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, Various Petitioner(s), v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	*	Autism Master File **NON-PARTY BAXTER HEALTHCARE CORPORATION RESPONSE TO PETITIONER'S MOTION TO ISSUE REVISED THIRD PARTY SUBPOENA**

INTRODUCTION

Non-party Baxter Healthcare Corporation ("Baxter") submits this Memorandum in Opposition to Petitioners' Motion to Issue Revised Third Party Subpoena (the "Motion"). In their motion, Petitioners seek the issuance of a subpoena to Merck and Co., Inc., ("Merck") that would direct Merck, a nonparty, to produce numerous documents including the Product License Application ("PLA") for its Recombivax HB vaccine. Because Petitioners' Motion makes clear their intent to seek similar subpoenas directed to other manufacturers, Baxter requests that it be allowed to submit a response to the motion as an interested party.

In approximately June 2000, Baxter Healthcare Corporation acquired the assets and liabilities of North America Vaccine, a company that manufactured and distributed one thimerosal-containing pediatric vaccine - Certiva. Thimerosal has been used in vaccines for many decades http://www.fda.gov/cber/vaccine/thimerosal.htm#thi (stating that thimerosal was

widely used as of 1930); Certiva, with thimerosal as a preservative, was approved by the FDA in July 1998. North American first shipped Certiva for commercial distribution in October 1998. The last Certiva shipment was in June 2000, with an expiration date of February 2001. Due to North America's late entry and short time in the market, it's market share was quite small. Despite the very narrow "window" in which Certiva was available to the public, and despite the fact that (to Baxter's knowledge, to date) no child asserting a vaccine-related injury due to thimerosal has demonstrated that he received Certiva, Petitioners have targeted Baxter as a "vaccine manufacturer".[1]

Congress has mandated that a precondition for Vaccine Court discovery is that the Special Master properly find that discovery "necessary" to his or her decisions. This limitation should apply with special force when the requested discovery sweeps broadly and is directed at a vaccine manufacturer, the very entity that the Vaccine Act intended to insulate from litigation. For the Special Master to find that he "needs" the requested discovery here would violate that congressional mandate. Accordingly, Petitioners' Motion should be denied.

ARGUMENT

Even If the Special Master Has Authority to Authorize Issuance of Non-party Subpoenas, He Lacks Authority Under Those Circumstances.

No court has ever adjudicated whether Congress has granted the Special Master authority to authorize issuance of a subpoena to a vaccine manufacturer. Assuming such authority exists in limited circumstances, it clearly is absent here.

---

[1] No subpoena has yet issued. However, if the Special Master issues the subpoena to Merck this will set a precedent to issue additional subpoenas to the other vaccine manufacturers. This is why Baxter joins Merck in its opposition to Petitioners' Motion. Baxter understands that if the Special Master determines that a subpoena is appropriate, the issuing court would be the Court of Federal Claims. Baxter reserves the right to challenge the Special Master's authority to issue a subpoena himself, should that occur.

I. Issuance of the subpoena would violate the Vaccine Act's objective of reducing the litigation burden for vaccine manufacturers.

Whatever the propriety of sweeping discovery in conventional products liability litigation, such discovery is not appropriate in this forum. Specifically, the discovery Petitioners' seek is contrary to Congress' stated primary purpose for creating the National Childhood Vaccine Injury Compensation Act (the "Vaccine Act").

