B. Explore whether exposure to MMR vaccine is a risk factor for ASD in a small number of children. Identify a marker for identifying children at risk for the "regressive" form of ASD.

C. Develop targeted investigations of whether or not measles vaccine-strain virus is present in the intestines of some children with ASD.
   - In conjunction with the CDC's National Immunization Program, the CPEA is beginning an autism regression and vaccination study that will assess the temporal association between MMR vaccination and autism, distinguishing between the early-onset and regressive forms.

D. Encourage all who submit reports to VAERS of any diagnosis of ASD thought to be related to MMR vaccine to provide as much detail and as much documentation as possible.
   - The committee encourages the government agencies responsible for VAERS (CDC and FDA), as well as immunization providers (physicians and nurses) and parents to use VAERS reporting system conscientiously and thoroughly.
   - In particular, case reports in VAERS or elsewhere of "rechallenge" should be identified, documented, and followed up.

E. Study the possible effects of different MMR immunization exposures.
   - It is naïve to ignore the fact that some parents are selecting alternative approaches to vaccination. Children who are immunized in an alternative manner, such as different vaccine types or at different ages, should be studied, although the number of children enrolled in these studies and issues of selection bias would affect the design and interpretation of the results.

F. Conduct further clinical and epidemiological studies of sufficient rigor to identify risk factors and biological markers of ASD in order to better understand genetic or environmental causes.
   - There is a need to support and continue the NIH- and CDC-funded research already under way on all aspects of ASD.
   - Epidemiological studies are needed to document the prevalence and incidence of

ASD, temporal trends, and the incidence and prevalence of different courses of ASD (e.g., regressive vs. early onset).

In answering this question please provide full and complete information, including the names of the people responsible for deciding what studies to perform and what not to perform and how to conduct such studies.

ANSWER:

32. The ATSDR study published in March of 1999 appears to represent a culmination of 7 years of research, yet it fails to even mention thimerosal more than twice in passing and failed to mention any of the medical literature discussing the mercury toxicity of thimerosal. With regard to that study, please provide the following:

a. The name, address and phone number of the principal investigator(s)
b. The source of funding for each study, including any additional funding that is being contemplated for current or future studies
m. The expected date of completion of the data gathering phase of the study
n. The expected date of the completion of the analysis phase of the study
o. The expected date of publication of any results from the study
p. The custodian of the study data
q. The stated purpose of the study
r. The methodology of the study, including the level of sensitivity anticipated, using standard epidemiological principles and
s. Who made the decisions to conduct the study and who decided upon the methodology

33. Please describe in full and complete detail any consideration the government has given to removing thimerosal from any other products, other than vaccines. Include in this response, the names of all products, whether they be for human use or veterinarian use (i.e. due to concerns about thimerosal getting into the country's meat supply, etc.), and provide the names and contact information for any individuals who may be involved in such decisions and who may have custody of documents concerning these decisions.

ANSWER:

34. Identify all conferences held or scheduled to be held that relate in any way to MMR, thimerosal or any other preservative in any vaccine, to which the government has been invited or which are being held by any professional agency to which they belong.

ANSWER:

35. Please describe in full and complete detail what work is being done at the FDA or any other agency to lower the safety limit for tuna and other large fish consumption by pregnant women, including, but not limited to the following information:

a. Who is involved;
b. What is the schedule for this work to be done; and
c. What input from the industry is involved.

ANSWER:

36. The NAS Report on methyl mercury stated that 50,000 children per year are already at the high range of organic mercury exposure, what is the government doing to find and study those kids?

ANSWER:

Requests for Production of Documents

Petitioners request that you produce the following documents that are in your possession,

custody or control.

When producing the documents, you should organize and label them where appropriate to correspond with the categories of this request.

If a document is withheld by you on the grounds of attorney-client privilege or attorney work product, identify such document by date, author, recipient, and subject matter (without disclosing its contents) sufficient to allow its description to the Court for the Court's ruling on your objection.

Requests

1. Produce a copy of all documents that are identified in answer to any of the interrogatories above or that are used in preparing answers to these interrogatories.

RESPONSE:

2. Produce a copy of all documents that are relevant in any way to the interrogatories and/or answers to interrogatories above, and more specifically, that relate to DPT, DtaP, HIB, Hepatitis B, and MMR vaccines, as well as Rhogam (a thimerosal containing product) and other thimerosal-containing products, as they relate to the development of autism spectrum disorder, PDD, gastrointestinal and neurological problems.

RESPONSE:

3. Please produce any documents, including emails, internal memorandum and other correspondence which discuss studies, proposed studies, testing, proposed testing, reviews of literature, etc. dealing with MMR vaccines or any thimerosal containing vaccines causing or contributing to autism or PDD.

RESPONSE:

4. Please provide access to the underlying data maintained by the Vaccine Adverse Event Reporting System (VAERS). Petitioners are not requesting copies of any of that data at this point, but would request that their designated experts be given access to the data under restrictions that would protect privacy, solely for the purpose of studying the data and assisting Petitioners in formulating additional discovery requests.

-Please provide all reports of adverse events related to MMR vaccine.

-Please provide all reports of adverse events related to any thimerosal containing vaccine

-Please provide all reports related to any vaccine resulting in Autism, ASD or any neurodevelopmental disorder.

Additionally, Petitioners' experts specifically need access to the following information:

a) We request the net number of doses of each type of vaccine distributed, yearly, from 1990 through 2002.

b) We request the net number of doses of each type of vaccine distributed by each manufacturer, yearly, from 1990 through 2002.

c) We request the net number of doses in each lot of each type of vaccine, yearly, distributed from 1990 through 2002.

d) We request the number of doses of each type of vaccine distributed broken down by pediatric and adults by year, by company and by lot from 1990 through 2002.

e) We request the number of doses of each type of vaccine distributed to each state from 1990 through 2002.

f) We request the number of doses of each type of vaccine distributed by each manufacturer, yearly, from 1990 through 2002 to each state.

g) We request the number of doses in each lot of each type of vaccine, yearly distributed from 1990 through 2002 to each state.

h) We request the number of doses of each type of vaccine distributed broken down by pediatric and adults by year, by company and by lot from 1990 through 2002 for each state.

i) We request all data, documents and publications related to the number of doses of vaccine distributed from 1990 through 2002.

This data is necessary to analyze and contrast the reaction rates for MMR vaccines or any thimerosal containing vaccines as compared with other vaccines, and to identify hot lots.

