



file interrogatories, or take depositions" in order "to replace the usual rules of discovery in civil actions in Federal Courts."

H.R. Conf. Rep. No. 101-386, at 512, 1989 U.S.C.A.A.N. 3018, 3115 (ellipses in original). Moreover, Congress made clear its intent that what discovery there may be in a Vaccine Act proceeding would only be directed to aiding the special master, as inquisitor, in reaching a decision on a petition:

The system is intended to allow the proceedings to be conducted in what has come to be known as an 'inquisitorial' format, with the master conducting discovery (as needed), cross-examination (as needed), and investigation. As we stated in the Report accompanying the original Act, 'In order to expedite the proceedings, the power of the special master is intended to replace the usual rules of discovery in civil actions in Federal courts.'

H.R. Conf. Rep. No. 101-386, at 516, 1989 U.S.C.A.A.N. 3018, 3119 (emphasis added). The special master has found that the legal and medical complexity of the issue to be resolved in the Omnibus Autism Proceeding justifies reasonable discovery. See Autism General Order #1 at 6. Consistent with Congress's limitations, that discovery must directly aid the special master in resolving the Vaccine Act petitions before him.

With this framework in mind, it is necessary to recognize that the Omnibus Autism Proceeding itself is the first, rather than the only, avenue of litigation which petitioners may pursue. The Act provides that petitioners may either accept the judgment entered by the United States Court of Federal Claims or reject it and file a civil action for damages. 42 U.S.C. § 300aa-21(a).

The Act provides that the Vaccine Injury Table, judicial determinations and judgments made in Vaccine Act proceedings "shall not be admissible" as evidence in civil action proceedings. 42 U.S.C. § 300aa-23(e). Moreover, "information submitted to a special master or the court in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express written consent of the person who submitted the information." 42. U.S.C. § 300aa-12(d)(4)(A). The Act's prohibitions against the disclosure and subsequent use of information related to vaccine claims apply equally to both parties. Judicial determinations, information submitted by a party, and the like cannot be used by a plaintiff in prosecuting a subsequent civil action, nor by a manufacturer or administrator in defending it. Clearly, the two pathways to recovery for vaccine-related injuries were meant to remain separate and distinct. This separation, and also this prohibition, logically should extend to all materials produced during the course of discovery in a Vaccine Act proceeding.

Absent the special circumstances of the Omnibus Autism Proceeding, and the Vaccine Act's limited waiver of sovereign immunity - allowing petitioners to file suit against the Secretary of Health and Human Services for alleged vaccine injuries - petitioners could not obtain discovery of the information respondent will produce. It is important to note that petitioners will not be deprived of any evidence they would have obtained in an ordinary civil action. In any subsequent action against a manufacturer or administrator, they would still

have access to the full range of evidence they could have permissibly obtained absent the intervening Vaccine Act claim. However, specific federal regulations govern "testimony by employees [of the Department of Health and Human Services] and production of documents [by the Department of Health and Human Services] in proceedings where the United States is not a party":

It is the policy of the Department of Health and Human Services to provide information, data, and records to non-federal litigants to the same extent and in the same manner that they are available to the general public.

45 C.F.R. § 2.1(b) (emphasis supplied). Additionally, regulation requires that,

[n]o Department of Health and Human Services employee may provide testimony or produce documents in any proceedings to which this part applies concerning information acquired in the course of performing official duties or because of the employee's official relationship with the Department of Health and Human Services unless authorized by the Agency head, after consultation with the Office of General Counsel, that compliance with the request would promote the objectives of the Department of Health and Human Services.

45 C.F.R. § 2.3(a). The procedures instituted under the Vaccine Act cannot be construed in such a way that they would effectively circumvent these regulations.

The Supreme Court has held that it is appropriate for an agency to refuse to comply with a court order for production of documents when doing so would result in non-compliance with that agency's own orders or regulations which prohibit the dissemination of such information. United States ex rel. Touhy v. Ragen, 340 U.S. 462 (1951) (finding that FBI special agent had

properly refused to produce subpoenaed material when order of the Attorney General directed such refusal; also found "no material distinction" between case in question and case of IRS collector who relied upon regulation of a similar character as Attorney General's order).

