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 NEURODEVELOPMENTAL DISORDER,	*	Autism Master File
VARIOUS PETITIONER(S),	*	
v.	*	**BRIEF OF AMICUS CURIAE AVENTIS PASTEUR INC. IN SUPPORT OF MERCK & CO.'S RESPONSE TO PETITIONERS' MOTION TO ISSUE REVISED THIRD PARTY SUBPOENA**
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

* *

With leave of Special Master Hastings granted on November 25, 2003, Aventis Pasteur Inc. files this brief as *amicus curiae* in support of Merck & Co.'s response to Petitioners' Motion to Issue Revised Third Party Subpoena (the "Motion").

I. Interest Of Aventis Pasteur Inc. In This Proceeding

Aventis Pasteur Inc., like Merck & Co., is a manufacturer of vaccines. Some of the thimerosal-containing vaccines at issue in this proceeding were manufactured by Aventis Pasteur Inc. Petitioners have proposed that subpoenas be issued "to the manufacturers of those products already identified as relevant vaccines in the Omnibus proceeding; that is, vaccines containing thimerosal, and the MMR vaccine." Motion at 5. Similarly, the Motion makes it clear that the proposed subpoena directed to Merck & Co. is only the *first* such discovery effort Petitioners intend to propound against the manufacturers of the vaccines at issue. *Id.*; *see also* Petitioners' Steering Committee

Memorandum Regarding Third-Party Discovery, September 4, 2003. Thus, although Petitioners have not, at this point, directed any discovery effort at Aventis Pasteur Inc., it is clear that Aventis Pasteur Inc. is among the targets of Petitioners' unprecedented and ill-advised effort to engage the vaccine manufacturers in litigation through the Omnibus Autism Proceeding. Because Aventis Pasteur Inc., as a vaccine manufacturer, is one of the entities which Congress intended to protect from costly, burdensome, and potentially ruinous litigation through the passage of the National Vaccine Injury Compensation Act, it is interested in the issue presently before the Special Master and submits this *amicus* brief to inform the Special Master of its opposition to the proposal for the issuance of subpoenas seeking discovery from vaccine manufacturers.

II. Introduction

One of two central purposes of the National Childhood Vaccine Injury Compensation Act, 42 U.S.C. § 300aa-1, *et seq.* (*hereinafter* "the Vaccine Act" or "the Act"), was to relieve vaccine manufacturers of the burdens of litigation that had come to threaten the country's vaccine supply. Congress passed the Vaccine Act in 1986 to establish a "new system for vaccine injury compensation". H.R. Rep. 99-908, at 7 (1986), *reprinted in* 1986 U.S. Code Congressional and Administrative News ("U.S.C.C.A.N.") at 6348. Congress recognized that despite the success of vaccines in preventing deadly and disabling diseases, some children would inevitably claim they were injured by vaccines and relying on the traditional tort system to provide compensation raised "two overriding concerns:" (1) the tort system had failed to provide fair and efficient compensation to persons injured by vaccinations, but (2) had brought about "an

unstable and unpredictable vaccine market, making the threat of vaccine shortages a real possibility." H.R. Rep. No. 99-908, at 5 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 6346. For persons claiming injury from vaccinations, "the opportunities for redress and restitution are limited, time-consuming, expensive, and often unanswered." *Id.* at 6, *reprinted in* 1986 U.S.C.C.A.N. at 6347. "This approach has also been ineffective for the manufacturers of childhood vaccines. This has become especially true in most recent years as the numbers of lawsuits [against vaccine manufacturers] has increased." *Id.* Congress recognized that as "[children] and their families have resorted in greater numbers to the tort system . . . , the prices of vaccines have jumped enormously," the "number of vaccine manufacturers has declined significantly," and existing vaccine manufacturers "question their continued participation in the vaccine market." *Id.* at 4, *reprinted in* 1986 U.S.C.C.A.N. at 6345.

As Congress recognized, the difficulties for vaccine manufacturers posed by the increasing number of tort lawsuits concerned not only "the possibility that vaccine-injured persons may recover substantial awards in tort claims," but also "the problems of time and expense" inherent in protracted and costly tort litigation:

> Lawsuits and settlement negotiations can take months and even years to complete. Transaction costs – including attorneys' fees and court payments – are high.

