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**IN THE UNITED STATES COURT OF FEDERAL CLAIMS**

**OFFICE OF SPECIAL MASTERS**



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| IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER, OR A SIMILAR NEURODEVELOPMENTAL DISORDER,<br><br>Various Petitioners,<br><br>v.<br><br>SECRETARY OF HEALTH AND HUMAN SERVICES,<br><br>Respondent. | AUTISM MASTER FILE<br>Special Master George Hasting |

**PETITIONERS' MOTION TO COMPEL DISCOVERY IN THE AUTISM OMNIBUS PROCEEDING**

The Petitioners' Steering Committee moves the Special Master to issue an order compelling the Respondent to produce documents and make witnesses available for deposition, as described below. This Motion is made on behalf of all petitioners with claims pending in the Omnibus Autism Proceeding, and is made pursuant to Vaccine Rule 7(b), RCFC 26, RCFC 30, RCFC 34, and RCFC 37. This Motion is further supported by the attached Exhibits and Memorandum of Law.

Petitioners seek an Order compelling the production of:

1. Documents requested in Petitioners' Request for the Production of Documents to the CDC, of September 12, 2003, attached as Exhibit A to this Motion.

2. One or more representatives of the National Institutes of Health to appear as an organizational witness for deposition, as requested in Petitioners Notice of Deposition of



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Organization, attached as Exhibit B to this Motion.

3. Documents relating to completed, published studies concerning possible links between thimerosal, the MMR vaccine, or a combination thereof, and the autism disorders at issue in this proceeding. This request is ongoing, and is intended to cover any relevant study that is published during the pendency of this Omnibus Proceeding. Specifically, for any such studies that were initiated, directed, supervised or funded by any federal government entity, or in which an employee of a federal government entity was an investigator or author, petitioners seek production of, or access to:

a.) The datasets or data compilations that the study investigators used or relied on to conduct the study;

b.) The calculations or other interpretive methodologies the study investigators relied on to conduct the study;

c.) Those portions of the files of study investigators, supervisors and sponsors (including the government entity participating in the study) that describe the (i) study's original scope, purposes, and design; (ii) changes to the study's scope, purposes or design that might have occurred during the course of the study; (iii) status reports generated during the course of the study, including reports of progress or problems; and (iv) minutes or any other record of meetings between study investigators or study sponsors during the design of the study, the course of the study and continuing to the present time;

d.) Documents recording any communications between the study's investigators and any other person (whether in or out of the government), concerning the design, progress or status of the study;

e.) All peer-review comments generated in response to the prepublication



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manuscript;

f.) Documents relating to the government entity's decision to fund, initiate, supervise or otherwise participate in the study, including (but not limited to) requests for bids, requests for grant applications, and all replies or responses thereto, and any received proposed contracts, grant proposals, funding applications, bids, or other requests for funding; and

g.) For any study the government intends to rely on in these proceedings, petitioners seek leave to take the deposition(s) of designated "lead" or "key" study investigator(s), after the relevant background documents regarding the study, as requested herein, have been reviewed by the petitioners.

4. For any studies concerning possible links between thimerosal, the MMR vaccine, or a combination thereof, and the autism disorders at issue in this proceeding *that are in progress or ongoing*, but not yet completed or published, and that were initiated, directed, supervised or funded by any federal government entity, petitioners seek:

a.) Documents describing the scope, purpose, goals, and design of the study, including the data to be relied on and the analytical methodologies and investigative protocols to be employed;

b.) Documents describing the budget and the timeline for the study;

c.) Documents that record any reports of the study's progress, status or problems made by the study investigators to the participating government entity; and

d.) Appearance for deposition of an organizational representative from the participating government entity, with the scope and subject matter for such depositions patterned closely after the CDC and ASTDR depositions already completed by petitioners.



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5. Documents relating to the Thimerosal Screening Analysis (TSA), and access to Vaccine Safety Datalink (VSD) datasets.

a.) To the extent that any study relying on analyses or interpretations of the VSD is published, petitioners seek discovery of documents as described in request No. 3 above, incorporated by reference as if fully set forth here.

b.) To the extent not covered by those requests, petitioners specifically request access to the diagnostic coding of the VSD health maintenance organizations used by the TSA investigators, up to and including the year 2003, and as far into 2004 as the data are available, for the same children already included in the TSA.

c.) Petitioners additionally request that their expert(s) be given access to designated VSD datasets as needed to validate and expand upon the epidemiological VSD analysis conduced by the Drs. Geier, with the data updated to include diagnoses through the present.

6. Those portions of the manufacturers' product license applications (PLAs) that have been withheld or redacted from the PLAs produced by Respondent.

For all of the reasons described in the attached Memorandum of Law, the Special Master should grant each of petitioners' Motions above in their entirety, and enter an Order compelling respondent to produce the requested discovery.

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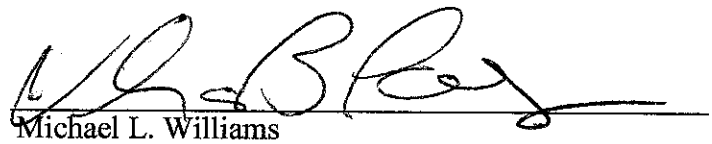
DATED this 8th day of March, 2004.

WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.

By: 

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## CERTIFICATE OF SERVICE

I hereby certify that on March 8, 2004, I served the foregoing **PETITIONERS' MOTION TO COMPEL DISCOVERY IN THE AUTISM OMNIBUS PROCEEDING** on the following individuals:

Vincent Matanoski
U.S. Department of Justice
Torts Branch, Civil Division
P.O. Box 146, Benjamin Franklin Station
Washington, D.C. 20044-0416

by United Parcel Service, next morning delivery.

WILLIAMS DAILEY O'LEARY CRAINE & LOVE, P.C.

Brenda D. Steinle , Assistant to Michael L. Williams
Of Attorneys for Petitioners' Steering Committee

cc: George Hastings
U.S. Court of Federal Claims
Office of the Special Master
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**MEMORANDUM IN SUPPORT OF PETITIONERS' MOTION TO COMPEL DISCOVERY IN THE AUTISM OMNIBUS PROCEEDING**



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# TABLE OF CONTENTS


TABLE OF CONTENTS ..... 2

TABLE OF AUTHORITIES ..... 3

I. INTRODUCTION ..... 4

II. SUMMARY OF THE ARGUMENT ..... 4

III. PROCEDURAL SETTING ..... 6

IV. POINTS AND AUTHORITIES ..... 7

A. THE DISCOVERY SOUGHT BY PETITIONERS IS NECESSARY AND RELEVANT TO THE GENERAL CAUSATION INQUIRY ..... 7

B. PETITIONERS' DISCOVERY REQUEST IS CONSISTENT WITH SIMILAR REQUESTS FOR THE DISCOVERY OF GOVERNMENT DOCUMENTS THAT ARE MADE AND GRANTED IN CIVIL LITIGATION ..... 11

C. THE DELIBERATIVE PROCESS PRIVILEGE THAT RESPONDENT INADEQUATELY RAISES IN OPPOSITION TO THESE REQUESTS DOES NOT BAR PRODUCTION OF THE REQUESTED DISCOVERY. ..... 13

D. PETITIONERS SHOULD BE GIVEN ACCESS TO THE VSD DATA UNDER A PROTOCOL DEVELOPED BY PETITIONERS' EXPERTS, WITHOUT THE COST AND DELAY OF THE FORMAL IRB PROCESS. ..... 19

E. THE HIGH LEVEL OF SCIENTIFIC ACTIVITY RELATING TO THE ISSUES IN THIS GENERAL CAUSATION INQUIRY SUPPORT THE PRODUCTION OF THE REQUESTED DISCOVERY. ..... 21

V. CONCLUSION ..... 22





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## TABLE OF AUTHORITIES

### Cases

*Abramson v. United States,* 39 Fed.Cl. 290, 293 ..... 13, 14, 15, 16, 17

*Cobell v. Norton,* 213 F.R.D. 1, 4-5 (D.D.C. 2003) ..... 14, 15

*EPA v. Mink,* 410 U.S. 73, 86 (1973) ..... 13

*In re: Diet Drugs Product Liability Litigation,* MDL No. 1203, 2000 U.S. Dist., Lexis 15170 (E.D. Pa., October 12, 2000) ..... 11

*Kaiser Aluminum & Chemical Corp. v. United States,* 141 Ct. Cl. 38, 49, 157 F.Supp. 939, 946 (1958 ..... 13

*Lurie v. Dept. of the Army,* 970 F.Supp. 19, 33-34 (D.D.C. 1997) ..... 15

*National Wildlife Fed'n v. United States Forest Serv.*, 861 F.2d 1114, 1116 (9th Cir. 1988) ..... 16

*State of Alaska v. United States,* 16 Cl.Ct. 5 (1988) ..... 13

*United States v. Reynolds,* 345 U.S. 1, 11, 73 S. Ct. 528, 533 (1953) ..... 17

*Walsky Constr. Co. v. United States,* 20 Cl.Ct. 317 (1990) ..... 14

*Yankee Atomic Electric Co. v. United States,* 54 Fed. Cl. 306, 310 (2002) ..... 14, 15, 16

### Statutes

**42 U.S.C. §300aa-12(d)(3)(B)** ..... 7



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## I. INTRODUCTION

Petitioners submit this Memorandum in support of their Motion to Compel. Petitioners in the Omnibus Autism Proceeding seek the production of documents, access to documents, and depositions relating to the issues of general causation as described in the instant Motion. The Motion and Memorandum are submitted pursuant to the February 9, 2004 Scheduling Order entered by Special Master Hastings.

