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

RESPONSE TO PETITIONERS' INTERROGATORIES AND REQUEST FOR PRODUCTION OF DOCUMENTS

Respondent submits the following response pursuant to Autism General Order #1.

Preliminary Statement

Discovery in cases under the National Vaccine Injury Compensation Program is governed by RCFC App. B, Rule 7. That rule provides, in part: "There shall be no discovery as a matter of right." In the unusual circumstance where informal discovery is insufficient, a party "may seek to utilize the discovery procedures provided by RCFC 26-37..." RCFC App. B, Rule 7(b).

In responding to petitioners' Interrogatories and Request for Production of Documents ["Requests"], respondent has been guided by the Chief Special Master's recitation of the issues in Autism General Order #1; specifically, petitioners' claim of

autism or autistic spectrum disorders ["ASD"] due to the administration of mumps-measles-rubella ["MMR"] and/or vaccines in which thimerosal had been used as a preservative. Respondent has conducted a diligent search and reasonable inquiry in response to the Requests, given their broad nature and the limited time for response. However, respondent has not completed its investigation of the facts related to this case, has not yet undertaken any discovery in this action, and has not completed its preparation for any trial that might be held in this matter. Its responses to these Requests are based upon information currently known to respondent and are given without prejudice to respondent's right to supplement, add to, amend, or modify its responses to these Requests. Moreover, respondent reserves the right to make use of, or introduce at any hearing or at trial, documents or facts not known to exist at the time of production, including, but not limited to, documents obtained in the course of discovery in this action. In formulating a response to petitioners' Requests, respondent surveyed the following components: the National Institutes of Health (NIH), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Agency for Toxic Substances and Disease Registry (ATSDR), and the Division of Vaccine Injury Compensation (DVIC).

Subject to the foregoing Preliminary Statement, respondent

makes the following General Objections to the Requests in their entirety, including each of petitioners' definitions, instructions and individual requests contained therein.

General Objections

Respondent makes the following General Objections, whether or not separately set forth in response to each and every request propounded by petitioners. The assertion of the same, similar, or additional objections or partial responses to petitioners' individual requests does not waive any of respondent's General Objections.

1. Respondent objects to the Requests to the extent that they attempt to impose on respondent any obligations or requirements that exceed, enlarge and/or alter those imposed by the Rules of the Court of Federal Claims ["RCFC"].

2. Respondent objects to the Requests to the extent that they seek information which is not relevant to the subject matter of this action in that it is neither admissible evidence nor reasonably calculated to lead to the discovery of admissible evidence related to petitioners' claim of autism or autistic spectrum disorders due to the administration of mumps-measles-rubella ["MMR"] or thimerosal-containing vaccines, as recited in the Chief Special Master's Autism General Order #1.

3. Respondent objects to the Requests to the extent that they seek confidential, private, or privileged information,

including, without limitation, information protected from disclosure by the attorney-client privilege, the work-product doctrine, the deliberative process privilege, the Privacy Act 5 U.S.C. § 552a, the right to privacy guaranteed by the United States Constitution, the Trade Secret Act, 18 U.S.C. § 1905, 21 C.F.R. §§ 20.61, 20.63, and 601.51, and/or any other applicable statutory, regulatory, or common-law privilege.

Respondent intends to preserve and assert all applicable privileges. Any inadvertent disclosure of privileged information shall not constitute a waiver by respondent of any applicable privileges or any other objection to the disclosure, production, or use during any proceeding of such information. To the extent respondent produces any confidential or private material, it will not do so except pursuant to an appropriate protective order to be entered in this action and any Court ordered modifications thereof, and reserves the right to redact irrelevant and/or privileged information from any documents that are produced.

4. Respondent objects to the Requests to the extent that they are vague, ambiguous, misleading, uncertain, unintelligible, overbroad, fail to specifically describe the information sought, are not defined, seek information outside the scope of Autism General Order #1, and/or would require respondent to speculate as to the nature and scope of the documents sought.

5. Respondent objects to the Requests to the extent that

they are unduly burdensome, compound and/or duplicative.

6. Respondent objects to the Requests to the extent that they purport to seek documents that are already in petitioners' possession, documents that are a matter of public record, and/or documents that are otherwise equally accessible to petitioners.