One of Congress' primary goals in passing the Vaccine Act was to ensure the country's vaccine supply by relieving vaccine manufacturers of the burden of litigation - a burden Congress found was driving those manufacturers out of the business *See Lowery v. Secretary of the Dep't of Health & Human Servs.*, 189 F.3d 1378, 1381 (Fed. Cir. 1999) (noting that "Congress instituted [the vaccine] compensatory program because the traditional civil tort actions against vaccine manufacturers were producing undesirable results ..."). Congress recognized that the cost of vaccine-related litigation had reduced significantly the number of manufacturers willing to sell childhood vaccines, making "the threat of vaccine shortages a real possibility." *Id.* at 5, *reprinted in* 1986 U.S.C.C.A.N. at 6346. Because "the high cost of litigation and difficulty of obtaining insurance was undermining incentives for vaccine manufacturers to remain in the vaccine market," Congress enacted the Vaccine Act. *Lowery*, 189 F.3d at 1381. *See also Thomas v. Secretary of the Dep't of Health & Human Servs.*, 27 Fed. Cl. 384, 387 (1992) (stating that the Vaccine Act was in part prompted by "the need to encourage the continued availability of important childhood vaccines by relieving the manufacturers of these vaccines from the burdensome costs of litigation imposed by vaccine-related negligence actions").

Through the Vaccine Act, Congress provided that third-party discovery is not available as a matter of right, but rather requires a finding of necessity by the Special Master. A party to the

Vaccine Court proceedings must file a motion setting forth 1) a particularized need, and 2) inability to obtain the requested discovery through informal means. (Vaccine Court Rule 7(a) and (b)). These requirements are examined in detail in Part II, *infra*. Congress did not intend that discovery would proceed with the wide net that is sometimes associated with proceedings in courts of general jurisdiction.

The approach Petitioners advocate carries the potential for abuse. Many of the attorneys for Petitioners are actively pursuing litigation against vaccine manufacturers in civil court. By extracting discovery from a vaccine manufacturer here, Petitioners' counsel can use the Vaccine Court as a vehicle for the ulterior purpose of preparing themselves for that litigation. As originally drafted, the proposed subpoena contained requests that were patently irrelevant to any issue in this omnibus proceeding, and mirrored themes that the plaintiffs are employing in the civil actions. For example, the requested subpoena at first sought information about:

> product packaging, . . . including documents about the relative costs, expenses or any other financial factor relating to a) the use of multi-dose vials versus single-dose vials, b) the use of single-dose pre-filled syringes, c) the use of preservatives . . . .

(Subpoena at 4.) This request was clearly directed at Petitioners'/Plaintiffs' counsel's theory that profit considerations drove vaccine manufacturers to supply vaccine in multi-dose vials (with the thimerosal preservative) rather than in single-dose syringes. Although that request does not appear in the revised subpoena, the fact that it was ever included, with no connection to causation issues, reveals that discovery in this forum may be driven less by "necessity" and more by the desire of counsel to "get a jump on" manufacturer discovery for use in subsequent civil litigation.

To permit broad discovery from a vaccine manufacturer would be directly contrary to what Congress intended the Vaccine Act to accomplish. If Petitioners are allowed to have

discovery, not only will vaccine manufacturers shoulder the burden that Congress intended to spare them, but the Act will become a vehicle for *increasing* that burden. Vaccine manufacturers will have to participate in discovery in *two* forums, rather than one. In short, issuance of the subpoena would turn the Vaccine Act on its head by creating more, rather than fewer, burdens on vaccine manufacturers.

II. Issuance of the subpoena would violate the discovery restrictions that Congress put into the Vaccine Act.

Congress made clear that discovery in the Vaccine Court is available only under limited circumstances. As shown below, those circumstances are not present here.

A. To the extent that the Special Master is ever authorized to issue a subpoena to a non-party, the circumstances under which he may exercise such authority are severely limited.

Congress intended the Vaccine Court to be a unique forum, with unique rules, serving a unique public interest. One of Congress' objectives for the Vaccine Court was to streamline compensation proceedings. For example, Congress directed that the rules for Vaccine Court were to: "provide for a less-adversarial, expeditious, and informal proceeding," 42 U.S.C. § 300aa-12(d)(2)(A); "include flexible and informal standards for the admissibility of evidence," 42 U.S.C. § 300aa-12(d)(2)B); and "include the opportunity for parties to submit arguments and evidence on the record without requiring routine use of oral presentations, oral examinations, or hearings." 42 U.S.C. § 300aa-12(d)(E).

