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.	No. Special Master Hastings

INTERROGATORIES AND REQUESTS FOR PRODUCTION OF DOCUMENTS

Petitioners, by counsel, propound the following Interrogatories to the Respondent. These discovery requests shall be deemed continuing in nature so as to require supplementation if further information becomes available that would be responsive to any of the discovery requests.

DEFINITIONS/INSTRUCTIONS

A. "Person" shall mean the plural as well as the singular and shall include any nature of person, corporation, partnership, joint venture, association, government agency, and every other form of entity cognizable at law.

B. "Identity" and "identify" when used in reference to an individual person means to state the full name, relationship to you, present or last known home and business addresses, home and business telephone numbers, and the present or last known position and business affiliation of such person. "Identify" when used in reference to documents, studies and other such items means to state the complete details surrounding such matters, including, but not limited to, the identity of anyone having custody of such materials, the authors, investigators, publication references, and other information designed to provide details about the nature of all such studies, documents or other matters referred to.

C. Unless otherwise indicated, these Interrogatories refer to the time, place, and circumstances of the design, manufacture and distribution of any MMR vaccines and any vaccines containing thimerosal, aluminum or any other heavy metals.

D. "You" and "your" means the defendant, her agents, employees, representatives, experts, investigators, attorneys, or anyone acting on behalf of the defendant.

E. The phrase "state the facts" with respect to a specified matter shall mean to state each and every fact, incident, event, condition, or circumstance pertinent to the matter.

F. All Interrogatories should be answered on the basis of the Respondent's knowledge or information and belief, including that learned through hearsay, and including the persons mentioned above in paragraph D.

G. If you cannot answer an Interrogatory after conducting a reasonable investigation, you should so state and answer to the extent that you can, stating what information that you do have, what information you cannot provide, and what efforts you have made to obtain the unknown requested information.

H. "Documents" is meant in the broadest sense. It is intended to include the original and/or any copy regardless of its origin or location, or any contract, agreement, invoice, book, pamphlet, periodical, letter, memorandum, telegram, report, record, study, handwritten note, map, drawing, working paper, chart, paper, graph, index, tape, data sheet, data processing card, e-mail, electronically stored information such as on computer disk or hard drive, file server, or other computer backup storage system, or any other written, recorded, computer generated, transcribed, punched, taped, filmed, photographic or graphic matter, however produced or reproduced to which defendant has had access. The term "document" also includes all tangible things, including products, devices, samples or models. It shall also mean any written, recorded or graphic matter however produced or reproduced and whether or not claimed to be privileged against discovery on any grounds, including, but not limited to, statements, reports, records, lists, memoranda, telegrams, correspondence, schedules, photographs, videotapes, sound recordings, microfilm, microfiche, files, and information stored in computers or other data or word processing equipment.

Interrogatories

1. Identify each and every person who has provided information used in answering these interrogatories and providing the documents requested, specifying what information that person provided.

ANSWER:

2. Please identify all studies, reports and other documents of which the Respondent is aware which report or discuss a possible relationship between vaccinations, thimerosal, ethyl mercury, methyl mercury, aluminum, and/or MMR vaccination and the development of neurodevelopmental disorders, autistic spectrum disorders, gastrointestinal disorders, or neurological injuries of any kind.

ANSWER:

3. Please identify all studies or investigations that have been or are in the process of being performed which the Respondent is aware of and which are directed toward looking at any possible relationship between vaccinations, thimerosal, ethyl mercury, methyl mercury, aluminum, MMR vaccination and the development of neurodevelopmental disorders, autistic spectrum disorders, gastrointestinal disorders, or neurological injuries of any kind.

ANSWER:

4. Please provide information concerning any animal studies of which Respondent is aware which have addressed any of the issues referred to above or which are being planned to address any such issues. Also, specifically describe in full and complete detail any animal models Respondent is aware of, which may be models for mercury toxicity, aluminum toxicity, or vaccine induced autism, vaccine induced gastrointestinal disorders, or vaccine induced neurological injury.

ANSWER:

5. Please identify any and all studies of which the Respondent is aware which have been or are being conducted by any HMO, military, manufacturers of vaccines, associations or other organizations outside of the government that are designed to look at any of the issues referred to above.

ANSWER:

6. Please identify any and all studies concerning the safety and efficacy of MMR vaccines or any other vaccinations containing mercury, mercury-containing compounds, or aluminum that have been relied upon in the licensing and evaluation process by federal agencies.

