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 DEVELOPMENTAL DISORDER,

Petitioner

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent

AUTISM MASTER FILE

Petitioners' Response to Merck and Amicus Curiae re Non-Party Discovery

I. INTRODUCTION

The Special Master should authorize the issuance of a subpoena directing Merck & Co., Inc. to comply with petitioners' Request for the Production of Documents pursuant to Vaccine Court Rule 7 and the Rules of the US Court of Federal Claims. Conducting third-party discovery in this instance is both reasonable and necessary, despite the protestations of Merck and those vaccine manufacturers who submitted *amicus* briefs to the Special Master. Allowing petitioners' limited inquiry into information that the manufacturers might have regarding the specific causation questions at issue in the Omnibus Proceeding is entirely consistent with the letter and spirit of the Vaccine Act and the rules of both the Court of Claims and the Vaccine Program.

The briefs of the vaccine manufacturers simultaneously underestimate the need for the requested information in resolving the causation questions presented by the Omnibus Proceeding, and greatly exaggerate the potential burden imposed by petitioners' request for relevant causation information in their effort to hide behind the limited "litigation shield" provided by the Vaccine Act. The manufacturers' overstated argument fails for three reasons.

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First, by focusing exclusively on the supposed burden of complying with limited causation discovery requests, the manufacturers completely ignore the Vaccine Act's stated goal of providing a fair, generous and expeditious process for compensating vaccine-injured children.

In addition, the manufacturers' memoranda regularly confuse the legislative intent to dramatically reduce the industry's *liability* exposure with a wholly imagined legislative intent to absolve the industry from any responsibility to provide factual information necessary to resolving issues of causation in thousands of cases in the vaccine compensation program. Petitioners are not suing the manufacturers and make no other claim on the corporate purse, and petitioners are not trying to draw the industry into litigation via the vaccine compensation program. To the contrary, petitioners sought to obtain the information from Merck cooperatively, and Merck chose to litigate the matter.

Finally, the petitioners do not seek information regarding issues of negligence, fault or liability. That inquiry likely would be inappropriate in the vaccine program's "no fault" system, and that is the type of inquiry that Congress sought to avoid in developing the compensation program. Instead, petitioners simply want to know what the industry knows about whether thimerosal or the MMR vaccine, or a combination thereof, can cause the autistic disorders and other neurological injuries suffered by the thousands of children with claims in the program.

Petitioners' request for authority to issue a subpoena is reasonable and necessary, and should be granted.

II. ARGUMENT

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

Petitioners seek information relevant to the central issue in the Omnibus Proceeding; that is, the general causation question of whether the MMR vaccine, the thimerosal component of other vaccines, or a combination of the two, 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. Merck and the other vaccine manufacturers take the remarkable position

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that all of the information and evidence the Special Master needs is contained in discovery produced by the respondent in the Omnibus Proceeding. *See, e.g.,* Merck's Response, pp. 8-9. Merck incorrectly believes that merely because respondent has produced "many thousands of pages" of documents, the Special Master and petitioners have all the relevant evidence needed to conclude the causation analysis. *Id.*

Petitioners would not seek the requested information from Merck, however, if the government documents produced so far in discovery provided the information needed to resolve the inquiry. 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. The gaps in the available science are described in various government sources as outlined below. Given the paucity of causation evidence produced by the government and available to petitioners, 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 use of thimerosal, including the use of thimerosal in the Hepatitis B product at issue—is a reasonable place for the Special Master to turn for causation evidence that the respondent admits it does not have. Petitioners do not disagree with Merck's argument (Merck's Response, pp. 4-6) that third-party discovery in the vaccine injury program requires a showing of necessity. Indeed, petitioners need only describe the information gaps identified by the respondent's own document production to provide a sufficient showing of necessity for the authorization to issue for the requested subpoena. 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 thimerosal-containing vaccines and neurodevelopmental disorders. The report concluded that

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the link between thimerosal in vaccines and neurodevelopmental disorders was "biologically plausible," but noted significant gaps in the evidence necessary to decisively answer the causation question:

- "The data regarding toxicity of low doses of thimerosal and ethyl-mercury are very limited, and only delayed-type hypersensitivity reactions have been demonstrated." *Immunization Safety Review: Thimerosal-Containing Vaccines and Neurodevelopmental Disorders,* Institute of Medicine, October 2001, pp. 3 and 27.

- There is a need for "far more evidence of the risks and benefits associated with thimerosal-bearing vaccines." *Id.* at 7.