RESPONSE:

5. Please provide access to the underlying data maintained by the Vaccine Safety Datalink System. Petitioners are not requesting copies of any of that data at this point, but would request that their designated experts be given access to the data under restrictions that would protect privacy, solely for the purpose of studying the data and assisting Petitioners in formulating additional discovery requests. Specifically, Petitioners experts request access to at least the following information:

a) Any documents, reports, abstracts and underlying data relating to the original Thimerosal analyses done by Thomas Verstraeten.

b) For any published government sponsored study related to MMR, thimerosal-containing vaccines, Autism, ASD or any neurodevelopmental disorder please provide the following for each study:

i) All underlying data
ii) Any and all documents related to the study protocol and design
iii) Any documents that relate to the inclusion or exclusion of subjects
iv) Any and all documents related to the analyses of the data

c) We request the net number of doses of each type of vaccine distributed, yearly, in the Vaccine Safety Datalink.

d) We request the net number of doses of each type of vaccine by each manufacturer distributed, yearly, in the Vaccine Safety Datalink.

e) We request the net number of doses of each type of vaccine in each lot distributed, yearly, in the Vaccine Safety Datalink.

f) We request all data, documents and publications related to the number of doses of vaccine distributed in the Vaccine Safety Datalink.

g) We request the number of doses of each type of vaccine distributed in the Vaccine Safety Datalink broken down by pediatric and adults by year, by company and by lot.

RESPONSE:

6. Please provide access to the underlying data maintained by the FDA Medical Products Reporting Program (MEDWATCH). Petitioners are not requesting copies of any of that data at this point, but would request that their designated experts be given access to the data under restrictions that would protect privacy, solely for the purpose of studying the data and assisting Petitioners in formulating additional discover requests. Specifically, Petitioners experts request access to at least the following information:

a) We request the number of doses of each type of medical product distributed, yearly, in the FDA Medical Products Reporting Program (MEDWATCH).

b) We request the number of doses of each type of medical product by manufacturer distributed, yearly, in the FDA Medical Products Reporting Program (MEDWATCH).

c) We request the number of doses of each type of medical product by lot, distributed, yearly, in the FDA Medical Products Reporting Program (MEDWATCH).

d) We request all data, documents and publications related to the number of doses of each type of medical product distributed in the FDA (MEDWATCH).

e) We request the number of doses of each type of medical product distributed in the FDA (MEDWATCH) broken down by pediatric and adults by year, by company and by lot.

RESPONSE:

7. Please provide access to the underlying data maintained by the National Health Interview Surveys (NHIS). Petitioners are not requesting copies of any of that data at this point, but would request that their designated experts be given access to the data under restrictions that would protect privacy, solely for the purpose of studying the data and assisting Petitioners in formulating additional discover requests.

RESPONSE:

8. Please provide access to any documents related to any requests for funding for studies relating to adverse events associated with the MMR vaccines or any thimerosal containing vaccines.

RESPONSE:

9. Please produce copies of any and all transcripts of hearings conducted prior to FDA approval of the measles-mumps-rubella (MMR) vaccine.

RESPONSE:

10. Please produce copies of any and all documents submitted to the FDA for review by vaccine manufacturers prior to the approval of the MMR vaccine.

RESPONSE

11. Please produce copies of any and all transcripts of hearings conducted prior to FDA approval of all thimerosal-containing vaccines

RESPONSE:

12. Please produce copies of any and all documents submitted to the FDA for review by vaccine manufacturers prior to the approval of all thimerosal-containing vaccines.

RESPONSE:

13. Please produce 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

RESPONSE:

14. The ATSDR published a peer review toxicological profile for mercury in March of 1999 that was prepared under government contract # 205-93-0606 by Research Triangle Institute. Please provide a copy of the administrative record relating to that contract, which should also include a copy of the September 1997 draft of the document, the peer reviewers comments that were not incorporated into the profile and the rationale for exclusion, and the data bases and non published literature that were reviewed by the authors of the profile. In addition, please produce copies or access to, the copies of all correspondence between any member of the Research Triangle Institute and ASTDR that relates to the planning, research, drafting or publication of the Toxicological Profile of Mercury. More specifically, please produce copies of any communications between Rob DeWoskin of the RTI and John Risher of the ASTDR that relate to the planning, research, drafting or publication of the profile and copies, or access to, all medical literature that was reviewed by the ATSDR in the preparation of the profile. Also, please provide copies, or access to, all comments received from doctors, medical organization, or pharmaceutical companies, between the time the September 1997 draft was published and the final profile of March 1999 was published. Also, please provide copies, or access to, all correspondence or records reflecting any communication between the ATSDR and the FDA on the subject matter of mercury or the mercury containing preservative, Thimerosal.

RESPONSE:

15. On June 7 – 8, 2000 the CDC sponsored a conference entitled "Scientific Review of Vaccine Safety Datalink Information" at the Simpsonwood Retreat Center in Norcross, Georgia. Please produce any and all related materials, including but not limited to the following:

q. Any Agenda, Handouts, packets distributed at conference, transcript of proceedings, any transparencies, slides or other materials shown with any presentation or by any attendee.

r. Any and all materials on the AICP work group on Thimerosal and immunization.

s. Each and every study, report, conference, meeting discussed or mentioned at that

conference.

t. Any and all materials discussed, mentioned or relating to any thing discussed by Dr. Verstraeten.

RESPONSE:

Respectfully submitted,

Ghada A. Anis, Esquire
Liaison Counsel for
Petitioners' Steering Committee
9711 Meadowlark Road
Vienna, Virginia 22182-1951
Tel: (703) 281-6395
Fax: (703) 281-5807

CERTIFICATE OF SERVICE

I certify that a copy of this pleading (and an electronic version of this pleading) was sent by priority mail this 2 day of August, 2002 to:

Vince Matanoski, Esquire
Trial Attorney, Civil Division
U.S. Department of Justice
P.O. Box 146, Ben Franklin Station
Washington, D.C. 20044

Ghada A. Anis

EXHIBIT B

In the United States Court of Federal Claims

ORIGINAL

OFFICE OF SPECIAL MASTERS

(Filed: November 7, 2003)

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

AUTISM UPDATE AND ORDER- -NOVEMBER 7, 2003

This Update describes a number of recent developments in the Omnibus Autism Proceeding that have occurred since the last Update dated September 24, 2003. I note that counsel for both parties and I have continued to work diligently on the Proceeding during that time period. Unrecorded status conferences were held on September 26, October 3, October 6. October 21, October 28, and November 3, 2003,[1] while counsel were also working extensively with one another throughout this period, in order to keep the Proceeding moving forward.

A. Number of cases

At this time, more than 3350 petitions in autism cases have been filed, and are stayed pending the conclusion of the Omnibus Autism Proceeding. Additional petitions continue to be filed regularly.

