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

MICHAEL L. WILLIAMS
mwilliams@wdolaw.com

KATHLEEN M. DAILEY
kdailey@wdolaw.com

LESLIE W. O'LEARY
loleary@wdolaw.com

DIANA L. CRAINE
dcraine@wdolaw.com

SUITE 1900
1001 SW 5TH AVE
PORTLAND, OREGON 97204-1135

TELEPHONE 503/295-2924
FAX NUMBER 503/295-3720
TOLL FREE 800/842-1595
WWW.WDOLAW.COM

LINDA C. LOVE
llove@wdolaw.com

BRIAN S. CAMPF
bcampf@wdolaw.com

THOMAS B. POWERS
tpowers@wdolaw.com

September 8, 2003

VIA OVERNIGHT MAIL

Clerk of the Court
U.S. Court of Federal Claims
717 Madison Place, NW
Washington, DC 20005-1011

Re: Petitioners' Steering Committee Memorandum Regarding Third-Party Discovery

Dear Clerk:

Enclosed for filing please find the original and a copy of Petitioners' Steering Committee Memorandum Regarding Third-Party Discovery.

Thank you.

Sincerely,

Dannee Kessler
Paralegal

dk:dk

c: Mark Raby, U.S. DOJ
Vince Matanoski, U.S. DOJ
Ghada Anis, P.S.C.

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF THE SPECIAL MASTERS

(SUBMITTED: September 4, 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.	PETITIONERS' STEERING COMMITTEE MEMORANDUM REGARDING THIRD-PARTY DISCOVERY

I. INTRODUCTION

Petitioners proposed to Respondent and to the Special Master that discovery of information and evidence be had directly from the various vaccine manufacturers whose products are at issue in this proceeding. This is especially important now that we have seen how much time and resources the FDA and DOJ must spend simply redacting commercial information from the vaccine license applications, commercial information that would normally be produced in civil litigation, even if subject to a confidentiality order. If Petitioners can get the PLA files directly from the manufacturers, the FDA and DOJ will save much time and money, and the manufacturers will, too, as they won't have to negotiate detailed redactions with Respondent.

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

The manufacturers are not parties to this action between the many hundreds of petitioners and the Secretary, and the issue of whether the Special Master has the authority to subpoena the production of documents and to subpoena the appearance of witnesses from the "third-party" manufacturers therefore arises.

The Special Master requested that petitioners submit a legal memorandum addressing the question of the Special Master's authority to conduct third-party discovery. This memorandum is provided in response to that request. Included as an exhibit is petitioners' first proposed subpoena *duces tecum,* requesting that third-party manufacturer Merck & Company, Inc. provide documents relevant to whether Merck's Hepatitis B vaccine ("Recombivax HB") caused or contributed to the injuries alleged by petitioners. Petitioners contacted Merck's attorneys last week, and provided today a copy of the attached exhibit to them. If petitioners and Merck cannot reach an agreement for the production of the documents requested, petitioners would, pursuant to the rules of the Vaccine Court, formally request that the Special Master issue the request in the form of a subpoena, as described below.

II. SUMMARY OF THE ARGUMENT

Based on the language of the National Vaccine Injury Compensation Act ("Vaccine Act"), the Vaccine Rules of the U.S. Court of Federal Claims, the Rules of the U.S. Court of Federal Claims, and relevant case law, the Special Master has the authority to conduct discovery directly against third-parties. The Special Master is authorized to issue subpoenas to compel the production of documents, to require the attendance of witnesses for depositions and hearings, and to enforce compliance by initiating contempt proceedings. The Special Master is also responsible for ensuring that third-party discovery is conducted in a way that protects the rights of non-parties and that the discovery does not impose undue burdens on a non-party.

III. POINTS AND AUTHORITIES

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

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

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 "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 discovery against non-parties. RCFC 45(c). Discovery against non-parties is 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 made clear by Special Master Hastings in a telephone conference call with

LAW OFFICES OF
WILLIAMS DARLEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

petitioners and respondent, 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 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), then 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.

C. Petitioners Will Confer with the Vaccine Manufacturers Informally, and will

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
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503/295-2924
503/295-3720 (facsimile)

Request Formal Third-Party Discovery from the Special Master only if Necessary.

