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December 2, 2003

Court of Federal Claims
Office of the Clerk
717 Madison Place
Washington, D.C. 20005

Re: Claims for Vaccine injuries resulting in Autism Spectrum Disorder, or a similar Neurodevelopmental Disorder v. Secretary of Health and Human Services,

Dear Clerk;

Please find enclosed for filing the originals and two copies each of *Non-Party Baxter Healthcare Corporation Response to Petitioner's Motion to Issue Revised Third Party Subpoena* and *Non-Party Baxter Healthcare Corporation's Motion for Leave to Proceed as an Interested Party* in the above referenced matter. Please file the originals and return the file stamped copies in the envelope provided.

Sincerely,

Butler, Snow, O'Mara, Stevens & Cannada

Donna Brown Jacobs

Donna Brown Jacobs

DBJ/lsd

JACKSON 827681v1

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 **AMICUS BRIEF BY NON-PARTY SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE AS TO ISSUES CONCERNING THIRD-PARTY DISCOVERY**

STATEMENT OF INTEREST

SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("SB") is not a party to these proceedings, but has been granted leave by the Special Master to submit this amicus brief as to third-party discovery sought by Petitioners from Merck & Co., Inc. ("Merck").[1] Like Merck, SB is entitled to the protections of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-1, *et seq.* ("Vaccine Act"). SB approves of, but will not restate here, the arguments set forth in Merck's Response to Petitioners' Motion to Issue Revised Third-Party Subpoena ("Response"). SB submits this amicus brief to elaborate further upon certain points made by Merck in its Response and to assist the Special Master in analyzing the various substantive and procedural concerns generally applicable to vaccine defendants that have been raised by

[1] Notice to Clerk and Order Modifying Briefing Schedule Re Merck Discovery (Fed. Cl. Spec. Mstr. Nov. 26, 2003).

Petitioners' request for a subpoena for expansive discovery to third parties, like Merck and SB—whom the Act was designed to protect from precisely such burdens.[2]

ANALYSIS AND AUTHORITIES

The Special Master is, of course, quite familiar with the history and purpose of the Vaccine Act, which, among other things, created the National Vaccine Injury Compensation Program.[3] As is the case with many aspects of the Vaccine Program, resorting to the Act's origin and Congress' stated objectives in its legislative history will provide the answers to the discovery questions posed here.

The Vaccine Act, passed in 1986, was a radical renovation of tort litigation born out of a national health crisis. One of the first of its kind, the Act sought to remedy two significant threats to the national vaccine supply: (i) the inadequacies of the state tort systems to compensate injured vaccinees quickly, predictably, and equitably; and (ii) the significant tort litigation burden on the companies supplying vaccines.[4] Congress carefully crafted a new program that displaced conventional tort law, at least initially, in favor of compensation proceedings in this Court: The program "represents an effort to provide compensation to those harmed by childhood vaccines ***outside the framework of traditional tort law.***"[5] The desired effects were to facilitate rapid and just compensation to injured vaccinees, while at the same time

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[2] At this time, no subpoena has been issued to SB or any other vaccine defendant. Unless and until a subpoena is requested as to SB, it is premature for SB to address the burdens and specific objections that an SB-specific subpoena would necessitate. SB reserves its right to challenge any aspect of any request for third-party discovery to SB directly, should one be made.

[3] *See* 42 U.S.C. § 300aa-10(a).

[4] *E.g.*, H.R. Rep. 99-908, at 7, *reprinted in* 1986 U.S. CODE, CONG. & ADMINISTRATIVE NEWS ("U.S.C.C.A.N.") 6344, 6347; *see also id.* at 6, *reprinted in* 1986 U.S.C.C.A.N. at 6347 ("Lawsuits and settlement negotiations can take months and even years to complete. Transaction costs—including attorneys' fees and court payments—are high.").

lightening the litigation burden on the vaccine manufacturers and suppliers. Both of these aims were integral to the legislative package.

Notably, Congress elected not to deny claimants alleging vaccine-related injuries access to the courts, but it did require that they first pursue their claims through this streamlined administrative process. This alternative resolution process was intended to require vaccinees to marshal their proof and take a "hard look" at their claims—notably, the scientific and medical basis for causation, which is the only substantive issue before the Vaccine Court—***before*** filing suit. According to the statute, the petitioner in Vaccine Court is required to assemble his or her proof, including an affidavit detailing the injury alleged and all relevant medical records, at the outset of the compensation proceeding. *See generally* 42 U.S.C. § 300aa-11(c)(1) & (2).[6] In fact, the petitioner must then either present this necessary proof of the claim or identify the particular records that are "unavailable to the petitioner and the reasons for their unavailability." *Id.* § 300aa-11(c)(3). As Chief Special Master Golkiewicz observed, "[t]he instruction that a petitioner file a detailed petition with all relevant medical records was obviously designed to enable the special master to promptly evaluate and rule upon the claim." *See* "Discussion of Issue of 'Short-Form' Petitions," Autism Master File, at 2 (Fed. Cl. Spec. Mstr. July 8, 2002).

