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UNITED STATES COURT OF 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 REPLY MEMORANDUM, AS AMICUS CURIAE, IN OPPOSITION TO PETITIONERS' MOTION TO ISSUE REVISED THIRD PARTY SUBPOENA

INTRODUCTION

Wyeth respectfully submits this reply memorandum of law, as amicus curiae, in opposition to Petitioners' Motion to Issue Revised Third Party Subpoena ("Motion").

Petitioners' responsive brief ("Response Br.") treats the proposed subpoena as if it were a routine request for arguably relevant information that should be summarily approved and honored. During the December 19 conference call among this Court, counsel for the parties, and counsel for the non-party vaccine-manufacturers (the "December 19 conference"), however, the Court rightly noted that a heightened standard of *necessity* -- rather than relevance -- governs the issuance of Vaccine Court subpoenas to non-parties. This heightened standard applies here regardless of the consolidation of various petitioners' cases in a single omnibus proceeding, because the standard is written into the Vaccine Act.

Although the Special Master indicated, at the December 19 conference, that the precise contours of the statutory standard for determining whether a non-party subpoena is "necessary" are unclear, Wyeth respectfully submits that federal case law concerning the "need"

for non-party subpoenas provides clear guidance on how to apply the "reasonable and necessary" standard to Petitioners' present application in this Court. Petitioners have not attempted to distinguish those authorities, cited in Wyeth's initial amicus brief, that establish that the type of discovery sought from non-party Merck would be deemed extraordinary and unwarranted even under the broad discovery standards applicable to full-blown federal civil litigation -- much less under the heightened discovery standards applicable here.

It is not appropriate, in any federal court setting, to impose discovery burdens on a non-party on the premise that such non-party might have generally relevant information. Even under traditional rules of civil procedure, a non-party will be protected from discovery unless the subpoenaing party shows a substantial need for the discovery, and Petitioners have not met that standard here.[1] The documents Petitioners propose to subpoena from Merck are either available from a party or a public source or are internal, unpublished, research studies that (1) constitute an improper substitute for a retained expert opinion and (2) would not be usable, in any event, under any evidentiary standard, to address the one and only issue at bar in Vaccine Court -- causation. Thus, the non-party discovery that Petitioners seek is not "necessary" under the well-established standard tests of "need" in the context of non-party discovery.

Petitioners' brief, moreover, ignores the Vaccine Compensation Program's creation of a less formal adjudication procedure, not involving vaccine manufacturers, and driven not by adversarial parties but by the Special Master's needs. Indeed, not only does Petitioners' proposed subpoena fail under the standard tests applicable to non-party discovery generally, but approving the subpoena here would contravene one of the specific purposes of the Vaccine Act.

[1] Additionally, under the Federal Rules of Civil Procedure, a non-party resisting discovery must first show that a subpoena would impose some burden, while here, notably, Merck is *not* required to show any burden, as it has done, in order for a heightened standard of necessity to apply.

Congress specifically intended to reduce vaccine manufacturers' litigation costs, and structured the Vaccine Compensation Program so that vaccine-injury claimants would not be litigating with vaccine manufacturers in Vaccine Court. Approving the subpoena would thus conflict with the Act and with Congress's express intent.

Petitioners concede that they do not know of any documents in Merck's possession that would support their claim that thimerosal causes the neurological injuries that Petitioners allege (Response Br. at 5) -- and Petitioners have no reasonable basis to believe that any such documents exist. All that Petitioners offer to show that the proposed subpoena for documents is "necessary" is their statement that Merck, as the manufacturer of Recombivax, is familiar with that vaccine and might have conducted relevant studies not made available to others. *See* Response Br. at 5. Essentially, then, Petitioners propose that this Court authorize a fishing expedition into Merck's files that directly contravenes the letter and intent of the Vaccine Act and the Vaccine Rules (in addition to being unheard of either in ordinary Claims Court proceedings or under the Federal Rules of Civil Procedure). Whether documents in Merck's possession are "necessary" to these proceedings must be established by Petitioners prior to the issuance of a subpoena for documents, as a statutorily-mandated prerequisite. Necessity is not a matter to be established after the subpoena is issued and Merck responds. This is true no matter whether documents are to be subpoenaed for production directly to the Petitioners, or for production first to the Special Master for *in camera* review. The Court should, accordingly, deny Petitioners' motion.