Petitioners admit that they are not entitled to "discovery as a matter of right [as] in civil litigation under the federal or state rules of procedure." Motion at 7. The closest the Act comes to possibly authorizing non-party subpoenas appears at § 300aa-12(d)(3)(B) which simultaneously limits such discovery by providing that:

> In conducting a proceeding on a petition, a special master . . . (iii) may require . . . the production of any documents as may be reasonable ***and necessary***.

(Emphasis added.) Congress also specified that the Vaccine Court rules were to "provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions in the United States Court of Federal Claims." 42 U.S.C. § 300aa-12(d)(2)(E). Vaccine Rule 7(c), in turn, states that "[w]hen ***necessary***, the special master upon request by a party may approve the issuance of a subpoena." (Emphasis added.)

Finally, the text of the statute makes it apparent that Congress did not intend for § 300aa-12(d)(3)(B)(iii) to make Vaccine manufacturers a target for broad-based discovery. That section - the only statutory authority upon which Petitioners rely - relates to what the Special Master may require "[i]n conducting a proceeding on a petition." Whatever else may be said of the "proceeding on a petition" language, surely Congress did not envision that a Special Master could appropriately direct industry to produce all of its documents on causation *and other topics* in considering the rather narrow questions presented in this omnibus proceeding.

By insisting that the Vaccine Court rules include "limitations" on discovery (42 U.S.C. § 300aa-12(d)(2)(E)) and that discovery be allowed only where "necessary" (42 U.S.C. § 300aa-12(d)(3)(B)(iii)), Congress clearly intended that discovery was not to proceed under the Federal Rules of Civil Procedure. Those rules allow discovery of "any matter, not privileged that is reasonably likely to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26. The standard for discovery in the Vaccine Court is much more rigorous.

Thus, in order to grant Petitioners' motion for issuance of a subpoena, the Special Master must do more than conclude that the requested subpoena describes documents that *could* be relevant. Instead, for each category of the desired discovery, the Special Master must find a specific reason why the discovery is "necessary" to his ability to adjudicate the issues, and why

the requested discovery should be had from the vaccine manufacturers. Accordingly, Petitioners should have to demonstrate what they presently have available to them *to prove causation*, what evidentiary gaps exist, how the requested materials might fill those gaps, and why they have to get those materials from vaccine manufacturers. The Special Master then must weigh that showing against the Congressional purpose of sparing the manufacturers the burdens of litigation.

B. Petitioners have not shown that issuance of the subpoena is "necessary."

Petitioners seek to subpoena from Merck and eventually from the other vaccine manufacturers (presumably including Baxter) the identical PLA documents that the FDA has been in the process of producing for the past eleven months. (Petitioners' Revised Request for the Production of Documents ("Subpoena") at A, "This request is intended to encompass all documents responsive to petitioners' earlier discovery request to the FDA . . ."). This is the only category of documents for which Petitioners even attempt to show a need. Petitioners complain that the FDA has been slow in providing documents, and attribute the delay to Respondent's need to redact trade secret information prior to production. This complaint, however, demonstrates nothing about a "need" to obtain the PLA documents directly from the manufacturers.

First, Petitioners ignore the fundamental principle that non-party discovery is not "necessary" simply because the requesting party wants to avoid the available alternative *See, e.g., 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). *See also Truswal Sys. Corp. v. Hydro Air Eng'g, Inc.*, 813 F.2d 1207, 1210 (Fed. Cir. 1987) (fact that producing entity is not a party to the litigation is highly relevant to assessing whether burden on the subpoenaed party is excessive); *CMedia, LLC v. Lifekey Healthcare, LLC*, 216 F.R.D. 387, 389 (N.D. Tex. 2003) (in assessing harm, prejudice, or burden to subpoenaed party, "one factor to be considered is whether the [producing] party is a nonparty to the litigation") Here, Petitioners' ability to obtain the PLA documents from the FDA shows that the subpoena *is not necessary.*

