ORIGINAL

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

FILED
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U.S. COURT OF
FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER, OR A SIMILAR DEVELOPMENTAL DISORDER, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	AUTISM MASTER FILE Special Master George Hasting

PETITIONERS' MOTION TO ISSUE SUBPOENA

TO MERCK & CO., INC., RE THE "MMR" VACCINE

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MOTION

Petitioners move the Special Master to authorize the issuance of a subpoena directing Merck & Company, Inc., to respond to petitioners' Request for the Production of Documents relating to Merck's measles-mumps-rubella vaccine product ("MMR"). The discovery request subject to the requested subpoena authority is attached as Exhibit A to this Motion, and was filed February 26, 2004 and served on February 25, 2004.

This Motion is made pursuant to 42 U.S.C. §300aa-12(d), RCFC 26-37 and 45, and Vaccine Rule 7, requesting that the Special Master authorize a Form 7(a) subpoena as described herein. This Motion is supported by the attached Memorandum of law and exhibits. The issuing of the requested subpoena is reasonable and necessary and is for good cause. This Motion should be granted, and the subpoena should issue as requested by petitioners.

MEMORANDUM OF LAW

I. FACTS

Petitioners and respondent have been engaged in extensive discovery in the Autism Omnibus Proceeding since shortly after entry of Chief Special Master Golkiewicz's "General Order No. 1" in July 2002. While respondent has produced thousands of pages of documents, discovery from respondent is ongoing and there remain unresolved disputes about the scope and content of any further discovery requested of respondent by petitioners. In addition to their requests to discover relevant information in the control or possession of the federal government, petitioners seek limited discovery of information that petitioners believe are in the hands of the various companies that manufactured the vaccine products at issue in the Omnibus proceeding.

Petitioners initially discussed with the Special Master and respondent the possibility of seeking discovery from the non-party vaccine manufacturers in September 2003, and petitioners conferred with counsel for one manufacturer—Merck & Co., Inc.—about the possibility of Merck informally providing the information requested by petitioners without need for a subpoena or any other action by the Office of the Special Masters or the U.S. Court of Federal

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Claims. Specifically, petitioners drafted a Request for the Production of Documents relating to the thimerosal component of Merck's Hepatitis B product (Recombivax) and asked Merck to provide the requested documents. After conferring with petitioners, respondent and the Special Master, Merck declined to provide the requested documents. Petitioners then revised their Request for Production and moved the Special Master to authorize the issuance of a subpoena compelling Merck to respond to the document request (see, *Petitioners' Revised Motion for Subpoena Re; Merck,* October 29, 2003). Merck intervened and opposed the Motion (see, *Merck's Motion for Leave to Proceed* and *Merck's Response to Petitioners' Motion to Issue Revised Third Party Subpoena,* November 14, 2003); several other vaccine manufacturers intervened and filed briefs opposing any discovery of non-party vaccine manufacturers (see, various filings of Wyeth, Baxter, SmithKline, and Aventis, December 3, 2003); petitioners responded to those filings (see, *Petitioners' Response to Merck and Amicus Curiae re Non-Party Discovery,* December 10, 2003, and Merck and the other vaccine manufacturers replied (see, various filings of Wyeth, Baxter, SmithKline, and Aventis December 29, 2003).[1]

Before petitioners' Motion for the issuance of a subpoena regarding Merck's Hepatitis B Recombivax product was to be heard, petitioners noted that respondent's production of the Recombivax product license application (PLA) was not complete. Since petitioners' Request for Production specifically requested production of the *entire* Recombivax PLA (including pages and portions of pages that would otherwise be withheld or redacted in the PLA disclosure and release process), it was apparent that a hearing on the Recombivax issue would be premature. That is, petitioners could not make any showing of necessity for the production of the complete PLA without first reviewing the PLA materials that had been produced.

At least 3200 pages of the Recombivax PLA had yet to be produced as of February 19, 2004, prompting petitioners to request a delay in any further briefing or hearing regarding the

[1] The various filings by petitioner, Merck and the intervening vaccine manufacturers are thoroughly recorded in the docket of the Omnibus Proceeding, and for the sake of brevity those filings are

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necessity of the requested Recombivax discovery from Merck. On February 19 the Special Master, after conferring with petitioner, respondent and the vaccine manufacturers, allowed petitioners' to shift the immediate focus of non-party discovery to the Merck MMR product instead of Recombivax because the government's production of MMR documents was essentially complete.[2]

The Special Master's Order of February 20, 2004, directed petitioners to file and serve the Request for Production of Merck's MMR documents, and directed petitioners to file this Motion showing why issuing a subpoena compelling Merck to produce the requested discovery is reasonable, necessary and for good cause.[3] This matter is set for hearing on May 26, 2004.

