ORIGINAL

UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

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

Various Petitioners,

-against-

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Autism Master File

WYETH'S MEMORANDUM, AS AMICUS CURIAE, IN OPPOSITION TO PETITIONERS' MOTION TO ISSUE REVISED THIRD PARTY SUBPOENA

INTRODUCTION

Wyeth respectfully submits this memorandum of law, as amicus curiae, in opposition to Petitioners' Motion to Issue Revised Third Party Subpoena ("Motion"). While Petitioners' Motion encloses only a proposed subpoena to Merck & Company, Inc. ("Merck"), the Motion expressly anticipates that essentially the same proposed subpoena would be directed to the manufacturers of, inter alia, all of the thimerosal-containing vaccines that are relevant to the Omnibus Autism Proceeding. Motion at 5. Prior to 2001, and during time periods relevant to this proceeding, Wyeth manufactured and distributed several types of vaccines containing thimerosal, including but not limited to: diphtheria, tetanus and whole cell pertussis vaccine ("DTP"); diphtheria, tetanus and acellular pertussis vaccine ("DTaP"); haemophilus influenza vaccine; and a combination DTP/haemophilus influenza vaccine. Accordingly, if petitioners are permitted to proceed with non-party discovery aimed at vaccine manufacturers, Wyeth reasonably anticipates that it will receive one or more subpoenas seeking, as to its multiple

vaccines, the types of documents requested of Merck with respect to its hepatitis B vaccine, marketed under the trade name Recombivax HB.

Petitioners' proposal for non-party discovery should be rejected, because it is in direct contravention of the plain language and intent of the Vaccine Act and its implementing rules, as the proposed discovery would go far beyond what is "reasonable and necessary" to these compensation proceedings. Indeed, Petitioners' ambitious discovery agenda, if adopted by the Court, would effectively replicate in Vaccine Court the expensive civil litigation discovery process that the Vaccine Act was enacted in large part to protect manufacturers against. Permitting such discovery would not be a reasonable exercise of the Special Master's authority. Petitioners' requests seek broad discovery relating to Merck's knowledge and conduct (including communications with the government and unpublished studies) that is largely irrelevant and lacks probative value in these proceedings, even under relaxed evidentiary standards. That discovery is therefore neither reasonably required nor necessary for resolution of the sole issue to be resolved in these proceedings: causation. To the extent any of the requested material may be marginally relevant to the petition, much of it is already available from the Respondent, and elsewhere, and thus seeking it from Merck is plainly neither necessary nor reasonable.

The compensation process established by Congress in the Vaccine Act is designed to be an inquisitorial process to determine causation-in-fact, without regard for fault, without replication of the adversarial process of civil litigation, and indeed with only so much discovery as is necessary for the Special Master to rule on causation-in-fact and damages. Even, however, under the broad discovery rules generally applicable in federal civil litigation, the discovery sought by Petitioners would appropriately be denied, because it would impose an undue burden upon non-parties. *A fortiori*, the markedly more restrictive non-party discovery standards

established under the Vaccine Rules and the Vaccine Act – designed to protect the very non-party against whom Petitioners seek to issue the proposed subpoena – compel denial of Petitioners' Motion in its entirety.

ARGUMENT

I. THE SPECIAL MASTER IS AUTHORIZED TO APPROVE THE ISSUANCE OF A SUBPOENA ONLY TO THE EXTENT "REASONABLE AND NECESSARY" TO A DETERMINATION OF CAUSATION

In granting discovery powers to the special masters, Congress explained that those powers should not be used to re-create an adversarial process, and that "[t]he system is intended to allow the proceedings to be conducted in what has come to be known as an 'inquisitorial' format, with the master conducting discovery *(as needed)* . . . ." H.R. 101-386 at 516 (1989) (emphasis added). The Vaccine Act accordingly provides that "the Special Master, in a proceeding on a petition, may require . . . the production of any documents as may be *reasonable and necessary*." 42 U.S.C. § 300aa-12(d)(3)(B) (emphasis added). Consistent with the Vaccine Act, Vaccine Rule 7(c) provides that *"[w]hen necessary*, the special master upon request by a party may approve the issuance of a subpoena." Vaccine Rule ("VR") 7(b) (emphasis added).

