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 Petitioners, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Autism Master File **Notice of Deposition of Organization: Federal Food and Drug Administration**

TO: THE UNITED STATES FOOD AND DRUG ADMINISTRATION ("FDA") AND ITS ATTORNEYS

PLEASE TAKE NOTICE that pursuant to 42 USC §300aa-12(d), the Office of the Special Masters directs petitioners, through their attorneys, to take the stenographic and videotape organizational deposition of the FDA beginning at 9:00 a.m. on January 7, 2004 at a place mutually agreed to by counsel. The deposition will continue day to day until complete. The FDA shall designate one or more persons who shall inform themselves and be prepared to testify on behalf of the agency regarding the following subjects:

(A) COMPLETED RESEARCH. For each project identified for any of the subcategories below: the grant or project number; any place on the worldwide web where information about the matter can be found; the title and location of any final or interim reports, articles or other output; any power point shows or slides summarizing the matter; the identity of the principal investigators; and the location of the protocol, the budget and periodic progress reports of the matter.

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1. Any completed research, survey, study or other investigation, whether published or not, conducted by the FDA or any of its subdivisions, or any entity employed by the FDA, under contract to the FDA, or funded by the FDA, regarding the human or animal health effects of thimerosal (since 1991).

2. Any completed research, survey, study or other investigation, whether published or not, conducted by the FDA or any of its subdivisions, or any entity employed by the FDA, under contract to the FDA, or funded by the FDA, regarding the human and animal health effects of ethyl mercury (since 1991).

3. Any completed research, survey, study or other investigation, whether published or not, conducted by the FDA or any of its subdivisions, or any entity employed by the FDA, under contract to the FDA, or funded by the FDA, regarding the human and animal health effects of the MMR combined vaccine or of any of its components (since 1991).

4. Any completed research, survey, study or other investigation, whether published or not, conducted by the FDA or any of its subdivisions, or any entity employed by the FDA, under contract to the FDA, or funded by the FDA, regarding the human and animal health effects of any preservatives, biocides, fungicides, adjuvants, stabilizing agents, and diluents used in pediatric vaccines (since the beginning of FDA).

5. Any completed research, survey, study or other investigation, whether published or not, conducted by the FDA or any of its subdivisions, or any entity employed by the FDA, under contract to the FDA, or funded by the FDA, regarding the prevalence or rate of occurrence of autism spectrum disorders ("ASDs") in the United States (since 1991).

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6. Any completed research, survey, study or other investigation, whether published or not, conducted by the FDA or any of its subdivisions, or any entity employed by the FDA, under contract to the FDA, or funded by the FDA, regarding the possible causes of ASDs in the United States (since 1991).

7. Any completed research on the epidemiology of autism or ASD's in any country other than the USA.

(B) ONGOING RESEARCH AND OTHER PROJECTS: For each of the subcategories below: the same information as set out above for completed projects, as well as the expected completion date and type of interim reporting on progress or expenses the project generates as it moves along. The designee(s) should be prepared to answer questions about ongoing studies, surveys, studies or other investigations regarding the:

1. Human and animal health effects of thimerosal;
2. Human and animal health effects of ethyl mercury;
3. Human and animal health effects of the MMR combined vaccine or of any of its components;
4. Human and animal health effects of any preservatives, biocides, fungicides, adjuvants, stabilizing agents, and diluents used in pediatric vaccines;
5. The prevalence or rate of occurrence of autism spectrum disorders ("ASDs") in the United States or in other countries; and
6. The possible causes of ASDs in the United States, specifically including any case control studies looking for data on environmental causes of autism or ASDs.

This issue area includes, for any study or research project identified, information regarding the design, goals, purposes, protocol and methodology of the project; the identity of any investigators, researchers, or others who are actually conducting the project; the funding source for the project; the anticipated completion date for the project; an anticipated publication

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date (if publication is a goal of the project); and the identity of any non-FDA consultants, experts, advisors or others who will in any way participate in the project. Petitioners received two letters from Respondent identifying several ongoing studies, and those two letters are attached as Exhibits 1 and 2 to this Notice of Organizational Deposition to make sure those studies are included in the designee's inquiries.