- The IOM "is unaware of risk assessments of thimerosal in pharmaceutical products" and recommends risk-based research. *Id.* at 9.

- The report discusses at length the lack of data regarding the toxicity or safety of ethyl mercury, the primary constituent of thimerosal. *Id.* at pp. 39-42.

- The report further details the lack of information about low doses of thimerosal, particularly noting the absence of toxicity data for the doses of thimerosal found in the pediatric vaccine schedule. *Id.* at 44-46.

- The IOM explicitly recognizes the gaps in science by recommending a number of biomedical, clinical, epidemiological, and basic scientific research areas in order to develop the evidence. *See, id.,* at pp. 8-13.

Additional government documents produced in discovery paint a similar picture of fundamental evidentiary gaps in the scientific picture of thimerosal and neurodevelopmental causation. The Food and Drug Administration's Center for Biologics Evaluation and Research website, for example, currently contains a "Frequently Asked Question" page (www.fda/cber.gov) that specifically identifies areas where evidence of causation is incomplete:

- "Additional studies to fill in gaps in our knowledge, such as whether the regressive subtype of autism is causally related to thimerosal in vaccines, is warranted."

- "Whether there is, or is not, any synergistic biological interaction between aluminum and mercury [in vaccine products] is unknown."

Similarly, the Environmental Protection Agency (EPA) and the Agency for Toxic Substances and Disease Registry (ATSDR) have identified the limited toxicological and pharmokinetic data regarding ethyl-mercury and thimerosal as an obstacle to setting science-

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based safety guidelines, exposure levels, and risk analyses. Both the EPA and ATSDR have also described the lack of data available describing the human health effects of low doses of ethyl-mercury and thimerosal.

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 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 and the other manufacturers might have that would fill in some of the information gaps described by respondent's discovery production, because only the keeper of the information knows what it has. It is reasonable, however, to believe that the manufacturers of a product might have information about the properties and characteristics of their 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 thimerosal-containing HepB 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 Recombivax product that it designed, tested, manufactured and distributed for over a decade 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

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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 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.

B. Authorizing the Requested Discovery is Within the Special Master's Authority Under the Vaccine Act.

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.

Merck incorrectly attempts to argue that the Special Master cannot authorize the requested subpoena. The Vaccine Rules, however, 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

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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. Upon a finding of good cause for non-party discovery, the Special Master may authorize petitioner to issue a subpoena in the form provided by the Vaccine Rules (Form 7A).

At best, Merck's procedural argument that the Special Master lacks authority to issue a subpoena makes a distinction without a difference. Whether the subpoena issues from petitioners with the Special Master's authority, or from the Court of Claims with the Special Master's approval changes nothing—the Special Master is empowered by V.R. 7(c) and RCFC 45 to decide that a subpoena is reasonable and necessary, and a subpoena issued based on such a finding may be directed to a non-party and is enforceable by the U.S. Court of Claims.

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.[1]

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

[1] Merck in fact concedes that the Special Master's discovery power is more limited than the discovery rights of parties under the Federal Rules. Merck's Response at 5-6.

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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.

The Office of the Special Masters created the Omnibus Proceeding to handle the unique demands the autism caseload presents to the program.[2] The Special Masters have generally authorized discovery in the Omnibus Proceeding, and that discovery—including the limited non-party document requests made by petitioners—is entirely consistent with the letter and the spirit of the statute, the rules of the Court of Claims, the rules of the Vaccine Court, the legislative history of the statute, and the relevant case law.

C. The Reasonable and Necessary Discovery of Causation Evidence from the Vaccine Manufacturers is Consistent with the Legislative Intent of the Vaccine Act.

The vaccine manufacturers have a uniquely myopic vision of the legislative purposes of the Vaccine Act, glossing over the explicit interest the petitioners have in Congress' promise of a vaccine compensation program that handles claims "quickly, easily, and with certainty and generosity." H.R. Conf.Rep. No. 101-386 (1989), 1989 U.S.C.C.A.N. 3018, 3115. As the record of the Omnibus Proceeding makes clear, the administration of these related autism claims has been frustratingly slow. Respondent, for example, first indicated in correspondence of January 3, 2003 that it would produce Product License Application documents (PLAs) in response to petitioners' Request for Production (filed in August 2002). Subsequent discussions indicated that at least 40 PLAs would likely be included in the document production. To date, however, petitioners have received only 3 PLAs, almost one full year after production began. Petitioners note that Congress contemplated a system that could adjudicate claims in less than one year (as provided by the 240-day "opt-out" provision at 42 U.S.C. §300aa-21); surely the

[2] The vaccine manufacturers make the rather obvious point that no Special Master has issued a subpoena to compel the production of documents from a vaccine manufacturer. *See, e.g.*, Brief of *Amicus Curiae* Aventis Pasteur at p. 7; Merck's Response at 6, fn. 4. The unique challenge of adjudicating cases in the Omnibus Proceeding, however, calls for unique discovery responses by the Special Master.

