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,

Various Petitioners,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent

AUTISM MASTER FILE

PETITIONERS' REPLY IN SUPPORT OF

ISSUING A SUBPOENA TO MERCK & CO., INC.

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I. INTRODUCTION

The Special Master should authorize the issuing of a subpoena as requested by petitioners because the requested discovery is *on its face* reasonably necessary to the general causation inquiry in the Omnibus Proceeding. Moreover, the petitioners' request is squarely within the scope of discovery permitted by statute and court rules. Merck's objections fail for two central reasons.

First, Merck incorrectly presumes that it, rather than the Special Master, is entitled to make the "necessity" determination that is required to support issuance of a subpoena. Merck erroneously attempts to set the standard so high that no claimant could ever clear the necessity hurdle, remarkably claiming, for example, that petitioners are obliged to present their entire causation case to Merck so that Merck could then deem what the necessary gaps might be. That position finds no support in the relevant law. It is up to the Special Master to decide what information he believes is reasonable and necessary to the conduct of his causation inquiry. As petitioners have consistently argued, the requested discovery is facially relevant, it is not available from other sources, and the requested discovery is much narrower than would be available as a matter of right in civil litigation. The discovery should therefore be ordered.

In addition, Merck attempts to create the mistaken impression that production of the reports prepared by Merck's own experts in the United Kingdom litigation requires the Special Master to wade into a "thicket" of thorny international law. That supposed "thicket," however, is entirely of Merck's creation, and can be avoided by following the appropriate law applicable to obtaining the discovery that was proffered in the U.K. litigation. The defense expert reports are subject to subpoena as requested by petitioners.

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While petitioners do withdraw specific discovery requests based on facts presented in Merck's responsive pleading, the remaining requests ought to be granted and a subpoena authorized as requested below.

II. ARGUMENT

A. The Federal Vaccine Act Authorizes the Special Master to Authorize the Requested Subpoena.

Merck's response opposing the discovery request fails because it incorrectly glosses over the authority of the Special Master to conduct discovery, and it misconstrues Congress' intent to protect vaccine manufacturers from lawsuits as a much broader intent to absolve the manufacturers from complying with nonparty discovery requests issued pursuant to the authority granted to the Special Masters. There is no doubt that discovery is unavailable as a matter of right in the NVIC, but there is also no doubt that discovery is explicitly available if the Special Master determines that it is reasonable and necessary. 42 U.S.C.§300aa-12(d). It is also clear that the scope and means of discovery in the NVIC are, by operation of the Rules of the Court of Claims and the Vaccine Court, virtually identical to the scope and means of discovery as conducted under the Federal Rules of Civil Procedure. 42 U.S.C.§300aa-12(d); RCFC 26-37; Vaccine Rule 7(b).[1]

Against this backdrop of explicit allowance for discovery in the NVIC and in the rules of court, Merck posits the unsupportable theory that Congress intended the prohibition against direct personal injury lawsuits by vaccine-injured people against vaccine manufacturers to additionally prohibit any exercise of discovery authority by the Special Masters. This position is not supported by the case law, including the cases Merck tries to rely on in its Response.

In *Thomas v. Sect'y of the Dep't of Health & Human Services,* 27 Fed.Cl. 384, 387 (Fed.Cl.Ct. 1992), for example, the court specifically described Congress' intent as "relieving the

[1] As detailed in Petitioners' Motion to Issue Subpoena to Merck & Co., Inc., re MMR Vaccine, pp. 6-9.

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manufacturers from the burdensome costs of litigation ***imposed by vaccine-related negligence actions***." (emphasis added) (cited in Merck's Response, p.5). Similarly, the Federal Circuit identified Congress' intent as wanting to avoid ***"civil tort actions against vaccine manufacturers"*** because the liability exposure created by vaccine litigation was producing "undesirable results." *Lowry v. Sect'y of the Dep't of Health & Human Services,* 189 F.3d 1378, 1381 (Fed.Cir. 1999) (emphasis added) (cited in Merck's Response, p. 3-4). The discussion of litigation costs in *Lowry* has absolutely nothing to do with the costs to Merck or any other manufacturer of simply complying with a subpoena or discovery request when the manufacturer has not been sued. The insurance coverage and litigation cost issues arise only where there is—not surprisingly—actual litigation pending against a manufacturer that exposes the manufacturer to financial liability in tort for vaccine-related injuries. There is no potential tort liability here, there is no lawsuit pending against Merck, and Merck faces no financial exposure for the vaccine-related injuries of any petitioner in this proceeding. The policy concerns and the issues of legislative intent expressed in *Thomas, Lowry*, and the legislative history simply are not implicated by this request for non-party discovery.