As proposed by petitioners, discovery would include third-party discovery directed to the various vaccine manufacturers whose products are at issue in the Omnibus Proceeding. Under the rules, petitioners must formally request that the Special Master approve and issue a subpoena. VR 7 (c). Once requested by petitioners, the Special Master would follow the guidelines under RCFC 45 in deciding whether to issue a subpoena, crafting a subpoena that is within the scope of RCFC 26-37, ensuring that the rights of the third-party vaccine companies are protected, and reviewing any objections or challenges to the subpoena. If the Special Master found in the exercise of discretion that third-party discovery against the vaccine manufacturers was "reasonable and necessary," the subpoena would issue in the form provided by the Vaccine Rules. VR 7(c) and Form 7A.

An important prerequisite for pursuing formal discovery against anyone, including non-parties, is an attempt by the party seeking discovery to obtain the evidence or information informally. This step is required by the Vaccine Rules. VR 7(a), (b).

Petitioners will therefore contact the attorneys for the various vaccine manufacturers from whom information and evidence is sought (and Petitioners have already contacted Merck's attorneys). If those efforts fail, petitioners will formally request that the Special Master issue subpoenas requiring the production of relevant documents and requiring the deposition testimony of relevant witnesses in the Omnibus Autism Proceeding. The subpoenas would include requests for evidence relating specifically to the issues of general causation as described in Autism General Order #1, and would involve specific requests directed to individual manufacturers seeking information on specific pediatric vaccine products. Petitioners further note that any informal or formal discovery conducted with third-parties would almost certainly be subject to some form of protective order, and petitioners will at every step meet and confer with all interested parties to design an appropriate form of such order.

Petitioners' proposed first request for the production of documents directed to Merck &

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

Company, Inc. is attached as an exhibit. If petitioners and Merck are unable to come to an agreement for the informal discovery of this information and evidence, then petitioners will formally ask that the Special Master issue this request for documents in the form of a From 7A subpoena. The exhibit is included at this point to advise the Special Master of the scope and nature of the third-party discovery petitioners seek from the vaccine manufacturers.

IV. CONCLUSION

The Special Master is authorized by the Vaccine Act, the Rules of the U.S. Court of Federal Claims, the Vaccine Rules, and relevant case law to conduct third-party discovery in proceedings under the NVIC. Third-party discovery is permitted under the terms described at RCFC 26-37, and as incorporated into the Vaccine Rules at VR 7. The discovery power of the Special Master includes the authority to issue subpoenas and enforce compliance with subpoenas pursuant to RCFC 45. If petitioners are unsuccessful in their efforts to obtain informal discovery from the vaccine manufacturers of information relevant to issues of general causation in the Omnibus Autism proceeding, then petitioners will formally request that the Special Master exercise his discretion to require third-party discovery, including the issuance of subpoenas.

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

DATED this 9th day of September, 2003.

Respectfully submitted,

By: _____

Michael L. Williams
Thomas B. Powers

Counsel for Petitioners' Steering Committee
1001 SW Fifth Avenue, Suite 1900
Portland, OR 97204
(503) 295-2924

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

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.

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

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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

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

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, 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.

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

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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 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

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

continued use of thimerosal in pediatric vaccines, whether those communications occurred before or after the announcement.

DATED this 8th day of September, 2003.

Respectfully submitted,

By: _____

Michael L. Williams
Thomas B. Powers

Counsel for Petitioners' Steering Committee
1001 SW Fifth Avenue, Suite 1900
Portland, OR 97204
(503) 295-2924

LAW OFFICES OF
WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

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CERTIFICATE OF SERVICE

I hereby certify that I caused a copy of the foregoing pleading to be delivered by this 8th day of September, 2003 to:

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

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

Ghada A. Anis
Liaison Counsel
Omnibus Autism Proceeding
Petitioners' Steering Committee
733 15th Street N.W., Suite 700
Washington, DC 20005

Dannee L. Kessler, Paralegal to
Michael L. Williams

continued use of thimerosal in pediatric vaccines, whether those communications occurred before or after the announcement.

DATED this 8th day of September, 2003.

Respectfully submitted,

By: _____
Michael L. Williams
Thomas B. Powers

Counsel for Petitioners' Steering Committee
1001 SW Fifth Avenue, Suite 1900
Portland, OR 97204
(503) 295-2924

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WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135
503/295-2924
503/295-3720 (facsimile)

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