ORIGINAL

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

(Filed: April 14, 2005)

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IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER OR A SIMILAR NEURODEVELOPMENTAL DISORDER	*	**AUTISM MASTER FILE**
VARIOUS PETITIONERS	*	
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

* *

DISCOVERY ORDER

On November 3, 2003, *Pediatrics* published an article entitled "Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized Health Maintenance Organization Databases" ("Thimerosal Screening Analysis"), which was authored by researchers for the Centers for Disease Control and Prevention (CDC), one component of respondent agency, Department of Health and Human Services, and others. This study utilizes data from the Vaccine Safety Datalink (VSD) Project. Petitioners have argued that in order for me "to render an informed and fair decision on general causation" (Pet. Exh. 84-32), I need to compel CDC to grant access to the dataset underlying this article to petitioners' experts, Dr. Harland Austin and Ms. Cathy Lally, so that Dr. Austin and Ms. Lally can analyze the data by making six specific changes to the methodology of the Thimerosal Screening Analysis. These specific changes have been outlined as Proposal I at Petitioners' Exhibit 82-19. Respondent maintains that I do not need petitioners' experts to conduct the proposed analyses to render an informed and fair decision on general causation. Nevertheless, respondent, with the consent of the relevant Managed Care Organizations (MCOs), will permit Dr. Austin and Ms. Lally to access the dataset provided that such access is under the terms as I have ordered them below.

I. General Matters

1. The Vaccine Safety Datalink (VSD) comprises a subset of electronic information collected by the participating MCOs for administrative and clinical purposes. This data is provided to CDC by the MCOs for the purpose of actively monitoring and studying vaccine-related adverse events. This data is collected and maintained at CDC under Section 306 of the Public Health Service (PHS) Act (42 U.S.C. § 242k) subject to an assurance of confidentiality under Section 308(d) of the PHS Act (42 U.S.C. § 242m(d)). The purpose of the assurance is to protect private and sensitive individual patient information contained in the data, as well as to protect proprietary information related to the individual MCOs. Under the assurance, information in the VSD that could lead to direct or indirect identification of patients or individual MCOs may only be used for the purposes stated above, unless the individuals or entities described in or supplying the data consent to such other use or disclosure.

2. The VSD files and study-specific datasets are available to external researchers by a mechanism set forth in CDC's Guidelines for Data Sharing Proposals from External Researchers: Vaccine Safety Datalink Project. Pursuant to these guidelines, and to federal law governing the protection of human research subjects, access to the VSD for the purpose of research development requires that the external researcher obtain approval for his or her research protocol from the appropriate Institutional Review Boards (IRB) of the relevant MCOs.

3. Petitioners request their experts, Dr. Austin and Ms. Lally, be granted access to a study-specific dataset of the VSD, namely the final dataset of the Thimerosal Screening Analysis. These experts have been hired by petitioners' counsel to aid in preparation for and/or presentation during the causation hearing in this action, 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 (hereinafter, "this Action"). The access provided to the VSD by means of this Discovery Order is exclusively for the purpose of trial preparation, and expressly not for the purpose of research development nor for the purpose of any release or presentation outside courtroom proceedings in this Action.

4. Exclusively to accommodate petitioners' need to prepare for the causation hearing in this Action, and barring any use of the dataset other than such hearing preparation, respondent will grant petitioners' experts, Dr. Austin and Ms. Lally, access to the final dataset of the Thimerosal Screening Analysis with the restrictions listed below in Subparts A-D. Accordingly, prior to access, Dr. Austin and Ms. Lally must execute the Affidavit of Compliance attached as Exhibit A to this Discovery Order.