In addition, if Congress had intended to limit discovery in the manner suggested by Merck, Congress easily could have done so. Congress could have inserted language into 42 U.S.C. §300aa-12(d) making it clear that the Special Masters' discovery power did not include non-party discovery against vaccine manufacturers, or otherwise restricting the scope of type of discovery that the Special Masters could conduct. In addition, Congress in 42 U.S.C. §300aa-11 could have prohibited discovery against manufacturers at the same time that direct tort actions were barred. If Congress intended the limitations on direct personal injury lawsuits against manufacturers to include a prohibition on discovery conducted apart from a lawsuit against the manufacturers, this certainly would have been a logical place to include language to that effect. The rules of the Court of Claims (at RCFC 26-37) or the Vaccine Rules (at VR 7) could have limited the scope of discovery against non-parties. Nowhere in the statute or the rules, however,

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did the legislature limit non-party discovery directed to vaccine manufacturers. Congress specifically permits the type of discovery sought by petitioners in this instance, and the Special Master is empowered to authorize the subpoena requested by petitioners.

Congress' silence on this issue does not create a blank slate upon which Merck can write self-interested protective language; to the contrary, Congress' choice of silence in this otherwise extremely comprehensive and detailed statute can only be construed to mean that Congress did not intend to limit discovery in the manner erroneously argued by Merck.

B. Petitioners Withdraw Certain of their Discovery Requests.

Petitioners' discovery request to Merck included four categories of documents: (A) specific pages of the product license application (PLA) for Merck's MMR vaccine that were blank or redacted in the production provided to petitioners by respondent; (B) product safety research documents (other than anything contained in the PLA) that were not part of the respondent's production of documents; (C) records of communications between Merck and the federal government; and (D) materials prepared in the course of litigation in the United Kingdom involving Merck's MMR products.

Based on Merck's description of the contents of the PLA materials requested, Merck's representations as to the content of the withheld and redacted material, and Merck's fact-based analysis of the contents of the requested PLA pages,[2] petitioners agree that the requested PLA documents are likely not necessary to resolving the general causation inquiry. Petitioners therefore withdraw their request for unredacted portions of the Merck MMR PLA (Request A). Petitioners do not concede the legal issues implicated by the original request. Petitioners maintain that if there was a factual basis for believing that the identified PLA pages contained facially relevant material, then the Special Master would have the power to authorize a subpoena

[2] See, Merck's Response at pp. 8-17, and Exhibits 1 and 2.

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requiring the production of the unredacted documents (subject to an appropriate protective order), as argued in petitioners' original motion.

In addition, petitioners withdraw their request for records of communications between Merck and the federal government (Request C) based on Merck's representation that the respondent has presumably produced any responsive material to the petitioners.[3] Assuming that Merck's presumption is correct, and absent any indication that Merck possesses responsive documents that the government does not have, petitioners agree to pursue these documents directly from the respondent as appropriate.

C. The Request for Product Safety Research Documents *on its Face* Seeks Information that is Reasonably Necessary to the General Causation Inquiry.

Merck's opposition to petitioners' request for product safety research documents (Request B) is based on the remarkable assumptions that the only information reasonably "necessary" to the causation inquiry is information provided in existing published, peer-reviewed studies, and that petitioners must somehow be able to identify in advance what information Merck might or might not have regarding any theory of general causation. Merck's position avoids the simple fact that petitioners have requested product safety research information that is facially relevant to the causation inquiry, that is exclusively in the possession of Merck, and that, because it is exclusively in Merck's possession, is not part of the research currently available to the Special Master or the petitioners.

Merck further confuses the issue by arguing that the requested information can only be "necessary" for purposes of 42 U.S.C. §300aa-12(d) if it fills a gap in petitioners' case, whereas the appropriate standard is whether the information is needed by the Special Master to evaluate petitioners' case and the respondent's case when they are presented. Merck's position on this issue it at odds with their argument elsewhere in the Response that necessity is evaluated from the perspective of the Special Master conducting an inquiry into causation. Merck's Response,

[3] See, Merck's Response at pp. 22-23.

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p. 6. Merck does not and cannot point to any authority for the proposition that non-party discovery can only be conducted by the Special Masters when petitioners affirmatively demonstrate an alleged "gap" in their proof.

Merck's flawed argument also attempts to create a logically and practically impossible standard for a showing of necessity—implying that petitioners must somehow anticipate what information Merck might have, and without knowing what the information is, then describe how the information would fit into petitioners' theory of causation. In this instance Merck refuses to say whether responsive documents exist in the first place, and certainly there is no way that petitioners could possibly identify what data they "need to get" from Merck.