ANSWER:

7. Please provide any and all information concerning any analyses that have looked at the composition of the vaccines referred to above. Included in this request would be any tests or studies that have looked at the actual materials which are contained in the vaccines, including not only the various antigens, but also things like thimerosal, formalin, or any other antigens, preservatives, contaminants, or chemicals, as well as any tests or analyses that have looked at the synergistic effects of such contents of vaccines.

ANSWER:

8. Please provide any and all protocols for manufacturing and testing any of the above referenced vaccines (either by the manufacturers or the Respondent) and any documents that might exist concerning changes that have been made and/or are contemplated.

ANSWER:

9. Please provide the numbers of doses of each of the MMR vaccinations and thimerosal-containing vaccinations distributed annually from 1990 through 2001, broken down by adult doses versus children's doses. What percentage of doses distributed each year are for adults and what percentage are for children?

ANSWER:

10. Please provide the numbers of doses of each of the above referenced vaccinations distributed annually from 1990 through 2001, designating the specific lot numbers and the numbers of doses manufactured and distributed in each such lot.

ANSWER:

11. Please give the names, positions, addresses and phone numbers of any government employees, including their department and institute information, who have knowledge or are working on the issues referred to in the above referenced interrogatories.

ANSWER:

12. What are the requirements necessary for a lot of vaccine to be defined as a "hot lot?"

ANSWER:

13. The Food and Drug Administration continually looks for lots that have received more serious reports that should be expected on the basis of such factors as size, time in use, and chance variation. When such a lot is detected, further investigations are initiated that could lead to recall of the lot under some circumstances. What is the number of serious adverse reports necessary for the FDA to consider that a lot has received more adverse reactions than would be expected based upon chance variation and what are the circumstances that could lead to the FDA's recall of a vaccine?

ANSWER:

14. Why was hepatitis B vaccine (containing thimerosal) to be given to newborns withdrawn? Please identify and produce all documents related to this decision.

ANSWER:

15. Supply any information that the government or manufacturers have concerning the presence of unintended viral contaminants in the MMR vaccines and any thimerosal containing vaccines. This should include the presence of whole viruses and viral sequences including but not limited to diarrhea virus, bacteriophages, chicken viruses, monkey viruses, human viruses or other viruses.

ANSWER:

16. Please supply any information the government or the manufacturers have on the levels of endotoxins or other toxins in any of the above referenced vaccines.

ANSWER:

17. Has the government ever recalled any lots of MMR vaccine or any thimerosal containing vaccine, and has any manufacturer ever voluntarily recalled any lot of these vaccines. Please supply any information and documents concerning such incidents.

ANSWER:

18. Has any government agency ever criticized or demanded changes in the package inserts of any manufacturer of MMR vaccine or thimerosal containing vaccines? If so please document these incidents.

ANSWER:

19. Has any government agency ever criticized the manufacturing processes regarding MMR vaccines or any thimerosal containing vaccines? If so please document all such incidences.

ANSWER:

20. Has the government ever found a manufacturer in violation of the regulations in regard to the manufacture, testing, packaging, advertising practices, storage or distribution of any MMR vaccines or any thimerosal containing vaccines? If so pleases document all such incidences.

ANSWER:

21. Does the government have any knowledge of the levels of P2 protein, myelin basic protein (MBP) or other potentially dangerous proteins or other potentially dangerous substances in MMR vaccines or any thimerosal containing vaccines? If so please supply all documents related to the levels and effects of such contamination.

ANSWER:

22. Does the government have any knowledge of any other contaminants that are or were contained in MMR vaccines or any thimerosal containing vaccines? If so please document these fully.

ANSWER:

23. Has any government agency or employee ever made recommendations concerning improving MMR vaccines or any thimerosal containing vaccines? If so please document fully.

ANSWER:

24. Has any government laboratory or any government funded laboratory or any other laboratory that the government knows about done any studies indicating any kind of problem with MMR vaccines or any thimerosal containing vaccines? If so please document these fully.

ANSWER:

25. Supply any information the government or the manufacturers have on adjuvants and preservatives used in MMR vaccines or any thimerosal-containing vaccines and supply any studies or other information they may have on the safety of the substances.

