IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF THE SPECIAL MASTERS

IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER, OR A SIMILAR NEURODEVELOPMENTAL DISORDER, Petitioner, v. **SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,** Respondent.	AUTISM MASTER FILE Special Master Hastings

PETITIONERS' RESPONSE TO RESPONDENT'S MOTION FOR PROTECTIVE ORDER

I. INTRODUCTION

On July 3, 2002 the Chief Special Master issued Autism General Order #1,[1] to "address an unusual situation facing the National Vaccine Injury Compensation Program". The unusual situation was the filing of hundreds of petitions in the National Vaccine Injury Compensation Program (hereinafter "Program") alleging vaccine-related neurological injuries arising from Thimerosal, a mercury-containing preservative used in many childhood vaccines, and the prospect of thousands of additional cases being swept into the

[1] *In re*: Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or A Similar Neurological Disorder, *Various Petitioners v. Secretary of Health and Human Services*, Autism Master File, Autism General Order #1, at 1.

Program.[2] In General Order #1, the Chief Special Master set out a procedure and master scheduling-order to "aggressively, but fairly manage the docket to ensure a timely presentation and resolution of the difficult legal and medical issues raised in these cases." The Chief Special Master also concluded that the "reality of the difficult medical issues involved... justifies petitioners' request for a reasonable discovery opportunity".

In accordance with the master scheduling order, Petitioners filed their request for production on August 2, 2002. On September 3, 2002, Respondent filed its response and objections and the parties commenced negotiations regarding a time-frame for production of responsive information. Although the parties had reached considerable agreement regarding both the scope of and the time-frame for the production of relevant information, Respondent now refuses to produce <u>any</u> information absent a protective order "to ensure that all discovery materials produced by respondent in the Omnibus Autism Proceeding is used solely within this action." Motion at p. 1. Thus, despite months of hard work and lengthy, detailed negotiations between the Parties, Respondent – the Department of Health and Human Services – now puts Petitioners and this Court on notice that it "will not

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[2] Vaccine manufacturers filed motions to dismiss civil cases arguing that cases alleging injuries due to thimerosal must to be filed in the Program. In those pending civil cases, the Department of Health and Human Services filed statements of interest arguing that "Plaintiffs cannot avoid the exclusive jurisdiction of the Court of Federal Claims and the procedures of the Program by erroneously arguing that thimerosal is an adulterant or contaminant." Statement of Interest by HHS at p. 21. HHS argued that "[t]he plain language of the statute and the determinations that have been made the by Secretary demonstrate that [Plaintiffs'] argument is fundamentally incorrect and without merit." *Id.*

voluntarily produce discovery material to petitioners without restriction [sic] ensuring that it is used in the Vaccine Act proceedings alone." Motion at p. 5.

II.
ARGUMENT

Rule 26(c) of the United States Court of Federal Claims provides that "[u]pon motion by a party...from whom discovery is sought...and for good cause shown, the court may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense...". Because Respondent's motion wholly fails to satisfy the requirements of Rule 26(c), this Court must deny the motion and order Respondent to begin producing relevant information in accordance with the previously agreed upon schedule.

A.
"...for good cause shown"

Rule 26(c) clearly requires Respondent to show "good cause" for the protection it seeks. See *In re Agent Orange Product Liability Litigation*, 821 F.2d 139, 145 (2nd Cir 1987) ("If good cause is not shown, the discovery materials in question should not receive judicial protection and therefore would be open to the public.") For good cause to exist, the party seeking protection bears the burden of showing specific prejudice or harm will result if no protective order is granted. *Phillips v. General Motors Corp.*, 307 F.3d 1206, 2002 U.S. App. Lexis 21489 (9th Cir. 2002); *Beckman Indus., Inc. v. International Ins. Co.*, 966 F.2d 470 (9th Cir. 1992); *San Jose Mercury News, Inc. v. United States Dist. Ct.*, 187 F.3d 1096 (9th Cir. 1999). Here, Respondent has made no such showing.

1.

Interestingly, in an apparent attempt to circumvent Rule 26(c)'s "good cause" requirement, Respondent points to section 23(e) of the Vaccine Act, which prohibits the introduction of the Vaccine Injury Table and certain judicial determinations made in a vaccine court proceeding as evidence in a subsequent civil proceeding. That prohibition, Respondent argues, when taken together with section 12(d)(4)(A), which limits disclosure of information "submitted" to the special master to third parties, shows that "the two pathways to recovery for vaccine-related injuries were meant to remain separate and distinct." Motion at p. 3. Thus, according to Respondent, "[t]his separation, and also this prohibition, logically should extend to all materials produced during the course of discovery in a Vaccine Act proceeding." Motion at p. 3.