II. POINTS AND AUTHORITIES

A. The Special Master Has The Legal Authority To Conduct Third-Party Discovery As Proposed By Petitioners.

A threshold issue is whether the Special Master has the legal authority to issue the requested subpoena and compel the discovery sought by petitioners. As argued in the earlier briefs submitted regarding the Recombivax product, and summarized below, the answer to that question is "yes"—the Special Master has the authority under the relevant statute and rules of court to authorize issuance of the requested subpoena.

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

The Rules of the U.S. 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

——————————— (Cont.)
referenced as necessary herein as they appear on the docket and are not attached.

[2] The Motion requesting a subpoena for Merck's Recombivax documents was withdrawn, and petitioners reserved the right to refile.

[3] In unrecorded telephone conferences involving the Special Master, counsel for the various vaccine manufacturers, and respondent, petitioners indicated that they might submit expert affidavits in support of this Motion. Petitioners, however, are not submitting such affidavits at this point simply because it is virtually impossible to craft an affidavit of "necessity" in a vacuum. That is, an expert cannot offer an opinion as to why production of a particular document is necessary when the expert has no idea what the document might say, or in fact whether the document exists. Petitioners reserve the right

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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 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.

2. <u>The Special Master is Also Authorized to Conduct Third-Party Discovery</u>

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

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to submit affidavits or other forms of expert testimony in their Reply, based on any specific issues raised by Merck's Response.

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such authority. While in Vaccine Court proceedings, the terms "the Court" and "the Special Master" are not synonymous, in this case, the discovery power of "the Court" and "the Special Master" *are* virtually identical, 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 U.S.C. 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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3. Authorizing the Requested Subpoena is Consistent with the Language and Intent of the Vaccine Act.

Merck may again attempt to erroneously argue, as it did in its Recombivax briefs of November 14 and December 29, 2003, that Congress intended to prohibit all discovery of any relevant information exclusively in the control of any vaccine manufacturer.

Congress clearly authorized the Special Master to conduct fact investigations, and recognized that limited discovery might be conducted if it would aid the Special Masters' inquiry:

> "The system is intended to allow proceedings to be conducted in what has become known as an 'inquisitional' format, with the master conducting discovery (as needed) . . . the power of the special master is intended to replace the usual rules of discovery in civil actions in Federal courts."

H.R. Conf. Rep. No. 101-386, 516, 1989 U.S.C.A.A.N. 3018, 3119. The Vaccine Act itself explicitly authorizes discovery that goes beyond merely the parties to the compensation proceeding. 42 U.S.C. §300aa-12(d)(3)(B)(iii) (the Special Master may "require the testimony of any person and the production of any documents as may be reasonable and necessary.") Discovery under the vaccine program's "inquisitional" model is authorized by the rules and the statute where such discovery is "important and necessary" to resolving the Special Master's causation inquiry. *Wittner,* 43 Fed.Cl. at 206.

Petitioners emphasize here that they do not request interrogatories or depositions, that they do not seek discovery of "liability" evidence, and they do not seek discovery of evidence that in a civil action might be relevant to punitive damages. The request for the production of documents is limited to a specific product, for a specific period of time, and seeks specific information about the link between one product and one type of injury. This is a much more limited scope of discovery than would be available to petitioners in the civil litigation setting under the Federal Rules of Civil Procedure, and as such it comports with Congress' grant of discovery power to the Special Master.

It also bears mention that this discovery is part of a consolidated inquiry designed to

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handle nearly 4000 related compensation claims in the program, a unique circumstance that required the Office of the Special Masters to design a process that necessarily includes a much wider use of discovery than would be typical in a proceeding on an individual petition. *See,* Autism General Order No. 1 at 6. The complexity of the scientific and medical issues, the severity of the claimed injuries, and the sheer volume of cases in the Omnibus Proceeding supports the use of more extensive discovery than is usual on a case-by-case basis.

B. The Limited Discovery Requested of Merck is Both Reasonable and Necessary to Resolving the Special Master's General Causation Inquiry.

Petitioners' instant Motion seeks information relevant to a central issue in the Omnibus Proceeding; that is, the general causation question of whether the MMR vaccine can cause autism and the other neurological injuries alleged by claimants in the compensation program. *See, Autism Master File, Autism General Order No. 1,* at 3, 6. By the government's own admissions in various discovery documents and in the public record, there are significant gaps in the scientific picture that Merck should be able to fill in by providing documents responsive to the petitioners' request. Given the gaps in the available scientific evidence produced by the government, the Special Master needs to look elsewhere for the information.