B. Discovery

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[1]Counsel participating in those conferences included Michael Williams, Kathleen Dailey, Thomas Powers, and Ghada Anis for petitioners; Vincent Matanoski, Mark Raby, Linda Renzi, Traci Manning, and Ann Donohue for respondent.

As indicated in my previous Autism Updates, a tremendous amount of work has been done by counsel for both parties concerning the petitioners' extensive discovery requests. I will not reiterate developments covered in my previous updates, but I will summarize below our progress and certain new developments in the discovery area.

1. General progress concerning initial Requests for Production

Much material responsive to the petitioners' extensive initial set of Requests for Production was made available to petitioners during the fall of 2002 via various government web sites, and petitioners' counsel have analyzed that data. Thousands of pages of additional material has been supplied to petitioners since December of 2002, and petitioners' counsel have analyzed those documents as well. At this point, the respondent has now essentially finished compliance with all of the petitioners' initial set of Requests for Production, except for the items discussed at points 2 and 3, immediately following.

2. The vaccine license application files

One category of documents requested, pursuant to petitioners' Requests for Production Nos. 10 and 12, involves vaccine license applications. In this area, efforts to produce material have proceeded more slowly, as detailed in my previous Autism Updates. The process of production of that material continues to move forward. Recently, the bulk of the Food and Drug Administration (FDA) file with respect to the Merck measles vaccine was submitted to the Petitioners' Steering Committee (hereinafter "the Committee"). Previously, the bulk of the files for the Merck MMR combined vaccine and the Merck mumps vaccine were submitted to the Committee. Large portions of the files pertaining to the Glaxo/SmithKline Hepatitis B vaccine, the North American Healthcare DtaP vaccine, and the Merck Hepatitis B vaccine will soon be submitted. And the files with respect to many additional vaccines are continuing to move at various stages through the arduous process toward disclosure.

3. Issue of access to study data

As indicated in previous Autism Updates, the parties have been in disagreement concerning the issue of production of materials relating to certain "ongoing and proposed studies." As previously indicated, they had chiefly focused their efforts on the goal of providing the Committee with pre-publication access to the data set of one particular study, known as the "Thimerosal Screening Analysis," but it was recently learned that the results of that study will in fact be published in early November of 2003, earlier than previously anticipated. The parties are currently working to see how they can enable the Committee to access the data promptly after the study is published.

The parties have also recently focused on a second recently-published study, known as the Stehr-Green study. The Committee has submitted a request for production of documents in the files

of the Center for Disease Control and Prevention ("CDC") relating to that study, respondent has filed a response,[2] and the parties are working to resolve the matter.

4. Organizational Depositions

The Committee has also recently filed an additional discovery request,[3] seeking to depose a representative of the CDC. Respondent filed a response to that request on October 27 (again, into the file in *Taylor v. HHS*, No.02-699V). However, after discussion of that request at the status conferences held on October 28 and November 3, respondent sought and received permission to file a supplemental response on November 7, 2003. We will then further discuss the matter at a conference scheduled for November 10, 2003.

The Committee intends to later file a similar request for deposition of an FDA official.

5. Non-party discovery

On October 7, 2003, the Committee filed a request for authorization to issue a subpoena to the vaccine manufacturer, Merck and Company, for certain documents pertaining to that company's vaccination for Hepatitis B known as "Recombivax." That request was discussed at status conferences on October 21 and October 28, 2003, with counsel from Merck participating in a portion of the latter conference. Merck's counsel indicated that Merck opposes the request. On October 29, the Committee filed a revised request for subpoena authorization. On October 30, I filed an Order setting a briefing schedule concerning the request, with Merck and the Committee to file briefs between November 14 and December 15, and oral argument to follow soon thereafter. I will promptly rule on the request once briefing and argument are complete.

C. Issue of the proper date for issuing "§ 12(g)(1) notices"

As discussed in my Update of September 24, a controversy has arisen in the autism cases concerning when the special master should issue the notice pursuant to 42 U.S.C. § 300aa-12(g)(1) (hereinafter the "§ 12(g)(1) notice"), which notice triggers the right of a Vaccine Act petitioner to withdraw his petition pursuant to 42 U.S.C. § 300aa-21(b). On September 3, 2003, I filed, in the individual autism case of *Stewart v. Secretary of HHS*, No. 02-819V, an opinion ruling against the respondent's proposed statutory interpretation concerning this controversy. (That published ruling was put into the Autism Master File by my Order of September 9, 2003, and thus can be accessed

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[2]That response was filed into the file of the individual autism case of *Taylor v. HHS*, No. 02-699V, rather than into the Autism Master file.

[3]With that discovery request, the discovery request noted above for the Stehr-Green study, and the "non-party discovery" to be discussed immediately below, the Omnibus Autism Proceeding has now moved into the "second round" of discovery, discussed in the initial general plan for the Proceeding.

on this court's Internet website, along with all other materials filed in the Autism Master File, at www.uscfc.uscourts.gov/osm/osmautism.htm.) Further, at the status conference held on October 3, 2003, respondent's counsel indicated that respondent will not attempt at this time to obtain interlocutory appellate review of my ruling concerning this issue in the *Stewart* case. Accordingly, I am in the process of filing, in each autism case in which respondent filed a "Motion for Appropriate Relief" identical to respondent's Motion in *Stewart*, a denial of respondent's motion.

Of course, when I file a "§12(g)(1) notice" (also known as a "Formal Notice") in a case, that does *not* end the case, but merely gives the petitioner the *option* of withdrawing the petition if desired. As I have noted in such notices, I stress that the parties to the Omnibus Autism Proceeding and I are working diligently to resolve the general causation issues as quickly as possible. Regular updates on the progress of that proceeding will be available at the Office of Special Masters' page on the court's website. I encourage all of the autism petitioners to remain in the Program until the conclusion of the Omnibus Autism Proceeding, to see if that proceeding develops a theory of proof that might be applicable to this case.

D. Issue of "judgments"

As noted in a previous Autism Update, I and other special masters are considering the overall issue when "judgments" should be entered in Vaccine Act cases. To assist in this review, the parties to the Omnibus Autism Proceeding filed briefs concerning this topic on July 30, 2003, and August 22, 2003, respectively. I then requested the parties' views on additional points with respect to that general issue, and briefs concerning those points were recently filed.

I will soon file an opinion discussing this topic, in an individual autism case. I will place that opinion into the Autism Master File.