Id. at 6-7, *reprinted* in 1986 U.S.C.C.A.N. at 6346-47. Congress was concerned that the instability in the vaccine market engendered by tort lawsuits "could create a genuine public health hazard in this country:"

> The loss of any of the existing manufacturers of childhood vaccines at this time could create a genuine public health hazard in this country. . . .

> [T]he withdrawal of even a single manufacturer would present the very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases.

Id. at 7, *reprinted* in 1986 U.S.C.C.A.N. at 6348.

Because of its "real concern about the future of Federal immunization initiatives," and its desire to safeguard the national vaccine supply, Congress included in the Vaccine Act the Compensation Program to provide claimants a just and efficient remedy while also protecting vaccine manufacturers from excessive litigation costs. *Id.* at 4-5, *reprinted in* 1986 U.S.C.C.A.N. at 6345-46; *Schafer v. American Cyanamid Co.*, 20 F.3d 1, 2-3 (1st Cir. 1994). The Program was intended to depart from the "traditional tort system" that threatened the national vaccine supply, *O'Connell v. Shalala*, 79 F.3d 170, 173 (1st Cir. 1996), and "represents an effort to provide compensation to those harmed by childhood vaccines ***outside the framework of traditional tort*** law." *Schafer*, 20 F.3d at 2 (emphasis added).

As part of its design of the Program, and in order to effectuate its goal of creating a compensation system that would operate in an expeditious and non-adversarial manner, Congress specifically rejected the discovery procedures available in traditional tort litigation:

> Other than the discovery specifically described as the prerogative of the Master, there is to be no other discovery in a compensation proceeding. In order to expedite the proceedings, the power of the Special Master is intended to replace the usual rules of discovery in civil actions in Federal courts. Because the only issues relevant to the compensation proceeding are whether the petitioner suffered a compensable injury and, if so, the extent of compensable damages, there should be no need for a wider inquiry, which might be appropriate in a civil action raising other issues. Thus, while the Special Master may compel any testimony or appearance, ***neither* party *is given power to cross-examine witnesses, file***

> ***interrogatories, or take depositions***. In this regard, the Committee expects the Special Master to be vigorous and diligent in investigating ***factual elements necessary to determine the validity of the petitioner's claim.***

H.R. Rep. No. 99-908, at 16-17, *reprinted in* 1986 U.S.C.C.A.N. at 6357-58 (emphasis added). Congress' intent is reflected in the Act itself, specifically 42 U.S.C. § 300aa-12(d)(2), (3), which provide:

> "There shall be no discovery in a proceeding on a petition other than the discovery required by the special master," §12(d)(3)(B);
>
> The Court of Federal Claims shall promulgate rules that *shall* "provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions...," § 12(d)(2)(E); and
>
> Any information required by the special master in a proceeding shall be limited to that which is both "reasonable and necessary," § 12(d)(3)(B)(i)-(iii).

Although Congress' original intent to provide an alternative to traditional tort litigation was made clear, that intent was not fully implemented in the early years of the Program. As Chief Special Master Golkiewicz wrote in *Stevens v. Secretary of HHS*, 2001 U.S. Claims LEXIS 67, at 120-121, No. 99-594 V, 2001 WL 387418 (Fed. Cl. Spec. Mstr. Mar. 30, 2001):

> In 1989, after determining that the participants of the Program were still "maintaining their traditional adversarial litigation postures," in violation of the Act's charges "'to compensate persons with recognized vaccine injuries without requiring the difficult individual determinations of causation to injury,'" to provide "a quick, flexible, and streamlined system," and to "administer[ ] awards 'quickly, easily, and with certainty and generosity,'" Congress fervently called upon the parties and the court

to rededicate themselves "to the creation of an expeditious, non-adversarial, and fair system." H.R. Rep. No. 101-247, at 509 (1989), reprinted in 1989 U.S.C.C.A.N. 1906, 2235. Congress observed:

> In proposing this legislation, the Committee reiterates its intent that the vaccine injury compensation system be informal, flexible, and expeditious, and that all participants proceed accordingly. The re-invention of the adversarial process will serve neither to compensate injured children nor maintain the stability of the immunization programs of the U.S. . . .With such re-dedication to the original goals of the program, the Committee anticipates that all participants will benefit. The system will provide compensation, eliminate the need for litigation, and assure the continued availability of and public confidence in immunizations in the U.S.

Id.