ANSWER:

26. In the case of *Sharkey v. HHS*, No. 99-699V, the Chief Special Master requested a report on planned and ongoing studies examining the safety of Hepatitis B vaccines. In response to that request, the Respondent filed Exhibit A, which is a report by Dr. Vito Caserta. Please update that report (since Hepatitis B vaccine contained thimerosal), and also please provide the same information for MMR vaccines and any thimerosal containing vaccines. Specifically, Exhibit A referenced the following studies, but this question is not limited to those studies. This question includes all studies, including the following:

A. "Another VAERS study is in press and will be published in the Journal of Clinical Epidemiology in the next few months. This study has developed and applied standardized case definitions for acute encephalopathy, encephalitis, and multiple sclerosis (MS). Although this study will not address causation, it is relevant to Hepatitis B vaccine because many claims allege MS.

B. A review was recently initiated in VAERS describing a case series of Hepatitis B vaccine recipients with reported allergy to yeast or latex. This review is a low priority in VAERS and it is not known if it will be completed.

C. A VAERS study is in the early planning stages to look at a comparison of disability after

Hepatitis B vaccine compared to other vaccines. It has not been decided whether this study should begin.

D. A VSD infant mortality study manuscript has been written and it is currently undergoing early revisions. This study will probably be published within the next 3 years.

E. The manuscript for a neonatal mortality study is currently being written. This study will probably be published within the next 4 years.

F. The VSD report on the thimerosal screening analysis has been written and is currently undergoing clearance. It will probably be published in the next 2 years.

G. A descriptive manuscript on anaphylaxis has been written and is undergoing early revisions. It will probably be published in the next 3 years.

H. The data collection is complete and the analysis is currently underway for an encephalopathy study.

I. The data collection is complete and the analysis is currently underway for a study on gender based differences in adverse events.

J. NIH, DoD, and USAID are not currently sponsoring any ongoing Hepatitis B vaccine safety research.

K. In Europe, the Cochrane Collaboration has prepared a protocol for a project that is partially funded by the World Health Organization (WHO). The Collaboration is searching for additional funding to complete the project. This project will perform systematic review of the evidence relating to the safety of Hepatitis B vaccine. The final report will include a review of all the available comparative studies on the vaccine and the hypothesized adverse events. The studies will be examined against a set of inclusion criteria, data will be extracted in a standardized way, and the quality of the different study designs will be assessed. The final product will be a competed database containing validated data extracted from the identified studies. The timeline for this study is very uncertain because of incomplete funding.

L. The NIH, the University of Rochester and the National Naval Medical Center are studying the levels of mercury in serum, hair and possibly other tissues after vaccination. This is a clinical study where infants are tested within a few weeks after routine immunizations. Data analysis is currently underway and follow-up studies are planned. Time to publication is unknown.

M. Another study from Sweden performed a randomized trial of pertussis vaccines, with and without thimerosal, given in the first year of life. Approximately 179 trial participants

were given an IQ and other cognitive tests at 5.5 years of age. The results should be available soon.

N. Another thimerosal study involves the WHO and the Public Health Laboratory Service in England. This is a cohort study of infants who received up to 150 mcg of Hg by 6 months of age. The study analyzed the UK General Practitioner Research Database between 1988 and 1996 (178,000 births). The results should be available soon.

O. Another NIH pilot study looking at infant macaques will evaluate whether the distribution of thimerosal and methyl mercury is the same. A parallel rodent study may also be done."

With regard to each study referenced above and with regard to any other studies identified, please provide any related documents.

With regard to each study referenced above and with regard to any other studies that are identified, please provide the following:

a. The name, address and phone number of the principal investigator(s);
b. The source of funding for each study, including any additional funding that is being contemplated for current or future studies;
c. The expected date of completion of the data gathering phase of the study;
d. The expected date of the completion of the analysis phase of the study;
e. The expected date of publication of any results from the study;
f. The custodian of the study data;
g. The stated purpose of the study;
h. The methodology of the study, including the level of sensitivity anticipated, using standard epidemiological principles; and
i. Who made the decisions to conduct the study and who decided upon the methodology?

ANSWER:

27. On October 1, 2001, the IOM report on *Thimerosal Containing Vaccines and Neurodevelopmental Disorders* (hereinafter "IOM Thimerosal Report") was published. In that report, reference is made on page 43 to evidence derived from the VAERS data. With regard to Table 4 on page 44, please specify for each case report exactly who "attributed" the adverse event to thimerosal.