7. Respondent objects to the Requests to the extent that they purport to impose on respondent the burden of ascertaining information that is not in respondent's possession, custody or control, and/or that cannot be found in the course of a reasonable search.

8. Respondent objects to the Requests to the extent that they call for organization of documents according to request. Respondent may produce documents as they are kept in the ordinary course of business.

9. Respondent objects to the Requests to the extent that they contain inappropriate and/or argumentative headings and sub-headings.

10. Respondent objects to the Requests to the extent that the Requests, including but not limited to the definition of "identity" and "identify," call for the home and business addresses and telephone numbers of respondent's employees. Such employees may be contacted only through counsel for respondent, and may not be contacted directly.

11. Respondent objects to the Requests to the extent that

they are not reasonably limited in time, place, or scope and would therefore impose a burden or expense on respondent that outweighs the likely benefit of the Requests.

12. Respondent objects to the Requests to the extent the definitions of "you" and "your" purport to request privileged information in the possession, custody, or control of respondent's agents or representatives, and to the extent that the terms include all persons who have ever acted or purported to act on behalf of respondent, and/or persons over whom respondent has no control.

13. Respondent objects to the definition of the phrase "state the facts" as overbroad and unduly burdensome, in that it is not limited in scope as to dates, places, entities, or issues so as to be reasonably calculated to lead to the discovery of admissible evidence on the issues recited in Autism General Order #1. As such, it provides respondent with no reasonable basis upon which to formulate a search or conduct a reasonable investigation within documents possibly numbering in the millions and which date back approximately 100 years, which may possibly relate to "every fact, incident, event, condition, or circumstance pertinent to the matter."

14. Respondent objects to the definition of "documents" as it is vague, overbroad, and unduly burdensome to the extent that it is meant "in the broadest sense" and seeks documents

"regardless of [their] origin or location." This definition is not sufficiently limited in time, place, or scope to allow respondent to formulate a search, conduct a reasonable investigation for responsive documents or to locate, prioritize, categorize, or produce responsive documents. Therefore, for the purposes of responding to these Requests, the term "document" will be interpreted by respondent to mean any document or tangible thing, that has been specifically proposed, funded, authored, drafted, or created by respondent or any of its employees in the course of their employment or in performing a statutory, mandate, duty or function that is currently within respondent's custody and control, subject to any and all applicable prohibitions from disclosure as noted in respondent's "General ObjectionS" above.

15. Respondent objects to the Requests to the extent they purport to require respondent to compile or analyze information to respond to a request rather than requiring respondent to provide information currently in respondent's possession, custody or control. Respondent also objects to the Requests to the extent that they purport to require respondent to compile or analyze information stored in electronic form that does not already exist in the form of a report, on the grounds that it would subject respondent to undue burden and expense.

16. Respondent objects to the Requests on the grounds that

they are vague, overbroad, and unduly burdensome to the extent that they require the disclosure of information or documents pertaining to matters outside the scope of this litigation, as defined in Autism General Order #1. Specifically, respondent objects to requests for information concerning "any MMR vaccine," "any vaccine containing thimerosal, aluminum, or any other heavy metals," "Rhogam," "tuna" and other medications or substances not covered by the National Vaccine Injury Compensation Program. Accordingly, to the extent that the Requests seek such information, they are neither relevant to the subject matter of this litigation nor reasonably calculated to lead to the discovery of admissible evidence.

Accordingly, for the purposes of responding to these Requests, the phrase "any MMR vaccine" will be interpreted by respondent to mean any measles-mumps-rubella ["MMR"] vaccine covered under the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 to -34. For the purpose of responding to these Requests, the phrase "any vaccine containing thimerosal" or the term "vaccines" will be interpreted by respondent to mean any diphtheria-tetanus-pertussis ["DTP"], diphtheria-tetanus-acellular pertussis ["DTaP"], hepatitis B ["HepB"], or hemophilus influenzae type b ["HIB"] vaccine covered under the Program to which thimerosal was added as a preservative ingredient ("covered vaccine"). Vaccines that may contain aluminum, heavy metals

other than mercury, or trace amounts of thimerosal, where thimerosal was not added to the final product as a preservative, will not be considered by respondent to be thimerosal-containing vaccines for the purposes of responding to these Requests.