(C) COMMUNICATIONS WITHIN THE FDA, AND BETWEEN FDA AND OTHER ENTITIES: Petitioners will ask the FDA about communications within the FDA and its subdivisions, and between the FDA and any non-FDA organizations, entities or individuals, regarding the following issues:

1. Meetings of the Simpsonwood panel in June 2000, including the following topics: the identity of the custodian(s) of all records, minutes, correspondence and any other documents generated by or as a result of the proceedings of that panel, before, during and after the June 2001 meeting; the names and contact information of any individuals, organizations or entities that were asked by the FDA to attend the June 2000, or who were asked to otherwise participate in those proceedings; the identity of any employees of the FDA or its subdivisions who participated in the planning of the Simpsonwood meeting, or who participated in any discussions regarding the scope, goals, purposes, or agenda of the meeting.
2. Communications between the FDA and any other subdivision of the federal government regarding the safety, or concerns about the safety, of thimerosal, ethyl mercury, the MMR vaccine or its components, or the preservatives, biocides, fungicides, adjuvants, stabilizing agents, and diluents used in pediatric vaccines (since 1991).
3. Communications between the FDA and any non-governmental entities, organizations or

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individuals regarding the safety, or concerns about the safety, of thimerosal, ethyl mercury, the MMR vaccine or its components, or the preservatives, biocides, fungicides, adjuvants, stabilizing agents, and diluents used in pediatric vaccines (since 1991).

4. Discussions, deliberations, research or any other consideration by the FDA of alternatives to the use of thimerosal in pediatric vaccines, including but not limited to a) substitute preservatives, b) less concentrated formulations of thimerosal, c) preservative-free vaccine packaging and formula options, and d) combining vaccines so as to complete the recommended vaccine schedule with fewer shots (since 1991).
5. FDA knowledge of other studies being conducted by industry, academia, or other governmental agencies (such as WHO, for example) underway on any of the above topics, which do not have any FDA involvement, but about which FDA is aware.
6. The status of the proposal to do neuropsychiatric testing of the children involved in the thimerosal screening analysis based on the Vaccine Safety Datalink (the so-called "Vertstraeten Study").

DATED this 16th day of December, 2003

By: _____
Michael L. Williams
Thomas B. Powers

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Attorneys for Petitioners' Steering Committee

CERTIFICATE OF SERVICE

I hereby certify that on December 16, 2003, I served the foregoing **Notice of Deposition of Organization: Centers for Disease Federal Food and Drug Administration** on the following individual(s):

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
Petitioner's Steering Committee
733 15th Street, NW, Suite 700
Washington, DC 20005

by regular mail.

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Dannee Kessler, Assistant to Michael L. Williams
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U.S. Department of Justice

Civil Division

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January 10, 2003

Sent by facsimile and U.S. mail

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Re: Omnibus Autism Discovery

Dear Jeff and Ghada,

As we discussed during the status conference on January 8, 2003, I am writing to provide you with information about ongoing and proposed research studies relevant to the Omnibus Autism Proceeding and your discovery requests.

The following is a research study currently underway at Centers For Disease Control and Prevention, National Center on Birth Defects and Developmental Disabilities:

* Metropolitan Atlanta Developmental Disabilities Surveillance Program MMR/Autism Study (Case-control Study). Researchers are in the process of conducting their final analyses and drafting a manuscript. The estimated publication date is December 2003.

The following are research studies being conducted by the Centers For Disease Control and Prevention, National Immunization Program:

EXHIBIT

* Thimerosal Screening Analyses (Cohort Study). Its manuscript has been submitted for publication. The estimated publication date for this study is December 2003.

* MMR/Autism Biopsy Study (Case-Control Study). This study is in its early stages. A protocol has been developed and received IRB approval. The estimated publication date for this study is June 2004.

* Trends in Hospitalization for NDD Study (Ecological Cohort Study). This study is also currently in its early stages. As above, the protocol has been developed and received IRB approval. The estimated publication date for this study is September 2005.