## II. SUMMARY OF THE ARGUMENT

Petitioners' requested discovery should be produced, and petitioners' motion to compel granted, because:

1. The requested discovery is directly relevant to the general causation inquiry at issue in the Omnibus Autism Proceeding, as all of petitioners' requests specifically seek information relating to the possible links between autism injuries and thimerosal, the MMR vaccine, or a combination of both. Contrary to respondent's opposition to the requests, there is nothing overly broad or vague about the requests in petitioners' Motion.

2. Compelling the requested discovery is squarely within the discretion of the Special Master's authority to investigate the facts necessary to reach a decision on general causation, particularly in this Omnibus Proceeding that consolidates thousands of individual claims in one proceeding on general causation. Given the number of claims, the severity of the claimed injuries, and the complexity of the science, it is critical that the petitioners be given access to the discovery sought herein, and that the Special Master have the benefit of the information. Respondent's claims of undue burden and hardship are unavailing in the face of the



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Vaccine Act's explicit interest in providing claimants with a fair process, a process that must include an opportunity to fully develop and put on a case based on the best available information.

3. Petitioners' discovery requests are not barred by the deliberative process privilege as respondent incorrectly attempts to argue. The privilege is not applicable to the requested materials, and respondent has utterly failed to satisfy *any* of the substantive or procedural elements required to properly assert the privilege. Moreover, even if respondent could attempt a showing that the privilege might apply, that privilege is not absolute. Under the relevant law, petitioners can overcome this qualified privilege and the discovery requests should be granted.

4. Petitioners' supplemental discovery requests are reasonable and necessary in light of the developing and expanding scope of scientific inquiry into the questions of general causation at issue in the Omnibus Proceeding. It is critical that the legal inquiry—as reflected in petitioners' supplemental discovery requests—keep pace with the relevant scope of scientific and medical investigation, particularly in instances where the federal government participates in the science, and will rely on the outcome of these studies at the trial on general causation. Respondent cites no legal authority in support of the proposition that the scope of discovery in an Omnibus Proceeding is forever circumscribed by the "state of knowledge" that served as the basis for discovery requests early in the proceeding. There is no merit in respondent's position that petitioners and the Special Master are forever barred from seeking relevant information simply because it was not requested in the original discovery promulgated at the outset of this proceeding.



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## III. PROCEDURAL SETTING

The discovery process in this Omnibus Proceeding formally began on August 2, 2002 when petitioners served their initial discovery requests pursuant to Autism General Order #1. In the intervening 18 months respondent has objected to some discovery requests and responded to others. Thousands of pages of documents have been produced (though heavily redacted due to manufacturers' objections to disclosure of "commercially valuable" information to petitioners), primarily consisting of product license applications (PLAs) and vaccine adverse event reports (VAERS). Three depositions of government employees have taken place. The parties have conferred both formally and informally regarding the scope and conduct of discovery in the Omnibus Proceeding. Petitioners will not recount that entire history here, as it is well documented in the record, including the filings of the parties and the Updates and Orders of the Special Master. While the parties have been able to agree on several discovery issues, there are others where the parties are at an impasse. Those contested issues are detailed in the Motion to Compel that this memorandum is appended to, and those issues are the subjects of this memorandum.

Procedurally, the issues are before the Special Master based on "Respondent's Response to Petitioners' Supplemental Discovery Requests and Motion for Enlargement of Time," filed on January 23, 2004 and attached as Exhibit C. This filing was submitted by respondent following an agreement between the parties and approved by the Special Master whereby respondent agreed to 1) summarize the outstanding discovery requests as petitioners' and respondent's counsel had described them in exchanges of emails[1] and telephone conferences, and then 2) respond to those discovery requests. The parties and the Special Master further agreed that



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respondent's filing would then serve as the basis for petitioners' Motion to Compel, and a briefing schedule was ordered. The instant Motion opens that briefing.

## IV. POINTS AND AUTHORITIES

### A. The Discovery Sought by Petitioners is Necessary and Relevant to the General Causation Inquiry.

#### 1. The Special Master is Authorized to Conduct the Requested Discovery

Both the Vaccine Act and the Vaccine Court Rules explicitly authorize the Special Masters to conduct discovery in a proceeding on a petition for compensation. 42 U.S.C. §300aa-12(d)(3)(B); Vaccine Rule 7(b) (authorizing the use of the "discovery procedures provided by RCFC 26 – 37" in Vaccine Court proceedings). The Special Master is granted considerable flexibility and discretion to investigate the facts of any claim in the program, including the ability to order discovery. It therefore matters little that discovery is not available "as a matter of right," so long as petitioners can convince the Special Master that the requested discovery—including the taking of deposition testimony and the production of any documents—is "reasonable and necessary" to resolving a material issue in a compensation claim. 42 U.S.C. §300aa-12(d)(3)(B). Respondent's repeated reliance on the lack of discovery as a matter of right is a *non sequiter* that avoids the real question of whether the requested discovery is relevant and necessary to the complex issues of general causation presented in this proceeding.

Petitioners' requests are, on their face, relevant. Petitioners specifically seek only those documents relating to studies or research that involve inquiries into the possible roles of either the MMR vaccine or thimerosal, and the autism injuries at issue. There can be little doubt that both the ongoing and completed studies subject to this discovery request are relevant—

[1] In particular, an email from petitioners' counsel Mike Williams to respondent on January 6, 2004 was intended to summarize the outstanding, contested discovery requests so that respondent could craft a response. That email is attached as Exhibit D.



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respondent itself identified the studies as responsive to petitioners' initial request for production in 2002.[2] Government witnesses have testified at depositions as to ongoing studies. The dispute arises largely because respondent refuses to acknowledge that the *types* of documents requested by petitioners are relevant, and respondent maintains that the only relevant, discoverable documents relating to the studies are the published studies themselves. That position, however, is incorrect.

**2. Discovery of the "Background" Documents Relating to Obviously Relevant Studies is Necessary to a Meaningful Consideration of the Scientific Validity and Reliability of these Studies.**

The study-related documents requested in petitioners' Motions No. 1, 3, 4 and 5 are relevant to the causation inquiry because the conclusions of a study are inevitably shaped by the manner in which the study was conducted, and petitioners ought to be able to test the validity and limitations of an obviously relevant study by exploring these supporting documents. Contrary to respondent's vague and unsupported claim that all the relevant information "is contained in the published report of the study" (Ex. C, p. 3), answers to critical evaluative questions regarding the methodology and design of a study are ***not*** self-evident.

Moreover, the court needs to make its decision based on a complete analysis of the best available reliable scientific evidence. Unless petitioners are permitted to examine how the conclusions of these studies were shaped by strategic choices of the investigators, there can be severe prejudice to petitioners' ability to challenge the evidence respondent intends to rely on, after respondent created the evidence in secret.

One example of need for access to the requested study documents—particularly documents relating to completed studies as requested in Motions No. 1, 3 and 5—is provided by

[2] See, letters from respondent to petitioners identifying the government studies that respondent averred were responsive to petitioners' First RFP. Exhibit E.



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comparing the "Phase I" and "Phase II" studies conducted by Thomas Verstraeten, et al. Based on analyses of information from selected health maintenance organizations participating in the VSD project, this "Thimerosal Screening Analysis (TSA)" sought to examine the possible link between exposures to thimerosal-containing vaccines and neurological and renal impairment. Without regurgitating the results of the two reports, it is significant that in general the Phase II study reported lower relative risks and less significant statistical associations between thimerosal exposure and neurological injuries than did Phase I. Since epidemiological evidence of the sort generated by the TSA is critically important to the general causation inquiry, it is critically important to develop an explanation of the differences between the two studies.

Some of the differences may be explained by differences in methodology that are self-evident. The second study, for example, included more subjects and a longer observation period than the first—a difference apparent from the published report. Other changes from one study to the next are apparent, but the ***reasons*** for the changes are not self-evident, and need to be explored in order for petitioners' experts and the Special Master to reach meaningful conclusions about the validity of the studies and the weight to give the studies in the general causation inquiry. Specific questions that can only be answered through the requested discovery include:

1. Why did the investigators allow for the disenrollment of children in the second report but not the first?

2. In the second report, the methodology was adjusted to recognize a clinic at one of the HMOs, an adjustment not made in the first report. Since most of the data were obtained from the clinic HMO, this adjustment factor could have a large impact on the study findings and could explain some of the apparent discrepancies between the two reports. It is



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necessary to know the rationale for the difference in the use of the adjustment factor in the two reports.