One problem with Respondent's "logic" is that the "two pathways to recovery" are not separate and distinct; on the contrary, they are inextricably intertwined. Those seeking compensation for vaccine-related injuries are compelled by statute to file a petition, in the first instance, in the Program. The filing of the petition tolls state law limitations periods. Petitioners, however, retain the right to return to the civil court system after 240 days or after rejecting a judgment. When they do they go carrying with them significant procedural, substantive and evidentiary limitations imposed by the Act. Respondent's suggestion that it is somehow unfair and improper for them to carry to civil court information obtained in the Program that might be relevant to obtaining compensation – that they might somehow "benefit" from the process - is simply preposterous.

Indeed, it is noteworthy that when filing its Statement of Interest in numerous civil proceedings around the country encouraging judges to dismiss vaccine-injury claims and send them through the Program, Respondent did not hold such a strong view of the "separateness" of the "pathways":

> Even if petitioners do not have their claims resolved within 240 days (and they can, and, in experience, often do, consent to an extension of this time period) and elect to leave the Program, they may still benefit from participation. For claims filed within the statute of limitations, claimants may begin assembling documents and information necessary to prosecute their claim and may petition the Federal Court of Claims for attorneys' fees and expenses associated with those activities.

HHS Statement of Interest at footnote 9.

Of course, the fatal flaw in Respondent's "logic" is that the statute does not extend the "prohibition" to materials and information obtained in discovery. Although the statute contemplates discovery, there is no statutory restriction on information obtained in discovery. Absent a clearly expressed legislative intention to the contrary, the plain language of the statute must be regarded as conclusive. *See, e.g. Consumer Product Safety Comm'n. v. GTE,* 447 U.S. 102, 108 (1980). Respondent has pointed to absolutely nothing in the legislative history of the Act that supports the broad prohibition it seeks.

Respondent also asserts that the Vaccine Act must be interpreted to impose the broad prohibition it seeks because to read the Act as it is written "would effectively circumvent" regulations that permit the Department of Health and Human Services to refuse to produce documents "in proceedings where the United States is not a party." Motion at p. 4. This argument is, of course, a nonsequitur since the United States is a party to this proceeding and thus there is no direct conflict between the Vaccine Act and

the regulations relied upon by Respondent. This Court must read the Act as it is written.

2.

Absent the broad prohibition Respondent inappropriately asks this Court write into the Vaccine Act, the requirements of Rule 26(c) control. Thus, the threshold question for this Court is simply whether Respondent has satisfied its burden to show "good cause" for the protection it seeks. The answer is clearly it has not.

The only discernible allegation of specific prejudice or harm appears at page 5 of Respondent's Motion:

> By allowing information that was initially discovered in a proceeding where the Secretary is a party to be used in one in which he is not, the discovery process in the Omnibus Autism proceeding effectively deprives the Secretary of Health and Human Services of the right of refusal described in Touhy and codified in federal regulations.

And so, finally we get to the heart of Respondent's concern: the Secretary of Health and Human Services wants to preserve its "right" to refuse to produce the information produced here in a subsequent civil proceeding involving a petitioner who opts out or rejects a judgment.[3]

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[3] Respondent's broad reading of the "right of refusal" described in *Touhy,* however, ignores the narrowly-drawn reasoning of the Court. *See Exxon Shipping v. United States Department of Interior*, 34 F.3d 774, 776 (9th Cir. 1994). (The Court in *Touhy* "specifically refused to reach the question of the agency head's power to withhold evidence from a court without a specific claim of privilege.") In his *Touhy* concurrence, Justice Frankfurter wrote:

> Issues of far-reaching importance that the Government deemed to be involved in this case are now expressly left undecided. But they are questions that lie near the judicial horizon.
>
> I wholly agree with what is now decided insofar as it finds that whether, when and how the Attorney General himself can be granted an immunity from the duty to disclose information contained in documents within his possession that are relevant to a judicial proceeding are matters not here for adjudication. Therefore, not one of these questions is impliedly affected by the narrow ruling on which the present decision rests.

Loss of this "right", however, cannot, by any stretch of the imagination, satisfy the "good cause" requirement of Rule 26(c). Indeed, on its face, the argument is absurd. How could the Department of Health and Human Services be prejudiced or harmed in any way by the loss of the "right" to refuse to produce information to a person to whom it has already produced the same information? The proposed justification for taking away the information at the end of the vaccine-court proceeding is to preserve the right to refuse to give it back! Moreover, because HHS would not be a party in a subsequent civil proceeding, it could not be prejudiced in any way by the outcome of the civil case. Respondent has wholly failed to even articulate a colorable basis for a protective order under Rule 26(c).