The mere speculation that Merck might have documents in its files that arguably bear on the issue of causation is entirely insufficient to justify issuance of the proposed subpoena in the absence of facts demonstrating the existence of such documents and the necessity of their

production.[2] Moreover, the fact that such documents might ultimately be obtained in civil litigation does not provide any basis under the text of the Vaccine Act or Vaccine Rules for their discovery here. Nor would the proposed fishing expedition (if it were permissible) in this forum serve Congress' intent to compensate individuals with vaccine-related injuries in Vaccine Court, because any relevant documents obtained from Merck could just as easily encourage civil litigation as they could discourage civil litigation. There is thus *no* policy argument based upon congressional intent -- just as there is no argument based upon the text of the Vaccine Act or Vaccine Rules -- that reasonably supports the issuance of the proposed subpoena.

Petitioners may obtain evidence relating to the matters at issue in Vaccine Court from many sources other than Merck or other vaccine manufacturers. If Petitioners want to present an expert opinion on whether thimerosal or any vaccine causes autism or other neurological disorders, Petitioners can retain and present those experts to the Court. This Court also has the power, and has been encouraged by Congress, to retain independent experts. There are, furthermore, reliable, published, peer-reviewed, studies concerning whether thimerosal causes neurological disorders, and those studies are available to Petitioners, or any expert, for critical examination.[3] Additionally, Merck has produced safety information relevant to its

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[2] Medical records are an example of the sort of documents that would be discoverable from a non-party, as they constitute indispensable evidence whose existence would be knowable to a petitioner, unlike the documents requested here.

[3] Wyeth notes that various public organizations given the specific task of determining whether thimerosal causes any neurological disorders have concluded, after conducting independent research and examining published studies, that there is no evidence of any association between exposure to the thimerosal preservative in vaccines and any neurological disorder. *See* The Global Advisory Committee On Vaccine Safety Concludes That There Is No Evidence of Toxicity In Infants, Children Or Adults Exposed To Thimerosal (Containing Ethyl Mercury) In Vaccines, *http*://www.who.int/vaccines-surveillance/ISPP/hot/Thiomersal.shtml (World Health Organization); Study Fails To Show A Connection Between Thimerosal And Autism, *http://www.aap.or/profed/thimaut-may03.htm* (American Academy of Pediatrics) ("No scientific data link thimerosal used as a preservative in vaccines with any pediatric neurological disorder, including autism."); Thimerosal & Vaccines: Q&A, *http://www.cdc.gov/nip/vacsafe/concerns/thimerosal/faqs-thimerosal.htm*, (Centers for Disease Control) ("There is no evidence that any vaccine or vaccine additive increases the risk of developing autism or any other behavior disorder."). That existing studies do not support Petitioners' claims is certainly not, however, a basis for permitting Petitioners to mount a fishing expedition in Vaccine Court directed to Merck or other non-party vaccine manufacturers. If anything, the lack of

vaccines to the government, and Petitioners are in the process of obtaining that information from Respondent.

ARGUMENT

I. PETITIONERS FAIL TO DISTINGUISH THE AUTHORITIES ESTABLISHING THAT THE PROPOSED NON-PARTY DISCOVERY IS IMPROPER

As Wyeth set forth in its initial amicus brief, the discovery provisions of the Vaccine Act and Vaccine Rules, being more restrictive than the discovery rules in the Claims Court and other federal courts, do not provide Petitioners with tools to conduct discovery as a matter of right, and limit discovery to what the Special Master determines is both reasonable and necessary. *See* 42 U.S.C. § 300aa-12(d)(2)(E); Vaccine Rule 7(c). Petitioners are therefore *not* entitled in Vaccine Court proceedings to discovery of all relevant or arguably relevant information. *Compare* Fed. R. Civ. P. 26(b)(1) *with* 42 U.S.C. § 300aa-12(d)(2)(E), Vaccine Rule 7(c). Although Petitioners argue that broader-than-usual discovery should be permitted because this Court has consolidated various petitioners' cases (Response Br. at 7-8), the rules of discovery that govern in this Court must apply according to their terms. The administrative convenience of the omnibus proceeding cannot and did not change the substantive law governing discovery in Vaccine Court. As a matter of statutory mandate, discovery cannot proceed here unless Petitioners demonstrate it to be both reasonable and necessary under the governing statute and rules. *See* 42 U.S.C. § 300aa-12(d)(2)(E); Vaccine Rule 7(c).