3. In the second report, CDC investigators did not analyze combined categories of adverse neurological outcomes as they had done in the first report. Some of the combined findings were statistically significant in the first report. Explaining the different conclusions requires an understanding of the rationale for deciding whether to combine categories of outcomes or not.

4. The second report introduced a requirement that the "control" group of children for the "case" group of children had made at least one visit to a clinic or emergency department at the same month of age as the "case" children, a requirement not included in the methodology of the first report. This change—inexplicable on its face—could have a tremendous bias effect on the results of the study, as the change might over sample sick children, create an unreliable comparison group, and mask any adverse effect of thimerosal exposure on neurological outcomes. Again, this is a change that must be explained if the studies are to be given their appropriate weight.

Similar questions will likely arise whenever petitioners and the Special Master consider the relevant, completed studies as they are published. Questions about the significance of a study's results, the validity of the methodology, whether bias is introduced into a study's methodology, and reconciling the results of various studies all require an inquiry beyond the published results, contrary to respondent's erroneous position. For all of these reasons, petitioners requested discovery in Motions 1, 3 and 4 is reasonable and necessary to resolving the general causation questions at issue, and the Motions should be granted.



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**B. Petitioners' Discovery Request is Consistent with Similar Requests for the Discovery of Government Documents that are Made and Granted in Civil Litigation.**

While discovery is not a matter of right in the vaccine program, the Special Master is authorized to conduct discovery, as discussed above, pursuant to RCFC 26 – 37. Those rules are in turn modeled on the Federal Rules of Civil Procedure, and in civil litigation conducted under the FRCP the type of discovery of government documents requested by petitioners is permissible.

As an example, U.S. District Court Judge Barbara Rothstein ordered in November 2003 that the FDA produce to the corporate defendant documents relating to the conduct of an epidemiological study involving the relationship between use of the defendant's product (phenylpropanalomine, or PPA) and strokes. While the Opinion and Order (attached as Exhibit F) focuses on whether the deliberative process applied in that case (with the Court rejecting the deliberative process objections raised by the FDA, as will be discussed later in this memorandum), the opinion describes why such documents are important and necessary to a parties ability to put on a case involving complex issues of causation where expert scientific testimony will be critical. Defendant's brief seeking that discovery is also attached (as Exhibit G) because it details the rationale for allowing the requested discovery despite the government's deliberative process objections.

Similar discovery requests were granted over the government's asserted deliberative process objections in multi-district litigation involving diet drugs (*See, e.g., In re: Diet Drugs Product Liability Litigation,* MDL No. 1203, 2000 U.S. Dist., Lexis 15170 (E.D. Pa., October 12, 2000), and similar requests are pending in multi-district litigation involving hormone therapy products. The authors and lead investigators of key studies are regularly deposed in pharmaceutical tort litigation, and litigants have even been given discovery of the medical records of individual subjects involved in key studies. Furthermore, Wyeth recently sought and



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received permission from the MDL court in Little Rock in the Prempro Drug Products litigation (involving cancers allegedly caused by Hormone Replacement Therapy) to subpoena the background documents and data sources from the NIH of the Women's Health Initiative, the largest single clinical trial study the NIH has ever done.

The procedural and factual contexts of the multi-district product liability litigations where such discovery is held to be relevant and necessary is analogous to the situation faced by the parties and the Special Master in the Omnibus Proceeding. In each case there are hundreds or thousands of individual injury claims related to use of, or exposure to, a particular product. In the MDLs and in the Omnibus Proceeding there are issues of causation common to all claims, or within significant sub-groups of the claims. In each instance the volume of cases would overwhelm the tribunal if adjudicated individually as to every issue of causation, and the claims are thus consolidated for purposes of addressing general causation. Decisions on causation in both the MDLs and in this program will depend heavily on expert testimony, which will in turn rely on analyses of published, relevant studies. Federal judges have been willing to compel the production of "background" material relating to federal scientific research in the MDLs because such information is considered important to one side or the other's ability to develop and present its case.

Those same compelling interests—relevance and necessity—ought to inform these proceedings. Since petitioners have demonstrated that the requested information is of the sort that is relevant and necessary to a thorough inquiry, the Special Master should exercise his discretion to conduct discovery by granting petitioners' Motions and compelling the production of the requested documents and the taking of the requested depositions.



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## C. The Deliberative Process Privilege that Respondent Inadequately Raises in Opposition to these Requests does not Bar Production of the Requested Discovery.

Respondent first raised the deliberative process privilege in its September 3, 2002 Response to petitioners' initial requests for production, and respondent continues to claim both formally and in informal communications that it believes the privilege applies so as to bar the requested discovery. As discussed earlier, the parties have since narrowed the contested discovery issues to those outlined in Respondent's Response of January 23, 2004, and the instant Motion. Respondent again asserts the deliberative process objection. The objection should be rejected because respondent utterly fails to satisfy any of the elements necessary to either establish that the privilege applies to the requested documents, or that the privilege, if it applies at all, should bar the requested discovery.

### 1. Respondent has not Satisfied the Basic Procedural Elements Required to Assert the Privilege.

The deliberative process privilege has its origins in the executive privilege doctrine.[3] *Abramson v. United States,* 39 Fed.Cl. 290, 293, citing *EPA v. Mink*, 410 U.S. 73, 86 (1973), citations omitted. "Within the scope of the executive privilege exists a deliberative process privilege which protects documents 'reflecting advisory opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies are formulated.'" *Id.*

[3] Petitioners do not dispute that the privilege is recognized in the Court of Federal Claims. The deliberative process privilege was first recognized by the United States Court of Claims in 1958 in *Kaiser Aluminum & Chemical Corp. v. United States*, 141 Ct. Cl. 38, 49, 157 F.Supp. 939, 946 (1958). At least one decision since *Kaiser* held that this privilege is not recognized by the Claims Court. *See, State of Alaska v. United States*, 16 Cl.Ct. 5 (1988). However, in *Abramson v. United States*, Judge Miller affirmed that the Court of Federal Claims recognizes the deliberative process privilege. *Abramson*, 39 Fed. Cl. 290, 294 (1997).



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To properly assert the privilege, courts have held that three procedural requirements must be met: (1) the head of the agency that has control over the requested document(s) or information must assert the privilege after personal consideration; (2) the head of the agency must state with particularity what information is subject to the privilege; and (3) the agency must provide the court with "precise and certain reasons" for maintaining the confidentiality of the requested document(s) or information. *Id.*, . citing *Walsky Constr. Co. v. United States*, 20 Cl.Ct. 317 (1990). Delegation of these procedural requirements to lesser ranking agency officials has been highly debated. The Federal Circuit, however, has held that an official other than the agency head may assert the privilege. *Yankee Atomic Electric Co. v. United States*, 54 Fed. Cl. 306, 310 (2002) ("so high a level of authorization" is not required). "It may be raised by individuals with specific and detailed knowledge of the documents in which the privilege is asserted." *Id.* The U.S. Supreme Court has proposed that this would include permitting the assertion of the privilege by as low a level of official as "any attorney representing the Government." *Id.*, at 310.

While the Department of Justice (DOJ) may therefore have the authority to assert the privilege in this proceeding on behalf of its client agencies, respondent has failed to either state with particularity what information is subject to the privilege, or to provide sufficiently precise and specific reasons for asserting it. Instead, respondent merely repeats the vague and unsupported claim that the requested discovery "may be privileged, or its disclosure otherwise prohibited by law." This bare claim is woefully insufficient under the relevant case law, whether in the Court of Claims or in the federal district courts. *See, e.g., Cobell v. Norton,* 213 F.R.D. 1, 4-5 (D.D.C. 2003) (detailed description of the information subject to the claim is required, as



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well as detailed explanation for why the privilege applies). Simply claiming that a document was part of a decision-making process and therefore privileged is not enough to meet respondent's burden. *Lurie v. Dept. of the Army,* 970 F.Supp. 19, 33-34 (D.D.C. 1997).

At no point since the privilege was first raised in September 2002 has respondent, or any official of one of its client agencies, offered even a scintilla of evidence identifying any specific document that might be subject to the privilege, nor has there been any explanation whatsoever of why a particular document might be subject to the privilege. There has been no privilege log produced identifying documents for which this privilege is claimed, and there are no affidavits explaining why any document is subject to the privilege. Respondent has the initial burden of proving that the privilege applies. *Cobell,* 213 F.R.D. at 4. Respondent in this case has not begun to meet the basic procedural threshold required to meet their burden, and the objection fails.

**2. The Requested Documents are not Covered by the Privilege Because they are Neither "Deliberative" nor "Pre-decisional"**

Even if respondent had adequately satisfied the procedural requirements for asserting the privilege, the privilege would not apply here because the requested documents are not "deliberative" in the sense contemplated by the privilege. They are "factual" rather than "deliberative," and thus not privileged.

In order for the deliberative privilege to apply, "a policy-making document must be both pre-decisional and deliberative." *Yankee Atomic Electric*, at 311. "A document is pre-decisional if it precedes, in temporal sequence, the "decision" to which it relates. [Consequently], to approve exemption of a document as pre-decisional, a court must be able to pinpoint an agency decision or policy to which the document contributed." *Abramson*, 39 Fed. Cl. 294. A document



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is 'deliberative' if it "contains opinions, recommendations, or advice pertaining to agency decisions." Id.