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inability to complete one aspect of discovery within one year is a slower result than the Vaccine Act anticipated.

The speed of discovery in these cases is not merely of academic interest. The vaccine manufacturers need to remember that there are some 4000 severely injured children in the Omnibus Proceeding, and that many of those children need significant medical care and concerted speech, behavioral and social therapies, and that many will require professional or institutional assistance in their daily activities. Additionally, some of those children might benefit substantially from intervention that is early rather than late, and that for many there is a "window of opportunity" where treatment can partially reverse or mitigate their injuries. The window of opportunity, however, closes with time, and the later interventions may well be less effective. Petitioners have a very real medical interest in quick and fair consideration of their claims—the current pace of PLA production is moving so slowly that it conflicts with the petitioners' interest in an expeditious proceeding.

The manufacturers are not being asked to pay compensation, only to provide responses to relevant and limited discovery requests so that the Special Master can fulfill his mandate to provide speedy compensation hearings. In the "balancing test" urged by the amicus briefs of the various manufacturers, the interest of thousands of severely injured children and their families (and the Special Master) in quickly collecting the information needed to conclude a fair and prompt causation inquiry outweighs the manufacturers' interest in wanting to avoid the cost and bother of collecting and photocopying responsive documents.

Just as the vaccine manufacturers ignore or underestimate the extent to which Congress intended to protect the interests of claimants in the program, they grossly overstate the degree to which Congress intended to remove them from any involvement in the vaccine injury

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compensation system. There is no doubt that Congress sought to insulate vaccine manufacturers from *liability* relating to vaccine injuries—that is the point of the legislative history language cited by Merck in its brief at pp. 2-3; Aventis in its brief at p. 3; Wyeth's memorandum at p. 4; and Baxter in its brief at p. 3. The manufacturers overstate their case, however, by contending that any request from the Special Master for information needed to adjudicate claims in the Omnibus Proceeding is by definition contentious, adversarial and litigious. That simply isn't the case.

The non-party discovery at issue is adversarial and litigious only because the manufacturers have decided to make it so. Petitioners contacted Merck and informally sought the needed documents, and Merck refused. The other manufacturers chose not even to wait for an informal inquiry before launching into full litigation mode before the Special Master. The manufacturers misrepresent the discovery request at issue as "full-blown" discovery. It clearly is not. As described earlier in this brief, petitioners do not seek liability discovery, they propound no interrogatories or requests for admissions, they notice no depositions, and they limit the inquiry to a specific product, for a specific period of time, and seek only causation evidence relevant to the causation theory in the injuries at issue in the Omnibus Proceeding.[3]

Finally, the manufacturers' insinuation that petitioners have an "ulterior motive" in seeking necessary and relevant information from non-parties is in equal parts nonsensical and

[3] The vaccine manufacturers' claim that the RFP directed to Merck is the equivalent of "full-blown civil discovery" is disingenuous. The manufacturers know that RFPs involving pharmaceutical or "toxic tort" lawsuits in the civil justice system are dramatically more expansive than petitioners' modest request in this case. These same manufacturers, for example, were served with document requests in an Oregon state court case involving vaccine injuries (*Eleanor Mead, et al. v. Aventis Pasteur, et al.*, Multnomah County Cir. Ct. Case No. 0107-07137. The case was eventually dismissed and is currently on appeal to the Oregon Court of Appeals). Those RFPs contained 71 requests, and addressed issues far beyond the limited causation issues presented by petitioners here. The manufacturers know what full-blown civil discovery looks like, and they know that what petitioners seek in this instance is *not* full-blown civil discovery.

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offensive. The "ulterior motive" allegation is pure nonsense because it defies common sense to believe that petitioners would decide that the admittedly limited, restrictive, discretionary discovery available in the vaccine program could somehow serve as the surrogate for the much more expansive discovery available *as a matter of right* in the federal and state courts. The "ulterior motive" allegation is offensive because it assumes that petitioners are abusing the vaccine compensation program. Nothing could be further from the truth. The petitioners and their counsel have made every effort to make the Omnibus Proceeding work, they are pursuing the best possible remedies available to them under the law, they are doing so with a significant commitment of energy and resources, and they are doing so in good faith.