17. Respondent objects to the Requests to the extent that they are not limited in temporal scope. Respondent notes that the vaccines at issue have an extensive regulatory history that, for some vaccines, spans approximately 100 years. Petitioners' theories of causation, as recited in Autism General Order #1, are premised on an alleged increase in the incidence of autism or ASD related to the above-mentioned vaccines from 1990 through 2001. Because respondent's document retention policies vary within its respective agencies and offices, a limitation on the period of these Requests is necessary in order to conduct a reasonable and focused investigation. Therefore, for the purposes of responding to these Requests, respondent has focused its initial investigation on the ten-year period from January 1, 1992 through the present, where applicable.

18. Respondent's reliance on any of these "GENERAL OBJECTIONS" in the response to a particular Request does not constitute a waiver of any other "GENERAL OBJECTION" with regard to that request.

19. Respondent intends that any objection on the grounds of relevance be read to mean that the information sought is neither

relevant to the subject matter of this litigation, as defined and set forth in the General Autism Order #1, nor reasonably calculated to lead to the discovery of admissible evidence.

20. In stating these objections, respondent does not waive, but intends to preserve, (a) all objections to the competency, relevancy, materiality, and admissibility for any purpose, of the responses to the Requests or the subject matter thereof, in any subsequent proceeding in, or the trial of, this or any other action; (b) the right to object on any grounds to the use of any response, or the subject matter thereof, in any subsequent proceeding in, or the trial of, this or any other action; (c) the right to object on any grounds at any time to a demand for further response to these or any other discovery procedures involving or related to the subject matter of the Requests directed to respondent; (d) the right to object on any grounds to any other or future discovery requests; and (e) the assertion of any privilege with respect to any response, or the subject matter thereof.

Subject to the General Objections and qualifications above, respondent submits the following responses to petitioners' individual requests.

Objections to Petitioners' Interrogatories

RCFC App. B, Rule 33(a) provides that, absent leave of the court, a party may propound interrogatories "not exceeding 25 in

number including all discrete subparts." The Interrogatories propounded by petitioners total more than 100, including discrete subparts.

Respondent contacted representatives of the Petitioners' Steering Committee to advise them that respondent would be objecting to petitioners' interrogatories, in part, because they exceeded the permissible number provided by RCFC 33. Respondent offered representatives of the Petitioners' Steering Committee the opportunity to designate those twenty-five interrogatories or subparts from their Interrogatories and Request for Production of Documents ("Requests") that they desired respondent to answer. Petitioners' representatives were further advised that respondent would not consider such designation as a waiver by petitioners of any right they may otherwise have to seek leave to obtain responses to other interrogatories or subparts of their Requests. Finally, respondent stated that, absent such designation, respondent would answer the first twenty-five interrogatories or subparts in the order that petitioners' representatives had propounded them.

Petitioners' representatives conferred and informed respondent that they preferred that respondent not answer any interrogatories at this time, but rather object to all on the basis that the number of interrogatories exceeded the limits imposed by RCFC 33. Petitioners' representatives stated they

would prefer that respondent proceed this way so petitioners' representatives could consult further regarding the interrogatories they propounded. This would permit them to establish a priority to the interrogatories, and then discuss the issue with respondent at a discovery conference between the parties that had been previously scheduled to take place on the morning of September 10, 2002. Petitioners' representatives advised that it was their preference that respondent wait until after this meeting to submit twenty-five responses so that respondent would answer those interrogatories or subparts named during the meeting.

Finally, petitioners' representatives indicated that, while they prefer that respondent answer in this manner at this time, they do not necessarily agree that the limits of RCFC 33 apply. Respondent agreed to petitioners' request with the condition that, while at this time respondent would solely respond that the interrogatories violated RCFC 33, respondent reserved the right to raise additional objections when called upon to further respond.

Accordingly, respondent objects to petitioners' interrogatories on the basis that, as propounded, the number of interrogatories and subparts exceed the limit set by RCFC 33. In making this response, respondent does not waive the right to object on any other basis if and when a further response to a

specific interrogatory is made.

As stated above, respondent is making this response at the specific request of representatives of the Petitioners' Steering Committee. Respondent was prepared to respond at this time to interrogatories propounded within the scope of the Rules of the United States Court of Federal Claims and subject to other applicable objections.

Objections and Responses to Petitioners' Request for Production of Documents

REQUEST:

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.