In keeping with its statutory aims, Congress stated a presumption against discovery in the Vaccine Court. 42 U.S.C. § 300aa-12(d)(3)(B) ("There may be no discovery in a proceeding on a petition other than the discovery required by the special master."); *see also* H.R. Rep. 99-908,

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[5] *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 2 (1st Cir. 1994) (emphasis added); *see also Owens ex rel. Schafer v. Am. Home Prods. Corp.*, 203 F. Supp. 2d 748, 752 (S.D. Tex. 2002) (noting that the "Program . . . works with greater ease and on a faster timetable than the civil tort system").

[6] Although the Office of Special Masters has modified that requirement in these omnibus proceedings, *see* Autism General Order #1 (Fed. Cl. Spec. Mstr. July 3, 2002), at 7, it apparently did not do so lightly. *See* "Discussion of Issue of 'Short-Form' Petitions," Autism Master File (Fed. Cl. Spec. Mstr. July 8, 2002) (characterizing the HHS Secretary's concern about suspending the requirements of detailing the alleged injury and filing medical records with the petition initially as "serious and important").

at 22, 1986 U.S.C.C.A.N. at 6363 ("Matters to be demonstrated before compensation can be awarded are relatively narrow and well-defined. Traditional discovery, cross-examination, pleadings, and trial are not allowed in the proceeding on a petition."); *see id.* at 16-17, *reprinted in* 1986 U.S.C.C.A.N. at 6357-58. Discovery is not allowed as a matter of right; however, the Special Master "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)(iii).

The power to compel such information is limited by statute and by rule to situations where reasonableness and necessity for the information has been demonstrated.[7] It is also subject to the overarching objectives of the Vaccine Act—one of which was to protect vaccine defendants from serving on the front lines of litigation. Each of these concerns must be weighed considering the requested discovery. Each of these considerations strongly counsels in favor of denying Petitioners' request for the proposed subpoena to Merck.

The authority to require additional evidence and information is provided so that the Special Master can conduct proceedings expeditiously and effectively. It is designed to benefit the Special Master's consideration of a particular matter—contemplating, for example, that a Special Master might resort to the subpoena power to obtain additional medical records he or she deems necessary to assess a petitioner's medical condition. H.R. Conf. Rep. No. 101-386 (1989), *reprinted in* 1989 U.S.C.C.A.N. 3018, 3119; H.R. Rep. No. 101-247 (1989), *reprinted in*

[7] For example, this authority is governed by the overarching directive that the Special Master make rules for the Vaccine Court, providing for (1) a less-adversarial, expeditious, and informal proceeding for the resolution of petitions, (2) limitations on discovery, and (3) replacement of the usual rules of discovery in civil actions in the Court of Federal Claims. 42 U.S.C. § 300aa-12(d)(2). The Vaccine Rules further carry out this mandate. *See* Vaccine Rule 7(a) & (b) (stating presumption that "[t]here shall be no discovery as a matter of right," and that informal and cooperative exchange of information is the ordinary and preferred practice, but if a party considers that informal discovery not to be sufficient, that party may seek to utilize discovery procedures provided by Federal Claims Court Rules 26-37 by filing a motion indicating the discovery sought and stating with particularity the reasons); *cf.* Vaccine Rule 1 (Special Master of the court "may regulate the applicable practice, ***consistent with [the Vaccine Rules] and with the purpose of the Vaccine Act, to decide cases promptly and efficiently.***" (emphasis added)).

1989 U.S.C.C.A.N. 1906, 2239.[8] Thus, it is to be used to supply an identifiable and essential missing piece to fill in a "gap" in the available proof in order to determine eligibility for compensation—not where information in the possession of third parties might have relevance to the proceeding.[9]

Far from identifying particular information that is necessary to their causation case and explaining why they are not able to obtain it from any other source, Petitioners have simply asserted that the Product License Application ("PLA") documents they are in the process of receiving from the Respondent are not coming fast enough and that other unspecified documents in the possession of the vaccine defendants might conceivably have value to their case. Petitioners have not provided the Special Master reason to find that the third-party discovery they seek from Merck is "necessary" or "reasonable," as the statute and rules command. Petitioners presumably cannot make this showing, especially considering the expansive list of materials already available to them that are detailed in Merck's Response at 8-9, 13-14.

Moreover, the burden to vaccine defendants, like SB, must be taken into account in the discovery calculus. Like Merck, SB has been heavily involved in the process of readying its PLA documents so that the Respondent can produce them to Petitioners without compromising

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[8] The legislative history makes clear that Congress intended the subpoena power to permit discovery of limited materials in rare circumstances where it is necessary for the Special Master to perform his or her function of "determin[ing] the validity of the petitioner's claim," H.R. Rep. 99-908, at 17, *reprinted in* 1986 U.S.C.C.A.N. 6344, 6358—***not*** to afford petitioners the same, broad-based discovery that they could seek in a civil action. Indeed, this provision has been specifically described as the "prerogative of the Special Master," H.R. Rep. 99-908, at 16-17, *reprinted in* 1986 U.S.C.C.A.N. 6344, 6357-58, further indicating that the purpose is to assist the Special Master in deciding compensation petitions, not to permit the petitioner to engage in the same discovery techniques available in a civil tort action.