Furthermore, substantial information clearly already is available to Petitioners. Petitioners have issued document requests to Respondent that are extremely broad. Among the fifteen categories of documents that Petitioners requested were "all documents that . . . relate to DPT, DtaP, HIB, Hepatitis B, and MMR vaccines, as well as Rhogam (a thimerosal containing product) and other thimerosal-containing products, as they relate to the development of autism spectrum disorder, PDD, gastrointestinal and neurological problems." (Document Request 2, Petitioners' Interrogatories and Requests for Production of Documents, filed August 2, 2002, at 18.) Petitioners also sought access to data from VAERS, and the Vaccine Safety Datalink, MEDWATCH, and the National Health Interview Surveys. (Requests No. 4-7.) In his September 24, 2003 Autism Update and Order, the Special Master noted that "the respondent has now finished compliance with all of the petitioners' Requests for Production" (except for the PLAs and unpublished study data). Petitioners also apparently have access to something called the Thimerosal Screening Analysis. (September 24, 2003 Autism Update and Order at 3.) In

other words, Petitioners have received and reviewed (and continue to receive and review) "many thousands of pages", all presumably relating to causation.[2]

Petitioners have not explained what information they need from the PLAs that is even relevant -- let alone "necessary" -- to the causation issue in this proceeding. Whatever that information is perceived to be, it surely is not in the PLA documents that contain trade secrets. Moreover, if Baxter is required to produce the Certiva PLA pursuant to a subpoena, Baxter intends to redact trade secrets and other confidential information prior to production.

In addition to the PLA documents, Petitioners seek (1) documents relating to Merck's communications with various government agencies (Subpoena at C) and (2) what Petitioners call "product safety research" documents. (*Id.* at B). Rather that articulating the "necessity" for these documents, Petitioners simply state that "[i]t is also likely that the vaccine manufacturers have information about the health and safety attributes of their products, that the respondent does not have." (Motion at 3.) As shown above, Petitioners must show much more than the potential for relevance. Here, they have provided no basis upon which the Special Master could find that these documents are necessary to a determination of the general causation issues and not otherwise available.

Nor could they. Documents related to the vaccine manufacturers' communications with federal agencies (Subpoena at C) are available from and, presumably, have already been provided by, Respondent. (*See* Request 13 of Petitioners' Requests to Respondent at 22, "all correspondence of any kind, emails, memos, letters, reports, etc., exchanged between the government and any vaccine manufacturer, any health and/or medical agency, or international organization in any country related to MMR, thimerosal, or any other preservative in any

---

[2] Indeed, this information seems to be of the type that Congress contemplated.

vaccine.") Given that Petitioners already have these documents, it is impossible to imagine how it might be "necessary" to get them again.

With respect to "product safety research" documents (Subpoena at B), Petitioners offer only the general observation that it is "likely that the vaccine manufacturers have information about the health and safety attributes of their products." No doubt, but Petitioners' burden is to demonstrate not only that each category of documents sought relates to whether thimerosal in vaccines causes autism, but also why the information already available is insufficient to prove causation. Because Petitioners have done nothing more than posit that the documents they seek are possibly relevant to their case, they have failed to demonstrate any justification for the Special Master to disregard Congress' intent to spare manufacturers the burdens of litigation.

III. The Vaccine Manufacturers Have A Right to Redact Trade Secret Information From Their Documents.

Petitioners argue that the current process by which PLA documents are produced to them by the FDA is "slow, cumbersome and costly." (Motion at 3). Therefore, Petitioners apparently seek both (1) to by-pass Respondent and obtain the PLA documents directly from the vaccine manufacturers, and (2) to force the vaccine manufacturers to turn over the documents without redacting trade secrets, and with only a confidentiality order in place to protect them. As set forth above, Baxter objects to producing the documents at all, and believes that the availability of the PLA documents from a party makes the subpoena not necessary. Even more importantly, however, Baxter maintains that no vaccine manufacturer should be forced to divulge its trade secrets, even with a protective order in place, and that if it has to produce the PLA documents, it is entitled to redact trade secret information from the documents prior to doing so.