A. Access for each of the experts is contingent upon the agreement that he or she will honor the confidentiality protections set forth in Part III, which constitute the same conditions of confidentiality that have been implemented to ensure the privacy of the data subjects in the Data Sharing Program, and to which an external researcher

gaining access to VSD data via the submission of an IRB-approved protocol to the Data Sharing Program would be bound;

B. Access for each of the experts is contingent upon the agreement that he or she will use the dataset access granted by this Discovery Order exclusively in his or her role as a consultant or expert for petitioners in this Action and not for any other purpose, including but not limited to the development of submissions to peer-reviewed publications, the development of presentations outside courtroom proceedings in this Action, and the development of material and conclusions for release in any electronic form whether through the internet or otherwise;

C. Access for each of the experts is contingent upon the agreement that he or she will use the dataset access granted to them by this Discovery Order to perform only those analyses specified below in Part IV, Parameters of Analyses, which consist of the specific analyses proposed by Dr. Austin in Petitioners' Exhibit 82-19; and

D. Means of access to the dataset is governed exclusively by the terms set forth below in Part II, Means of Access. If during the course of the experts' access, either party determines that certain of the terms in Part II, Means of Access, are unduly burdensome, the matter will be resolved by me after a hearing on the issue and the presentation of evidence, if needed.

5. By the terms of this Discovery Order, petitioners and their counsel are similarly prohibited from developing or releasing material for presentation outside courtroom proceedings in this Action that is based upon analysis and/or conclusions generated as a result of the access to the dataset that their experts have been granted by means of this Discovery Order. These constraints encompass, but are not limited to formal publication, release, or presentation and informal publication, release, or presentation in oral, written, and electronic form whether through the internet or otherwise.

6. Although this Discovery Order limits the use of petitioners' experts' dataset access to hearing preparation, respondent does not intend for this Discovery Order to serve in any way as a broad restriction on public access to the dataset or a blanket prohibition on the development of IRB-approved research on the dataset for peer-review publication. On the contrary, nothing in this document prohibits any researcher, including but not limited to Dr. Austin and Ms. Lally, from conducting IRB-approved research on this dataset through the usual Data Sharing Program, or from seeking to publish such IRB-approved research in peer-reviewed journals, if such expert is subsequently acting in the capacity of external researcher following IRB approval.

7. Finally, this Discovery Order sets forth the role, obligations, and prohibitions of the technical monitor, a CDC representative who will remain on location as Dr. Austin and Ms. Lally access the dataset pursuant to this Discovery Order.

II. Means of Access

1. Notwithstanding the manner in which the CDC's Research Data Center (RDC) at the National Center for Health Statistics (NCHS) is otherwise operated, petitioners' experts, Dr. Austin and Ms. Lally, will access the final dataset of the Thimerosal Screening Analysis through the CDC's RDC at NCHS in Hyattsville, MD, by means of the process set forth in this Discovery Order.

2. Petitioners' lead counsel will notify respondent's lead counsel in this Action of the intention of Dr. Austin and Ms. Lally to report to the CDC's RDC at NCHS at least two weeks prior to the requested reporting date.

3. Due to the facility's limitations and the confidentiality issues at stake, only Dr. Austin and Ms. Lally will be scheduled to be present in the CDC's RDC at NCHS by means of this Discovery Order.

4. The final dataset of the Thimerosal Screening Analysis will be securely delivered to the CDC's RDC at NCHS by a technical monitor, assigned by the CDC, who will remain on-site whenever petitioners' experts, Dr. Austin and Ms. Lally, are in the RDC. The role of the "technical monitor" will be limited to the following:

(a) At the request of petitioners' expert, the technical monitor will provide technical guidance and answer any questions related to the format and structure of the final dataset of the Thimerosal Screening Analysis.

(b) The technical monitor will perform a disclosure review of the "output." "Output," for purposes of this Discovery Order, is defined as any and all documents generated by the petitioners' experts while they are present at the CDC's RDC at NCHS, including all computer-generated documents and all personal notes. The only output petitioners' experts may remove from the RDC are summary tables that provide no means for the identification of individual patients or individual MCOs. (Any summary table that includes one or more cells with counts less than five is considered identifiable information and therefore will be restricted from leaving the RDC.) None of petitioners' experts will be allowed to take with him or her any output not deemed by the technical monitor to meet this criteria. The technical monitor will destroy this rejected output without further disclosure to any other individual, including but not limited to any employees, agents, or other representatives of respondent.