In this case, one may sensibly assume that Merck—with its obligations to provide safe and effective licensed vaccine products and its' decades-long production of the MMR vaccine—is a reasonable place for the Special Master to turn for causation evidence that the respondent admits it does not have. As will be detailed below, non-party discovery by the Special Master is both reasonable and necessary given the information gaps in key areas of the causation inquiry.

First, the Institute of Medicine, the organization chartered by Congress to provide medical and public health advice to the federal government, published in October 2001 a comprehensive review of immunization safety that focused on the possible causal link between the MMR vaccine and autism spectrum disorders (ASDs). While the report concluded that existing epidemiological studies do not support a causal connection between the MMR and

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ASDs, the report carefully qualified that position by noting significant gaps in the science—gaps that may be filled-in by information contained in the requested documents. As described in the reports Executive Summary:

- "[I]t is important to recognize the inherent methodological limitations of such [epidemiological] studies in establishing causality. Studies may not have sufficient precision to detect very rare occurrences on a population level. *Immunization Safety Review: Measles-Mumps-Rubella Vaccins and Autism,* Institute of Medicine, 2001, p.5.

- The passive Vaccine Adverse Event Reporting System (VAERS)—which constitutes a huge portion of the discovery produced by respondent—is "uninformative in assessing causality." *Id.*

- The IOM noted the debate in the United Kingdom surrounding the findings of Wakefield, et al., in support of a biological model of causation. *Id.* at 5-6. The debate over whether vaccine-strain measles infections are causally related to ASDs and inflammatory bowel diseases was central to the MMR litigation in England that is the subject of petitioners final category of requested documents (category "D"). Given the "fragmentary" nature of the biological causation evidence as described by the IOM (*id.* at 6), production of the requested documents is critical.

- Recognizing that the biological etiology of the MMR's possible link to ASDs cannot be disproved based on the reviewed science, and understanding the seriousness of the ASDs injuries such as those suffered by petitioners, the IOM concluded that "all possible etiologies" be considered. *Id.* at 7.

In addition, the Centers for Disease Control website (cdc.gov.nip/vacsafe/concerns/autism) contains a "Frequently Asked Questions" section that discusses the MMR-autism link at several points, and notes the need for additional research to resolve the conflicting conclusions between studies examining issues of biological causation. The CDC site echoes the IOM concerns that the inherent limitations of population studies may fail to detect a causal connection between the relatively rare occurrence of late-onset (or regressive) autism and the MMR vaccine, reinforcing the need for additional data as applied to the specific injury cases before the Special Master.

In short, the investigatory and scientific establishment of the federal government has surveyed the causation landscape and identified serious and significant information gaps that the

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data available to the government cannot fill. These information gaps limit the Special Master's investigation and make third-party discovery necessary.

Petitioners obviously cannot describe what specific information Merck might have that would fill in some of the information gaps in respondent's discovery production, because only the keeper of the information knows what it has. It is reasonable, however, to believe that the manufacturer of a product might have information about the properties and characteristics of its own product that is not generally available to others. Drug companies, for example, often conduct toxicology studies, pharmokinetic studies, clinical trials, product use surveillance programs, and other investigations relating to their products, particularly relating to product safety. It is precisely this sort of limited information regarding Merck's MMR product that petitioners seek, and it is precisely this sort of information that is unavailable through the documents produced in discovery by respondent.

Merck's familiarity with the MMR product that it designed, tested, manufactured and distributed for over twenty-five years is an additional reason for allowing the requested discovery. In *Wittner v. Sec'y Dept. Health and Human Servs.*, 43 Fed.Cl. 199 (1999), the Special Master called as a witness petitioner's treating pediatric neurologist, despite petitioner's objection that the doctor had been retained as a consulting expert and was privy to confidential information about the case. The Special Master found that the doctor's testimony was "important and necessary to the proper resolution of the case" specifically because the doctor could be presumed to have more knowledge about the case than any other witness (*Id.* at 206)—just as Merck likely has more information about its own product than any other source of information identified in respondent's discovery production. Where, as here, a non-party has significant information that the Special Master decides is "important and necessary" to the case, discovery of that non-party is appropriate.

If Merck does not have any information responsive to petitioners' discovery request (at least, information not otherwise available to the Special Master), then it should say so and there

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is nothing to litigate. If Merck, however, does have responsive documents, then their production is necessary to completing the Special Master's causation inquiry, and the necessity for their production supports the authorization of the requested subpoena.