No proof of negligence or product defect is required in a compensation proceeding. Rather, causation is the *only* liability issue that is to be determined, and thus is the only issue with respect to which any discovery could be reasonable or necessary. As Congress has expressly instructed, "[b]ecause the only issues relevant to the compensation proceeding are whether the petitioner has suffered a compensable injury and, if so, the extent of the compensable damages, there should be no need for a wider inquiry, which might be appropriate in a civil action raising other issues." H.R. Rep. No. 99-908 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6357.

II. THE PROPOSED NON-PARTY DISCOVERY IS UNREASONABLE IN LIGHT OF CONGRESS'S INTENT TO PROTECT VACCINE MANUFACTURERS FROM LITIGATION COSTS

Congress enacted the Vaccine Act as a result of two overriding concerns: (1) the inadequacy of the traditional tort system for compensating vaccine-injury claimants in a fair and expeditious manner, and (2) the financial burdens imposed upon vaccine manufacturers by traditional tort litigation, which threatened the national vaccine supply. *See* H.R. Rep. No. 99-908 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6347-48, 6353-54. Congress "anticipate[d] that the speed of the system, the no-fault nature of the required findings, and the relative certainty and generosity of the system's awards will divert a significant number of potential plaintiffs from litigation." 1986 U.S.C.C.A.N. 6344, 6354. Petitioners' proposed subpoena to Merck would subvert Congress's intent by imposing upon a non-party the burden of an expensive discovery process (perhaps the most burdensome aspect of litigation) before these petitioners are even allowed to commence civil actions against Merck in state or federal district court. Moreover, by effectively turning petitioners and Merck into Vaccine Court adversaries – even though the Secretary is the only respondent to Vaccine Court proceedings – the broad non-party discovery requested by petitioners would contravene Congress's intent that potential civil litigation plaintiffs take a first, hard look at the vaccine compensation program *before* pursuing potential tort claims against vaccine manufacturers. 1986 U.S.C.C.A.N. 6344, 6347-48. Indeed, the very real possibility exists that the Vaccine Court will be converted into a facilitator of increased civil litigation – a consequence that would indeed turn congressional intent on its head.[1] Under these circumstances, the Special Master cannot reasonably authorize issuance of the proposed subpoena.

[1] Petitioners' ulterior purpose of utilizing these proceedings to facilitate civil litigation was clearly revealed in Petitioners' original Request For Production of Documents from Merck. That original Request sought

III. THE PROPOSED NON-PARTY DISCOVERY SEEKS INFORMATION THAT CAN BE OBTAINED FROM OTHER SOURCES

It is unreasonable to subject a vaccine manufacturer – which by design cannot be a party to vaccine compensation proceedings – to onerous discovery such as that proposed here. Indeed, the subpoena proposed here would not even survive a challenge under the liberal discovery standards of the Federal Rules of Civil Procedure. It is well established, under the Federal Rules of Civil Procedure as well as the Claims Court rules, that discovery is not available from non-parties where the information sought can be obtained from parties and other sources. *Haworth, Inc. v. Hermana Miller, Inc.*, 998 F.2d 975, 978 (Fed. Cir. 1993) (holding that the district court properly denied a motion to compel non-party production of documents where the requesting party had not sought discovery from a party before burdening the non-party); *Carl Zeiss Stiftung v. V.E.B. Carl Zeiss, Jena*, 40 F.R.D. 318, 328 (D. D.C. 1966) (refusing to order non-party production where the documents were privileged and available from other sources); *Anker v. G.D. Searle & Co.*, 126 F.R.D. 515, 521-522 (M.D.N.C. 1989) (holding that the requesting party did not demonstrate a substantial need for the information where the information could be obtained from other sources); *Westinghouse Elec. Corp. v. Carolina Power and Light Co.*, No. 91-4288, 1992 WL 370097, at *1 (E.D. La. Nov. 30, 1992) (same). Here, Petitioners improperly attempt to obtain discovery from non-party Merck that can be obtained from other sources.