Petitioners who want withdraw from the program to pursue civil litigation certainly have that option, and any petitioner exercising that option has access to the discovery tools available in the civil justice system. Any petitioner seeking expansive discovery from a vaccine manufacturer in order to support a civil lawsuit can simply file a lawsuit after properly withdrawing from the program. To imply that those petitioners remaining in the program are motivated in this non-party discovery action by anything other than securing the best possible compensation available to them in the program is totally without foundation.

Congress intended that the Special Master have the power to conduct limited discovery where it was needed to ensure that the vaccine injury compensation met its goal of providing the fair and speedy resolution of claims. In this case, the discovery is reasonable and necessary, it is appropriately limited, and there is no threat whatsoever that the manufacturers will face the liability exposure that Congress sought to avoid.

D. Merck is not Entitled to "Other Material" Available to the Special Master.

Citing not a single authority, Merck erroneously claims that it is entitled to demand that

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the Special Master turn over the entire discovery between petitioners and respondent to Merck so that Merck can sit in judgment over decisions about what is or is not necessary to the Special Master's adjudication of the causation inquiry. Merck apparently wants to have its cake, and eat it, too—complaining on the one hand that petitioners' RFP creates an imagined litigation burden, while on the other hand proposing collateral litigation over the issue of "necessity." Merck cannot have it both ways, and Merck cannot substitute its finding of necessity for the Special Masters' discretionary determination of necessity.

Merck's proposal amounts to the remarkable requirement that petitioners and respondent put on their entire cases for causation for Merck's review, imposing a huge burden on the parties merely so that Merck can pick and chose which corporate documents it will collect and photocopy. It is not surprising that Merck cannot cite to any legal source of such an imagined right. In addition, Merck's request should be denied because it would require the disclosure of petitioners' and respondents' experts testimony before the parties are ready to file any expert reports or affidavits in the general causation hearing. Merck would also impermissibly require the disclosure of petitioners' work product by inquiring into what petitioners plan to do with any future access to CDC data related to causation issues.

Finally, Merck's request should be denied because it is prohibited by the Vaccine Act. Under the statute, "information submitted to a special master or the court in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express written consent of the person who submitted the information." 42 U.S.C. §300aa-12(d)(A)(4). Congress sought to keep the administrative claims program and the civil justice system completely distinct by prohibiting the disclosure of inter-party discovery to non-parties. Further evidence of the distinction between the program and the courts is found in the statute's bar to the admissibility of any of the Special Masters' findings of fact or conclusions of law in subsequent civil litigation involving a claimant. 42 U.S.C. §300aa-23(e). Merck clearly is trying to use this opportunity to gain a "sneak preview" of potential liability cases it might face from petitioners who either withdraw from the program or reject a judgment in the program. As such, this

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backdoor effort to circumvent the nondisclosure requirement of the Vaccine Act should be denied.

E. Merck is not Inappropriately being "Singled Out" For Discovery

Petitioners have made it clear that they intend to request that the Special Master authorize other subpoenas to other vaccine manufacturers seeking relevant causation evidence relating to other vaccines at issue in the Omnibus Proceeding. In that sense, Merck is not being "singled out." Other vaccine manufacturers apparently don't feel that Merck is singled out, as they have weighed in with adversarial *amicus* briefs in the absence of any formal or informal requests for information from the Special Master or petitioners. In addition, it is rational for the Special Master to examine what is a matter of first impression on a case-by-case basis, addressing the overarching legal and procedural issues in this first instance in order to establish the parameters governing similar requests in the future. There is nothing arbitrary and capricious in making discovery decisions in the sequence in which the discovery dispute arises, a process clearly outlined in the Special Masters' Order of October 30, 2003 and in the Special Master's Update of November 7, 2003.

Merck's claim that the Special Master is acting without any "reasoned basis" in resolving petitioners' Motion for authority to issue a subpoena is wholly without merit, and the subpoena should be authorized.

F. Production of the PLAs Subject to a Protective Order is Appropriate.

Merck's argument that trade secrets are absolutely off-limits in discovery fails because the cases Merck relies on[4] depend on a critical fact not present in these cases; that is, discovery of trade secrets subject to a protective order was prohibited because all of the parties to the discovery dispute were competitors in the market. Motions to compel the disclosure of trade secrets in each case was denied because, as the *American Standard* opinion describes, disclosure

[4] *Westinghouse Electric Corp. v. Carolina Power and Light,* No. 91-4288, 1992 WL 370097 (E.D. La. Nov. 30, 1992); *American Standard, Inc. v. Pfizer, Inc.,* 828 F.2d 734 (Fed.Cir. 1987); *Allen v. Howmedica Leibinger,* 190 F.R.D. 518 (W.D.Tenn. 1999).