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:

Respondent incorporates by reference all of its General Objections as though fully set forth herein. As noted in respondent's Objections to Interrogatories above, counsel for the parties are cooperating to focus petitioners' Interrogatories so that they comply with RCFC 26 and 33 and would permit a response

by respondent. As this Request is for documents related to the interrogatories, and it has not yet been determined which interrogatories respondent will be answering, respondent is currently unable to answer this Request.

REQUEST:

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, DAP, HIM, 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:

Respondent incorporates by reference all of its General Objections as though fully set forth herein. As noted in respondent's Objections to Interrogatories above, counsel for the parties are cooperating to focus petitioners' Interrogatories so that they comply with RCFC 26 and 33 and would permit a response by respondent. As this Request is for documents related to the interrogatories, and it has not yet been determined which interrogatories respondent will be answering, respondent is currently unable to answer this Request.

REQUEST:

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:

Respondent incorporates by reference its General Objections as if fully set forth herein. Respondent objects to the Request on grounds that it is vague, overbroad, and unduly burdensome. Specifically, respondent objects to the terms "studies," "proposed studies," "testing," "proposed testing," and the phrase "reviews of literature etc." Further, respondent objects to this Request because it is not sufficiently limited in time, place, or scope to allow respondent to formulate a search or conduct a reasonable investigation that will likely yield responsive documents. Respondent also objects to the Request to the extent it seeks or would require the disclosure of information, which is confidential, commercial, proprietary, or trade secret information, which is protected from disclosure under the Trade Secret Act, 18 U.S.C. § 1905, 21 C.F.R. §§ 20.61, 20.63, and 601.51 or any other applicable statutory, regulatory or common law privilege, including but not limited to the deliberative process privilege and/or the attorney-client privilege.

Subject to the foregoing objections and to the extent the requested information is already maintained in a form suitable under the law for public disclosure, respondent will produce responsive documents for inspection and copying by petitioners, under a protocol and production schedule to be determined.

REQUEST:

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 [sic] 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:

Respondent incorporates by reference its General Objections as if fully set forth herein. Respondent objects to this Request on the grounds that it is ambiguous and compound. As dividing the request for production into three parts permits respondent to provide more responsive information, respondent submits the following responses to individual parts of this request:

"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."

Respondent objects to this portion of the Request on the grounds that providing access to the "underlying data maintained by the Vaccine Adverse Event Reporting System (VAERS)" would require disclosure of information that is confidential, commercial, proprietary, or trade secret information, which is protected from disclosure under the Trade Secret Act, 18 U.S.C. § 1905, 21 C.F.R. §§ 20.61, 20.63, and 601.51, the Privacy Act, 5 U.S.C. § 552a, and other applicable statutory, regulatory or

common law privileges.

Subject to the foregoing objections and to the extent the requested information is already maintained in a form suitable under the law for public disclosure, petitioners may inspect and copy information responsive to this request at the following Internet addresses:

http://www.vaers.org/info.htm

http://www.fda.gov/cber/vaers/articles.htm

"-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."

Respondent objects to this portion of the Request on the grounds that it is vague, overbroad, and unduly burdensome. Specifically, respondent objects to the term "all reports of adverse events" as this phrase is paired with both "MMR vaccine" and "thimerosal containing vaccine" and to the phrase "all reports related to any vaccine resulting in . . . neurodevelopmental disorder" on the grounds that these requests are vague, overbroad, and unduly burdensome, and they encompass a subject matter that is beyond the scope of Autism General Order #1. Respondent objects further on the grounds that providing the requested "reports" would require the disclosure of information that is confidential, commercial, proprietary, or trade secret

information, which is protected from disclosure under the Trade Secret Act, 18 U.S.C. § 1905, 21 C.F.R. §§ 20.61, 20.63, and 601.51, the Privacy Act, 5 U.S.C. § 552a, and other applicable statutory, regulatory or common law privileges.

Subject to the foregoing objections and to the extent the requested information is already maintained in a form suitable under the law for public disclosure, petitioners may inspect and copy information responsive to this request at the Internet addresses listed above in response to the first portion of this Request.

"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."