Moreover, Petitioners' proposed requests are extensive. In addition to seeking unredacted product license applications, including trade secret information, Petitioners seek unpublished studies, studies in Merck's possession but produced by others, and documents

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information conceivably relevant to fault, but having no conceivable relevance whatsoever to causation, such as documents relating to the financial implications of utilizing multi-dose vials rather than single-dose vials of

relating to Merck's communications with the government, including documents identifying Merck employees who participated in the "Simpsonwood meeting."

First, with respect to vaccine license applications, the Special Master's Autism Update and Order, dated September 24, 2003, ("9/23 Update"), notes that those applications are being produced by the Respondent, albeit at a slow pace. Since they are being produced, it is plainly not necessary to subpoena those documents from a non-party vaccine manufacturer. Nor have Petitioners shown why it is necessary for Merck or any vaccine manufacturer to disclose trade secret information that is redacted from the product license applications available from Respondent.

Second, it is not necessary to subpoena Merck in order to obtain communications between it and the government, because such communications can be, and have already been, requested from Respondent (*see* Request 13 of Petitioners' Requests to Respondent at 22), and the production of such information has already begun, *see* 9/23 Update at 2 – 4.

Third, with respect to the requests for published research studies, such studies are, by definition, available in the public domain.

The one category of requested information that could not generally be expected to be available from other sources is the set of requests for unpublished product safety research conducted by a vaccine manufacturer. As to that category of requests (as further discussed below), requiring the production of unpublished research conducted by a vaccine manufacturer would not be reasonable or necessary to the causation inquiry, in light of the more appropriate and readily available alternatives.

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vaccines. *See* Request for Production of Documents: Merck & Company, Incorporated, attached to Motion to Issue Third Party Subpoena, filed October 7, 2003, at 4.

IV. THE PROPOSED NON-PARTY DISCOVERY SEEKS EVIDENCE THAT IS LARGELY IRRELEVANT, AND UPON WHICH THE COURT COULD NOT REASONABLY RELY IN DETERMINING CAUSATION

To the extent that the proposed subpoena seeks documents concerning Merck's knowledge and conduct (in particular, unpublished research studies conducted by or known to the vaccine manufacturers), Petitioners seek information that is largely irrelevant, and of only marginal reliability. In support of their request for such information, Petitioners fail to cite, and cannot cite, any Vaccine Court case in which *any* discovery, of any type, has ever been required from a vaccine manufacturer. Furthermore, the cases that Petitioners do cite, which come up outside the Vaccine Court context, actually illustrate why Petitioners proposed discovery would be impermissible even under the ordinary federal or Claims Court rules of civil procedure.

In *Capital Partners,* cited in Petitioners' Motion at page 6, the operator of a parking garage adjacent to a railroad sued the Federal Railroad Administration ("FRA") for alleged breach of the contract for operation of the garage, following the FRA's failure to approve parking rate increases for certain railroad passengers. *See Capital Partners , Inc. v. United States*, 49 Fed. Cl. 607, 609-10 (Fed. Cl. 2001). The plaintiff garage operator sought to depose non-party Amtrak concerning, among other things, the meaning of certain disputed contractual terms, as those terms are used generally in the railroad industry. *See id.* at 612. The court found that the plaintiff was essentially seeking an expert opinion from Amtrak, and that the plaintiff had failed to demonstrate that such an expert opinion could not be obtained from other sources. *Id.* The court further noted that "whether Amtrak has ever 'taken a position' about the meaning of these terms is not relevant to this litigation."[2] *Id.* Thus, the court granted Amtrak's motion for a protective order prohibiting the discovery sought by the plaintiff. *Id.* Similarly, the non-

[2] The court permitted limited discovery from Amtrak concerning the meaning of certain terms as they were used in a specific contract between Amtrak and one of the parties to the litigation. *See Capital Partners* at 612.

party discovery proposed by the Petitioners here essentially seeks from Merck an expert opinion concerning thimerosal safety, notwithstanding that Petitioners can obtain such an expert opinion elsewhere. Moreover, Merck's positions regarding thimerosal safety, while they might be relevant to tort claims, are not the sort of evidence upon which this Court could reasonably rely to determine whether thimerosal, as a matter of fact, causes autism or other neurological disorders. A substantial body of public, peer-reviewed research is available, as set out at pages 12-14 of Merck's opposition brief, in which Wyeth joins. It is appropriate for the Court to examine the publicly available research, and neither reasonable nor necessary for the Court to require production of any additional, unpublished research from a non-party vaccine manufacturer.