A. Petitioners have no right to receive irrelevant trade secret information.

As noted earlier, the vast majority (if not all) of the trade secret information contained in the PLAs is irrelevant to issues of causation. Under no authority (even outside the Vaccine Court setting) is a party entitled to production of irrelevant material. Therefore, unless and until Petitioners can articulate a reasoned argument why the vaccine manufacturers' trade secrets are relevant to the narrow causation issue in this proceeding, the vaccine manufacturers have no obligation to produce their trade secrets.

B. Only redaction, and not mere entry of a protective order is sufficient to safeguard the vaccine manufacturers' interests.

Baxter's and the other vaccine manufacturers' trade secrets are valuable. Congress has acknowledged the importance of safeguarding the fruits of research and development efforts by imposing on government agencies the requirement that they purge trade secret information from PLAs prior to making them public. Now, Petitioners want Merck and eventually others to put those assets at risk and divulge its trade secrets without a showing that the information is "necessary" to this proceeding.

Like the proverbial bell that once rung cannot be unrung, a trade secret loses value once it is no longer secret. A protective order offers little comfort: that someone might be held in contempt, or a fine imposed, does nothing to offset the loss once precious trade secrets become known to competitors.

1. The Court must balance the potential harm to vaccine manufacturer against the benefit of hastening discovery.

Petitioners do not dispute that the information that the vaccine manufacturers seek to redact is protected trade secret information. Neither do Petitioners dispute that the trade secret information in the PLAs is irrelevant to determining causation. Since Petitioners do not argue

that they have some need for the trade secret information, the only benefit to production of the PLA documents in unredacted form is a hastening of the discovery process. Petitioners argue that their interest in hurrying up the discovery process trumps vaccine manufacturers' interest in protecting its trade secrets. Petitioners are wrong. Because the trade secret information is irrelevant to the issues here, a balancing test requires that the information be redacted prior to production.

In *CMedia*, 216 F.R.D. at 387, one of the parties sought to prove its claim that its party opponent charged unreasonably high prices by subpoenaing costing and pricing information from a competitor of its opponent. The non-party competitor challenged the subpoena, claiming that the pricing information was its trade secret. The court stated that it had to "balance the need for discovery" and the "relevance of the discovery to the case against the potential harm, prejudice or burden" to the subpoenaed party. *Id.* at 389. After significantly narrowing the subpoena, so that it compelled production only of information that was directly relevant to the very specific issues in the case, the court ordered production of documents containing the non-party's trade secret pricing information "in such a manner as to assure confidentiality." *Id.* at 391. In that case, because the trade secret information ***was*** the relevant information, redaction was not an option and, instead, the court entered a protective order that allowed only the attorneys to see the documents in question. *Id.*

Here, redaction ***is*** an option, and is the only course of action that will "assure" the continued confidentiality of the vaccine manufacturers' trade secrets. In any event, forcing a non-party manufacturer to reveal valuable trade secrets *that are irrelevant to the issue in dispute* may be expedient, but it is also unreasonable and an incorrect application of the relevant balancing test.

C. Petitioners cannot be permitted to do an end run around the statutory and court-imposed requirement that the FDA produce the PLA documents in redacted form.

