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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 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

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CERTIFICATE OF SERVICE

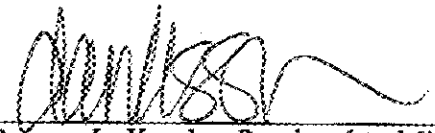
I hereby certify that on October 6, 2003, I served the foregoing **MOTION TO ISSUE THIRD PARTY SUBPOENA** on the following individual(s):

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
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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,

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