In that same House Report, Congress also reiterated its emphasis upon the use of discovery only when, and to extent, necessary to the Special Master's determination:

> The Committee reiterates its concern that these authorities not be used to re-create an adversarial process before the Special Masters. The 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), cross-examination (as needed), and investigation. As was stated in the Report accompanying the original Act, "In order to expedite the proceedings, the power of the Special Master is intended to replace the usual rules of discovery in civil actions in Federal courts." The parties are, of course, free to request that the Master develop the record by obtaining necessary information. (For example, the Master might be asked to subpoena further records.)

H.R. Rep. No. 101-247, at 509 (1989), reprinted in 1989 U.S.C.C.A.N. 1906, 2235.

Petitioners might wish to emphasize the final sentence of this passage and highlight it as authority for the subpoenas they seek. It is true that Congress recognized that there might be a need for discovery from non-parties in some circumstances and provided the authority for such discovery as might be both reasonable and necessary. But read in the proper context of the overall legislative history, it is clear that Congress

intended any such discovery be limited to narrow ***factual*** questions and provided that any such discovery be ***strictly constrained by the rule of necessity***. Thus, where deemed necessary by the Special Master – serving in the role of an inquisitor – Congress provided the authority for the development of a complete record.

In the history of the Compensation Program, while adjudicating thousands of cases involving alleged vaccine-related injuries, it has ***never*** been "necessary" to subpoena documents from a vaccine manufacturer.[1] As shown in Merck & Co.'s response and as set forth below, because the proposed discovery at issue is neither reasonable nor necessary here, that discovery is not authorized by the Vaccine Act, and Petitioners' request should be denied.

III. Requiring A Vaccine Manufacturer To Respond To Petitioners' Traditional, Broad, And Contention-Based Discovery Requests Is Not Authorized Under The Vaccine Act's Stringent Limitations On Discovery.

As shown by Merck & Co. in its response, the discovery proposed by Petitioners would turn the Compensation Program "on its head," engaging vaccine manufacturers in compensation claims through costly and burdensome adversarial discovery in direct contravention of the purposes for which the Program was established. But in addition to violating the policy and purpose behind the Act, Petitioners' proposed discovery is not authorized by the Act or the rules because Petitioners have failed to demonstrate that the discovery is either reasonable or necessary. In addition, Petitioners' limited attempt to

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[1] *See* Order Concerning Subpoena Request Re Merck, Court of Federal Claims Office of Special Masters, Autism Master File (October 30, 2003) (Hastings, Special Master), at 3: "[This is an issue of first impression under the Program. I am unaware of any cases in which Program petitioners have sought formal discovery from a vaccine manufacturer."

justify the invasive procedure they propose is utterly unavailing as their only reference to the need for discovery from the manufacturers (delays in production by the Respondent caused by the redaction of trade secret information) will not be affected by the procedure they propose.

A. The Proposed Discovery Is Neither Reasonable Nor Necessary

Petitioners are not ***entitled*** to any discovery under the Vaccine Act. Rule 7 of the Vaccine Rules of the United States Court of Federal Claims ("There shall be no discovery as a matter of right.") It is only the Special Master who is entitled to seek discovery under the Vaccine Act, and only then when it is found to be both reasonable and necessary. 42 U.S.C. § 300aa-12(d)(B)(v) ("There may be no discovery in a proceeding on a petition other than that discovery required by the special master."). The legislative history behind the Act makes clear Congress intended a limited, non-adversarial, factual-based discovery conducted by the Special Master for petitions brought under the Act and that traditional, broad, adversarial discovery conducted by the parties is contrary to the purpose of the Act. Unlike non-Program cases in the Court of Federal Claims or traditional civil litigation in other courts, discovery in Program cases is not governed by the broad standard of Rule 26. Instead, the Vaccine Act provides that "a special master (i) may require such evidence as may be ***reasonable and necessary***, (ii) may require the submission of such information as may be ***reasonable and necessary***, (ii) may 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) (emphasis added). As such, this requirement is more stringent than the Rule 26 of the Federal Rules of Civil Procedure or

Rule 26 of the Rules of the United States Court of Federal Claims standards for discovery calling for relevant information and/or information "reasonably calculated to lead to the discovery of admissible evidence." Therefore, it is insufficient for petitioners to show that the documents sought only might be relevant or reasonably calculated to lead to the discovery of admissible evidence. Rather, under the Vaccine Act, discovery, especially from a non-party must be shown to be ***both reasonable and necessary***, meaning ***limited and narrowly tailored to specific facts:***

> Because the only issues relevant to the compensation proceeding are whether the petitioner suffered a compensable injury and, if so, the extent of compensable damages, ***there should be no need for a wider inquiry, which might be appropriate in a civil action raising other issues***. . . . In this regard, the Committee expects the Special Master to be vigorous and diligent in investigating the ***factual elements necessary*** to determine the validity of petitioner's claim.