E. Issue of timeliness of petition filing

In several autism cases, there are pending motions by respondent seeking dismissal on the ground that the petitions were not timely filed. Such motions may be more complicated in autism cases than in previous Vaccine Act cases, due to the fact that in most of the autism cases it is alleged that the vaccinee was injured by a *series* of vaccinations, rather than a single vaccination. These motions have also been potentially made more complex by a recent ruling in *Setnes v. Secretary of HHS*, 57 Fed. Cl. 175 (2003). In one case in which a dismissal motion is pending, *Wood v. Secretary of HHS*, No. 02-1317V, I have invited the Petitioners' Steering Committee to file a brief, which was recently filed. I intend to rule soon on the dismissal motion in that case, and thereafter turn to the other pending dismissal motions. At the request of the Committee, I will consider placing certain documents from that *Wood* case--certainly including my ruling on the motion--into the Autism Master File.

F. Filing records via compact disc

A committee, including a representative of the Petitioners' Steering Committee, a representative of respondent, and personnel from the Office of the Clerk of this court, is currently developing a procedure by which, in autism cases, voluminous records could be filed with the court via compact disc rather than via a "paper copy." That Committee will soon report to me, and I will then file into the Autism Master File an order permitting the filing of records in autism cases via such method.

G. Attorneys' fees

The Petitioners' Steering Committee has recently forwarded to me a memorandum that outlines the Committee's proposed procedures concerning the eventual application for attorneys' fees and costs with respect to this Omnibus Autism Proceeding. At the status conference on October 28, respondent's counsel noted concerns about the proposed procedures and the notion that fees and costs could be compensated in any proceeding that was not a "proceeding on a petition." Respondent's counsel indicated that these views would be submitted in writing. On October 29, 2003, I filed into Autism Master File a Notice concluding that the memorandum presents an appropriate method for accounting for attorney time and expenditures in the Proceeding.

H. Future proceedings

The next status conference in the Omnibus Autism Proceeding is scheduled for November 10, 2003.

George L. Hastings, Jr.
Special Master

EXHIBIT C

In the United States Court of Federal Claims

ORIGINAL

OFFICE OF SPECIAL MASTERS

(Filed: September 24, 2003)

* *

IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER OR A SIMILAR NEURODEVELOPMENTAL DISORDER

AUTISM MASTER FILE

VARIOUS PETITIONERS,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

* *

AUTISM UPDATE AND ORDER--SEPTEMBER 24, 2003

This Update describes a number of recent developments in the Omnibus Autism Proceeding that have occurred since the last Update dated June 27, 2003. I note that counsel for both parties and I have continued to work diligently on the Proceeding during that time period. Status conferences were held on July 7, July 24, August 12, August 28, September 3, and September 17, 2003,[1] while counsel were also working extensively with one another throughout this period, in order to keep the Proceeding moving forward.

A. Petitioners' Steering Committee

Substantial changes have taken place within the Petitioners' Steering Committee. Jeffrey Thompson has moved to a new law firm, and is no longer a lead participant in the autism cases. I thank him for his outstanding service, which greatly advanced the Omnibus Autism Proceeding. The

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[1] Counsel participating in those conferences included Jeffrey Thompson, Ghada Anis, Michael Williams, Kathleen Dailey, Thomas Powers, and Thao Ho for petitioners; Vincent Matanoski, Mark Raby, Gregory Fortsch, and Ann Donohue for respondent. In addition, a large number of additional members of the Petitioners' Steering Committee participated in the in-person conference held on August 12, 2003.

new co-chair of the Committee, in place of Mr. Thompson, is Michael Williams of Portland, Oregon. Remaining as the other co-chair is John Kim of Houston. The Committee's "liaison counsel" is still Ghada Anis, who can be reached at the Committee's office as follows:

Petitioners' Steering Committee
733 15th Street, N.W.
Suite 700
Washington, D.C. 20005

Phone: (202) 393-6411
Email: Ghada@AutismPSC.com
Fax: (202) 318-7518

A new complete roster of the Petitioners' Steering Committee is attached at the end of this Update.

B. Discovery

As indicated in my previous Autism Updates, a tremendous amount of work has been done by counsel for both parties concerning the petitioners' extensive discovery requests. I will not reiterate developments covered in my previous updates, but I will summarize below our progress and certain new developments in the discovery area.

1. General progress concerning Requests for Production

Much material responsive to the petitioners' extensive Requests for Production was made available to petitioners during the fall of 2002 via various government web sites, and petitioners' counsel have analyzed that data. Many thousands of pages of additional material has been supplied to petitioners since December of 2002, and petitioners' counsel have analyzed those documents as well. At this point, the respondent has now essentially finished compliance with all of the petitioners' Requests for Production, except for the items discussed at points 2 and 3, immediately following.

2. The vaccine license application files

One category of documents requested, pursuant to petitioners' Requests for Production Nos. 10 and 12, involves vaccine license applications. In this area, efforts to produce material have proceeded more slowly, due in part to the massive amount of material involved, and in part to the cumbersome procedures required under federal law for disclosure of material submitted by vaccine-makers during the licensing process. The process of production of that material continues to move forward. Extensive Food and Drug Administration (FDA) files with respect to certain license applications for the MMR combined vaccination and the mumps vaccination have been disclosed to the Petitioners' Steering Committee (hereinafter "the Committee"), and the files with respect to many additional vaccinations are moving through the arduous process toward disclosure. This

process, however, involves not only review of these files by government lawyers to determine which materials are appropriate for disclosure, but also involves the vaccine manufacturers who submitted the licensing applications, giving such manufacturers an opportunity to object to disclosure. Despite many months of hard work by many government employees, there is still much work to be done in order to complete disclosure of the rest of the many files being sought. Further, after studying the files disclosed thus far, Committee members have asserted that because of redactions from the files made during the review process, the files as disclosed have been less helpful than anticipated.

Accordingly, while the parties will continue the process of review and disclosure of the FDA's vaccine license application files, Committee members have proposed a new discovery approach toward obtaining the same information, in the hopes of obtaining it more speedily. Committee members are currently preparing requests for third-party discovery from the vaccine manufacturers themselves, and are contacting counsel for such manufacturers to initiate that discovery process. The Committee expects to file very soon the first such formal request for discovery from a manufacturer.

3. Issue of access to unpublished study data

I have indicated in previous Autism Updates that the parties have been in disagreement concerning the issue of production of materials relating to certain "ongoing and proposed studies." As I have noted, the parties have engaged in extensive ongoing efforts to resolve that issue. Specifically, they have focused their efforts on the goal of providing the Committee with pre-publication access to the data set of one particular study, known as the "Thimerosal Screening Analysis." After long negotiations, the two sides have at times apparently come close to agreement on a procedure for making that data set available to the Committee pursuant to a confidentiality agreement, but have not ever been able to reach complete agreement. At the status conference held on August 12, 2003, petitioners' counsel requested that a hearing be scheduled for late September, at which the parties would present to me any argument and/or evidence concerning the issue of whether I should compel disclosure of that data set under a confidentiality agreement. On August 12, the week of September 29 was set aside for that purpose, although the parties pledged to continue to attempt to settle the issue in the meantime. At the September 3 conference, it was agreed that the date of September 30 would be set aside for the hearing, and that briefs concerning the issue would be filed on September 23.