ANSWER:

28. On page 45 of the IOM Thimerosal Report, the committee concludes that there are problems with the VAERS data. Problems include underreporting, lack of detail, inconsistent diagnostic criteria, and inadequate denominator data. Please provide information concerning any reports, communications, studies or other data that have addressed any or all of these problems. Also, please provide any evidence that these problems do or do not apply equally to all vaccines.

ANSWER:

29. Beginning on page 45 of the IOM Thimerosal Report, the committee discusses the VSD study (Verstraeton 2001). With regard to that study, please provide the following information:

a. The name, address and phone number of the principal investigator(s);
b. The source of funding for each study, including any additional funding that is being contemplated for current or future studies;
c. The expected date of completion of the data gathering phase of the study;
d. The expected date of the completion of the analysis phase of the study;
e. The expected date of publication of any results from the study;
f. The custodian of the study data;
g. The stated purpose of the study;
h. The methodology of the study, including the level of sensitivity anticipated, using standard epidemiological principles; and
i. Who made the decisions to conduct the study and who decided upon the methodology?

Also, please provide all information concerning the Simpsonwood panel, including but not limited to the following:

j. Names, affiliations, and contact information for all members;
k. The custodian of all minutes, correspondence and other documents generated by or as a result of the proceedings of that panel, before, during and after the meeting in June of 2000; and
l. Describe in full and complete detail the proceedings of that panel, or, in lieu thereof, produce all documents, such as minutes, memorandum, read-aheads, correspondence, emails, and other documents of any kind.

ANSWER:

30. The IOM issued a report in 2001 on Thimerosal-Containing Vaccines and Neurodevelopmental Disorders. In that report, the IOM made specific recommendations. What has the government done with regard to any of the following recommendations?

a. The use of the Thimerosal-free DTaP, Hib, hepatitis B vaccines in the United States, despite the fact that there might be remaining supplies of thimerosal-containing vaccine available. Did the government use the suggested mechanisms to accomplish this goal? Why or why not?
   i. "Dear Doctor" letters
   ii. Existing supplies bought back from providers by vaccine makers or the CDC.

b. Full consideration be given by appropriate professional societies and government agencies to removing thimerosal from vaccines administered to infants, children, or pregnant women in the United States.

c. Appropriate professional societies and governmental agencies review their policies about the non-vaccine biological and pharmaceutical products that contain thimerosal and are used by infants, children and pregnant women in the United States.

d. A review and assessment of how public health policy decisions are made under uncertainty in order to develop suggestions to improve the decision making process about vaccines in the future.

e. A review of the strategies used to communicate rapid changes in vaccine policy and research on how to improve those strategies.

f. A diverse public health and biomedical research portfolio that involves several different agencies.

g. Case-control studies examining the potential link between neurodevelopmental disorders and thimerosal-containing vaccines.

h. Further analysis of neurodevelopmental outcomes in the cohorts of children outside the United States who did not receive thimerosal-containing doses as part of a clinical trial of DTaP vaccine.

i. Conducting epidemiological studies that compare the incidence and prevalence of neurodevelopmental disorders before and after the removal of thimerosal from vaccines.

j. Increased efforts to identify the primary sources and levels of prenatal and postnatal background exposure to thimerosal (e.g., Rho (D) Immune Globulin) and other forms

of mercury (e.g., maternal consumption of fish) in infants, children, and pregnant women to identify populations at higher risk for mercury toxicity.

k. Incorporation of Phase III of the VSD studies as part of an overall package of research and geared to accurately identify neurodevelopmental conditions of concern.

l. Research on how children, including those diagnosed with neurodevelopmental disorders, metabolize and excrete metals—particularly mercury.

m. Continued research on theoretical modeling of ethylmercury exposures, including the incremental burden of thimerosal with background mercury exposure from other sources.

n. Careful, rigorous and scientific investigations of chelation when used in children with neurodevelopmental disorders, especially autism.

o. Research to identify a safe, effective and inexpensive alternative to thimerosal for countries that decide they need to switch.

p. Research in appropriate animal modes on neurodevelopmental effects of ethylmercury.

In answering this question please provide full and complete information, including the names of the people responsible for deciding what studies to perform and what not to perform and how to conduct such studies.