C. Discovery of the Entire, Unredacted MMR PLA is Necessary Because of Significant Gaps in the Documents Produced by Respondent.

As part of the initial phase of discovery in the Omnibus Proceeding, 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." By November 18, 2002 petitioners and respondent agreed on the scope of Request No. 10, and agreed that documents referred to as "Product License Applications" ("PLA's") were the materials most responsive to the requests. Over one year later the responsive documents were completely produced. In reviewing the thousands of pages of documents contained in the Merck MMR PLA, petitioners identified dozens of pages as missing, entirely blank, or so heavily redacted as to be indecipherable. The specific pages are identified in Exhibit B.[4]

This list includes only those missing materials that might reasonably contain relevant material, either because 1) they are preceded or followed by product safety or testing documents; 2) they contain unredacted references to product safety or testing; or 3) their context provides no clue whatsoever to their content, and they may well contain relevant information. The list specifically excludes obviously irrelevant documents (petitioners, for example, do not list the many completely redacted pages that detail Merck's standards for maintaining the chicken coops used to provide the chicken eggs used in the production of components of the MMR vaccine).

Production of the identified pages is necessary because if those pages contain information

[4] Exhibit B is being filed separately and will not be served on Merck until final resolution of any disclosure issues raised by respondent pursuant to the confidentiality requirements imposed by the Vaccine Act on discovery in the compensation program. It is anticipated that those issues will be resolved in a telephone status conference with the Special Master on Wednesday, March 24, 2004.

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relevant to the general causation inquiry, the information by definition is not otherwise available to petitioners; that is, only Merck knows if any relevant information exists, only Merck knows the substance of the information, only Merck knows if the information is duplicative of other documents available to petitioners, and Merck exclusively controls access to the information. Petitioners of course cannot describe with any specificity why information that might be contained in the undisclosed portions of the PLA is "necessary," because petitioners at this point don't have any idea what the documents might contain. Petitioners and the Special Master should at least be permitted to review the withheld documents to make a determination of necessity, unless Merck can demonstrate that the requested documents do not contain any relevant information.[5]

D. The Requested Documents from the United Kingdom Litigation are Necessary to this General Causation Inquiry.

Injury claims arising in the United States alleging a link between the MMR and ASDs are obviously adjudicated in the NVIC program pursuant to the Vaccine Act, but in the United Kingdom hundreds of MMR-autism lawsuits were filed directly in the civil courts. Those claims were coordinated in the "MMR Litigation" proceedings, and Merck (a significant distributor of the MMR in the U.K as well as the U.S.) was one of the principal defendants. Based on information and belief, it is petitioners' understanding that both sides in the U.K. litigation produced reports and statements by various expert witnesses in preparation for a trail beginning in April 2004 that would address issues of causation. It is petitioners' further understanding that the expert reports and statements were essentially complete as of September 30, 2003 when public funding for the plaintiffs' case (through Britain's Legal Services Corporation) was

[5] Petitioners are prepared to conduct this requested discovery of withheld PLA material pursuant to an appropriate protective order issued by the Special Master. Petitioners—severely injured infants and children—have no interest in the trade secrets or confidential business information that might be contained in the withheld portions of the PLA. Merck simply does not face the "disclosure risk" in this instance that it might otherwise face in a proceeding involving a party that is a business competitor of Merck's.

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terminated.[6] In addition, petitioners understand that the various expert reports were designed to provide a comprehensive survey and analysis of the scientific evidence relating to any alleged causal link between the MMR and ASDs, including epidemiology, clinical evidence, biological models of etiology, and the like.

Reports of this type are essential elements of discovery in the U.S. federal court system and in the civil justice systems of the vast majority of states. The federal rules require parties to identify and disclose their experts and to provide expert reports as a matter of course, as well as permitting the deposition of experts. FRCP 26(a)(2). The federal rules require disclosure of all materials provided to the expert, including work product, and even if the expert ultimately did not rely upon the materials in forming the opinion. It is therefore reasonable on its face to believe that "trial ready" expert testimony from all sides in the U.K. litigation is necessary to a thorough evaluation of many of the same scientific issues of general causation as are presented in this Omnibus Proceeding.