H.R. Rep. No. 99-908 at 16-17 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6357-58 (emphasis added).

Petitioners have not and cannot make the requisite showing of reasonableness and necessity. In analyzing the reasonableness and necessity of requiring vaccine manufacturers to respond to Petitioners' discovery requests, it is important to take two things into consideration. First, even under the Federal Rules of Civil Procedure, discovery from non-parties is not nearly as broad as discovery from parties.[2] Second, because the Vaccine Act was intended to relieve vaccine manufacturers of the burden of

[2]Compare Rules 33, 34, and 36 of the Federal Rules of Civil Procedure and the Rules of the United States Court of Federal Claims setting forth discovery procedures for parties to Rule 45 of the Federal Rules of Civil Procedure and the Rules of the United States Court of Federal Claims setting forth discovery procedures for non-parties.

litigation expenses, Petitioners must show why it is reasonable and necessary – notwithstanding the Congressional objective of sparing vaccine manufacturers the burden of litigation expenses – that the documents at issue be sought from the vaccine manufacturers.

While giving lip service to the requirements of the Act, Petitioners assert as their only justification for seeking documents directly from the manufacturers that the process of document production from the FDA has been too slow. This argument does nothing to justify requiring a non-party vaccine manufacturer to produce documents.

First, the fact that the process of document production from the FDA is moving slowly due to statutorily required redactions does not render it reasonable or necessary that the documents be produced by the vaccine manufacturers. In fact, it is highly unlikely that the Petitioners' requests directed to vaccine manufacturers will have the alleged desired result of speeding up the production process. This is particularly true in light of the fact that while the vaccine manufacturers have virtually completed the task of redacting the documents to be produced by the FDA, the vaccine manufactures would still have to redact any documents they are ordered to produce directly. Additional authority for such redactions is found in United States Court of Federal Claims Rule 45(c)(3)(A)(B), under which Petitioners are not entitled to documents which disclose trade secrets or other confidential research, development, or commercial information or any documents that disclose "any unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study

made not at the request of any party" absent a showing of substantial need for the material that cannot be otherwise met without undue hardship.

Second, the fact that the Petitioners seek from a non-party documents available to them from the FDA, the opposing party, (a) violates the fundamental principle – applicable even under the more lenient standards of ordinary federal discovery – that when documents are available from a party, they are not to be sought from a non-party, *see, e.g., Haworth, Inc. v. Herman Miller, Inc.*, 998 F.2d 975, 978 (holding that "the district court could properly require [a party] to seek discovery from its party opponent before burdening a nonparty . . .."), and (b) defeats any claim of necessity. A showing of necessity as called for by the Act requires something more.

The case of *Wittner v. Sec'y Dept. Health and Human Servs.*, 43 Fed. Cl. 199 (1999), provides an excellent example of evidence that is reasonable and necessary. In *Wittner*, the petitioners brought a claim under the Vaccine Act for their child's encephalopathy alleging that the condition was caused by DPT vaccinations. *Id.* at 201. The Special Master allowed the Secretary of the Department of Health and Human Services to elicit testimony from Dr. Nigro, a pediatric neurologist who had treated the child, but who had also been hired by petitioners as a non-testifying expert consultant. *Id.* at 205. There the Special Master concluded that despite Dr. Nigro's confidential relationship with petitioners as a non-testifying expert consultant, his testimony in the case was "important and necessary to the proper resolution of the case." *Id.* at 206. The Federal Court of Claims affirmed the decision of the Special Master noting that "no other doctor identified in the record spent as much time treating the child's neurologic

condition, especially during the critical early part of his life," and that "Dr. Nigro's medical records pervade[d] the record and played an important role in the case." *Id.* at 206.