ANSWER:

31. The IOM issued a report in 2001 on Measles-Mumps-Rubella Vaccine and Autism. In that report, the IOM made specific recommendations. What has the government done with

regard to any of the following recommendations?

A. Currently, a number of research studies are in progress regarding the etiology, brain structure and/or function, developmental course, and epidemiology of ASD ("autistic spectrum disorders"). In order to evaluate and compare these current and future studies the IOM recommended use of accepted and consistent case definitions and assessment protocols for ASD in order to enhance the precision and comparability of results from surveillance, epidemiological, and biologic investigations.

B. Explore whether exposure to MMR vaccine is a risk factor for ASD in a small number of children. Identify a marker for identifying children at risk for the "regressive" form of ASD.

C. Develop targeted investigations of whether or not measles vaccine-strain virus is present in the intestines of some children with ASD.
   - In conjunction with the CDC's National Immunization Program, the CPEA is beginning an autism regression and vaccination study that will assess the temporal association between MMR vaccination and autism, distinguishing between the early-onset and regressive forms.

D. Encourage all who submit reports to VAERS of any diagnosis of ASD thought to be related to MMR vaccine to provide as much detail and as much documentation as possible.
   - The committee encourages the government agencies responsible for VAERS (CDC and FDA), as well as immunization providers (physicians and nurses) and parents to use VAERS reporting system conscientiously and thoroughly.
   - In particular, case reports in VAERS or elsewhere of "rechallenge" should be identified, documented, and followed up.

E. Study the possible effects of different MMR immunization exposures.
   - It is naïve to ignore the fact that some parents are selecting alternative approaches to vaccination. Children who are immunized in an alternative manner, such as different vaccine types or at different ages, should be studied, although the number of children enrolled in these studies and issues of selection bias would affect the design and interpretation of the results.

F. Conduct further clinical and epidemiological studies of sufficient rigor to identify risk factors and biological markers of ASD in order to better understand genetic or environmental causes.
   - There is a need to support and continue the NIH- and CDC-funded research already under way on all aspects of ASD.
   - Epidemiological studies are needed to document the prevalence and incidence of

ASD, temporal trends, and the incidence and prevalence of different courses of ASD (e.g., regressive vs. early onset).

In answering this question please provide full and complete information, including the names of the people responsible for deciding what studies to perform and what not to perform and how to conduct such studies.

ANSWER:

32. The ATSDR study published in March of 1999 appears to represent a culmination of 7 years of research, yet it fails to even mention thimerosal more than twice in passing and failed to mention any of the medical literature discussing the mercury toxicity of thimerosal. With regard to that study, please provide the following:

a. The name, address and phone number of the principal investigator(s)
b. The source of funding for each study, including any additional funding that is being contemplated for current or future studies
m. The expected date of completion of the data gathering phase of the study
n. The expected date of the completion of the analysis phase of the study
o. The expected date of publication of any results from the study
p. The custodian of the study data
q. The stated purpose of the study
r. The methodology of the study, including the level of sensitivity anticipated, using standard epidemiological principles and
s. Who made the decisions to conduct the study and who decided upon the methodology

33. Please describe in full and complete detail any consideration the government has given to removing thimerosal from any other products, other than vaccines. Include in this response, the names of all products, whether they be for human use or veterinarian use (i.e. due to concerns about thimerosal getting into the country's meat supply, etc.), and provide the names and contact information for any individuals who may be involved in such decisions and who may have custody of documents concerning these decisions.

ANSWER:

34. Identify all conferences held or scheduled to be held that relate in any way to MMR, thimerosal or any other preservative in any vaccine, to which the government has been invited or which are being held by any professional agency to which they belong.

ANSWER:

35. Please describe in full and complete detail what work is being done at the FDA or any other agency to lower the safety limit for tuna and other large fish consumption by pregnant women, including, but not limited to the following information:

a. Who is involved;
b. What is the schedule for this work to be done; and
c. What input from the industry is involved.

ANSWER:

36. The NAS Report on methyl mercury stated that 50,000 children per year are already at the high range of organic mercury exposure, what is the government doing to find and study those kids?

ANSWER:

Requests for Production of Documents

Petitioners request that you produce the following documents that are in your possession,

custody or control.

When producing the documents, you should organize and label them where appropriate to correspond with the categories of this request.

If a document is withheld by you on the grounds of attorney-client privilege or attorney work product, identify such document by date, author, recipient, and subject matter (without disclosing its contents) sufficient to allow its description to the Court for the Court's ruling on your objection.