On August 28, respondent's counsel announced that the results of the study in question will in fact be published sometime in November of 2003, earlier than previously anticipated. The parties then attempted to determine what the procedures would be for petitioners to access the data set once the study is published, and to determine whether pre-publication access under a confidentiality agreement could still substantially speed up the Committee's access to the data set. At the conference held on September 17, 2003, petitioners' counsel indicated that according to the information available to them, the post-publication access process might be lengthy, and they wished to proceed with the existing plan to put before me, via briefs to be filed on September 23 and hearing to be held on September 30, the parties' positions concerning whether I should order pre-publication

disclosure via a confidentiality agreement. Therefore, at that September 17 conference, I directed that the parties file briefs concerning that issue by September 23, and that a hearing be held on September 30, if agreement was not reached.

On September 19, 2003, however, the Committee informed my office that after further discussions between the two sides, the petitioners no longer desired a hearing on September 30. Instead, the Committee will continue to work on settlement of the issue with respondent's representatives.

4. Future schedule for discovery and other aspects of Omnibus Autism Proceedings

Quite obviously, the discovery process in the Omnibus Autism Proceedings has not gone as speedily as anticipated. I do not lay blame or fault on anyone for this occurrence. As I have observed in previous Autism Updates, I believe that all parties involved have been working very hard on this discovery process. It is clear that a huge effort involving a number of government agencies has taken place, in an effort to provide a thorough response to the discovery requests. A large amount of material has already been provided, and I continue to perceive that both sides are acting diligently, and in good faith. I note that in those areas where discovery is not yet complete, opposing counsel have worked amicably with each other with the goal of completing production cooperatively. The parties have not yet reached an impasse concerning any issue that they have needed to present to me for formal resolution, although I have always been ready to resolve any dispute if so requested. Indeed, I reiterate my thanks to all counsel involved for their tremendous efforts, in these difficult matters.

One chief reason for delay, however, has been the cumbersome process of discovery of the vaccine license applications, as explained above. It is the hope of all involved that by proceeding at this time directly to third-party discovery from the vaccine manufacturers, we may be able to more quickly obtain the same basic material that the petitioners' representatives had hoped to obtain from the vaccine license application files. This strategy, we hope, will speed the discovery process to a conclusion. I note, as a caution, however, that there has been very little experience with such third-party discovery from vaccine manufactures during the history of the Vaccine Act, so it is difficult to predict exactly how long such a process will take.

Accordingly, since we are only now proceeding to the "second round" of discovery, from the manufacturers, it is now clear that we will not be able to comply with all the dates for the final activities of the Omnibus Autism Proceeding--*i.e.*, the dates for the designations of experts, the filing of expert reports, and the hearing on the general causation issue--as set forth in the "Master Scheduling Order" attached to the *Autism General Order # 1* filed on July 3, 2002. At the joint request of the parties, I hereby formally modify that Master Scheduling Order by suspending those activity dates for an indefinite period of time. I will set new dates for those stages of the Omnibus Autism Proceeding at a future time.

I do promise, however, that I and counsel for both sides in the Omnibus Autism Proceeding will devote vigorous effort toward completing the remaining discovery as soon as is humanly possible. I reiterate that all counsel, as well as myself, have been doing, and will continue to do, everything in our power to expeditiously conclude discovery matters so that we can move forward toward the conclusion of the Omnibus Autism Proceeding.[2]

C. Number of cases

At this time, more than 3,200 petitions in autism cases have been filed, and are stayed pending the conclusion of the Omnibus Autism Proceeding. Additional petitions continue to be filed regularly.

D. Inclusion of documents from individual autism cases in the Autism Master File

Occasionally, procedural issues came up in an individual autism case which may be of general interest to the autism petitioners. At the suggestion of the Petitioners' Steering Committee, I have begun to place copies of select documents respecting such issues into the Autism Master File, so that such documents may be easily accessed by persons interested in the autism cases. For example, on September 9, 2003, I filed, into the Autism Master File, an Order to which I attached two rulings concerning procedural issues that I made in the individual autism case of *Stewart v. Secretary of HHS*, No. 02-819V. I will continue, from time to time, to file copies of similar documents from individual autism cases into the Autism Master File.

E. Issue of the proper date for issuing "§ 12(g)(1) notices"

A controversy has arisen in the autism cases concerning when the special master should issue the notice pursuant to 42 U.S.C. § 300aa-12(g)(1) (hereinafter the "§ 12(g)(1) notice"), which notice triggers the right of a Vaccine Act petitioner to withdraw his petition pursuant to 42 U.S.C. § 300aa-21(b). Previously, the practice under the Vaccine Act has been for the special master to issue such a notice 240 days after the date upon which the petition was *filed*. The respondent has now taken the position, however, that if a petition is filed that is not accompanied by all of the materials specified under 42 U.S.C. § 300aa-11(c), then the "§ 12(g)(1) notice" should not be issued until 240 days after the petitioner files the *last of those specified materials*. Respondent has filed motions asserting that statutory interpretation in many of the autism cases in which "short-form petitions" have been filed since July of 2002.

On September 3, 2003, I filed, in the individual autism case of *Stewart v. Secretary of HHS*, No. 02-819V, an opinion ruling against the respondent's proposed statutory interpretation concerning this controversy. (That published ruling was put into the Autism Master File by my Order of

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[2]Of course, no individual petitioner is *obligated* to wait for the outcome of the Omnibus Autism Proceeding. Any petitioner who at any time wishes to introduce evidence in order to attempt to prove his or her own case will be permitted to do so.