There cannot be any hardship or burden imposed on Merck by producing these documents to petitioners and the Special Master—petitioners' request amounts to nothing more than asking for a set of photocopies of readily identifiable, discrete, specific and relevant documents. The experts have been identified and retained, the evidence analyzed, reports written, and conclusions made. There is no undertaking incumbent upon Merck other than sharing the information that is already available. In addition, Merck cannot argue that producing the U.K. expert material would expose Merck to any risk of harm—Merck prepared their expert materials fully expecting them to be disclosed in litigation where Merck was a party, so disclosure in this setting where Merck faces no liability exposure whatsoever cannot pose any risk to Merck. Similarly, Merck presumably has the plaintiffs' expert statements and reports and prepared rebuttals and cross-examinations based on those documents, so there can be no element of additional risk posed by sharing them in this proceeding where Merck need not be concerned

[6] Review of the decision to terminate public funding was denied in February 2004.

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with any liability exposure.

For all of these reasons, there is good cause for seeking from Merck those expert reports that address central issues of general causation in the MMR-autism inquiry, and good cause is evident on the face of the request. Such discovery is available as a matter of course in civil litigation in virtually every jurisdiction in the Untied States, and it ought to be pursued in this matter involving many hundreds of seriously injured children.

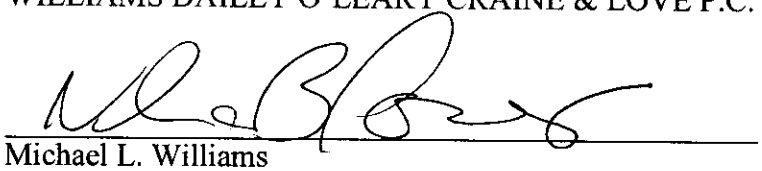
III. CONCLUSION

For all of the reasons described above there is good cause for pursuing the limited, specific and facially relevant discovery requested by petitioners. It is reasonable to believe that scientific and medical information known to Merck, but not known to petitioners, is necessary to a thorough development of the evidence in these consolidated claims. It is also reasonable to require production of the limited, specific and facially relevant requested discovery where it is available only to Merck and not otherwise available to petitioners or the Special Master. Merck assumes no onerous burden and suffers no hardship by producing information that it already has, readily available, in a setting where Merck faces no liability or any demand on its purse.

Petitioners' Motion should be granted, the Special Master should authorize a subpoena, and Merck should be required to produce the requested documents.

DATED this 22nd day of March, 2004.

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



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A

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 **Petitioners' Steering Committee's Request for the Production of Documents: Merck & Company, Incorporated**

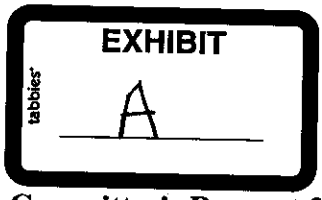
TO: MERCK & COMPANY, INC., ("MERCK") AND ITS ATTORNEYS

PLEASE TAKE NOTICE that pursuant to 42 USC §300aa-12(d), RCFC 34 and 45, and Vaccine Rule 7, you are directed to produce to the Petitioners' Steering Committee 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 "MMR," consisting of the combined vaccines for measles, mumps and rubella.



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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 MMR. 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 include all documents or portions of documents that were withheld, redacted, or otherwise made unavailable to petitioners in those MMR PLA documents already delivered to petitioners by the respondent.

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 Produce documents relating to:

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 MMR or the single-antigen measles component thereof.

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

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

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

Produce 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 safety, or concerns about the safety, of MMR or the single-antigen measles component thereof.

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

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

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

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

3. Copies of any expert reports, summaries, witness statements and depositions prepared by any other party to the UK MMR litigation and served on Merck.

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DATED this 25th day of February, 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

(Exhibit B has been filed into the Master Autism File, but is not being placed on the website for the Omnibus Proceeding due to the provisions of 42 U.S.C. § 300aa-12(d)(4)(A).)

CERTIFICATE OF SERVICE

I hereby certify that on March 22, 2004, I served the foregoing **PETITIONERS' MOTION TO ISSUE SUBPOENA TO MERCK & CO., INC., RE THE "MMR" VACCINE** on the following individual(s):

Vincent Matanoski
U.S. Department of Justice
Tort Branch, Civil Division
1425 New York Avenue, N.W., Room 3126
Washington, DC 20005

Mark Raby
U.S. Department of Justice
Tort Branch, Civil Division
1425 New York Avenue, N.W., Room 3126
Washington, DC 20005

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

Dino Sangiamo
Venable, LLP
1800 Mercantile Bank & Trust Bldg.
2 Hopkins Plaza
Baltimore, MD 21201

by United Parcel Service, next morning delivery.

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

cc: George Hastings, Special Master
U.S. Court of Federal Claims
Office of the Special Master
529 14th St. N.W. #302
Washington, D.C. 20045

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