Requests

1. Produce a copy of all documents that are identified in answer to any of the interrogatories above or that are used in preparing answers to these interrogatories.

RESPONSE:

2. Produce a copy of all documents that are relevant in any way to the interrogatories and/or answers to interrogatories above, and more specifically, that relate to DPT, DtaP, HIB, Hepatitis B, and MMR vaccines, as well as Rhogam (a thimerosal containing product) and other thimerosal-containing products, as they relate to the development of autism spectrum disorder, PDD, gastrointestinal and neurological problems.

RESPONSE:

3. Please produce any documents, including emails, internal memorandum and other correspondence which discuss studies, proposed studies, testing, proposed testing, reviews of literature, etc. dealing with MMR vaccines or any thimerosal containing vaccines causing or contributing to autism or PDD.

RESPONSE:

4. Please provide access to the underlying data maintained by the Vaccine Adverse Event Reporting System (VAERS). Petitioners are not requesting copies of any of that data at this point, but would request that their designated experts be given access to the data under restrictions that would protect privacy, solely for the purpose of studying the data and assisting Petitioners in formulating additional discovery requests.

-Please provide all reports of adverse events related to MMR vaccine.

-Please provide all reports of adverse events related to any thimerosal containing vaccine

-Please provide all reports related to any vaccine resulting in Autism, ASD or any neurodevelopmental disorder.

Additionally, Petitioners' experts specifically need access to the following information:

a) We request the net number of doses of each type of vaccine distributed, yearly, from 1990 through 2002.

b) We request the net number of doses of each type of vaccine distributed by each manufacturer, yearly, from 1990 through 2002.

c) We request the net number of doses in each lot of each type of vaccine, yearly, distributed from 1990 through 2002.

d) We request the number of doses of each type of vaccine distributed broken down by pediatric and adults by year, by company and by lot from 1990 through 2002.

e) We request the number of doses of each type of vaccine distributed to each state from 1990 through 2002.

f) We request the number of doses of each type of vaccine distributed by each manufacturer, yearly, from 1990 through 2002 to each state.

g) We request the number of doses in each lot of each type of vaccine, yearly distributed from 1990 through 2002 to each state.

h) We request the number of doses of each type of vaccine distributed broken down by pediatric and adults by year, by company and by lot from 1990 through 2002 for each state.

i) We request all data, documents and publications related to the number of doses of vaccine distributed from 1990 through 2002.

This data is necessary to analyze and contrast the reaction rates for MMR vaccines or any thimerosal containing vaccines as compared with other vaccines, and to identify hot lots.

RESPONSE:

5. Please provide access to the underlying data maintained by the Vaccine Safety Datalink System. Petitioners are not requesting copies of any of that data at this point, but would request that their designated experts be given access to the data under restrictions that would protect privacy, solely for the purpose of studying the data and assisting Petitioners in formulating additional discovery requests. Specifically, Petitioners experts request access to at least the following information:

a) Any documents, reports, abstracts and underlying data relating to the original Thimerosal analyses done by Thomas Verstraeten.

b) For any published government sponsored study related to MMR, thimerosal-containing vaccines, Autism, ASD or any neurodevelopmental disorder please provide the following for each study:

i) All underlying data
ii) Any and all documents related to the study protocol and design
iii) Any documents that relate to the inclusion or exclusion of subjects
iv) Any and all documents related to the analyses of the data

c) We request the net number of doses of each type of vaccine distributed, yearly, in the Vaccine Safety Datalink.

d) We request the net number of doses of each type of vaccine by each manufacturer distributed, yearly, in the Vaccine Safety Datalink.

e) We request the net number of doses of each type of vaccine in each lot distributed, yearly, in the Vaccine Safety Datalink.

f) We request all data, documents and publications related to the number of doses of vaccine distributed in the Vaccine Safety Datalink.

g) We request the number of doses of each type of vaccine distributed in the Vaccine Safety Datalink broken down by pediatric and adults by year, by company and by lot.