Respondent objects to this portion of the Request on the grounds that it is overbroad and unduly burdensome. Respondent objects further to the use of the term "hot lots" because the term is undefined, vague, and ambiguous. In addition, to the extent that subparts (a) through (i) request access to dose distribution "by each manufacturer" or "by company," respondent objects on the grounds that permitting such access would disclose information that is confidential, commercial, proprietary, or trade secret information, which is protected from disclosure under the Trade Secret Act, 18 U.S.C. § 1905, 21 C.F.R. §§ 20.61, 20.63, and 601.51, or other applicable statutory, regulatory or common law privileges. To the extent that subparts (a) through(i) request access to dose distribution "in each lot" or "by lot," respondent cannot provide access because it does not maintain the requested information. To the extent that subparts (a) through (i) request access to dose distribution "broken down

by pediatric and adult doses," respondent cannot provide access because it does not maintain the requested information.

Subject to the foregoing objections, respondent will produce for inspection and copying by petitioners non-confidential, non-privileged data that pertains to vaccine distribution to the extent that such information has already been compiled for public disclosure and published to date through the CDC's method of distribution surveillance, called Biologics Surveillance. This production will take place under a protocol and schedule to be determined.

REQUEST:

5. Please provide access to the underlying data maintained by the Vaccine Safety Datalink System. Petitioners are not requesting copies of any of the 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 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:

Respondent incorporates by reference its General Objections as if fully set forth herein. As an initial matter, respondent objects to this Request on the grounds that it is ambiguous and compound. As dividing the request for production into subparts permits respondent to convey information that is more responsive, respondent submits the following breakdown and responses:

"Please provide access to the underlying data maintained by the Vaccine Safety Datalink System. Petitioners are not requesting copies of any of the 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."

Respondent objects to this portion of this Request on the grounds that providing access to "the underlying data maintained by the Vaccine Safety Datalink System" would require the disclosure of proprietary, confidential, commercial, or trade secret information, which is protected from disclosure under the Trade Secret Act, 18 U.S.C. § 1905, 21 C.F.R. §§ 20.61, 20.63 and 601.51, and any other applicable statutory, regulatory or common law privilege.

Subject to the foregoing objections, access to information in the Vaccine Safety Datalink System will be made available under guidelines which will be established by respondent. The data will be made available to perform only the approved analyses under a controlled setting and subject to any applicable statutory, regulatory or common law protections or privileges.

"Specifically, Petitioners experts request access to at least the following information:

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

Respondent objects to this portion of this Request to the extent that it requests information that is confidential, commercial, proprietary, or trade secret information, which is protected from disclosure under the Trade Secret Act, 18 U.S.C. § 1905, 21 C.F.R. §§ 20.61, 20.63, and 601.51, the Privacy Act, 5 U.S.C. § 552a, and any other applicable statutory, regulatory or

common law privilege, including but not limited to the deliberative process privilege.

Subject to the foregoing objections, respondent will produce the documents requested in this subpart of this Request for inspection and copying by petitioners, to the extent that such documents remain within the possession, custody, or control of respondent, under a protocol and a schedule to be determined.

"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"

Respondent further objects to this request to the extent that it is vague and ambiguous and is not a logical subpart of this Request. Respondent also objects on the grounds that this request is overbroad and unduly burdensome. Respondent further objects to this portion of this Request to the extent that it requests information that is confidential, commercial, proprietary, or trade secret information, which is protected from disclosure under the Trade Secret Act, 18 U.S.C. § 1905, 21 C.F.R. §§ 20.61, 20.63, and any other applicable statutory, regulatory or common law privilege, including but not limited to

the deliberative process privilege. Respondent interprets this subpart to request the information for any published, government-sponsored study related to MMR and/or thimerosal-containing vaccines covered by 42 U.S.C. § 300aa-14(a) and autism or ASD which used the VSD as their primary source of information.

Subject to the foregoing objections, respondent will produce for inspection and copying by petitioners the documents requested in this subpart, if such material exists, to the extent that such documents remain within the possession, custody, or control of respondent, under a protocol and a schedule to be determined.

"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."

Respondent objects to this portion of this Request on the grounds that it is overbroad and unduly burdensome. Respondent further objects to this portion of this Request to the extent that it requests information that is confidential, commercial,

proprietary, or trade secret information, which is protected from disclosure under the Trade Secret Act, 18 U.S.C. § 1905, 21 C.F.R. §§ 20.61, 20.63, and any other applicable statutory, regulatory or common law privilege, including but not limited to the deliberative process privilege. Respondent also objects to petitioners' request to the extent that subparts (c) though (g) require analysis or compilation of data rather than production of responsive documents in respondent's possession, custody, or control.