[9] The Vaccine Court's case law indicates that the subpoena power has traditionally been exercised in limited situations, such as to subpoena a treating physician or to obtain additional medical records. *See, e.g., Vant Erve v. Sec'y of Health & Human Servs.*, 1997 WL 383144 (Fed. Cl. 1997) (in which the Special Master subpoenaed additional medical records); *DeRoche v. Secretary of HHS*, 2002 WL 603087 (Fed. Cl. 2002) (mentioning the Special Master's willingness to subpoena the treating physician). It has not been used to order broad discovery from third-parties.

trade secrets. Petitioners have not offered any reason to conclude that SB should be put to the additional and time-consuming task of producing these same documents from its own files. The fact that Petitioners do not even try to articulate a need for "product safety research" documents, much less attempt to narrow the scope of this request to an identifiable document or set of documents, makes this request patently unreasonable on its face. Sustaining Petitioners' request under these circumstances would simply encourage use of the Vaccine Court as a clearinghouse for conventional discovery.

There is no question Congress fully appreciated the threat to its Program goals posed by traditional adversarial discovery. In fact, in 1989, when Congress amended the Vaccine Act to address certain problems in Vaccine Court proceedings, it sounded the alarm that the Program goals were being sacrificed through a retreat to the adversarial process, contrary to the intent of the original legislation. *Stotts v. Sec'y of Dep't of Health & Human Servs.*, 23 Cl. Ct. 352 (Fed. Cl. 1991). The Congressional Committee appointed to report on the Program observed the insidious infiltration of the adversarial system into what was intended to be an "expeditious, less adversarial, and fair system" and found it to be entirely unacceptable:

> Congress intended a quick, flexible, and streamlined system. [The original legislation] called for a compensation procedure that administered awards "quickly, easily, and with certainty and generosity." The system was intended to be "fair, simple, and easy to administer" and "to compensate persons with recognized vaccine injuries without requiring the difficult individual determinations of causation of injury." . . .
>
> . . . [R]ather than establishing such a system, all participants have, to some degree, maintained their traditional adversarial litigation postures. The Claims Court has issued rules for vaccine proceedings that force proceedings to be formal and that virtually foreclose any opportunity for petitioners or respondents to proceed without litigators at their sides. . . . Respondents have . . . mounted defenses incompatible with a no-fault system of compensation.
>
> . . . [T]he Conferees reiterate their 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 Conferees anticipate 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.

H.R. Conf. Rep. No. 101-386 (1989), *reprinted in* 1989 U.S.C.C.A.N. 3018, 3115-16 (emphasis added).

CONCLUSION

As explained, the discovery gates are closed as to parties—and certainly as to non-parties—unless the statutory standards of necessity and reasonableness are first met. *See* 42 U.S.C. § 300aa-12(d)(3)(B). Ordering wide-ranging discovery from third-party manufacturers will undermine the Vaccine Program's principal goals. Congress made clear that compensation proceedings under the Vaccine Act were to proceed quite differently from traditional tort litigation—both for the benefit of the petitioners and the vaccine manufacturers. In light of the repeated expressions of concern over the traditional adversary process and its attendant litigation costs throughout the legislative history of the Act, there can be no credible claim that Congress would sanction the broad discovery sought here.

Dated: December 3, 2003

Respectfully submitted,

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*Application for admission to the United States Court of Federal Claims pending

CERTIFICATE OF SERVICE

I hereby certify that on December 3, 2003, I served the foregoing Amicus Brief by Non-Party SmithKline Beecham Corporation d/b/a GlaxoSmithKline as to Issues Concerning Third Party Discovery on the following individuals via facsimile and email transmission:

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December 3, 2003

VIA HAND DE

PLEASE DATE STAMP AND RETURN THANK YOU

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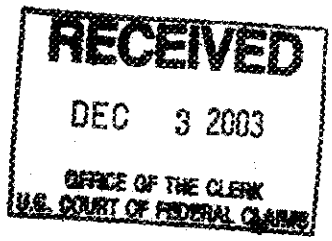

Re: *in Autism Spectrum Disorder, or in a Secretary of Health and Human* deral Claims, Office of the Special

Dear Clerk:

Enclosed please find the original and three copies of the Amicus Brief by Non-Party SmithKline Beecham Corporation d/b/a GlaxoSmithKline as to Issues Concerning Third Party Discovery. Please file the enclosed in your usual manner, returning a file-stamped copy to me via the courier provided.

Thank you for your attention to this matter. If you have any questions, please do not hesitate to contact me at (512) 536-5216.

Very truly yours,

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MHG/lak
Enclosures

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