The FDA is required by law to redact trade secret information provided to it in the licensing process. *See* 18 U.S.C. § 1905; 21 U.S.C. § 331(j); 5 U.S.C. § 552(b)(4); 21 C.F.R. §§ 20.61(c) & 314.430; *Chrysler Corp. v. Brown*, 441 U.S. 281, 285, 318 (1979) (holding that an agency's disclosure of trade secret information constitutes an unlawful agency action). Congress imposed that requirement on the FDA in order to provide an incentive for manufacturers to divulge all relevant information to the licensing entity, secure in the knowledge that they would not lose their trade secrets as a result. *See Critical Mass Energy Project v. Nuclear Regulatory Comm'n*, 975 F.2d 871, 872 (D.C. Cir. 1992). Courts have strictly interpreted the FDA's statutory duty to redact trade secret information from PLAs, and have held that even a litigant's interest in having access to a full administrative record does not trump a manufacturer's interest in protecting its trade secrets. *See MD Pharmaceutical, Inc. v. DEA*, 133 F.3d 8, 13-15 (D.C. Cir. 1998) (holding that a third-party's interest in a complete administrative record provides "no support for the proposition that [the] party ... must have unfettered access to all information considered by the agency. Such a proposition, we should note, would be rather remarkable"); *Zeneca v. Shalala*, No. WMN99-307, 1999 WL 167139, **3-4 (March 4, 1999) (refusing to order the production of trade secrets under a protective order); *Serono Labs., Inc. v. Shalala*, 35 F. Supp.2d 1, 4 (1999) (even when FDA was willing to produce PLA pursuant to a protective order, *i.e.*, without redaction of trade secret information, court did not allow because such action on the FDA's part would have been "arbitrary, capricious and unreasonable and contrary to law").

Consistent with these holdings, the Special Master has implicitly found that the requirement to redact trade secret information applies in the context of producing documents to

the Vaccine Court petitioners. It would be nonsensical, then, to allow claimants to do an end-run around the Court's ruling by requiring the manufacturers to produce the documents in unredacted form, with only a protective order in place as security.

In *Serono Labs*, the court determined that the FDA could not produce a full administrative record that contained drug manufacturers' trade secrets pursuant to a protective order, but had to "create three versions of the administrative record, an unexpurgated record which contains the entire record and a version from which Ferring's trade secrets have been removed to give to Serono, and a version from which Serono's trade secrets have been removed to be given to Ferring." The court noted that such an obligation was "unquestionably onerous" and suggested that if the process seemed to take too long, Serono (who argued for production of the administrative record without trade secret redaction) could invoke the court's power to "expedite agency action." Notably, the court said nothing about Serono's circumventing the law altogether by obtaining a non-party subpoena to Ferring. To the contrary, the court ruled that "a party . . . is under no obligation to accept less than the absolute protection the statute creates for its trade secrets." *Id.* at 3; *see also MD Pharmaceutical*, 133 F.3d at 15 (holding that protective order was insufficient and requiring redaction of trade secrets from PLA).

CONCLUSION

For the reasons set forth above, Petitioners' Motion should be denied.

Respectfully submitted,

Date: December 2, 2003

BAXTER HEALTHCARE CORPORATION

BY: _____
LEE DAVIS THAMES (MSB #8061)
DONNA BROWN JACOBS (MSB # 8361)

ITS ATTORNEYS

OF COUNSEL:

BUTLER, SNOW, O'MARA, STEVENS
& CANNADA, PLLC
AmSouth Plaza, 17th Floor
210 East Capitol Street
Jackson, MS 39201
Phone: 601-948-5711

CERTIFICATE OF SERVICE

I, Donna Brown Jacobs, one of the attorneys for the defendant Baxter Healthcare Corporation, do hereby certify that I have this day caused to be mailed, via United States mail, first-class postage fully prepaid, true and correct copies of the foregoing.

Vincent Matanoski
U. S. Department of Justice
Torts Branch, Civil Division
P.O. Box 146, Benjamin Franklin Station
Washington, D.C. 20044-0416

Ghada Anis
Petitioners' Steering Committee
733 15th Street, N.W., Suite 700
Washington, D.C. 20005

Michael L. Williams
Williams Dailey O'Leary Craine & Love, P.C.
1001 SW 5th Avenue, Suite 1900
Portland, Oregon 97204-1135

THIS the 2nd day of December 2003.

DONNA BROWN JACOBS

JACKSON 820851v1