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would effectively include all of the discloser's competitors. 828 F.2d at 741. In this case, the petitioners and respondent would be the only parties to whom the information would be disclosed, and Merck would suffer no economic harm if the trade secrets were known by a group of DOJ attorneys and neurodevelopmentally injured children and their attorneys. The economic harm argument central to Merck's authorities simply does not exist in this case.

Moreover, petitioners do *not* concede, as Merck incorrectly claims, that the trade secret information in the PLAs is "irrelevant." Merck's Response at p. 18. It is petitioners' position that the PLAs are missing documents (either redacted or simply unaccounted for in the document numbering system created by respondent) that may well be relevant. Petitioners of course cannot make a case for the relevance of documents that petitioners cannot see, but petitioners may reasonably believe that relevant information is being withheld when pages that appear to relate to product testing or product safety are blank, redacted or missing. At the very least, petitioners are entitled to the Special Master's *in camera* review of the redacted material for a determination of relevance. If relevant, the issues of privilege and disclosure may then be resolved on a document-by-document basis under the "balancing test" applicable to the disclosure of potentially secret or confidential materials subject to a protective order.

III. CONCLUSION

The Special Master should authorize the issuance of petitioners' requested subpoena to Merck pursuant to Vaccine Rule 7 and the RCFC. The non-party discovery subject to the subpoena is reasonable and necessary to the Special Master's inquiry into the issues of general causation in the Omnibus Proceeding. Authorizing the subpoena is within the Special Master's authority under the Vaccine Act, the RCFC and the Vaccine Rules. Furthermore, conducting this non-party discovery is entirely consistent with the letter and the spirit of the Vaccine Act's explicit goals of providing fair and speedy resolution of compensation claims in the NVIC program. In addition, the requested discovery is appropriately limited and does not implicate the Vaccine Act's goal of reducing the liability exposure of the vaccine manufacturers.

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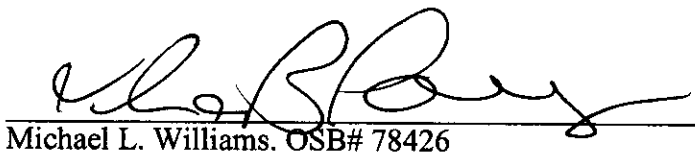
There is nothing arbitrary about resolving the non-party discovery issue on a case-by-case basis as an initial matter, and any trade secrets that might be disclosed by the requested discovery can be fully protected by an appropriate confidentiality or protective order.

For all of these reasons, the Special Master should authorize petitioners to issue a Form 7(A) subpoena to Merck & Co., Inc., for the production of documents in the Omnibus Proceeding.

DATED this 10th day of December, 2003.

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



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December 10, 2003

VIA OVERNIGHT MAIL

Clerk of the Court
U.S. Court of Federal Claims
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Re: Petitioners' Response to Merck and Amicus Curiae re: Non-Party Discovery

Dear Clerk:

Enclosed for filing please find the original and a copy of Petitioners' Response to Merck and Amicus Curiae re: Non-Party Discovery.

Thank you.

Sincerely,

Thomas B. Powers

TBP/dk

c: Vince Matanoski, U.S. DOJ
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December 10, 2003

VIA OVERNIGHT MAIL

Special Master George Hastings
U.S. Court of Federal Claims
717 Madison Place, NW
Washington, DC 20005-1011

Re: Petitioners' Response to Merck and Amicus Curiae re: Non-Party Discovery

Dear Special Mater Hastings:

Enclosed is a courtesy copy of Petitioners' Response to Merck and Amicus Curiae re: Non-Party Discovery. This document was filed with the clerk of the court today, and served on all parties as specified in the attached certificate of service.

Thank you

Sincerely,

Thomas B. Powers

TBP/dk

c: Vince Matanoski, U.S. DOJ
Ghada Anis, P.S.C.
Bradley S. Wolff
Marcy Hogan Greer
Donna Brown Jacobs
Maria Rodriguez
Raymond G. Mullady, Jr.

CERTIFICATE OF SERVICE

I hereby certify that on December 10, 2003, I served the foregoing **Petitioners' Response to Merck and Amicus Curiae re Non-Party Discovery** on the following individual(s):

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