Respondent does not maintain such documents as part of the Vaccine Safety Datalink. To the extent dose information is maintained by respondent agency, it is done through Biologics Surveillance. Accordingly, respondent hereby incorporates the response set forth to Request for Production of Documents Number 4 in response to subparts (c) through (g).

REQUEST:

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 by 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, to 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:

Respondent incorporates by reference its General Objections as if fully set forth herein. Respondent objects to this Request because it seeks the disclosure of information that is neither relevant to the litigation nor reasonably calculated to lead to the discovery of admissible evidence. MEDWATCH monitors adverse events related to all medications except vaccines. Further, information related to the number of doses is confidential, commercial, proprietary information, which is protected from disclosure under the Trade Secret Act, 18 U.S.C. § 1905, 21 C.F.R. §§ 20.61 and 20.63, and/or other statutory, regulatory or common-law privileges.

Subject to the foregoing objections, petitioners may inspect and copy information responsive to this Request at the following internet address: http://www.fda.gov/medwatch/.

REQUEST:

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 discovery requests.

RESPONSE:

Respondent incorporates by reference its General Objections as if fully set forth herein. Respondent further objects to this Request on the ground that providing access to the underlying data as requested would require the disclosure of information that is confidential, commercial, proprietary, or trade secret information, which is protected from disclosure under the Trade Secret Act, 18 U.S.C. § 1905, 21 C.F.R. §§ 20.61, 20.63, and 601.51, the Privacy Act, 5 U.S.C. § 552a, and other applicable statutory, regulatory or common law privileges. Respondent objects further on the grounds that this request is vague and overbroad, and it seeks access to a large amount of protected information that is beyond the scope of litigation as defined by Autism General Order #1.

Subject to these objections, petitioners may inspect and copy the requested information, which is already maintained in a form suitable under the law for public disclosure and currently available for review. Access to documents responsive to this request can be obtained from the National Center for Health Statistics (NCHS) website, which has the full NHIS electronic data files in public use form from 1997 to 2000 (2001 data is

expected out in December). The most recent year is available for download at:

http://www.cdc.gov/nchs/nhis.htm#2000_NHIS

The questionnaires for 2000 are available at:

ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Survey_Questionnaires/NHIS/2000/qsamchld.pdf

The information maintained in the aforementioned public file includes responses to all questions that were asked on the survey, but the date of the immunization is represented only as month and year for the purpose of maintaining confidentiality. Furthermore, users of the NHIS immunization data should note that no editing was done to the raw data for responses to the immunization questions, and as a result there may be some data in the "other" categories that might have been recorded to more appropriate response categories to yield more precise statistics. Finally, to the extent that petitioners' experts request more detailed data on the demographics of the children themselves (e.g., geographic specificity), which information is not included on the public release for confidentiality reasons, a focused request could be submitted for consideration by the Research Data Center under a protocol and schedule to be determined.

REQUEST:

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

RESPONSE:

Respondent incorporates by reference its General Objections as if fully set forth herein. Respondent further objects to this Request on the grounds that it is overbroad, unduly burdensome, and beyond the scope of litigation as defined by Autism General Order #1. Respondent objects to "any documents" as vague and overbroad. Respondent objects to the phrase "adverse events" as overbroad and not relevant to the subject matter of this litigation. Respondent objects to the phrase "requests for funding" as vague and will interpret this phrase to mean grant applications submitted between January 1, 1992 and August 1, 2002 to respondent agency.

Subject to the foregoing objections, and to the extent permitted by law, respondent will produce for inspection and copying by petitioners any grant application within its custody, possession and control, wherein the grant application requests funding for studies relating MMR vaccine, and/or vaccines covered by 42 U.S.C. § 300aa-14(a) that were preserved with thimerosal, to autism and ASD.

REQUEST:

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

RESPONSE:

Respondent incorporates by reference its General Objections

as if fully set forth herein. Respondent objects to this Request on the grounds that it is vague, ambiguous, overbroad and unduly burdensome. Specifically, respondent objects to the term "hearings" because it is ambiguous and not sufficiently limited in time, place, or scope to allow respondent to formulate a search or conduct a reasonable investigation that will likely yield responsive documents.