Direct representations have been made by petitioners in the presence of the special master and of the respondent regarding petitioners' intent to use the information discovered in the Omnibus Autism Proceedings in future civil actions. 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.

Consistent with these regulations, the Act's limited waiver of sovereign immunity, and the circumscribed scope and purpose of discovery under the Act, respondent will not voluntarily produce discovery material to petitioners without restriction ensuring that it is used in Vaccine Act proceedings alone. Because petitioners are unwilling to accept this restriction, respondent has moved for the entry of a protective order. Were petitioners to move to compel production in the absence of a protective order for any other purpose unrelated to resolution of their Vaccine Act claims, the special master would be without authority to compel such production. The scope of his authority is limited to

promulgating discovery in aid of his resolution of a Vaccine Act petition.

As such, a protective order is necessary to ensure that all discovery material produced by respondent will only be used in the Omnibus Autism Proceeding. The protective order should prohibit the use of discovery material outside the Omnibus Autism Proceeding and restrict petitioners from divulging any such discovery material to anyone who has not filed notice with the Court stating that they have opted into the Omnibus Autism Proceeding.<sup>2</sup> The protective order would not restrict any otherwise permissible use of discovery material within the context of the Omnibus Autism Proceeding. A proposed order accompanies this motion.

#### Conclusion

A protective order is necessary to ensure that discovery material is not used outside the context of the Omnibus Autism Proceeding and to ensure compliance with federal regulations.

Respectfully submitted,

ROBERT D. McCALLUM, JR.  
Assistant Attorney General

HELENE M. GOLDBERG  
Director  
Torts Branch, Civil Division

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<sup>2</sup> Photocopies, or any other reproduction, of the discovery material should be subject to the same protection as the discovery material in their original form.

JOHN LODGE EULER  
Deputy Director  
Torts Branch, Civil Division

MARK W. ROGERS  
Assistant Director  
Torts Branch, Civil Division



VINCENT J. MATANOSKI  
Assistant Director  
Torts Branch, Civil Division



MARK C. RABY  
Trial Attorney  
Torts Branch, Civil Division

Date: 19 NOV 2002

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

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IN RE: CLAIMS FOR VACCINE )  
INJURIES RESULTING IN AUTISM )  
SPECTRUM DISORDER, OR A SIMILAR )  
NEURODEVELOPMENTAL DISORDER, )  
 )  
Various Petitioners, ) Autism Master File  
 )  
v. )  
 )  
SECRETARY OF HEALTH AND )  
HUMAN SERVICES, )  
 )  
Respondent. )  
\_\_\_\_\_)

**PROTECTIVE ORDER**

Respondent's Motion for Protective Order is GRANTED. It is, therefore, ORDERED that:

**Definitions**

1. "Action" means In Re: Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder, or a Similar Neurodevelopmental Disorder v. Secretary of Health and Human Services, also known as the "Omnibus Autism Proceeding."

2. "Discovery Material" means all documents or other information produced or disclosed in this Action by the Secretary of Health and Human Services in response to a discovery demand under the Rules of the United States Court of Federal Claims, that is not otherwise in the public domain. Documents and other information that fall within this definition of "Discovery



Material" remain "Discovery Material" indefinitely, without regard to the conclusion of the Omnibus Autism Proceeding.

3. "Document" means any written or graphic matter, no matter how produced, recorded, stored, or reproduced, and includes transcripts, interrogatory responses, e-mails, and other electronically stored data. The term "Document" also includes all Documents previously produced by the Secretary of Health and Human Services in response to the discovery demand.

4. "Petitioners' Counsel of Record" means (a) all attorneys designated as members of Petitioners' Steering Committee for this Action; (b) all attorneys subsequently designated as members of Petitioners' Steering Committee for this Action; and (c) all members of the law firms of attorneys who meet the criteria of 4(a) and 4(b), whose involvement is reasonably necessary to assist those attorneys in preparing this Action for trial.

5. "Party" means petitioners and respondent, the Secretary of Health and Human Services.

6. "Qualified Persons" means:

- (a) the Court; and
- (b) Petitioners' Counsel of Record.