Factual information is not protected by the privilege. *Abramson* at 294; *Yankee Atomic Electric*, at 311. Only information or documents that are "confidential inter-agency memoranda on matters of law or policy" are protected. *National Wildlife Fed'n v. United States Forest Serv.*, 861 F.2d 1114, 1116 (9th Cir. 1988).

Under this standard, none of the requested documents qualify for the privilege. Specifically, Motions No. 1, 3, 4 and 5 request pre-decisional, factual information including datasets, calculations, interpretive methodologies, progress and status reports, information about changes to the study while it was ongoing, design and protocol information, and fact-based explanations for any changes or adjustments made to the studies. None of these requests seek deliberative materials, and none of them seek pre-decisional materials. The only requests for pre-decisional materials are those relating to the government's process for soliciting and awarding bids for potential studies, or otherwise funding such studies. While those documents are pre-decisional, they are not deliberative, as they seek the fact-record supporting decisions to fund or sponsor a given study.

Similarly, the deposition requests regarding the NIH (Motion No. 2), and for depositions of study investigators as the studies are completed (Motion No. 3) do not implicate privileged information. These depositions are *per se* post-decisional, as they could only occur either while a study was under way or after it was completed; that is, the deposition would occur after a decision had been made to conduct the study, and to conduct the study in a particular way.



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Finally, it is not clear whether respondent intends to assert the deliberative process as to Motion No. 6, petitioners' request for unredacted product license applications (PLAs). It appears from respondent's Response of January 2004 that other specific objections are raised instead (trade secret, confidential commercial information, personal privacy information) and the deliberative privilege is not mentioned. Petitioners reserve the right to move against the deliberative process objections if specifically asserted by respondent's pending Response to this Motion.

In short, the deliberative process privilege does not apply to any of the requested information in this Motion because petitioners seek fact-based documents and information rather than deliberative information, and because the information sought is not pre-decisional. Respondent fails completely to meet its strict legal burden of showing that the privilege applies at all. Respondent's objection should be rejected, petitioners' Motions should be granted, and the requested discovery should be produced.

### 3. Even if the Privilege Applied, it is a Qualified Privilege and Petitioners can Overcome the Privilege to Gain Access to the Requested Information.

The privilege is a qualified one; that is, it is not absolute, and may be "overcome upon a showing of evidentiary need weighed against the harm that may result from disclosure." *Abramsom*, 39 Fed.Cl. 290, 295. "Clarifying the nature of 'compelling need', the U.S. Supreme Court in *United States v. Reynolds*, 345 U.S. 1, 11, 73 S. Ct. 528, 533 (1953) explained that "the showing of necessity which is made will determine how far the court should probe in satisfying itself that the occasion for invoking the privilege is appropriate."" *Id.* The court must strike a balance between the Government's interest in frank deliberations and the need for full disclosure in an adversarial process. *Id.*



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Judge Rothstein's Order in the PPA litigation concisely summarizes the "balancing of the interests" analysis in terms applicable to the instant case. Specifically, the Special master here must consider 1) the interest of the petitioners seeking the information, 2) the relevance of the evidence and the availability of other evidence, 3) the role in the litigation of the government entity asserting the privilege, 4) the seriousness of the proceedings, and 5) the public's interest in knowing how effectively the government is operating. Exhibit F, at 5-8.

Here, as detailed above, petitioners have a compelling need for the information and documents requested. All of the information, data and documents sought by petitioners are within the exclusive control of respondents. No same or similar documents, data or information exists, and petitioners cannot obtain it from any other source. Absent the requested data, information and documents, petitioners' experts have no means to verify the data published by various government scientists such as Dr. Verstraeten and Dr. Stehr-Green and relied upon by respondent in claiming that there is no connection between thimerosal and neurological disorders, or between the MMR vaccine and the claimed neurological injuries.

In addition, the government's role in the proceedings is extremely significant, even more so than in the civil cases where the production of government documents has been compelled despite the claim of privilege. Here, of course, the government regulated the products at issue, the government is actively investigating the safety of the products at issue, and the government is a party to the proceedings. Given the pervasive role of the federal government in every aspect of these proceedings, petitioners ought to be able to discovery the requested information.

Further, there is no doubt about the seriousness of these proceedings involving over 3700 children alleging severe and serious neurological and neurodevelopmental injuries.



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Finally, the public has an interest in full disclosure of the requested information. First, vaccine-injured children are required by law to seek relief in this forum, and the public has an interest in ensuring that the mandatory administrative program provides claimants with a full and fair opportunity to develop and present their cases. That concern is heightened given the extraordinary caseload represented by the Omnibus Proceeding. The public's faith in the integrity of the program relies on transparency, and the public interest in a perceived fair proceeding is undermined if the government can withhold the requested information. In addition, the public relies on the federal government to appropriately regulate the nation's vaccine program and to provide trustworthy information about vaccines and immunization programs. Again, public trust is undermined when the government pulls a shroud of secrecy over its own scientific proceedings.

By any measure, the balance of the interests weighs overwhelmingly in favor of rejecting the deliberative process privilege objection, granting the petitioners' Motions, and compelling the production of the requested documents.

**D. Petitioners Should be Given Access to the VSD Data under a Protocol Developed by Petitioners' Experts, Without the Cost and Delay of the Formal IRB Process.**

This issue has been in dispute for 18 months, and at one point was close to resolution by agreement between the parties. At this point, however, respondent clearly objects to petitioners' request that petitioners' experts be allowed access to the VSD data under a protocol designed by petitioners, such access to include data reviewed by a recent research project conducted by Dr. Geier. Respondent maintains that petitioners can access the data only by exhausting the cumbersome and costly procedure pursuant to the "Guidelines for Data Sharing Program for External Researchers: Access to CDC's Vaccine Safety Datalink Data (VSD)."



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This objection should fail because petitioners are simply not "external researchers" as contemplated by the CDC guidelines. Petitioners and their experts have not received funding to conduct a study, nor are they planning to review the data to publish a peer-reviewed note or report. They are not seeking access to the data in order to satisfy the work product requirements of a university or other research institute. Petitioners are not looking to parlay their access to the data into journal articles, grant proposals, bids for contracts, or any other enterprise. Nothing about petitioners' requested access fits any common-sense definition of what an "external researcher" would do with the data. Instead, petitioners seek access to better determine whether they might have, in fact, been injured by the vaccine products at issue. They seek access to information collected, controlled, stored, managed and studied by the government in order to test the sufficiency of the government's own "causation case" against the petitioners. It is purely a legal fiction to maintain, as respondent insists on doing, that petitioners are merely some disinterested "external researchers" seeking access to the data.

Maintaining this fiction has cost petitioners months of delay in developing their case, and the fiction ought to be discarded and petitioners should be given access to the data. Additional delay imposed by compliance with respondent's objection is not acceptable to petitioners at this stage in the proceedings.[4] To the extent that the government is concerned about the

[4] The CDC process by which "external researchers" can obtain access to CDC datasets is slow and cumbersome, and limits the effectiveness of petitioners' trial preparation. Before access can be granted, an external researcher must (1) submit a proposal to the CDC outlining the proposed project, the researchers/investigators, a summary of the project purpose and public health benefits, and methods of proposed analytic study; (2) (a) must submit an application for review and approval to the Institutional Review Boards of the participating health maintenance organizations for use of the VSD datasets identifying the proposed project and the manner in which the external researcher plans to maintain the confidentiality of all data, and (b) provide a copy of the IRB approval to the CDC before the CDC will "begin the process of creating and/or formatting the approved datasets; and (3) pre-pay the CDC for a minimum of two consecutive days of use of "work stations with computers" at the CDC. The cost for a two-day minimum use is $3,208.85. Each additional day of use is charged at $779.58 per day, also to be paid in advance.

Once permitted access to the CDC's RDC, external researchers my only work under the supervision of approved CDC staff, may only use the computers pre-loaded with approved datasets by the CDC technicians, may not bring into the RDC any personal equipment such as cell phones, pagers, computers, etc that would allow them to



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confidentiality of identifying information contained in the data, petitioners will agree to permit a "third-party audit" of the data to remove potentially identifying personal information, and petitioners will agree to any other confidentially provisions designed to protect the integrity of patient privacy. Other than that, petitioners should be given access to the data under a protocol of petitioners' design.

**E. The High Level of Scientific Activity Relating to the Issues in this General Causation Inquiry Support the Production of the Requested Discovery.**

Respondent repeatedly insists that no further discovery should be conduced in this proceeding because the requested discovery was not requested during the original discovery planed over one year ago. That position is not supported by any legal authority, and it defies reality. This is not a single claim involving a discrete injury to a single child arising from one shot, where the injury is generally similar to other reported injuries associated with the same product. While the vaccine compensation program's traditionally limited, brief and narrow discovery makes sense for such a claim, it makes no sense in this proceeding involving over 3700 claims of severe injuries, presenting complex and novel issues of science and medicine. There has been a veritable explosion of scientific research into many of the issues relating to this general causation inquiry—justice, fairness, thoroughness and procedural rigor require that these legal proceedings keep pace with the relevant science.