5. Each of petitioners' experts is prohibited from bringing into the RDC any device that would allow him or her to communicate while in the RDC with persons on the outside, including but not limited to cell phones, pagers, email devices, and computers of any type.

6. CDC's RDC may charge petitioners for their experts' use of the facilities and personnel to the same extent as CDC would charge an external researcher who was granted access to the VSD data files under the Data Sharing Program currently in place and discussed above in Section I.2.

CDC's RDC may collect the payment of expenditures seven days prior to the scheduled arrival of petitioners' experts, Dr. Austin and Ms. Lally, at the RDC.

III. Confidentiality Protections

1. By requiring petitioners' experts to access the dataset by means of the RDC process, Parts I and II of this Discovery Order make every effort to assure that the identity of data subjects and MCOs cannot be disclosed. However, because it may be possible in rare instances – through complex analysis and with outside information – for petitioners' experts to ascertain from the dataset the identity of particular persons or MCOs, and because considerable harm could ensue if this were done, petitioners' experts are also subject to the following provisions:

(a) Petitioners' experts will not use or permit others to use the data in any way other than as provided by this Discovery Order;

(b) Petitioners' experts will not release nor permit others to release the datasets or any part of them to any person except as provided by this Discovery Order;

(c) Petitioners' experts will not attempt to link nor permit others to link the dataset with individual identifiable records from any other CDC or non-CDC dataset;

(d) Petitioners' experts will not attempt to use the datasets or permit others to use them to learn the identity of any person or establishment included in any set.

2. If the identity of any person or establishment should be discovered inadvertently then:

(a) petitioners' experts will not make any use of this knowledge;

(b) petitioners' experts will report the incident to petitioners' counsel, who will notify respondent's counsel of the incident; however, petitioners' experts will inform no one of the discovered identity;

(c) the information that would identify an individual or establishment will be safeguarded or destroyed as requested by CDC through respondent's counsel.

3. Finally, petitioners' experts will make every effort to release all statistical information in such a way as to avoid inadvertent disclosure. For example:

(a) No data on an identifiable case or MCO should be derivable through subtraction or other calculation from the combination of tables in a given document produced by petitioners' experts;

(b) No data should permit disclosure when used in combination with other known data.

IV. Parameters of Analyses

Petitioners' experts, Dr. Austin and Ms. Lally, are limited in their analyses of the dataset to those parameters exactly as articulated by Dr. Austin's "Proposal I," submitted as Petitioners' Exhibit 82-19. In particular, petitioners' experts may use the following alternative methods of data analysis, and only the following alternative methods of data analysis, to those used in the Thimerosal Screening Analysis:

1. Do not require at least one clinic visit for comparison children.

2. Stop following children at time of first disenrollment.

3. Do not adjust for clinic at HMO B.

4. Report findings for combined categories of neurologic degenerative and neurodevelopmental disorders.

5. Combine the data for HMO A and HMO B.

6. Do the following analysis combining all 3 HMOs: Evaluate any outcome reported in the interim analysis of February 29, 2000, or in the *Pediatrics* publication for which there are at least 50 cases overall at the 3 HMOs. The data will be stratified by HMO and an overall rate ratio will be obtained.