Although Claims Court and other federal court proceedings are subject to different discovery standards (more liberal than those of Vaccine Court), cases denying non-

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support for Petitioners' claims following numerous studies by various reputable organizations argues *against* subjecting vaccine manufacturers to discovery here, because there is no reasonable basis to believe that research which may be obtained from vaccine manufacturers -- or anyone else -- would support Petitioners' compensation claims.

party discovery in those fora nonetheless amply demonstrate, *a fortiori,* why the non-party discovery that Petitioners propose here is not "reasonable and necessary." It is well established, under the Federal Rules of Civil Procedure and the Claims Court rules, 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."[4] *Anker v. G.D. Searle & Co.,* 126 F.R.D. 515, 521-522 (M.D.N.C. 1989). *Accord, Capital Partners , Inc. v. United States*, 49 Fed. Cl. 607, 609-10 (Fed. Cl. 2001); *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 cases where a party seeks to subpoena what is essentially an expert opinion from a non-party -- as opposed to critical facts regarding the non-party's direct involvement in the case -- and where an expert opinion can be obtained from retained experts and published sources, courts will decline to permit the non-party subpoena. *See, e.g. Anker* 126 F.R.D., at 521-522; *Capital Partners* 49 Fed. Cl., at 612. Those cases are consistent with the general rule that discovery is not available from non-parties where the information sought can be obtained from parties or other sources. *See e.g., Haworth, Inc. v. Hermana Miller, Inc.*, 998 F.2d

[4] One critical difference between the standard in this Court and in federal courts governed by the Rules of Civil Procedure should, however, be noted: a non-party does not need to show that requested discovery would impose any burden in order for the standard of necessity set forth in 42 U.S.C. § 300aa-12(d)(2)(E) and Vaccine Rule 7(c) to apply. Under both the Federal Rules of Civil Procedure and the Claims Court rules, a subpoena may be issued for any relevant documents, and a non-party is generally required to demonstrate some burden in a motion to quash or for a protective order, after which the Court will inquire into whether a substantial need outweighs the burden. *See Capital Partners* 49 Fed. Cl., at 611. In Vaccine Court, however, a subpoena may only be issued, in the first instance, if the Special Master determines that the subpoena is necessary. 42 U.S.C. § 300aa-12(d)(2)(E); Vaccine Rule 7(c). Once an *independent* threshold determination of necessity is made, the Vaccine Court must then determine whether issuance of the subpoena is "reasonable" under 42 U.S.C. § 300aa-12(d)(2)(E), considering the burden upon the non-party and any other relevant circumstances. Thus, it would be improper for the Court to authorize issuance of the subpoena, in whole or in part, merely because the Court believes there is no burden upon Merck (as the Court suggested, in the December 19 conference, is the case with respect to Request (C)(2)). The subpoena cannot issue unless the Court first makes an independent, threshold, determination that it is necessary to obtain the requested documents from non-party Merck. *See* 42 U.S.C. § 300aa-12(d)(2)(E); Vaccine Rule 7(c). Because no such determination can be made with respect to any of Petitioners' requests, the proposed subpoena should be denied in its entirety.

975, 978 (Fed. Cir. 1993); *Carl Zeiss Stiftung v. V.E.B. Carl Zeiss, Jena*, 40 F.R.D. 318, 328 (D. D.C. 1966).