Cutting off discovery before the science is complete, or limiting discovery so as to preclude inquires into the reliability, validity and weight of the science that is complete, cannot be justified merely because the current scope of discovery was not contemplated at the outset of the proceeding. Such an outcome would represent the triumph of form over substance.

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communicate with anyone outside of the CDC RDC. Only two external researchers may be permitted access at a time. See Guidelines for Data Sharing Program for External Researchers: Access to CDC's Vaccine Safety Datalink Data, www.cdc.gov/nip/vacsafe/vsd/VSDGuidelines.txt.



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Petitioners current requests are specific, relevant and necessary. Respondent's objections are vague, unsupported by legal authority, and not supported by any showing whatsoever of hardship or burden. As such, the objections are insupportable, and they should be rejected.

## V. CONCLUSION

For all of the above reasons, each of petitioners Motions to Compel should be granted in their entirety, and the Special Master should order the production of the requested discovery.

DATED this 8th day of March, 2004.

WILLIAMS DAILEY O'LEARY CRAINE & LOVE P.C.

By: 

Michael L. Williams
Thomas B. Powers
Counsel for Petitioners' Steering Committee

Williams Dailey O'Leary Craine & Love, P.C.
1001 SW Fifth Avenue, Suite 1900
Portland, Oregon 97204
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## CERTIFICATE OF SERVICE

I hereby certify that on March 8, 2004, I served the foregoing **MEMORANDUM IN SUPPORT OF PETITIONERS' MOTION TO COMPEL DISCOVERY IN THE AUTISM OMNIBUS PROCEEDING** on the following individuals:

Vincent Matanoski
U.S. Department of Justice
Torts Branch, Civil Division
P.O. Box 146, Benjamin Franklin Station
Washington, D.C. 20044-0416

by United Parcel Service, next morning delivery

WILLIAMS DAILEY O'LEARY CRAINE & LOVE, P.C.

Brenda D. Steinle , Assistant to Michael L. Williams
Of Attorneys for Petitioners' Steering Committee

cc: George Hastings
U.S. Court of Federal Claims
Office of the Special Master
529 14th St. N.W. #302
Washington, D.C. 20045


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ORIGINAL

**IN THE UNITED STATES COURT OF FEDERAL CLAIMS**

**OFFICE OF SPECIAL MASTERS**

| | |
|---|---|
| IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER, OR A SIMILAR NEURODEVELOPMENTAL DISORDER,<br><br>Various Petitioners,<br><br>v.<br><br>SECRETARY OF HEALTH AND HUMAN SERVICES,<br><br>Respondent. | AUTISM MASTER FILE<br>Special Master George Hasting |

**EXHIBITS A-G**

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# A

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

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|---|---|
| IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER, OR A SIMILAR NEURODEVELOPMENTAL DISORDER,<br><br>Various Petitioners,<br><br>v.<br><br>SECRETARY OF HEALTH AND HUMAN SERVICES,<br><br>Respondent. | AUTISM MASTER FILE<br><br>**Requests for the Production of Documents: Centers for Disease Control and Prevention** |

**TO: THE UNITED STATES CENTERS FOR DISEASE CONTROL AND PREVENTION ("CDC") AND ITS ATTORNEYS**

PLEASE TAKE NOTICE that petitioners, through their attorneys, request the production of the documents described herein. The documents requested relate to a study and report published in 2003 in the American Journal of Preventive Medicine, volume 25, number 2. The principle author of the study was Dr. Paul Stehr-Green, and the study will be referred to herein as "the study" or "the Stehr-Green study." The published study reports that the National Immunization Program of the Centers for Disease Control and Prevention ("CDC") provided financial support for the compilation of data used in the investigation and the preparation of the report. Petitioners therefore direct this request for the production of documents to the CDC, including any of its employees, agents, officers, political subdivisions, as well as any person or entity employed by, under contract to, or funded by CDC.

The term "document" in these requests is meant in its broadest sense. It is intended to include the original and/or any copy regardless of origin or location, of any contract, agreement,



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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.

The CDC shall produce documents regarding the following subjects:

**REQUEST NO. 1:** All the data compilations or datasets the Stehr-Green study investigators used or relied upon in calculating the autism rates in each country studied for each year the country was studied.

**RESPONSE:**

**REQUEST NO. 2:** All the data compilations or datasets the Stehr-Green study investigators used or relied upon in calculating the rates of vaccine coverage in each country studied for each year the country was studied.

**RESPONSE:**

**REQUEST NO. 3:** All the data compilations or datasets, and the calculations or other interpretive methodologies, that the Stehr-Green study investigators used or relied upon in estimating thimerosal and ethyl mercury exposure for each country studied for each year the country was studied.



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**RESPONSE:**

**REQUEST NO. 4:** All correspondence, including phone logs, memoranda, letters, email, and any other recording or memorialization of any correspondence relating to the study that were sent or received between the investigators (and by "investigators", we mean the named authors of the study, and also Roger Bernier and Susan Chu) and any other persons (whether in or out of the government) while the study was being designed and while it was pending.

**RESPONSE:**

**REQUEST NO. 5:** All correspondence, including phone logs, memoranda, letters, email, and any other recording or memorialization of any correspondence relating to the study which were exchanged among any of the investigators while the study was being designed and while it was pending.

**RESPONSE:**

**REQUEST NO. 6:** All peer-review comments generated in response to the draft manuscript.

**RESPONSE:**

**REQUEST NO. 7:** All documents describing the design of the study and the study protocols.



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**RESPONSE:**

**REQUEST NO. 8:** All documents relating to CDC's decision to fund the study, including but not limited to: requests for proposals, requests for grant applications, requests for bids, proposed contracts for investigation, and all replies and responses thereto; and all grant proposals, funding applications, bids, proposed contracts, and any other request for funding.

**RESPONSE:**

**REQUEST NO. 9:** Billings for time and work on the study as submitted by every author, investigator and consultant who participated in the study in any manner.

**RESPONSE:**

**REQUEST NO. 10:** All progress reports, updates, status reports or any other communication describing the progress of the study both as it was designed and as it was underway.

**RESPONSE:**

**REQUEST NO. 11** Minutes, notes, and any other record of meetings between the study investigators, including any meetings during the design of the study, the conduct of the study, the peer review of the study, and continuing to the present time.



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**RESPONSE:**

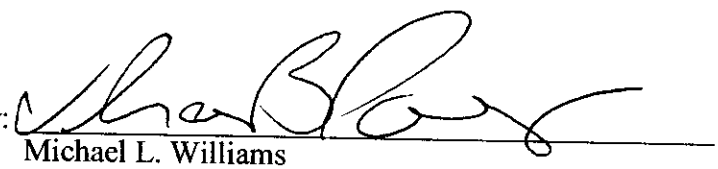
**REQUEST NO. 12** Notes or other record of the conversation with WC Thompson about other relevant studies that were underway, and any communications, in any medium, between WC Thompson and any of the study investigators.

**RESPONSE:**

**REQUEST NO. 13** Any correspondence of any kind received by any of the investigators about the study, whether critiquing it or praising it, since it was published.

**RESPONSE:**

DATED this 29th day of September, 2003

By: 

Michael L. Williams
Thomas B. Powers
Counsel for Petitioners' Steering Committee

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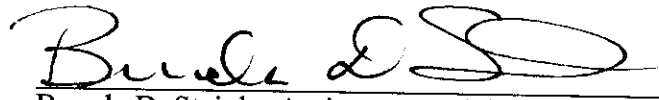
## CERTIFICATE OF SERVICE

I hereby certify that on September 12, 2003, I served the foregoing **Request For Production Of Documents** on the following individual(s):

Vincent Matanoski
U.S. Department of Justice
Torts Branch, Civil Division
P.O. Box 146, Benjamin Franklin Station
Washington, D.C. 20044-0416

by regular mail and facsimile.

WILLIAMS DAILEY O'LEARY CRAINE & LOVE, P.C.



Brenda D. Steinle, Assistant to Michael L. Williams
Attorneys for Petitioners' Steering Committee



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# B

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

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|---|---|
| IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER, OR A SIMILAR NEURODEVELOPMENTAL DISORDER,<br><br>Various Petitioners,<br><br>v.<br><br>SECRETARY OF HEALTH AND HUMAN SERVICES,<br><br>Respondent. | Autism Master File<br><br>**Notice of Deposition of Organization: National Institutes of Health (NIH)** |

**TO: THE UNITED STATES NATIONAL INSTITUTES OF HEALTH ("NIH") AND ITS ATTORNEYS**

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

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



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

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

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

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

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



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

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

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

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

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



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

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

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



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

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

DATED this 16th day of December, 2003

By: _____

Michael L. Williams
Thomas B. Powers

Williams Dailey O'Leary Craine & Love, P.C.
1001 SW Fifth Avenue, Suite 1900
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Attorneys for Petitioners' Steering Committee



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## CERTIFICATE OF SERVICE

I hereby certify that on December 16, 2003, I served the foregoing **Notice of Deposition of Organization on National Institute of Health (NIH)** on the following individual(s):

Vincent Matanoski
U.S. Department of Justice
Torts Branch, Civil Division
P.O. Box 146, Benjamin Franklin Station
Washington, D.C. 20044-0416

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

by regular mail.