September 9, 2003, and thus can be accessed on this court's Internet website, along with all other materials filed in the Autism Master File, at www.uscfc.uscourts.gov/osm/osmautism.htm.) Since the above-described motions filed by respondent in all of the "short-form petition" cases raise the identical legal issue, that ruling in *Stewart* would seem to mean that I would begin to issue the "§ 12(g)(1) notices" in the "short-form petition" cases as the appropriate date arrives in each such case. However, respondent's counsel have indicated that they are considering whether to attempt to obtain interlocutory appellate review of my ruling concerning this issue by means of seeking a writ of mandamus in the *Stewart* case. Respondent's counsel anticipate that a decision whether to seek such appellate review will likely be made by October 3, 2003. Further, respondent's counsel have requested that, if respondent elects to seek such appellate review, I then refrain from issuing "§ 12(g)(1) notices" in *Stewart* and in the other "short-form petition" cases until the appellate review process in *Stewart* is complete. We should know very soon whether respondent will elect to seek appellate review concerning this controversy. Meanwhile, I am currently considering the above-described request by respondent that I refrain from issuing "§ 12(g)(1) notices" if respondent does seek such review. Once I know whether such review will be sought, I will promptly issue another of these "Autism Updates," to inform the autism petitioners of the status of developments concerning this issue.

F. Issue of "judgments"

As noted in a previous Autism Update, I and other special masters are considering the overall issue when "judgments" should be entered in Vaccine Act cases. To assist in this review, the parties to the Omnibus Autism Proceeding filed briefs concerning this topic on July 30, 2003, and August 22, 2003, respectively. I have since requested the parties' views on additional points with respect to that general issue, with briefs on those points to be filed by October 15, 2003.

Soon after those briefs are filed, I will file an opinion discussing this topic, in an individual autism case. I will place that opinion into the Autism Master File.

G. Issue of timeliness of petition filing

In several autism cases, there are pending motions by respondent seeking dismissal on the ground that the petitions were not timely filed. Such motions may be more complicated in autism cases than in previous Vaccine Act cases, due to the fact that in most of the autism cases it is alleged that the vaccinee was injured by a *series* of vaccinations, rather than a single vaccination. These motions have also been potentially made more complex by a recent ruling in *Setnes v. Secretary of HHS*, 57 Fed. Cl. 175 (2003). In one case in which a dismissal motion is pending, *Wood v. Secretary of HHS*, No. 02-1317V, I have invited the Petitioners' Steering Committee to file a brief by October 6, 2003. After that brief is filed, I intend to rule on the dismissal motion in that case, and thereafter turn to the other pending dismissal motions. At the request of the Committee, I will consider placing certain documents from that *Wood* case--certainly including my ruling on the motion--into the Autism Master File.

H. Future proceedings

The next status conference in the Omnibus Autism Proceeding is scheduled for September 26, 2003.

George L. Hastings, Jr.
Special Master

EXECUTIVE COMMITTEE

Kim, John	Co Chair
Williams, Michael	Co Chair
Anis, Ghada	Liaison
Bjorklund, Sheila	
Dailey, Kathleen	
Hamilton, John (Jack),	
Ho, Thao	
Lewis, Richard	
Michel, Dominique	
Millrood, Tobias	
Taylor, Robert	

LEGISLATIVE LIAISON

Kim, John

COST & ACCOUNTING SUBCOMMITTEE

Lewis, Richard	Co Chair
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Savola, L.H. Steven	
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Taylor, Robert	
Thomas, Joseph	
Villasante, Roberto	
Webster, Jason	

EXHIBIT D

ORIGINAL

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

IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER, OR A SIMILAR NEURODEVELOPMENTAL DISORDER, Various Petitioners, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Autism Master File **MOTION TO ISSUE THIRD PARTY SUBPOENA**

I. MOTION

Petitioners move the Special Master to issue a subpoena directing Merck & Company, Inc., to respond to petitioners' Request for the Production of Documents. The discovery request subject to the instant subpoena is attached to this Motion as Exhibit A. This Motion is made pursuant to 42 USC 300aa-12(d); RCFC 26-37 and 45; and Vaccine Rule 7, and requests that the Special Master issue a Vaccine Rule Form 7(a) subpoena directing Merck & Co. to comply with petitioners' request for the production of documents.

Petitioners conferred with counsel for the third-party designated in this discovery request and the third-party Merck & Co. declined to produce any of the requested documents, and represented to petitioners that they would object to, or move against, any subpoena or other discovery request issued by petitioners or the Special Master. The issuance of a subpoena as requested herein is reasonable and necessary, and is for good cause, as will be detailed below.

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II. BACKGROUND FACTS

Petitioners are the approximately 3000 children with compensation claims pending in the Omnibus Autism proceeding established in the National Vaccine Injury Compensation Program's Office of the Special Masters. The Omnibus proceeding was established on July 3, 2002 by Autism General Order #1, signed by Chief Special Master Golkiewicz. The Omnibus proceeding is supervised by Special Master Hastings.

A central goal of the Omnibus proceeding is to manage the very high volume of autism injury cases in the NVICP in a fair, efficient, and timely manner. As the Chief Special Master wrote in the General Order, the Omnibus proceeding seeks to "ensure a timely presentation and resolution of the difficult medical and legal issues raised in these cases." The initial process in the Omnibus proceeding is an inquiry into the "general causation" issues presented by these claims; that is, whether the vaccines at issue can cause the injuries claimed by petitioners, and whether the conclusions of the general causation inquiry will be applied to the individual cases. The General Order explicitly provided that extensive discovery would occur, and that the discovery process would culminate in a general causation hearing. The Special Master and counsel for the petitioners and respondent then developed a discovery schedule.

As part of that discovery schedule, petitioners served a set of requests for the production of documents to respondent on August 2, 2002. Request No. 10 sought "all documents submitted to the FDA for review by vaccine manufacturers prior to the approval of the MMR vaccine." Request No. 12 sought "all documents submitted to the FDA for review by vaccine manufacturers prior to the approval of all thimerosal-containing vaccines." By November 18, 2002 petitioners and respondent agreed on the scope of Request Nos. 10 and 12, and agreed that documents referred to as "Product License Applications" ("PLA's") were the materials most responsive to the requests. In the eleven months since agreeing on the scope of the requests and the types of documents to be produced, however, very little progress has been made in the actual

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production of the documents.

The ongoing delay in the production of these relevant, important documents is one reason why there is good cause for the Special Master to issue the subpoena requested in this Motion, as will be detailed below. It is also likely that the vaccine manufacturers have information about the health and safety attributes of their products that the respondent does not have. That information is critical to resolving the causation issues confronting the more than 3000 seriously injured children in the autism proceeding. Third-party discovery is the only means of getting this information.

III. THE PLA PROCESS: SLOW, CUMBERSOME AND COSTLY

The parties and the Special Master have become increasingly frustrated by the significant delays inherent to the production of the PLA's. Two significant obstacles to the timely production of the documents are 1) the volume of documents identified by respondent as potentially relevant and responsive (approximately 400,000 pages); and 2) the "cumbersome" process governing the disclosure of the documents. *See,* Autism Update and Order—May 9, 2003, p. 2; Autism Update and Order—June 27, 2003, p. 2. Of the 400,000 pages of documents relating to dozens of PLA's, petitioners have received only approximately 2,600 pages of a single PLA after nearly 11 months of discovery.

