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),	*	**REPLY BRIEF OF AMICUS CURIAE AVENTIS PASTEUR INC. IN SUPPORT OF MERCK & CO.'S RESPONSE TO PETITIONERS' MOTION TO ISSUE REVISED THIRD PARTY SUBPOENA**
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

* *

I. Introduction

In their opening briefs, Merck and the *amici* demonstrated (1) that the Vaccine Act was established for the dual purposes of providing fair and efficient compensation to persons injured by vaccines and protecting vaccine manufacturers from the burdens of litigation which threatened the stability of the nation's vaccine supply; (2) that Congress designed the Compensation Program as an alternative to tort litigation and intended that the Program operate "outside the framework of traditional tort law;" (3) that, in designing the Program, Congress anticipated that there should be little, if any, traditional discovery in a proceeding on a petition and provided that such discovery as may be had shall be strictly limited to that which is required by the Special Master in order to fill a "gap" in the record; and (4) that when discovery is sought from vaccine manufacturers – the very entities which were intended and designed to be shielded from the adjudication of vaccine-related injury claims – additional considerations mandate a very

strict application of the Special Masters' powers to conduct discovery and to limit discovery to that which is genuinely reasonable and necessary to the adjudication of a petition. Applying these overarching principles to the Petitioners' Motion, Merck and the *amici* showed that the discovery sought by Petitioners was not limited to an inquiry about a fact or facts necessary to fill a gap in the record and which might be obtained only from the vaccine manufacturers, but is instead exactly the type of broad, general, and burdensome search for *potentially* relevant documents which is permitted in other types of litigation but prohibited under the Act.

In response, Petitioners argue (1) that the Compensation Program was designed to protect vaccine manufacturers only from liability *judgments*, not from the other burdens and expenses of litigation; (2) that a "gap" exists – not in the factual record, but in the absence of science which might support their claims – and that this asserted gap justifies their requested discovery; and (3) even if the very information Petitioners seek from Merck and intend to seek from the other manufacturers is available from other sources, and even if the studies described by Petitioners are contained in the regulatory documents and will be produced by Respondent, their need for speed in the production of documents should outweigh the intent and design of Congress and justify the use of an unprecedented, unauthorized search for whatever the vaccine manufacturers might know about the "properties and characteristics of their own product[s]." Each of these arguments lacks merit, for the reasons already demonstrated in the opening briefs and as further discussed below.

Because Petitioners have failed to establish the threshold burden of proving the reasonableness and necessity for their proposed discovery from the vaccine manufacturers, Petitioners' Motion to issue a third party subpoena should be denied.

II. Argument

A. The Compensation Program was designed to protect vaccine manufacturers from more than liability judgments.

Contrary to Petitioners' characterization of Congress' "legislative intent to reduce the industry's *liability* exposure,"[1] the legislative history of the Vaccine Act shows indisputably that Congress was concerned about the costs of litigation even where allegedly vaccine-injured persons recovered no compensation. As noted in Aventis' opening brief, Congress said that for persons claiming injury from vaccinations, "the opportunities for redress and restitution are limited, time-consuming, expensive, and often unanswered." H.R. Rep. No. 99-908, at 6 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 6347. For vaccine manufacturers, the increasing number of tort lawsuits raised concerns not only about "the possibility that vaccine-injured persons may recover substantial awards in tort claims," but also of "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. Both types of cost, those incurred in the defense of lawsuits as well as possible liability judgments, concerned Congress because they had caused an instability in the vaccine market which "could create a genuine public health hazard in this country." *Id.* at 7, *reprinted* in 1986 U.S.C.C.A.N. at 6348.

Petitioners either miss the significance of the cost and burden to be imposed upon the vaccine manufacturers should their proposed subpoena be issued or else they have deliberately

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[1] Petitioners' Response to Merck and Amicus Curiae re Non-Party Discovery (the "Response"), at 2 (emphasis in original).

chosen to misrepresent the effects of a subpoena requiring the production of documents of the scope they propose.[2] In either event, it is readily apparent from any objective consideration of the proposed discovery that compliance would entail a great deal more than a mere "bother" and that the costs and burdens Petitioners would have the Special Master impose upon the manufacturers are precisely the type of litigation costs of time, human resources, and money that Congress designed the Vaccine Act to protect manufacturers against.

Because requiring vaccine manufacturers to respond to discovery in the Compensation Program is generally contrary to the intent and design of Congress, only an extremely strong necessity could overcome the barriers to allowing such discovery in a proper case. Petitioners in this case have come nowhere close to what would be required of them for the issuance of the subpoena they propose.