WILLIAMS DAILEY O'LEARY CRAINE & LOVE, P.C.

Dannee L. Kessler, Assistant to Michael L. Williams
Attorneys for Petitioners' Steering Committee





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**(Pages 7 through 12 of Exhibit B have been filed into the Master Autism File, but are not being placed on the website for the Omnibus Proceeding due to the provisions of 42 U.S.C. § 300aa-12(d)(4)(A). )**

**(Exhibit C has been filed into the Master Autism File, but is not being placed on the website for the Omnibus Proceeding due to the provisions of 42 U.S.C. § 300aa-12(d)(4)(A). )**

# D

## Tom Powers

**From:** Tom Powers
**Sent:** Thursday, January 15, 2004 10:36 AM
**To:** George Hastings (E-mail)
**Cc:** Matanoski, Vincent (E-mail); Mark Raby (E-mail); Mike Williams
**Subject:** FW: Autism: Conferring re further discovery

**ClientNumber:** 054500

Special Master Hastings,
Attached below is the conferring email regarding outstanding discovery issues sent from the PSC to respondents as we discussed on this morning's phone call. As Mr. Matanoski indicated, he will likely append this to the government's filing that responds to at least some the issues below, to be submitted by the end of next week. The text below is the full email, with the exception of the original headings and salutation lines that have been deleted. It was send by Mr. Williams on January 6, 2004.

Thomas B. Powers
Williams Dailey O'Leary Craine & Love, PC
1001 SW Fifth Avenue, Suite 1900
Portland, OR 97204
Phone: (503) 295-2924
Fax: (503) 295-3720

Tom Powers and I would like to schedule a time to talk to you and Mark sometime tomorrow or Thursday, to go over our specific remaining discovery requests of the gov't and to go over your objections to them--see what we can work out. During our last conf call with SM Hastings, before the holiday break, I said I thought we could file a comprehensive motion to compel and suppoting brief by mid January. My team of support lawyers has conferred and now tells me we simply cannot do the job right unless we take until Feb. 15 or so. I hope you could agree to this extension, and besides, this will give us more time to confer about specifics. In part, it is also because we believe there will be relevant information concerning ongoing epidemiology studies provided in some detail at the Feb. 9 IOM Vaccine Safety Committee meeting, and we need that information for our brief.

To give us a focus for our telephone call(s), here is the short version of the further discovery petitioners feel they need from the government:

1. FINISHED STUDIES. With respect to studies in which the government is a participant or funder, studies which are completed and published, petitioners seek copies of the investigators' and study supervisers' and sponsors' files (containing the first study design documents, changes in the protocol over time, emails to and from the investigators about any problems or progress, comments from the peer reviews of the paper---the exact same kind of discovery of a finished study that the vaccine manufacturers routinely seek and get---Wyeth has had such discovery of the Mayo Clinic, of Yale University, and is seeking it from NIH studies in the hormone therapy litigation), and eventually, for any study on which the government intends to rely in the causation hearing, depositions of two or three of the investigators after we have had a chance to review the files. Right now the two studies which fall into this category are the Stehr Green et al. study on the Swedish-Danish data, and the Verstraeten et al. CDC VSD study.

There will be more of these studies published over time, and we will be requesting the exact same discovery of some of them, at least.

2. ONGOING STUDIES. With respect to studies with government involvement or sponsorship that are ongoing, we want to finish the depositions of organization we started--we did the CDC and ASTDR, but you have stopped us so far from the same discovery of NIH and FDA and any other government agency (DOE? The miltitary?) which is involved in scientific or medical research on thimerosal's effects or on autism's causes and prevalence over time. So first we want to do those depositions.

But for the studies we now can identify, we want to see the operative protocol for each study, its budget and timeline, and any progress or status reports made by the investigators back to the sponsor or superviser at the gov't agency. This would be a rolling discovery of each major study. We don't yet have the transcript of the CDC depo, but should have it soon. Then we can be very specific about what we want on the studies identified there.

3. ACCESS TO VSD DATA SETS. With respect to the Geiers' VSD analysis, we would like to specify through one of our epidemiology statistical experts exactly what data set we need access to from the VSD. The Geiers have given me their permission to access what they were shown on the two days they vistited the facility, but this specific description I will send you may perhaps be treated as a new protocol request---that is one thing we need to confer about.

As I have told you, these same two experts tell me it would be futile to visit the facility to examine the final data set used by the Verstraeten CDC authors, without first seeing all the documents concerning the strategic and tactical decisions made by the investigators during the evolution of this study. And part of this request is that we be given access to the diagnostic coding of the VSD HMO's used by Verstraeten beyond the year 2000, but also through 2003 coding. I think we may almost be at the point where our experts need to talk to your scientists to see what can be done.

4.OBTAINING NON REDACTED LICENSE APPLICATIONS. Finally, we want to see the entire license applications for each vaccine at issue,and until and unless we win the subpoena fight, this discovery remains almost useless to us because of the major redactions you were required by the manufacturers to make.

That is all the discovery we seek. Please let us know when one or more good times to call you in next two or three days is, thanks.

**(Exhibit E has been filed into the Master Autism File, but is not being placed on the website for the Omnibus Proceeding due to the provisions of 42 U.S.C. § 300aa-12(d)(4)(A). )**

# F

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

IN RE: PHENYLPROPANOLAMINE (PPA) PRODUCTS LIABILITY LITIGATION,

This document relates to all actions

MDL NO. 1407

ORDER GRANTING WYETH'S MOTION TO COMPEL PRODUCTION OF DOCUMENTS FROM THE FOOD AND DRUG ADMINISTRATION AND DENYING THE GOVERNMENT'S MOTION TO QUASH

THIS MATTER comes before the Court on Wyeth's (formerly known as American Home Products Corporation) Motion to Compel Production of Documents from the Food and Drug Administration ("FDA") and the Government's Motion to Quash.[1] Having heard the arguments of counsel and having reviewed the briefs and letter briefs submitted by the parties,[2] the Court rules as follows:

[1]This matter was transferred to this Court by order of a magistrate judge from the United States District Court for the District of Columbia pursuant to In re Subpoenas Served on Wilmer, Cutler & Pickering and Goodwin Proctor LLP, 255 F. Supp. 2d 1 (D.D.C. 2003) (holding that where the underlying litigation is subject to a consolidated proceeding, non-party discovery disputes should be decided by the MDL judge).

[2]Letter briefs in support of Wyeth's motion were filed by some of the manufacturing defendants in MDL 1407, including Novartis Consumer Health, Inc. ("Novartis"), GlaxoSmithKline ("GSK") and Bayer Corporation ("Bayer").

## I. INTRODUCTION

This case involves a third-party subpoena served on the FDA by Wyeth concerning documents relating to the FDA's regulation of Phenylpropanolamine ("PPA"). The subpoena seeks production of certain documents withheld by the FDA when it responded to a subpoena issued in a case now pending in MDL 1407, Kerrigan v. Whitehall Robins (the "Kerrigan subpoena"). In response to the Kerrigan subpoena, the FDA asserted the deliberative process privilege, and produced a log showing that some documents had been withheld, redacted, or released only in part. Wyeth's subpoena seeks all documents and information withheld from the FDA's production in response to the Kerrigan subpoena for which the FDA specifically asserted the deliberative process privilege.

The Government asserts that the deliberative process privilege protects the documents from disclosure, contending that the documents withheld reflect the agency's internal decision-making process, disclosure of which would chill future agency dialogue.

The parties were unable to resolve this dispute, and Wyeth moved to compel production of these documents. The FDA in turn moved to quash Wyeth's subpoena. The Court has reviewed the withheld documents in camera to determine whether the deliberative process privilege protects the documents at issue.

## II. DISCUSSION

### A. Background

In the early seventies, the FDA began reviewing and publishing reports regarding the safety of PPA-containing products. In the seventies, eighties and early nineties, the FDA held public meetings, and sought comment regarding the safety and effectiveness of PPA-containing over-the-counter products. Despite some evidence suggesting that PPA might pose a health risk to consumers, the FDA never classified PPA as unsafe or required the withdrawal of PPA-containing products from the market. In late 2000, however, after evaluating data from the Yale Hemorrhagic Stroke Project, the FDA asked the manufacturers of PPA to voluntarily discontinue marketing PPA-containing products. The manufacturers acceded to this request.

### B. The Deliberative Process Privilege

The deliberative process privilege is a qualified privilege allowing government agencies to withhold those documents that would reveal opinions, deliberations or recommendations constituting the process by which government policies are formulated. In re Sealed Case, 121 F. 3d 729, 737 (D.D.C. 1997). The primary policy behind the privilege is to encourage candid debate among governmental decision-makers. Id.