Petitioners cannot, and do not, cite any case in which the type of non-party discovery being sought here has been permitted under similar circumstances. The case of *Wittner v. Sec'y, Health & Human Servs.*, 43 Fed.Cl. 199 (1999), cited by Petitioners (Response Br. at 5), is wholly inapposite. There, discovery was permitted from a petitioner's treating physician, as a *fact* witness who had first-hand knowledge of that petitioner's case, including, necessarily, unique facts concerning the timing and nature of symptoms he observed, and his diagnoses, all of which were necessary to address specific causation. *See Wittner v. Sec'y, Health & Human Servs.*, 43 Fed.Cl. 199, 206 (1999). In contrast, Petitioners here seek from Merck (in addition to published research and PLAs clearly available from other sources) internal research on general causation (akin to the general expertise discovery sought from non-parties in *Anker* and *Capital Partners*, as discussed in Wyeth's initial brief at pages 7-9). Petitioners do *not* seek particularized facts necessary to establish specific causation for any petitioner, such as the timing and nature of a particular petitioners' symptoms or diagnoses.

Unlike the doctor in *Wittner*, who was in the unique position of having observed and diagnosed the petitioner contemporaneously with the alleged symptoms of vaccine-related injury, there is no reason to believe that Merck is uniquely aware of particular facts that would allow Merck to reach a uniquely informed opinion on any Petitioner's claim of causation. Any qualified expert can testify as to general causation. The ingredients of Merck's vaccines, including thimerosal, have been fully disclosed pursuant to federal regulations, are known, and can be thoroughly studied independently for any potential adverse effects. Thus, Petitioners essentially seek an expert opinion from Merck on general causation despite the availability of

amply informed expert opinion and published research elsewhere. The non-party discovery that Petitioners seek is therefore improper. *See, e.g., Anker* 126 F.R.D., at 521-522 (prohibiting discovery of research documents and testimony from non-party doctor where retained experts could provide analysis of relevant, published research); *Capital Partners* 49 Fed. Cl., at 612 (prohibiting discovery from non-party, Amtrak, concerning the general usage of certain terms in railroad industry -- despite relevance of expert opinion in that regard-- while permitting particularized fact discovery from Amtrak concerning intended meaning of terms in specific contract at issue, to which Amtrak was a party.).

II. CONGRESS INTENDED TO PROTECT VACCINE MANUFACTURERS FROM LITIGATION TRANSACTION COSTS AS WELL AS LITIGATION LIABILITY

Petitioners concede that Congress intended to reduce litigation *liability* for vaccine manufacturers, but suggest that the transaction costs which Merck would face as a result of the proposed subpoena are not a matter of legislative concern. Response Br. at 9-10. Petitioners' suggestion is belied by the legislative history of the Act, which indicates Congress's recognition, in enacting the statute, that "[l]awsuits and settlement negotiations can take months and even years to complete . . . [and] [t]ransaction costs . . . are high." H.R. Rep. No. 99-908 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 6346-47. *See also Schafer v. American Cyanamid* 20 F.3d 1, 1 (1st Cir. 1994) (noting complaints of vaccine manufacturers concerning litigation expenses, as well as occasional recoveries, preceding passage of the Act). Here, the proposed subpoena, which includes, among other things, a request for all documents "relating to" research studies and vaccine safety issues -- and, as Merck has indicated, would require an arduous search of documents generated over many years -- would impose upon Merck substantial transaction

costs that would be inconsistent with the intent of the Vaccine Act.[5] The fact (which Petitioners emphasize) that Congress also intended to provide an efficient and relatively generous compensation remedy for persons injured by vaccines does not trump Congress's purpose to protect vaccine manufacturers from litigation costs. In order to promote its policy purposes, Congress *explicitly* provided for only limited discovery in this Court, based upon a standard of necessity, rather than a broad standard of relevance. *See* 42 U.S.C. § 300aa-12(d)(2)(E). Thus, consideration of both the purposes *and* express language of the Vaccine Act counsels against this Court's permitting broad discovery that would go beyond what is permitted under even the relatively liberal federal court and Claims Court discovery rules.