V. Production of SAS Programs

In addition to requesting that Dr. Austin and Ms. Lally be permitted access to the final dataset of the Thimerosal Screening Analysis, which as set forth above is to be granted in strict accordance with the terms of this Discovery Order, petitioners have also requested that Dr. Austin and Ms. Lally be permitted access to the SAS programs used to generate the results that were published in the Thimerosal Screening Analysis in *Pediatrics* on November 3, 2003. In this regard, in addition to the final dataset, CDC will also produce the SAS programs used to generate the published results of this study described in Tables 2, 3, 4, 5, 6, and 7 and Appendices 2, 3, and 4. The means by which Dr. Austin and Ms. Lally will gain access to the SAS Programs will be the sole exception to the application of any and all provisions of this Discovery Order to the SAS Programs. That is, unlike the final dataset which will be transferred to Dr. Austin and Ms. Lally by the CDC's technical monitor upon arrival at the CDC's RDC at NCHS pursuant to Section II.4 of this Discovery Order, the SAS Programs used to generate the published results of the Thimerosal Screening Analysis described in Tables 2, 3, 4, 5, 6, and 7 and Appendices 2, 3, and 4 will be transferred in the form of computer discs from CDC to Dr. Austin and Ms. Lally via each party's legal counsel in this Action, at least two weeks prior to the scheduled arrival of Dr. Austin and Ms. Lally at the CDC's RDC at NCHS. Notwithstanding this manner of transfer of the SAS Programs as the sole exception, all other provisions of this Discovery Order, including those related to nondisclosure and confidentiality,

apply with equal force to any and all SAS programs and to any and all information derived from the SAS programs to which CDC grants access in accordance with this Discovery Order.

IT IS SO ORDERED.

George L. Hastings, Jr.
Special Master

NOTE: The text of this Discovery Order has been adopted verbatim from the proposed order filed by the Petitioners' Steering Committee on April 8, 2005. This text is the product of extensive negotiations between that Committee and respondent's counsel, and has been approved by both. An identical Discovery Order is simultaneously being filed into the record of Taylor v. HHS, No. 02-699V.

EXHIBIT A

AFFIDAVIT OF COMPLIANCE WITH DISCOVERY ORDER

State of _____ AFFIDAVIT OF _____
County of _____

_____ (Name of Affiant), being duly sworn upon his/her oath, deposes and says:

1. I have been contacted to advise or assist the petitioners' attorneys in the case of 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," ongoing in the United States Court of Federal Claims, Office of Special Masters.

2. In this capacity, I have read the attached Discovery Order. I understand all of its terms and restrictions. I understand that I may use the access provided for in this Order to the Vaccine Safety Data Link (VSD) and the access provided for in this Order to the SAS Programs used to generate the results that were described in Tables 2, 3, 4, 5, 6, and 7 and Appendices 2, 3, and 4 of the Thimerosal Screening Analysis published in *Pediatrics* on November 3, 2003, solely for the purpose for which I was actually contacted, retained, or employed. Further, I acknowledge that the work I perform on this dataset via access granted through the Discovery Order is NOT IRB-approved research. As such, I understand that while I may use this access to advise or assist counsel or to testify as a witness in this matter, I may NOT use information gained from this access, or opinions and conclusions derived from this access, to develop research material for publication or for presentation outside the courtroom proceedings in this Action. I also understand that the work I may perform on this dataset is limited to a reanalysis of the Thimerosal Screening Analysis under the parameters specified in Part IV of the Discovery Order, and I agree to limit the scope of my investigation to comply with Part IV of the Discovery Order.

3. I also understand all the terms and restrictions in the Discovery Order that pertain to protecting the confidentiality of the data subjects and the individual MCOs. I agree to abide by each and every one of these terms and restrictions. I understand that non-compliance with any of these terms and restrictions would constitute a violation of the special master's Discovery Order, thereby subjecting me, and potentially the counsel and parties to this Action with whom I am associated, to sanctions imposed by the United States Court of Federal Claims.

I signed this affidavit on _____ (date) at _____ (city, state).

[signature of affiant]

[printed/typed name of affiant]

SUBSCRIBED AND SWORN TO BEFORE ME on _____,2005 at _____ (city, state)

Notary's seal