Further, Respondent objects to this request to the extent that it seeks transcripts of congressional or other public hearings that are not within respondent's possession, custody, or control, that are a matter of public record, are already in the possession of petitioners, or that could be sought and obtained from some other source in a more convenient, less burdensome, or less expensive manner. Accordingly, respondent interprets the phrase "any and all transcripts of hearings conducted prior to FDA approval of the measles-mumps-rubella (MMR) vaccine" to mean "any and all transcripts of FDA hearings conducted as part of their approval process of the MMR vaccine."

Subject to the foregoing objections, respondent will produce responsive documents for inspection and copying by petitioners, under a protocol and production schedule to be determined.

REQUEST:

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:

Respondent incorporates by reference its General Objections as if fully set forth herein. Respondent objects to this Request on the grounds that it is vague, ambiguous, overbroad and unduly burdensome. Accordingly, respondent interprets the phrase "any and all documents submitted to the FDA for review by vaccine manufacturers prior to the approval of the MMR vaccine" as "any and all documents submitted to the FDA by vaccine manufacturers as part of FDA's approval process of the MMR vaccine." Respondent also objects to this Request to the extent that is seeks or would require the disclosure of documents of confidential, commercial, proprietary or trade secret information, which is protected from disclosure under the Trade Secret Act, 18 U.S.C. § 1905, 21 C.F.R. §§ 20.61, 20.63, and 601.51 or any other applicable statutory, regulatory or common law privilege, including but not limited to the deliberative process privilege and/or the attorney-client privilege.

Subject to the foregoing objections, respondent will produce responsive documents for inspection and copying by petitioners, under a protocol and production schedule to be determined.

REQUEST:

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

RESPONSE:

Respondent incorporates by reference its General Objections as if fully set forth herein. Respondent objects to this Request on the grounds that it is vague, ambiguous, overbroad and unduly burdensome. Specifically, respondent objects to the term "hearings" because it is ambiguous and not sufficiently limited in time, place, or scope to allow respondent to formulate a search or conduct a reasonable investigation that will likely yield responsive documents.

Further, respondent objects to this request to the extent that it seeks transcripts of congressional or other public hearings that are not within respondent's possession, custody, or control, that are a matter of public record, are already in the possession of petitioners, or that could be sought and obtained from some other source in a more convenient, less burdensome, or less expensive manner. Accordingly, respondent interprets the phrase "any and all transcripts of hearings conducted prior to FDA approval of all thimerosal-containing vaccines" to mean "any and all transcripts of FDA hearings conducted as part of their approval process of vaccines containing thimerosal as a preservative, and which were licensed and approved by FDA for distribution in the United States during the period from January 1, 1992 to August 1, 2002."

Subject to the foregoing objections, respondent will produce responsive documents for inspection and copying by petitioners,

under a protocol and production schedule to be determined.

REQUEST:

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:

Respondent incorporates by reference its General Objections as if fully set forth herein. Respondent objects to this Request on the grounds that it is vague, ambiguous, overbroad and unduly burdensome. Accordingly, respondent interprets the phrase "any and all documents submitted to the FDA for review by vaccine manufacturers prior to the approval of all thimerosal-containing vaccines" as "any and all documents submitted to the FDA by vaccine manufacturers as part of FDA's approval process of all vaccines containing thimerosal as a preservative and which were licensed and approved by FDA for distribution in the United States during the period from January 1, 1992 to August 1, 2002."

Respondent also objects to this Request to the extent that it seeks or would require the disclosure of documents of confidential, commercial, proprietary or trade secret information, which is protected from disclosure under the Trade Secret Act, 18 U.S.C. § 1905, 21 C.F.R. §§ 20.61, 20.63, and 601.51 or any other applicable statutory, regulatory or common law privilege, including but not limited to the deliberative process privilege and/or the attorney-client privilege.

Subject to the foregoing objections, respondent will produce responsive documents for inspection and copying by petitioners, under a protocol and production schedule to be determined.