RESPONSE:

6. Please provide access to the underlying data maintained by the FDA Medical Products Reporting Program (MEDWATCH). Petitioners are not requesting copies of any of that data at this point, but would request that their designated experts be given access to the data under restrictions that would protect privacy, solely for the purpose of studying the data and assisting Petitioners in formulating additional discover requests. Specifically, Petitioners experts request access to at least the following information:

a) We request the number of doses of each type of medical product distributed, yearly, in the FDA Medical Products Reporting Program (MEDWATCH).

b) We request the number of doses of each type of medical product by manufacturer distributed, yearly, in the FDA Medical Products Reporting Program (MEDWATCH).

c) We request the number of doses of each type of medical product by lot, distributed, yearly, in the FDA Medical Products Reporting Program (MEDWATCH).

d) We request all data, documents and publications related to the number of doses of each type of medical product distributed in the FDA (MEDWATCH).

e) We request the number of doses of each type of medical product distributed in the FDA (MEDWATCH) broken down by pediatric and adults by year, by company and by lot.

RESPONSE:

7. Please provide access to the underlying data maintained by the National Health Interview Surveys (NHIS). Petitioners are not requesting copies of any of that data at this point, but would request that their designated experts be given access to the data under restrictions that would protect privacy, solely for the purpose of studying the data and assisting Petitioners in formulating additional discover requests.

RESPONSE:

8. Please provide access to any documents related to any requests for funding for studies relating to adverse events associated with the MMR vaccines or any thimerosal containing vaccines.

RESPONSE:

9. Please produce copies of any and all transcripts of hearings conducted prior to FDA approval of the measles-mumps-rubella (MMR) vaccine.

RESPONSE:

10. Please produce copies of any and all documents submitted to the FDA for review by vaccine manufacturers prior to the approval of the MMR vaccine.

RESPONSE

11. Please produce copies of any and all transcripts of hearings conducted prior to FDA approval of all thimerosal-containing vaccines

RESPONSE:

12. Please produce copies of any and all documents submitted to the FDA for review by vaccine manufacturers prior to the approval of all thimerosal-containing vaccines.

RESPONSE:

13. Please produce all correspondence of any kind, emails, memos, letters, reports, etc. exchanged between the government and any vaccine manufacturer, any health and / or medical

agency, or international organization in any country related to MMR, thimerosal or any other preservative in any vaccine

RESPONSE:

14. The ATSDR published a peer review toxicological profile for mercury in March of 1999 that was prepared under government contract # 205-93-0606 by Research Triangle Institute. Please provide a copy of the administrative record relating to that contract, which should also include a copy of the September 1997 draft of the document, the peer reviewers comments that were not incorporated into the profile and the rationale for exclusion, and the data bases and non published literature that were reviewed by the authors of the profile. In addition, please produce copies or access to, the copies of all correspondence between any member of the Research Triangle Institute and ASTDR that relates to the planning, research, drafting or publication of the Toxicological Profile of Mercury. More specifically, please produce copies of any communications between Rob DeWoskin of the RTI and John Risher of the ASTDR that relate to the planning, research, drafting or publication of the profile and copies, or access to, all medical literature that was reviewed by the ATSDR in the preparation of the profile. Also, please provide copies, or access to, all comments received from doctors, medical organization, or pharmaceutical companies, between the time the September 1997 draft was published and the final profile of March 1999 was published. Also, please provide copies, or access to, all correspondence or records reflecting any communication between the ATSDR and the FDA on the subject matter of mercury or the mercury containing preservative, Thimerosal.

RESPONSE:

15. On June 7 – 8, 2000 the CDC sponsored a conference entitled "Scientific Review of Vaccine Safety Datalink Information" at the Simpsonwood Retreat Center in Norcross, Georgia. Please produce any and all related materials, including but not limited to the following:

q. Any Agenda, Handouts, packets distributed at conference, transcript of proceedings, any transparencies, slides or other materials shown with any presentation or by any attendee.

r. Any and all materials on the AICP work group on Thimerosal and immunization.

s. Each and every study, report, conference, meeting discussed or mentioned at that

conference.

t. Any and all materials discussed, mentioned or relating to any thing discussed by Dr. Verstraeten.

RESPONSE:

Respectfully submitted,

Ghada A. Anis, Esquire
Liaison Counsel for
Petitioners' Steering Committee
9711 Meadowlark Road
Vienna, Virginia 22182-1951
Tel: (703) 281-6395
Fax: (703) 281-5807

CERTIFICATE OF SERVICE

I certify that a copy of this pleading (and an electronic version of this pleading) was sent by priority mail this 2 day of August, 2002 to:

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