The party claiming the privilege has the burden of proving its applicability. Cobell v. Norton, 213 F.R.D. 1, 4 (D.D.C. 2003). To properly assert the deliberative process privilege, the government must establish that the information is both

predecisional and deliberative. In re Sealed Case, 121 F. 3d at 737. A formal invocation requires a claim by the head of the department having control over the requested information,[3] an assertion of the privilege based on actual personal consideration by that official, and a detailed specification of the information for which the privilege is claimed, explaining why it falls within the scope of the privilege. Cobell, 213 F.R.D. at 5.

Since the deliberative process privilege is a qualified privilege, even if it applies, it may be overcome by a sufficient showing of need. In re Sealed Case, 121 F. 3d at 737. Once the elements of the privilege are met, the burden shifts to the party seeking disclosure to show that its need for the information outweighs the government's interest in confidentiality. Cobell, 213 F.R.D. at 5. "This need determination is to be made flexibly on a case-by-case, ad hoc basis." In re Sealed Case, 121 F. 3d at 737.

C. Applicability of the privilege

After reviewing the documents in camera, the Court finds that the documents are within the class of documents that the deliberative process privilege is designed to protect. These documents are both predecisional and deliberative. In re Sealed Case, 121 F. 3d at 737. Many reflect the personal opinions of a particular employee, rather than a position adopted by the FDA

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[3]In this case, given the time pressure created by the state court trial, the Court ordered the FDA to designate an appropriate individual within the agency able to perform the necessary review and assertion in a timely manner.

itself. Cobell, 213 F.R.D. at 6. There are also a number of drafts of the same documents, and such drafts are typically protected by the privilege. Id. The Court's inquiry, however, does not end with this conclusion.

D. Balancing the interests

The government having established that the documents fall within the ambit of the privilege, the burden shifts to Wyeth to establish that its need for the information outweighs the government's interest in confidentiality. In re Sealed Case, 121 F. 3d at 737-38. Wyeth and the other manufacturing defendants proffered several reasons for needing the documents. The most compelling of these is the position taken by the plaintiffs in coordinated proceedings in Lutz v. Bayer, and O'Neill v. Novartis AG, currently in trial in California state court. The presiding judge in that consolidated case has allowed the plaintiffs to argue to the jury[4] that in the years prior to 2000, the FDA concluded that PPA was unsafe, and informally advised the manufacturing defendants of its position. Plaintiffs also have been permitted to argue that the FDA's reason for not issuing a finding that PPA was unsafe was political pressure. Wyeth and the other manufacturing defendants in MDL 1407 contend that the FDA's decisions were based solely on an analysis of scientific data, and that prior to 2000, they were never informed by the FDA that the agency considered PPA to be unsafe. Defendants claim that

[4]Defendants have read to the Court portions of plaintiffs' opening statements.

without the complete set of FDA documents, they are unable to dispute plaintiffs' allegations.

In balancing the interests of parties, this Court considered the following factors: (1) the interest of the private litigant; (2) the relevance of the evidence sought; (2) the availability of other evidence; (3) the role of the government in the litigation; (4) the impact of disclosure upon the effectiveness of government employees; (6) the seriousness of the litigation; and (7) the public's interest in knowing how effectively government is operating. In re Sealed Case, 121 F. 3d at 737-38; Cobell, 213 F.R.D. at 3.

1. *Interest of the private litigant*

Wyeth has demonstrated a compelling need for the documents on behalf of the manufacturing defendants in the California case. Without the documents, defendants have no way of disputing plaintiffs' claims that the FDA had reached a conclusion early on as to PPA being unsafe, and had informed the manufacturers of this conclusion.

2. *Relevance of the evidence/ Availability of other evidence*

There are no alternative forms of evidence that would be as useful as internal FDA documents outlining the agency's thought processes over the years in formulating its decisions concerning PPA.

3. *Role of the FDA in the litigation/ Impact of disclosure upon the effectiveness of government employees*

The Court is of the opinion that because the regulation of

PPA by the FDA is not ongoing, the agency's interest in confidentiality is somewhat lessened. Further, although the FDA is not party to lawsuits alleging injuries stemming from the ingestion of PPA-containing products, its role as regulator of the drug for over 20 years is not insignificant.

4. *The seriousness of the litigation*

There can be no doubt as to the seriousness of the litigation, given the number of cases pending in MDL 1407, and the gravity of the injuries claimed.

5. *The public's interest in knowing how effectively government is operating*

Finally, the public has a strong interest in knowing whether government agencies are performing their regulatory duties properly. "[W]here there is reason to believe the documents sought may shed light on [an allegation of] government misconduct, the [deliberative process privilege] is routinely denied, on the grounds that shielding internal government deliberations in this context does not serve the public's interest in honest, effective government." In re Sealed Case, 121 F. 3d at 738 (citations and quotation marks omitted).

After considering these factors, this Court concludes that Wyeth's need overcomes the government's privilege claim, and that Wyeth's motion to compel disclosure of the documents withheld by the FDA should be granted.[5]

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[5]Certain documents provided to the Court for in camera review contain no information that could be of any use to defendant. For example, there are several documents that consist

The Court remains acutely aware, while performing the balancing test, of the importance of protecting candid discussions of agency employees and officials and protecting the integrity of agency decisions. Cobell, 213 F.R.D. at 4. The Court is also cognizant of the potential threat to FDA resources if in every case involving litigation over the safety of a drug, the FDA was forced to search its documents in order to assert the deliberative process privilege or produce all documents regardless of the privilege. The critical work of the FDA would be seriously undermined by such a burden.

This dispute involves two unique circumstances that merit further discussion. First and foremost, is the ruling referenced above by a California state court judge which has allowed the plaintiffs in those consolidated cases to present evidence that the FDA bowed to political pressure urging it not to classify PPA as unsafe, while at the same time informing defendants that the drug was unsafe.

Second, there is the 20 year history of the FDA's involvement with the regulation of PPA, which has been long and extremely complex. See Background section, p.3.

The Court emphasizes that this ruling is strictly limited to the facts of this case. The instant matter presented a specific set of circumstances, which, taken together, have led the Court to conclude that the documents, though part of the deliberative

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solely of handwritten notes of unknown origin. These basically useless documents (see p.9, lines 8-9) need not be produced.

process, should be produced.

## III. CONCLUSION

For the foregoing reasons, the Court GRANTS Wyeth's Motion to Compel. The FDA's Motion to Quash is DENIED. The Court ORDERS the FDA to produce all information and documents that were provided to the Court for in camera review and for which the FDA claims the deliberative process privilege, except documents bearing the following bates numbers: PHE 0138, PHE 0139, PHE 01795, PHE 01864, PHE 01865, PHE 01866, PHE 03552. The FDA should produce these documents to Wyeth immediately.

DATED at Seattle, Washington this 12th day of November, 2003.

/s/ Barbara Jacobs Rothstein
BARBARA JACOBS ROTHSTEIN
UNITED STATES DISTRICT JUDGE

# G

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

| | | |
|---|---|---|
| IN RE: PHENYLPROPANOLAMINE (PPA) PRODUCTS LITIGATION | ) | |
| | ) | CIVIL ACTION FILE |
| | ) | NO. |
| | ) | MDL Docket No.: 1407 |
| | ) | Case Pending in the United States District Court of the Western District of Washington, Seattle |

**WYETH'S BRIEF IN SUPPORT OF ITS MOTION TO COMPEL DOCUMENTS FROM THIRD PARTY, UNITED STATES FOOD AND DRUG ADMINISTRATION**

Wyeth (formerly known as American Home Products Corporation), respectfully submits this Memorandum in Support of its Motion to Compel Documents from Third Party, United States Food and Drug Administration ("the FDA").

## I. BACKGROUND AND PROCEDURAL HISTORY

### A. UNDERLYING LITIGATION

The underlying multi-district litigation involves hundreds of product liability lawsuits where plaintiffs allege they have suffered personal injury from the use of over-the-counter (OTC) medicines containing Phenylpropanolamine ("PPA"), produced and distributed in the past by numerous companies, including Wyeth. For decades, PPA was used as a decongestant in products such as

Robitussin CF, Alka Seltzer Plus Cold, Dimetapp, etc. and as an appetite suppressant in diet aids, such as Accutrim and Dexatrim.

On August 28, 2001, the Judicial Panel on Multidistrict Litigation ("the Panel") issued a transfer order consolidating fourteen (14) PPA-related actions from the various federal district courts into an MDL proceeding in the Western District of Washington, all "rooted in the complex core questions concerning the safety of Phenylpropanolamine (PPA)."[1] Since that time, the Panel has issued twenty-two (22) transfer orders conditionally transferring over four hundred (400) related cases to the Western District of Washington pursuant to 28 U.S.C. § 1407.[2] Hundreds of PPA cases outside the MDL are also pending in state courts across the country.

B. BRIEF OVERVIEW of THE FDA REGULATION of PPA

While by no means canvassing the entire regulatory history of PPA, this section will provide an overview of the FDA's role in regulating OTC products and specifically its rulemaking activities specific to PPA.