It is also reasonable to believe that Merck's long experience with the MMR product and its components gives Merck unique insight—if not unique research information and data—into whether the product might be causally related to the injuries at issue in this Omnibus Proceeding. There is no way to know whether that is the case without seeing a substantive response to the discovery request; that is, either a representation that responsive documents do not exist, or production of the responsive documents themselves.

Merck also overstates the alleged burden placed upon it by petitioners' request. First, Merck inaccurately attempts to equate this request with full-blown discovery of the sort that would occur if Merck were involved in litigation. As discussed above, however, Merck is not being sued, and Merck is well aware that the requested non-party discovery is dramatically more limited than it would be if there was a lawsuit pending directly against Merck. In addition, the supposed "litigation burden" Merck claims to suffer is largely Merck's own creation. Rather than voluntarily supplying the requested information in a setting where it faces no liability and no financial exposure, Merck has created collateral litigation. While it certainly is Merck's right to resist non-party discovery, Merck should not then complain about a litigation burden that is largely of its own creation.

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On balance, Merck's exaggerated claims of burden and expense are outweighed by the interest of petitioners and the Special Master. The hundreds of seriously injured children in the Omnibus Proceeding should be entitled to the information they need to fully develop their case for causation, especially information held by a company that faces no liability exposure or financial risk by disclosure. The Special Master, specifically empowered by Congress to inquire into matters he believes are necessary to the case, should also be entitled to product safety information that is uniquely held by the one entity most familiar with the product. Ultimately the Special Master is charged with reaching a fact-based decision about causation, based on information presented by the parties but also based on information collected by the Special Master through the exercise of his discretionary discovery authority. It is axiomatic that better decisions are informed by more facts rather than fewer facts, an interest served by authorizing a subpoena as requested by petitioners.

D. Petitioners are Entitled to The Defense Expert Reports and other Defense Documents Produced or Prepared in the United Kingdom Litigation.

Petitioners in this instance seek the plaintiff and defendants' expert reports prepared in U.K. litigation involving Merck's MMR vaccine product, as well as documents produced by Merck to the plaintiffs' discovery requests in the U.K. Petitioners do *not* concede the request for Merck's produced discovery documents as Merck's response incorrectly suggests. Petitioners do concede, however, that if the plaintiffs in the U.K. are not represented by counsel as Merck avers, then Merck is not obliged to obtain disclosure agreements from each of those *pro se* claimants as required to permit the release of the plaintiffs' expert reports to non-parties (i.e., the petitioners in this proceeding). Absent a duty to obtain the required disclosures, Merck likely is not obliged to produce the requested plaintiff reports, and petitioners withdraw that request.

Petitioners are, however, entitled to the expert reports prepared by experts retained by Merck itself, and to Merck documents that Merck produced. Merck mistakenly urges the Special Master and the U.S. Court of Federal Claims to "defer" to an English rule of civil procedure, but

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the applicable rules of foreign relations law do not compel that result. In this case, Merck claims that an English rule of civil procedure (CPR §31.22) limits production of the documents. That is not the case. In evaluating whether to authorize this subpoena seeking privately held documents that might be located in a foreign country, the courts apply a "balancing test" based on the *Restatements of Law, Foreign Relations Law of the United States,* §442. *In re Grand Jury Subpoena Dated August 9, 2000,* 218 F.Supp.2d 544 (2002).

Under the *Restatement of Law (Third), Foreign Relations Law of the United States,* §442(1)(c) (1987), a court confronted with a request for the production of documents located abroad may consider several factors. First, the information must be important to the proceeding in which it is requested. In this case, it is difficult to imagine why reports prepared by presumably qualified medical and scientific experts, with access to information not available to petitioners, would not be important to resolving questions of causation in this proceeding. The expert reports were apparently prepared specifically to address the issue presented in this general causation inquiry. Given the creation of 30 different expert reports by the defendants in the U.K. litigation leads to the reasonable conclusion that the full set of reports represents a comprehensive survey of the causation issues that on its face would be informative in this setting. The same importance attaches to documents produced by Merck in response to the U.K. litigant's requests for causation discovery.

In addition, tracking the *Restatement,* §442(1)(c), the court should take into account the degree of specificity of the request. In this instance, the request is very specific, as petitioners seek the individual expert reports prepared by a particular party in a particular action. Based on Merck's Response, we now know that there are exactly 25 expert reports that Merck either jointly or individually produced,[4] and those are the documents subject to this request. The request could only be more specific if petitioners knew the titles or authors of the reports so that

[4] Merck's Response, fn. 9, p. 28.