Here, Petitioners have not shown and cannot show it is necessary to obtain documents responsive to their request from Merck or any other vaccine manufacturer. Petitioners have not pointed to any gap in their evidence. Petitioners do not even indicate why the Special Master needs this information to make the general determination of whether the vaccinations in question can cause autism and/or similar disorders. Nor do Petitioners even allege that the information sought from the non-party vaccine manufacturer is not available from any other source.[3] Rather, Petitioners merely allege that obtaining documents from the opposing party in this case is too slow.

Petitioners' proffered reason for the proposed discovery does not approach the "reasonable and necessary" standard. Petitioners have shown nothing even indicating the need for the information they propose to seek by subpoena. Moreover, Petitioners have clearly failed to show why it is necessary – notwithstanding the Congressional objective of sparing vaccine manufacturers the burden of litigation expenses – that the documents at issue be sought from the vaccine manufacturers. Because the discovery sought by Petitioners is neither reasonable nor necessary, the Motion should be denied.

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[3]Again, the mere fact that the Petitioners seek from a non-party documents available to them from the FDA violates the fundamental principle – applicable even under the more lenient standards of ordinary federal discovery – that when documents are available from a party, they are not to be sought from a non-party. *See, e.g., Haworth, Inc. v. Herman Miller, Inc.*, 998 F.2d 975, 978 (holding that "the district court could properly require [a party] to seek discovery from its party opponent before burdening a nonparty . . ..").

B. The Proposed Discovery Is Contrary To The Vaccine Act's Call For Limited, Non-Adversarial Discovery

Petitioners' discovery requests should also be denied on the ground that the Motion seeks broad-based discovery in an adversarial context contrary to the intent and spirit of the Act. Although Petitioners have somewhat narrowed their requests to Merck, such requests remain the type of general, broad-based requests typically associated with traditional, adversarial discovery in courts of general jurisdiction, and even as narrowed, Petitioners' requests are merely an attempt to have the Special Master act as a conduit for the traditional, adversarial discovery sought by Petitioners.

Petitioners' requests are not limited to the narrow ***facts*** necessary for the Special Master to determine the very limited issue before the Court which was recognized by Congress as "whether the petitioner suffered a compensable injury," H.R. Rep. No. 99-908 at 16 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6357, and by this Court as Aan inquiry into the *general causation issues* involved in these cases – *i.e.*, "whether the vaccinations in question can cause autism and/or similar disorders, and if so in what circumstances . . .." (Autism General Order #1, July 7, 2003).

The Program was not designed, and is not structured, for petitioners to use the discovery process to develop their theory of causation from non-party vaccine manufacturers – which Congress sought to protect – rather than from their own expert witnesses and scientific research available to such experts. Congress expected petitioners to obtain their expert evidence elsewhere and limited the Act's discovery process to non-adversarial, ***factual–based*** discovery.

If, for example, there arose a dispute between a petitioner and the Secretary as to the existence of some fact that could only be answered by reference to information in the possession of a vaccine manufacturer, under those circumstances, the Special Master might deem it both reasonable and necessary to require the vaccine manufacturer to produce the document proving or disproving the disputed fact. That type of limited, factual-based inquiry, in contrast to the Petitioners' general and broad-based requests, is the type of discovery authorized under the Act. The discovery requests proposed by Petitioners here is not.

CONCLUSION

Contrary to both the letter and the spirit of the Vaccine Act, Petitioners propose to involve the vaccine manufacturers in burdensome, expensive, and unnecessary adversarial litigation, the very situation Congress sought to prevent by enacting the Vaccine Act. Petitioners seek to subpoena vast numbers of documents, but have not shown, and cannot show, the necessity for obtaining these documents at all, much less from the manufacturers, in the context of their Program petitions. The process Petitioners have requested is therefore neither reasonable nor necessary and it is, accordingly, not authorized by the Vaccine Act and Vaccine Rules.

For all of the above-stated reasons, Aventis Pasteur Inc. respectfully prays that the Petitioners' Motion be denied.

Respectfully submitted, this 3rd day of December, 2003,

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CERTIFICATE OF SERVICE

I hereby certify that I caused a copy of the foregoing pleading to be delivered by U.S. mail, with a courtesy copy by electronic mail, this 3rd day of December, 2003 to:

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I have also provided courtesy copies to counsel for Merck & Co., Inc., SmithKline Beecham Corporation d/b/a GlaxoSmithKline, Wyeth, and Baxter Healthcare, Inc.

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