III. PETITIONERS DO NOT DISPUTE THAT THIS COURT COULD NOT REASONABLY RELY UPON MERCK'S INTERNAL, UNPUBLISHED, STUDIES TO DETERMINE THE CAUSATION ISSUE

As Wyeth noted in its initial brief, unpublished internal studies by vaccine manufacturers would be *inadmissible to establish causation* in a civil action, as they 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). This fact (among others) belies Petitioners' contention that they do not seek information concerning fault. As the Immunization Safety Review Committee of the Institute of Medicine ("IOM") has recognized, a body of published, peer-reviewed, epidemiological research is needed to establish causation -- notwithstanding that the IOM generally will give cautious, limited, consideration to unpublished research for the purpose of determining whether a causation theory is "plausible." *See Immunization Safety Review: Thimerosal-Containing Vaccines and Neurodevelopmental Disorders*, at 25 (Institute of

[5] In Wyeth's case, should a similar subpoena be issued concerning Wyeth's several, well-established, vaccines (including, for example, the whole cell form of the DTP vaccine that has been in production since the 1940s) an especially extensive and arduous search would be required to uncover all responsive documents.

Medicine, 2001). While this Court is not bound by the rules of evidence applicable in federal court, the fact that Petitioners seek documents that could not reasonably be relied upon to establish causation by a preponderance of the evidence under traditional evidentiary standards should weigh heavily in this Court's consideration of whether Petitioners' proposed non-party discovery is both "reasonable and necessary." In light of the limited evidentiary utility of unpublished research generally, the Court should not permit discovery of such information from Merck, as it cannot be considered reasonable and necessary to a causation determination.

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

Petitioners seek to compel Merck to produce PLAs in order to speed the discovery process in these proceedings (Response Br.at 8-9), notwithstanding that Petitioners cannot reasonably argue that it is "necessary" to obtain the PLAs from Merck when they are available from Respondent. The Vaccine Act and the Vaccine Rules do not provide for the Special Master to approve subpoenas for the sake of speed, or, generally, for the sake of convenience. A subpoena may be authorized only on the ground that it is "necessary." *See* Vaccine Rule 7(c). It is simply not necessary for Petitioners to obtain the PLAs from Merck, as those documents are being produced by Respondent. And there is no reason to believe that obtaining those documents directly from Merck would significantly speed discovery in any event, as Merck would still be required to go through the process of review and redaction in which it is involved in connection with its production of the PLAs to Respondent. If Petitioners desire to speed the PLA-production process, they could, as Merck has suggested, limit their request to Respondent so that it seeks only clinical information in the PLAs, in order to reduce disputes concerning redaction of irrelevant sections, and the time spent on redaction. Moreover, to the extent that certain portions of the PLAs are redacted, that is no reason to require production of the

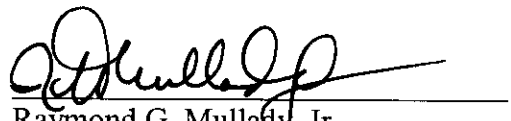
unredacted sections from Merck absent a specific showing, with respect to particular redactions, why Petitioners reasonably believe that production of the redacted information is necessary. *See* 42 U.S.C. § 300aa-12(d)(2)(E); Vaccine Rule 7(c). Petitioners have made no such showing.

Petitioners' additional requests to Merck for *published* research studies and documents concerning communications with the government are also improper because they seek, respectively, information available in the public domain, and information available from Respondent. Indeed, the fact that Petitioners seek to know whether published research not conducted by Merck or any entity affiliated with Merck (which research Petitioners could readily obtain from the public domain) is *in Merck's possession*, provides a further indication that Petitioners, despite their protestations to the contrary, are seeking evidence of fault, on the basis of Merck's knowledge, *in particular*, rather than evidence of causation itself. Additionally, as discussed above, the substantial body of relevant, published, peer-reviewed research (as specifically cited at pages 13-14 of Merck's initial response to Petitioners' motion) renders it unnecessary for this Court to seek additional, unpublished, research from Merck. Finally, it is more appropriate for the Special Master to retain independent experts on causation, as Congress has specifically advised in order to avoid unnecessary adversarial proceedings (*see* H.R. 101-386 at 516 (1989)), than to approve the issuance of the proposed non-party subpoena.

CONCLUSION

For all of the foregoing reasons, 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 29, 2003, I served the foregoing Wyeth's Reply Memorandum, As Amicus Curiae, In Opposition To Petitioners' Motion to Issue Revised Third Party Subpoena on the following individuals:

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