The PLA documents are subject to a disclosure process that imposes a huge burden on respondent and its client agencies, creates significant public costs, and causes delays that seriously jeopardize the ability of the Omnibus proceeding to complete the general causation inquiry in any reasonable amount of time. The PLA documents are materials originally generated and maintained by vaccine manufacturers as required under various federal statutes and regulations, and must be submitted to the FDA as part of the process by which the FDA approves and licenses the vaccines for use. Although in the possession of the FDA, the FDA is limited by statute and regulation in its ability to disclose the contents of the documents or to

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release the documents to third parties, including petitioners, without review and approval by the manufacturers.

As explained by respondent and understood by petitioners, the DOJ receives and reviews petitioners' request for production of a PLA and then passes the document request on to the FDA. The FDA must then review the requests for production in order to identify potentially relevant documents. The agency must then notify the manufacturer of the request, and the manufacturer has an independent opportunity to review the potentially responsive documents before the documents are released to the FDA and DOJ for delivery to petitioners. Based on that review, the manufacturer tells the FDA that the manufacturer will not permit the disclosure of some documents, may withhold some documents, and may redact portions of some documents, all on the bases of various statutory and regulatory confidentiality provisions (e.g., trade secrets, proprietary information, etc.).

The FDA and the manufacturer then conduct what is basically collateral litigation over the legitimacy of the non-disclosure designations. It is only when this protracted process is complete that petitioners see the first page of a PLA. The respondent is also obliged to create and produce a privilege log identifying the withheld material. Even then, the documents produced so far are heavily redacted.

The result of this process is a tremendous and unnecessary burden of time and expense on respondent and its client agencies and very significant delays in the production of documents that are relevant to central issues of causation in thousands of cases involving very seriously injured children. The discovery delays created by interposing respondent and its client agencies as an intermediary between the vaccine manufacturers and the petitioners completely undermine the Omnibus proceeding's central goal of ensuring a "timely presentation and resolution of the difficult medical and legal issues raised in these cases."

It is for this reason that petitioners propose that the Special Master issue subpoenas to the non-party vaccine companies requiring these "third parties" to produce documents directly to

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petitioners, pursuant to petitioners' requests for production, as described below. This proposal completely avoids the problems that bedevil the current effort to move discovery forward by eliminating the government's role as an intermediary.

IV. PETITIONERS' PROPOSAL FOR THIRD-PARTY DISCOVERY

Petitioners propose that the Special Master issue subpoenas to the manufacturers of those products already identified as relevant vaccines in the Omnibus proceeding; that is, vaccines containing thimerosal, and the MMR vaccine. Petitioners further propose that the third-party discovery directed to the vaccine manufacturers be conducted pursuant to the discovery process described in the Rules of the US Court of Federal Claims at RCFC 26-37. Recognizing the vaccine manufacturers' interest in maintaining the confidentiality of some information (in addition to the protections provided in the Rules), petitioners further propose that any third-party discovery conducted by the Special Master in this case should be subject to an appropriate protective order.

The first RFP proposed by petitioners is enclosed with this Motion (to Merck, seeking relevant information about its thimerosal-containing hepatitis B vaccine). The scope of the discovery request includes the PLA material as well as other documents directly relevant to the general causation issues that are central o the Omnibus proceeding. Petitioners anticipate that the RFPs directed to other manufacturers relating to other relevant vaccines would be essentially the same as this first RFP.

V. THE SPECIAL MASTER HAS THE LEGAL AUTHORITY TO CONDUCT THIRD-PARTY DISCOVERY AS PROPOSED BY PETITIONERS

A. The Court of Claims is Authorized to Conduct Third-Party Discovery

The Rules of the US Court of Federal Claims explicitly authorize the Court of Claims to conduct discovery against persons who are not parties to litigation in the Court. The Court may issue a subpoena requiring any person to "attend and give testimony or to produce and permit inspection and copying of designated books, documents or tangible things," and the subpoena

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"may be joined with a command to appear at trial or hearing or deposition." RCFC 45(a)(1)(D). The subpoena power of the Court is not limited to parties; in fact, the rules specifically describe the limits on subpoenas directed to non-parties. RCFC 45(c). Third-party subpoenas are authorized subject to the protections described at RCFC 45(c)(1) and (2), and non-parties are provided the right to move to quash or modify a subpoena. RCFC 45(c)(3). The scope of discovery within the subpoena power of the Court under RCFC 45—whether of parties or non-parties—is generally described and limited by RCFC 26. *Capital Properties, Inc. v. The United States,* 49 Fed.Cl. 607, 611 (2001) (discovery against non-parties must meet "good cause" standard under RCFC 26(c)).

Court of Claims cases have authorized several forms of discovery against non-parties. In *Capital Properties,supra,* the Court allowed plaintiff to take the pre-trial deposition of a non-party (a representative of the state of Rhode Island), required Rhode Island to produce relevant documents, and required Amtrak (also a non-party) to produce documents. Extensive document production was ordered by the Court against a corporation that was not a party to litigation between an Indian tribe and the United States. *Navajo Nation v. The United States,* 46 Fed.Cl. 353 (2000). The Court permitted discovery of proprietary business information in *Levine v. The United States,* 226 Ct.Cl. 701 (1981). In all of these cases the Court ordered some form of the various discovery devices generally permitted under RCFC 27 – 36, subject to the scope and limitations of RCFC 26.

B. The Special Master is Also Authorized to Conduct Third-Party Discovery

The rules and relevant cases make it clear that the Court of Claims is authorized to compel discovery from non-parties, giving rise to the question of whether the Special Master has such authority. As indicated by Special Master Hastings in a telephone conference call with petitioners and respondent discussing the issue of third-party discovery, the terms "the Court" and "the Special Master" are *not* synonymous. In this case, however, the discovery power of "the Court" and "the Special Master" *are* synonymous, as the Vaccine Rules specifically give the

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Special Master discovery authority essentially concurrent with that of the Court.

Under Vaccine Rule 7, there is no discovery as a matter of right in Vaccine Court proceedings. The rule is consistent with the language of the Vaccine Act allowing only such discovery as "required by the special master," rather than discovery as a matter of right in civil litigation under the federal or state rules of procedure. 42 U.S.C. 300aa-12(d)(3)(B). The statute also explicitly allows the Special Master to "require such evidence as may be reasonable and necessary" and to " require the testimony of *any person* and the production of *any documents* as may be reasonable and necessary." 42 U.S.C. 300aa-12(d)(3)(B)(i), (iii) (emphasis added). Congress, by giving the Special Master the authority to conduct discovery as to "any" people and "any" documents, expressly allowed the Special Master to conduct discovery not limited to the parties in a compensation proceeding. The rules of the Vaccine Court, promulgated under 42 USC 300aa-12(d)(2), therefore specifically allow the Special Master to require third-party discovery.