* Thimerosal Follow-up Study (Cohort Study). This study is at a slightly earlier stage. A protocol has been developed and submitted to the IRB. It is awaiting approval. The estimated publication date for this study is December 2005.

The National Immunization Program is also in the process of developing three other related studies. Protocols for these particular items have not been completed yet:

* Trends in NDD Proposal (Ecological Cohort Study).

* Thimerosal/Autism Study (Case-Control Study).

* Italy Thimerosal Study (Cohort Study).

In addition to the studies listed here that are being conducted at the CDC, the client agency informs me that there are a few ongoing relevant studies that are supported by the National Institutes of Health through grants or contracts to outside entities. Despite that these studies are being conducted outside the agency, we are happy to provide you with a list of the relevant ongoing research projects and the expected dates of their completion. That information is still being gathered, and I will provide it to you as soon as possible.

I appreciate your willingness to work with us to narrow the scope of the issues related to ongoing and proposed studies, and I look forward to working with you in this regard.

Sincerely,

Vincent J. Matanoski

Vincent J. Matanoski
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cc: Special Master George Hastings (by facsimile)

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February 28, 2003

Sent by facsimile and U.S. mail

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Re: Omnibus Autism Discovery

Dear Jeff and Ghada,

As I indicated in my January 10, 2003 letter, I am writing to provide you with updated information about ongoing and proposed research studies relevant to the Omnibus Autism Proceeding and your discovery requests.

National Institutes of Health

There are four extramural research studies currently underway which are funded through grants or contracts by the National Institutes for Health (NIH). There are no extramural studies being conducted directly by the Institute. The ongoing studies are:

National Institute of Allergy and Infectious Diseases

* Evaluation of a Simplified Childhood Immunization Schedule

EXHIBIT

Research is still in planning stage. The estimated date of completion is late 2005. Data may be made publicly available in late 2005 or early 2006.

* Assessment of Mercury Levels and Metabolism in Infants Receiving Vaccines Containing Thimerosal
This study is still in the planning phase. The expected date of completion is the end of 2003. Data may be made publicly available in mid-2004.

National Institute of Environmental Health Sciences

* Environmental Factors in the Etiology of Autism
The planning phase is over and the study is beginning its second year. There is an estimated completion date of 2006.

National Institute of Child Health and Human Development

* Autism Vaccine Study "Regression" Study
This study is in its early stages. The estimated completion date for this study is late 2005.

Food and Drug Administration

The Food and Drug Administration (FDA) has one funded research study underway. There is also a proposal to conduct an animal study. They are as follows:

* Enhanced Follow-up of Reports of Autism Spectrum Disorders to VAERS: Clinical Description of Adverse Events and Characterization of Vaccine Risk Perception of Parents
This study is being conducted in two parts. The manuscript about the risk perception portion of the study (the second part) is in preparation. The first part of the study is in the process of obtaining medical records and performing preliminary analysis of the survey data. The anticipated completion date is January 2004.

* Thimerosal and the National Toxicology Program
This proposed study is in its very early planning stages. Only an preliminary proposal for the study exists. There is no anticipated date for completion of this study if approved.

Centers for Disease Control

Finally, the Centers for Disease Control (CDC) has reviewed the letter I sent to you on January 10, 2003. They have offered the following updates and clarifications of those studies listed:

* MMR/Autism Biopsy Study
This is extramural research being conducted through a cooperative agreement with the American Academy of Pediatrics.

* Trends in Hospitalization for NDD Study
Our previous letter indicated that a protocol had been developed and received IRB approval. This was incorrect. There is no protocol required for this study as it is conducted using public use data.

* Trends in NDD Proposal
Our previous letter indicated that the Trends in NDD proposal (different from the Trends in Hospitalization proposal above) was one of three additional studies that the National Immunization Program was in the process of developing. However, it has been decided that this study will not be conducted.

This should complete the list of ongoing studies and proposed research studies. I appreciate your willingness to work with us to narrow the scope of the issues related to ongoing and proposed studies, and I look forward to working with you again in this regard.

Sincerely,

Vincent J. Matanoski

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cc: Special Master George Hastings (by facsimile)