B. Petitioners misrepresent the state of the science.

Petitioners do not controvert the vaccine manufacturers' argument that in order to authorize discovery in a Program proceeding as necessary, the Special Master must find that there exists a gap in the available evidence – that missing piece of the puzzle – which could only be filled by obtaining the information from a non-party. To the contrary, Petitioners adopt the argument and attempt to demonstrate the existence of such a gap by arguing that there are

[2] While seeking to require the manufacturers to produce documents responsive to broad, sweeping requests including five separate requests for "[a]ny research, survey, study, test or other investigation, whether published or not" concerning the vaccine and its constituent parts, Petitioners' Request for Production of Documents, Petitioners attempt to minimize the burden they ask the Special Master to impose by suggesting, alternatively, that the scope of the subpoena is sufficiently narrow such that Merck could identify precise information sought and then "[i]f Merck does not have any information responsive to petitioners' discovery request ... it should say so and there is nothing to litigate," Response at 6, or that the burden is of little consequence and should be disregarded because "the manufacturers' interest in wanting to avoid the cost and bother of collecting and photocopying responsive documents" is outweighed by Petitioners' need for speed in the collection of documents, Response at 9.

recognized "significant gaps in the [scientific] evidence necessary to decisively answer the causation question."[3]

As support for their argument, Petitioners rely chiefly upon the October, 2001 IOM report,[4] as well as other, mostly unspecified, government agency statements.[5] While it is true that the IOM found a lack of research necessary to prove or disprove the "biologically plausible" hypothesis that thimerosal-containing vaccines might cause neurodevelopment disorders when it concluded its study in 2001, Petitioners disingenuously represent, at least by implication, that nothing has changed since that time. In so doing, they have inexplicably ignored the extensive, and growing, volume of scientific literature which answers many of the questions raised by the IOM.[6] The credible studies which have been published since the IOM's report will no doubt be relied upon to *disprove* the causation hypothesis. Perhaps that is why Petitioners failed or refused to acknowledge their existence in constructing an argument for a gap in the available science. These articles exist nevertheless and their existence belies Petitioners' argument that a gap in the science makes discovery from the vaccine manufacturers "necessary."

Accordingly, Petitioners' Motion is not supported by the existence of a gap in the record or available evidence – either factual or scientific – which could make their broad and burdensome discovery requests reasonable and necessary.

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[3] Petitioners' Response at 3-5.

[4] *Immunization Safety Review: Thimerosal-Containing Vaccines and Neurodevelopmental Disorders,* Institute of Medicine, October 2001.

[5] Petitioners' Response at 3-5.

[6] Some of the recently published works were cited by Merck in its opening brief, at 13-14.

C. The desire for a speedy resolution does not justify the proposed discovery.

Aventis Pasteur agrees with Petitioners that the Compensation Program was designed to be efficient and expeditious. The parties have an interest in and a right to bring these proceedings to conclusion in a reasonable timeframe. It is understandable that the pace of the production of PLA documents has led to frustration and the desire for alternatives. But none of these concerns, however legitimate, justify overriding the intent and design of Congress and abandoning one of the essential purposes for which the Program exists by dragging the vaccine manufacturers into these proceedings and requiring them to bear the burdens of litigation and the substantial costs that would be incurred in responding to the proposed discovery.

Aventis Pasteur and the other vaccine manufacturers addressed why Petitioners' desire for speed was not sufficient to establish reasonableness and necessity and why that desire could not justify the proposed discovery in the opening briefs. Those arguments will not be repeated here as Petitioners have responded only by rearguing the point made in their Motion that the current process is slow and cumbersome.

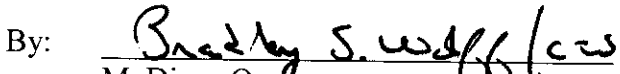
III. Conclusion

Petitioners have failed to establish that the discovery they seek is reasonable and necessary. For the many reasons shown by Merck and the *amici* in their opening and reply briefs, it is neither reasonable nor necessary to engage the vaccine manufacturers in these proceedings and impose the burdens of discovery upon them in order to fulfill Petitioners' desire to sift through voluminous documents in a search for something that might be relevant and admissible. While such a broad fishing expedition might be permitted by some courts, it is not authorized and should not be allowed in these proceedings.

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

Respectfully submitted, this 29th day of December, 2003,

SWIFT, CURRIE, McGHEE & HIERS, LLP

By: 

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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 29th 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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