B.
"...which justice requires"

Even if one were to accept the absurd proposition that loss of a hypothetical right to refuse to produce information to a person to whom you had already produced the

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> Specifically, the decision and opinion in this case cannot afford a basis for a future suggestion that the Attorney General can forbid every subordinate who is capable of being served by process from producing relevant documents and later contest a requirement upon him to produce on the ground that procedurally he cannot be reached. In joining the Court's opinion I assume the contrary B that the Attorney General can be reached by legal process.

United States ex rel. Touhy v. Ragen, 340 U.S. 462, 470 (1951) (Frankfurter, J., concurring).

information constituted a particularized harm, the inquiry under Rule 26 does not end. If a court finds particularized harm will result from disclosure of information to the public, then it still must balance the public and private interests to decide whether a protective order is necessary. *Phillips,* Lexis 21489 at *9. In doing so, this Court has broad discretion to balance these interests in the interests of justice. See *Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 23 (1984) (Rule 26 confers "broad discretion on the trial court to decide when a protective order is appropriate is required").

Here, both the facts and the equities argue against the protection Respondent seeks. Petitioners allege injuries caused by childhood vaccines. These children, and their families, may be the "innocent statistics" of our nation's necessary war on disease, for whom the Vaccine Compensation Program was created. *See* 132 Cong. Rec. H9943 (daily ed. Oct. 14, 1986). The legislation creating the Program specifically preserves the right of these Petitioners to file a subsequent civil action if they are dissatisfied with their award. See 42 U.S.C. § 30011-21(a). This right was part of the careful balance struck by the Vaccine Act. See 132 Cong. Rec. E3486 (Oct. 9, 1986).

Yet, Respondent now seeks restrictions on information produced in this proceeding that could impair a Petitioner's ability to prove his or her case in civil court, effectively diluting Petitioners statutory right to opt out or reject a settlement. Respondent thus seeks to place more of the risk of our national vaccine policy onto the shoulders of the innocents – a result clearly contrary to the purpose and intent of the Vaccine Act and clearly contrary to the interests of justice. The proposed justification – a preservation of a technical right to refuse to produce the same information in the subsequent proceeding – is simply too

tenuous to outweigh the compelling interests those who may have been injured by mandatory vaccines have in obtaining fair compensation.[4] Justice clearly does not require the protection Respondent seeks; on the contrary, justice requires that the Respondents motion be denied.[5]

III.
CONCLUSION

Respondent seeks a protective order pursuant to Rule 26(c) restricting Petitioners' use of all materials obtained in discovery solely to this proceeding. Respondent, however, has wholly failed to satisfy the "good cause" requirement of Rule 26. Moreover, because the interests of justice require that Petitioners be afforded the opportunity to seek fair compensation for alleged vaccine-related injuries in accordance with the provisions of the Vaccine Act, this Court must reject Respondent's tenuous arguments, deny the motion, and order Respondent to begin producing relevant information in accordance with the previously agreed upon schedule.

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[4] Interestingly, the regulation upon which Respondent relies provides for disclosure of information even when the government is not a party if the Agency determines that "compliance with the request would promote the objectives of the Department of Health and Human Services". 45 C.F.R. § 2.3(a). Petitioners find it disappointing that Respondent apparently has concluded that disclosure of information relating to Thimerosal in vaccines and adverse events does not "promote" these objectives.

[5] Respondent's position on this issue approaches the "fox-hunting theory of justice" Justice Frankfurter warned of in his *Touhy* concurrence. Justice Frankfurter was correct when he wrote that such an approach to justice "ought to make Bentham's skeleton rattle." *Touhy*, 340 U.S. at 473 (Frankfurter, J., concurring)

Respectfully submitted,

Jeffrey S. Thompson by Ghada Anis

Jeffrey S. Thompson
Williams Bailey, L.L.P.
8441 Gulf Freeway, Suite 600
Houston, TX 77017-5001
Telephone: (713) 230-2207

CERTIFICATE OF SERVICE

I hereby certify that I caused a copy of the foregoing pleading to be hand delivered this 25 day of November, 2002 to:

Vince Matanoski
Trial Attorney, Civil Division
U.S. Department of Justice
P.O. Box 146, Ben Franklin Station
Washington, D.C. 20044

And

Mark Raby
Trial Attorney, Civil Division
U.S. Department of Justice
P.O. Box 146, Ben Franklin Station
Washington, D.C. 20044

Ghada Anis

Ghada A. Anis