REQUEST:

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:

Respondent incorporates by reference its General Objections as if fully set forth herein. Respondent objects to this Request on the grounds that it is vague, ambiguous, overbroad and unduly burdensome. Further, Respondent objects to this Request because it is not sufficiently limited in time, place, or scope to allow respondent to formulate a search or conduct a reasonable investigation that will likely yield responsive documents. Specifically, respondent objects to the term "the government" as overbroad, as it seeks information not within respondent's possession, custody, or control, and instead interprets this term to mean "respondent."

Respondent objects to this Request because it is overbroad and not reasonably calculated to lead to the discovery of admissible evidence. Specifically, it requests "correspondence . . . " related to MMR, thimerosal or any other preservative in any vaccine." As this exceeds the scope of the issues as they are

recited in Autism General Order #1, respondent interprets this request as seeking correspondence relating to MMR and/or vaccines in which thimerosal has been used as a preservative during the period from January 1, 1992 to August 1, 2002 causing autism or ASD.

Respondent also objects to this Request to the extent that is seeks or would require the disclosure of documents of confidential, commercial, proprietary or trade secret information, which is protected from disclosure under the Trade Secret Act, 18 U.S.C. § 1905, 21 C.F.R. §§ 20.61, 20.63, and 601.51 or any other applicable statutory, regulatory or common law privilege, including but not limited to the deliberative process privilege and/or the attorney-client privilege.

Respondent objects to this Request as unreasonably cumulative or duplicative. To the extent that the information sought in this Request will be part of the information supplied in response to petitioners' Request for Production of Documents #3, as noted above and subject to the foregoing objections, respondent will produce responsive documents for inspection and copying by petitioners, under a protocol and production schedule to be determined.

REQUEST:

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:

Respondent incorporates by reference its General Objections as if fully set forth herein. Respondent further objects to this Request to the extent that it seeks information that is not within Respondent's knowledge, possession, custody, or control. Respondent objects to the request for "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" as overly broad. Respondent further objects to the request for "copies of all correspondence between any member of the Research Triangle Institute and ASTDR" and "any communications between Rob DeWoskin of the RTI and John Risher of the ASTDR" on the grounds that

"ASTDR" is not an entity within respondent agency.

Subject to these objections, and assuming petitioners meant to reference the ATSDR, or the Agency for Toxic Substances and Disease Registry, respondent will produce the documents requested in the second sentence of the request for inspection and copying by petitioners, with the exception of "non-published literature" since no non-published literature was used by the authors of the profile, to the extent that such documents remain within the possession, custody, or control of respondent, under a protocol and a schedule to be determined. Respondent does not have documents in its possession, custody or control in response to petitioners' request for correspondence or records of communication between the ATSDR and the FDA regarding mercury or Thimerosal.

REQUEST:

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:

Respondent incorporates by reference its General Objections as if fully set forth herein. Respondent also objects on the grounds that this request for "any and all related materials," "any and all materials on the AICP work group on Thimerosal and immunization," "each and every study report, conference, meeting discussed or mentioned at that conference," and "any and all materials discussed, mentioned, or relating to anything by Dr. Verstraeten" on the grounds that these requests are vague, overbroad, cumulative, and unduly burdensome. Furthermore, respondent objects to petitioners' request for materials "on the AICP work group" under subpart (r) on the grounds that no such entity exists. Assuming that petitioners meant to reference the "ACIP," or the Advisory Committee on Immunization Practices, respondent objects on the grounds that deliberations of an "ACIP work group" may contain information that is confidential, commercial, proprietary, or trade secret information, which is protected from disclosure under the Trade Secret Act, 18 U.S.C. § 1905, 21 C.F.R. §§ 20.61, 20.63, and 601.51, the Privacy Act, 5 U.S.C. § 552a, and other applicable statutory, regulatory or

common law privileges, including but not limited to the deliberative process privilege.

Subject to these objections, respondent will provide access to the material requested in subpart (q) under a protocol and a schedule to be determined, to the extent that such documents remain within the possession of respondent. Furthermore, with respect to subpart (r), respondent will undertake to obtain information about the status of an ACIP work group on Thimerosal and immunization.

Respectfully submitted,

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Dated: September 3, 2002

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CERTIFICATE OF SERVICE

I certify that on this 3rd day of Sept, 2002, a copy of RESPONSE TO PETITIONERS' INTERROGATORIES AND REQUEST FOR PRODUCTION OF DOCUMENTS was served, by first class mail, postage prepaid, upon:

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