"Qualified Persons" also means any individual who meets any of the definitions set out below in subparts (c), (d), (e), and (f), provided that prior to the disclosure of any Discovery

Material to such an individual, the Qualified Person described in 6(a) or 6(b) proposing to make such disclosure shall: (1) deliver a copy of this Protective Order to the individual; (2) explain its terms to the individual; and (3) secure the signed agreement of the individual to abide by the terms of this Protective Order:

- (c) any attorney of record for a pending Vaccine Act case, who represents a petitioner that opted into this Action but which attorney of record is not a member of Petitioners' Steering Committee for this Action;
- (d) any member of the law firm of an attorney who meets the criteria of 6(c), whose involvement is reasonably necessary to assist that attorney in preparing this Action for trial.
- (e) all experts and consultants who have been retained by Petitioners' Counsel of Record for the purpose of assisting Petitioners' Counsel of Record in preparing this Action for trial, and the employees of any such experts and consultants; and
- (f) all experts who are not employed by any party to this litigation and who are retained by the Court in connection with this Action, and the employees of any such experts.

7. "Third Party" means any natural person, partnership, corporation, association, or other legal entity not named as a Party to this Action.

### General Provisions

8. This Protective Order applies to all Discovery Material produced by the Secretary of Health and Human Services, whether revealed in a Document, deposition, interrogatory response, or otherwise.

9. This Protective Order shall not affect the right of any Party or Third-Party to oppose production of Documents or other information on any ground permitted by the Rules of the Court of Federal Claims, including any applicable privilege. This Order shall not affect the scope of discovery by any Party that is not otherwise proper under the Rules of the Court of Federal Claims.

10. Nothing in this Protective Order shall prejudice any Party or Third-Party from seeking amendments hereto or from seeking restrictions on the rights of access to and use of Discovery Material or from seeking other modifications.

11. Upon completion of this Action, all copies of Discovery Material shall be returned to the Secretary of Health and Human Services, or in the alternative, destroyed by Petitioners' Counsel of Record and any other Qualified Person in possession of such material. If Petitioners' Counsel of Record or other Qualified Persons opt to destroy the documents subject to this Protective Order, they shall certify in writing to the Court and the Secretary of Health and Human Services that all such

documents have been destroyed.

Permissible Use of Discovery

12. Discovery Material shall not be used for any purpose other than the preparation of litigation for this Action.

13. Discovery Material produced by the Secretary of Health and Human Services shall not be copied or reproduced except to the extent such copying or reproduction is reasonably necessary to the conduct of this Action. All such copies or reproductions shall be subject to the terms of this Protective Order. All copies of Discovery Material shall be maintained in the exclusive possession of persons described in 6(a) and 6(b), and not shared, released or disclosed to any individual except a Qualified Persons described in 6(c), 6(d), 6(e), and 6(f).

14. Qualified Persons defined in paragraph 6(c), 6(d), 6(e), and 6(f) shall be deemed bound by the terms of this Protective Order. Such a Qualified Person must sign a confidentiality agreement using the following form:

"I hereby acknowledge that I [name, position of employment], am about to receive Discovery Material. I certify my understanding that such information is to be provided to me pursuant to the terms and restrictions of the Protective Order [dated entered] in In Re: Claims for Vaccine Injuries Resulting

in Autism Spectrum Disorder, or a Similar Neurodevelopmental Disorder v. Secretary of Health and Human Services. I have been given a copy of and have read this Order and agree to be bound by its terms. I understand that by signing this form and receiving Discovery Material, I am subject to the imposition of any and all penalties and sanctions that may be imposed by applicable law for my violation of the Protective Order."

IT IS SO ORDERED:

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George L. Hastings, Jr.  
Special Master

**CERTIFICATE OF SERVICE**

I certify that on this 19<sup>th</sup> day of November, 2002, a copy of respondent's MOTION FOR PROTECTIVE ORDER was served, by first class mail, postage prepaid, and facsimile upon:

Ghada A. Anis  
SHOEMAKER & ASSOCIATES  
9711 Meadowlark Road  
Vienna, VA 22182

Jeff Thompson  
WILLIAMS BAILEY, L.L.P.  
8441 Gulf Freeway, Suite 600  
Houston, TX 77017-5001

Melissa A. Pachikara