The Immunization Safety Review Committee of the Institute of Medicine ("IOM"), charged by the Vaccine Act with reviewing possible adverse consequences of vaccines, has noted that conclusions on causation generally require "a body of consistent and well-controlled epidemiological research," and that "[p]ublished reports that have been subjected to a rigorous peer review process carry the most weight in the committee's assessment." *Immunization Safety Review: Thimerosal-Containing Vaccines and Neurodevelopmental Disorders*, at 25 (Institute of Medicine, 2001). The IOM has further noted that, "[i]n general, the committee cannot rely heavily on unpublished data in making its plausibility assessment because they have not been subjected to a rigorous peer review process, and therefore must be interpreted with caution." *Id.* Applying these guidelines, although unpublished studies might have some relevance to a causation inquiry, it cannot be said that obtaining such studies from a non-party vaccine manufacturer is both reasonable and necessary to determine causation. Indeed, such unpublished studies would not even be admissible *to establish causation* in a civil action,

because such sources are not the type of sources reasonably relied upon by scientists and medical professionals. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.* 113 S.Ct. 2786 (1993).

Even if unpublished research studies could conceivably have some relevance to the general causation issue (which is not necessarily the case), Petitioners are required to show *more* than general relevance to obtain the discovery they seek. Even under the Federal Rules of Civil Procedure, it is well-established that "plaintiffs must show more than general relevancy in order to compel . . . documents of a non-party, non-fact witness . . .[and] must show a substantial need which outweighs the burden and prejudice to the non-party." *Anker v. G.D. Searle & Co.*, 126 F.R.D. 515, 521-522 (M.D.N.C. 1989). *Accord, Westinghouse Elec. Corp. v. Carolina Power and Light Co.*, No. 91-4288, 1992 WL 370097, at *1 (E.D. La. Nov. 30, 1992). Thus, in *Anker v. G.D. Searle & Co.*, the court refused to compel production of research and testimony from a non-party doctor, where plaintiffs failed to demonstrate that the non-party doctor's records and opinions were critical to the plaintiffs' case, and where relevant studies were publicly available and subject to critical examination. *Anker*, 126 F.R.D. 515 at 521-22. Petitioners here have not demonstrated, and cannot demonstrate, that any documents in the possession of the vaccine manufacturers are critical to the causation inquiry, and the fact that such documents might be generally relevant simply does not suffice to require the vaccine manufacturers' involvement in broad discovery in these proceedings. Published, peer-reviewed research is available and, following its February 2004 meeting, the IOM will publish its review of the relevant published research on thimerosal, which review will be available to this Court.

Should the Special Master find that the record is insufficient after completion of party discovery, the Special Master has the ability – and indeed is encouraged by Congress – to retain independent experts on causation, rather than resorting to non-party discovery from

vaccine manufacturers. *See* H.R. 101-386 at 516 (1989) ("the master may find it most expeditious to receive outside advice rather than attempt a full adversarial proceeding on the question of causation. The Act authorizes such action by the master and the Conferees would encourage its use as appropriate."). It is simply not reasonable or necessary for this Court, instead of relying upon ample published research, and independent expert advice, to require production of internal, unpublished research from a non-party vaccine manufacturer. Such an approach would plainly be at odds with the language and purposes of the Vaccine Act and would not even pass muster under the Federal Rules of Civil Procedure.

CONCLUSION

For all of the foregoing reasons, as well as the reasons stated in non-party Merck's Response to Petitioners' Motion to Issue Revised Third Party Subpoena, filed November 14, 2003, Wyeth respectfully requests that the Special Master deny Petitioners' Motion to Issue Revised Third Party Subpoena.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 3, 2003, I served the foregoing Wyeth's Memorandum, as Amicus Curiae, in Opposition to Petitioners' Motion to Issue Revised Third party Subpoena on the following individuals:

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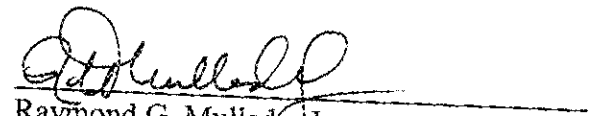

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