The Vaccine Rules grant the Special Master the authority to conduct any of the discovery that is within the power of the Court of Claims under the RCFC. VR 7(b) (authorizing the use of the "discovery procedures provided by RCFC 26-37" in proceedings before the Special Masters). The rules specifically authorize the Special Master to issue subpoenas pursuant to RCFC 45. VR 7(c). Vaccine Rule 7 therefore incorporates the discovery and subpoena rules of the Court of Claims, giving the Special Master discretion to conduct discovery as permitted under RCFC 26-37 and RCFC 45. Since the rules of the Court of Claims and the relevant case law authorize the Court to require discovery from non-parties, and the Special Master has the discretion to utilize all of the discovery power provided to the Court, the Special Master has the authority to conduct discovery involving non-parties.

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VI. CONCLUSION

Petitioners have demonstrated that there is good cause supporting discovery directed to third-parties as described above, and that the issuance of a subpoena is reasonable and necessary in this case. The Special Master has the legal authority to issue the subpoena requested by petitioners. The Special Master therefore should issue a Form 7(a) subpoena to Merck & Co., Inc., directing Merck to comply with petitioners' Request for the Production of Documents as attached to this Motion.

DATED this 6th day of October, 2003.

By: _____
Michael L. Williams
Thomas B. Powers

Williams Dailey O'Leary Craine & Love, P.C.
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CERTIFICATE OF SERVICE

I hereby certify that on October 6, 2003, I served the foregoing **MOTION TO ISSUE THIRD PARTY SUBPOENA** on the following individual(s):

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

Ghada Anis
Petitioner's Steering Committee
733 15th Street, NW, Suite 700
Washington, DC 20005

by regular mail and facsimile.

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

Dannee L. Kessler, Paralegal to Michael L. Williams
Attorneys for Petitioners' Steering Committee

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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 DISORDE0R, Various Petitioners, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Autism Master File **Request for the Production of Documents: Merck & Company, Incorporated**

TO: MERCK & COMPANY, INC., ("MERCK") AND ITS ATTORNEYS

PLEASE TAKE NOTICE that pursuant to 42 USC §300aa-12(d), RCFC 34 and 45, and Vaccine Rule 7, the Office of the Special Masters directs you to produce for inspection the following documents that are in your custody or control.

When producing these documents, you should organize and label them where appropriate to correspond with the categories of this request.

If a document is withheld by you on the grounds of attorney-client privilege or attorney work product, or any other privilege as provided by law, identify such document by date, author, recipient and subject matter (without disclosing its contents) sufficient to describe the document so that the Special Master may rule on your objection.

All of the categories of information described below relate to Merck's biologic product known as "Recombivax HB," and refer in every instance to that product, which is a vaccine for Hepatitis B.

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A. Product License Applications

Produce all of those documents contained in the Product License Applications ("PLAs") for the years 1990 to 2003 for Recombivax HB. This request is intended to encompass all documents responsive to petitioners' earlier discovery request to the FDA seeking PLA materials for this product. This request directly to Merck to produce PLA documents directly to petitioners is intended to be an alternative to, and a substitute for, producing those documents to FDA for eventual delivery to petitioners.

In addition to the PLA documents requested above, Merck is directed to deliver to petitioners any documents relating to the following categories. It is intended that the following requests seek only those documents not otherwise included in the PLAs requested above.

B. Product Safety Research:

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 or animal health effects of thimerosal.

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 human and animal health effects of ethyl mercury.

3. 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 and animal health effects of the Recombivax HB vaccine or of any of its components, including all formulations of the product.

4. Any research, survey, study, test or other investigation, whether published or not,

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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 and animal health effects of any preservatives, biocides, fungicides, adjuvants, stabilizing agents, and diluents used in any formulation of Recombivax HB.

5. 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 a) human or animal health effects of thimerosal, b) human or animal health effects of ethyl mercury, c) human or animal health effects of the Recombivax HB vaccine or of any of its components, including all formulations of the product, and d) human or animal health effects of any preservatives, biocides, fungicides, adjuvants, stabilizing agents, and diluents used in any formulation of Recombivax HB.

B. Product Packaging:

1. The process and procedure undertaken by Merck or any of its predecessor corporations for deciding the form of packaging to used for the distribution of Recombivax HB, in all of its formulations. This request specifically includes any documents describing or discussing product safety and efficacy issues relating to

a) the use of multi-dose vials versus single-dose vials,

b) the use of single-dose, prefilled syringes,

c) the use of preservatives, biocides, fungicides, stabilizers, diluents and any other component of the licensed product in addition to the antigen itself.

2. Any discussion, analysis, evaluation or any other consideration regarding the relative costs, expenses or any other financial factor relating to

a) the use of multi-dose vials versus single-dose vials,

b) the use of single-dose, prefilled syringes,

c) the use of preservatives, biocides, fungicides, stabilizers, diluents and any other

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component of the licensed product in addition to the antigen itself, for the Recombivax HB product.

C. Communications Between Merck and the U.S. Government:

Documents relating to any communications between Merck and any agency or division of the U.S. federal government, including but not limited to the Centers for Disease Control and Prevention, the Food and Drug Administration, and the Department of Health and Human Services, and any of the subdivisions of those entities, regarding the following issues:

1. Meetings of the Simpsonwood panel in June 2000, including the following topics:

   a) The identity of the custodian(s) of all records, minutes, correspondence and any other documents generated by or as a result of the proceedings of that panel, before, during and after the June 2001 meeting;

   b) The identity of any employees of Merck or its subdivisions who participated in planning Merck's participation in the Simpsonwood meeting, or who participated in any discussions regarding the scope, goals, purposes, or agenda of the meeting.

2. Communications between Merck and the federal government regarding the safety, or concerns about the safety, of thimerosal, ethyl mercury, the Recombixax HB vaccine or its components, or the preservatives, biocides, fungicides, adjuvants, stabilizing agents, and diluents used in pediatric vaccines.

3. Communications between Merck and the federal government regarding the joint announcement by the FDA, USPHS, and CDC in July 1999 regarding concerns about the continued use of thimerosal in pediatric vaccines, whether those communications occurred before or after the announcement.

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DATED this 6th day of October, 2003.

Respectfully submitted,

By: _____
Michael L. Williams
Thomas B. Powers

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