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they could be requested by name. Merck presumably has its other document production labeled and organized and Merck could very readily identify and produce them pursuant ot this request.

In addition, the court should determine whether the information originated in the United States. On this issue petitioners anticipate that the balance may favor Merck, as it is likely that most, if not all, of the expert information originated in or was developed in Great Britain.

Further, in this instance the petitioners have no alternative means of securing the requested expert reports or document production, short of duplicating the discovery request to those of Merck's co-defendants in the U.K. litigation who might have jointly produced the same reports or propounded the same discovery. This discovery request is the only practical means the petitioners have of obtaining the specific and facially relevant expert information prepared on Merck's behalf and in the possession and control of Merck, as well as the documents Merck produced.

Finally, the court should balance England's interest in enforcing its procedural rule of civil disclosure against the interest of the United States in obtaining the information. The balance weighs heavily in petitioners' favor on this consideration. The English rule at issue, even as described by Merck, is clearly designed to protect a litigant from the damage that might be caused if an adverse party disclosed to a third party harmful information that the adversary obtained through the course of the litigation. It is for this reason that the "consent to disclosure" requirements might legitimately relieve Merck of an obligation to disclose the plaintiff reports, particularly where the adverse parties are unrepresented and consent would likely be extremely burdensome. The foreign state's interest in enforcing this protective procedural rule, however, is *de minimus* when the discovery request seeks information that the party itself produced; that is, information that was not obtained from an adversary. The interest of the Untied States in obtaining the information is significant, as the information is facially relevant to resolving critical issues of fact presented by hundreds of seriously injured children seeking relief in a federally designed and administered compensation program.

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Merck's status as a non-party in the Omnibus Proceeding is, despite Merck's protestations to the contrary, not a bar to producing the requested U.K. documents. Subject to the "balancing test" of the *Restatement,* even foreign non-parties are subject to extensive discovery in the United States where consideration of the §442(1)(c) factors favors the party requesting the discovery. *See. eg., First Am. Corp. v. Price Waterhouse LLP,* 154 F.3d 16 (2d Cir. 1998). The cases Merck relies upon are inapposite because the compliance with the discovery request in those instances would have placed the non-parties at risk of *criminal* liability in the foreign state. *Cochran Consulting, Inc., v. Uwatec USA, Inc.,* 102 F.3d 1224, 1230 (Fed.Cir. 1996); *United States v. First Nat'l Bank,* 699 F.2d 341 (7th Cir. 1983); *In re Sealed Case,* 825 F.2d 494 (D.C.Cir. 1987).

By complying with the requested discovery request Merck would not run afoul of either British criminal law or of any substantive British law. The only foreign law at issue is a civil procedural rule that, applied in this case, is designed to protect parties other than Merck in the U.K. litigation. Contrary to Merck's response, U.S. courts are willing to order discovery under similar circumstances, and the Special Master should do the same here. *See, In re Sealed Case,* 825 F.2d at 497-498.

E. <u>Merck is not Entitled to Information made Available to the Special Master.</u>

Merck's response renews the motion for "information" made and rejected over five months ago by the Special Master. *See, Order re Merck's "Motion for Information re: Discovery",* Autism Master File, November 26, 2003. Merck seeks discovery of all of the discovery material produced to the petitioners by respondent in this proceeding, a request clearly and explicitly prohibited by 42 U.S.C. §300aa-12(d)(4)(A). Notwithstanding the language of the statute and the November 26, 2003 denial of a virtually identical request, Merck again seeks information that they are not entitled to. The request for "information' should again be denied.

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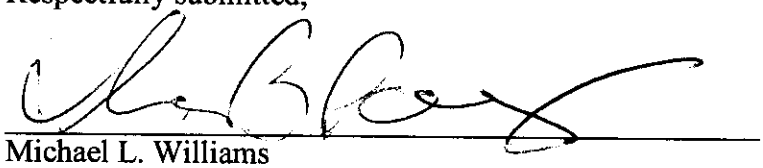
III. CONCLUSION

For all of the reasons described above, petitioners seek an Order of the Special Master authorizing a subpoena directing Merck to comply with Requests B and D(1) and (2) as originally requested in Petitioners' Request for the Production of Documents directed to Merck & Co., Inc.

DATED this 7th day of May 2004.

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that on May 7, 2004, I served the foregoing **PETITIONERS' REPLY IN SUPPORT OF ISSUING A SUBPOENA TO MERCK & CO., INC.**, on the following individual(s):

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