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[1] A copy of the Panel's initial transfer order is attached as Exhibit "A."

[2] Copies of the Conditional Transfer Orders are attached collectively as Exhibit "B."

The FDA, of course, is the governmental agency responsible for regulating OTC products, including products containing PPA. In 1972, the FDA launched an evaluation of OTC drugs, including those containing PPA, by convening advisory panels to review the safety and effectiveness of various categories of OTC products. As originally constructed, the review process was intended to classify OTC products as either Category 1 (safe and effective); Category II (not safe and effective); or Category III (insufficient data to assess safety). In 1976, the FDA published an advisory panel report for nasal decongestants, which deemed PPA "safe and effective as a nasal congestant." *See, e.g.*, 41 Fed. Reg. 38312 (1976).

In 1982, the FDA published the advisory panel's report for weight control OTC products. 47 Fed. Reg. 8466. The FDA's advisory panel for weight control products -- like the panel for nasal decongestants -- concluded that PPA was "generally recognized as safe and effective" in OTC weight loss products. In that publication, however, the FDA for the first time publicly acknowledged some reports allegedly associating PPA with a transient increase in blood pressure. 47 Fed. Reg. 8466. The FDA did not, however, request the manufacturers to stop selling PPA-containing products or to remove products containing PPA from the market. Then, in 1985, when the FDA announced its

tentative monograph for nasal decongestants, the FDA deferred any final action concerning PPA because of so-called "unresolved" safety concerns with the ingredient. *See* 50 Fed. Reg. 2220 (1985). Again, however, the agency did not request the manufacturers to stop selling PPA-containing products or to remove products containing PPA from the market.

Throughout the seventies, eighties and early nineties, the FDA held public meetings and sought comment regarding the safety and effectiveness of PPA in OTC products, particularly with respect to weight control products. *See, e.g.*, 53 Fed. Reg. 2436, 53 Fed. Reg. 23180, 53 Fed Reg. 30522, 55 Fed Reg. 45788, 56 Fed. Reg. 13295, 56 Fed. Reg. 37992, 56 Fed. Reg. 38391, 57 Fed. Reg. 27658. In 1994, the FDA issued its final monograph for OTC nasal decongestants, but because of "unresolved safety issues" concerning PPA, the agency again deferred discussion of the substance. 59 Fed. Reg. 43386. However, as late as 1996, with specific regard to the use of PPA in weight control products, the FDA publicly affirmed that it did not believe that "use of PPA in such products represents a substantial public health risk." *See* 61 Fed. Reg. 5912, 5913. In fact, as late as April 2000, the FDA publicly acknowledged that PPA had always been treated by the agency as proposed Category I (i.e.,

generally recognized as "safe and effective").[3] That characterization is consistent with the FDA's explicit refusal, publicly expressed as late as 1996, to require the withdrawal of PPA drugs from the market. *See* 61 Fed. Reg. 5912, 5913 (1996). In that regard, it was not until November 3, 2000 that the FDA, based on a single epidemiological study, asked PPA manufacturers to "voluntarily discontinue marketing any drug products containing [PPA]."[4] All manufacturers of PPA-containing drugs, of course, promptly complied. As of this date, however, the FDA has yet to issue any final rule requiring manufacturers to stop selling PPA-containing products.

Central to the plaintiffs' arguments in the PPA litigation is that manufacturers of PPA products failed to timely and adequately warn plaintiffs and the consuming public about the purported risk of developing hemorrhagic stroke from the use of PPA products. To support that contention, the plaintiffs in the PPA litigation are mischaracterizing the FDA's historical treatment of PPA. For example, the generic expert on regulatory

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[3] *See* April 13, 2000 letter from Dr. Charles Ganley to Dr. Walter Kernan (attached as Exhibit "C").

[4] *See* FDA letter of November 3, 2000 (attached as Exhibit "D").

issues designated by the MDL plaintiffs, James Parker,[5] maintains that the FDA pronouncements, as early as 1985, "put industry on notice . . . that PPA was not acceptable because of safety concerns." *See* Exh. "E" at ¶ 4 (p. 17).

Consequently, the plaintiffs in the PPA litigation have specifically raised the views and regulatory intent of the FDA as a critical issue. Moreover, the regulatory history is especially significant because the agency's standard for determining that a drug poses a substantial health risk is significantly lower than the standard of proof necessary for a plaintiff to establish general causation. *See, e.g., Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 991 (8th Cir. 2001) ("The FDA evaluates pharmaceutical drugs using different standards than the causation standards at issue in the present case . . . The FDA will remove drugs from the market upon a lesser showing of harm to the public than the preponderance-of-the-evidence or more-likely-than-not standards used to assert tort liability."). Given that lower standard, the fact that the FDA took no regulatory action concerning PPA throughout the period in which plaintiffs claim there was mounting, publicly

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[5] A copy of James Parker's expert report, filed in the MDL proceeding, is attached as Exhibit "E").

available evidence that PPA was a cause of hemorrhagic stroke is powerful evidence. For those precise reasons, the FDA documents subpoenaed are critical to the manufacturers' defense of these actions and to an understanding of the scientific evidence concerning the safety of PPA products.

C. WYETH'S SUBPOENA to THE FDA

On September 27, 2002, Wyeth issued a subpoena on the FDA pursuant to Rule 45 of the Federal Rules of Civil Procedure ("MDL Subpoena").[6] The MDL Subpoena requested the FDA to produce an extremely finite number of documents it withheld in responding to a subpoena issued by a plaintiff in another PPA case, then pending in the United States District Court of Massachusetts, styled as *Kerrigan v. Whitehall Robins*, Civ. No. 01-CV-10325-DWP. ("Kerrigan Subpoena").[7] In partial response to the Kerrigan Subpoena, the FDA produced a privilege log (otherwise known as a "Vaughn index"), asserting that the subpoena sought production of documents that were confidential or part of the deliberative process, or both.[8]

The MDL Subpoena requested the FDA to produce "all documents identified on the [Kerrigan] Vaughn Index that were

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[6] A copy of the MDL Subpoena is attached as Exhibit "F."
[7] A copy of the Kerrigan Subpoena is attached as Exhibit "G."
[8] A copy of the *Vaughn* index at issue is attached as Exhibit "H."

either withheld, redacted, or released only in part because of a claim of deliberative process." *See* Exh. "F." In a letter dated October 8, 2002, the FDA objected to the MDL Subpoena, through its Associate Chief Counsel for Enforcement, Patricia J. Kaeding ("the FDA letter").[9] In that letter, the FDA claims the subpoena requires disclosure of privileged or other protected matter, including material that was part of the deliberative process, or that contained trade secret or otherwise confidential or private information. Further, the FDA claims that the subpoena is unduly burdensome under Rule 45(c)(3)(iv) in that it is overly broad, seeks documents that are subject to a preexisting subpoena in another case, and that the subpoena somehow otherwise fails to provide sufficient time for the FDA to defend its assertion of deliberative process or to comply with the subpoena. Finally, the FDA claims that the subpoena does not comply with the agency's regulation for the production of documents.

In an attempt to resolve this discovery dispute informally, Wyeth's counsel responded to the FDA's objections in a November 13, 2002 letter.[10] In that letter, Wyeth's counsel responded to

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[9] A copy of the October 8, 2002 letter is attached as Exhibit "I."

[10] A copy of the November 13, 2002 letter is attached as Exhibit

each of the FDA's lodged objections and offered to open a dialogue with the FDA concerning the scope of production of the subpoenaed documents. Rather than enter a dialogue, the FDA in an e-mail response to Wyeth's letter continued to assert the privilege claim for the vast majority of the withheld and/or redacted documents.[11] Its only concession was to withdraw the deliberative privilege claim for a small number of documents, which primarily consisted of one-line e-mails with little or no substantive value.[12]

## II. ARGUMENT AND CITATION TO AUTHORITY

Contrary to the FDA's assertions, and as more fully described below, each of the FDA's lodged objections are without any factual or legal merit.

### A. THIS COURT SHOULD COMPEL THE FDA TO PRODUCE THE SUBPOENAED DOCUMENTS, BECAUSE THE FDA HAS FAILED TO MEET ITS BURDEN OF PROVING THAT THE DOCUMENTS ARE SUBJECT TO THE DELIBERATIVE PROCESS PRIVILEGE AND BECAUSE WYETH HAS A PARTICULARIZED NEED FOR THE DOCUMENTS THAT OUTWEIGHS THE FDA'S INTEREST IN MAINTAINING THEIR CONFIDENTIALITY

As noted, the MDL Subpoena seeks production only of that finite number of documents withheld on the basis of deliberative

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"J."

[11] A copy of the FDA's November 19, 2002 e-mail response is attached as Exhibit "K".

[12] A copy of the FDA's November 25, 2002 letter enclosing the supplemental documents is attached as Exhibit "L".

process, all of which the FDA has already unearthed, identified, organized and bates labeled. It does not seek production of documents withheld on any other basis; nor does it seek production of documents containing confidential or otherwise private information.

The FDA has not met its burden of proving that the subpoenaed documents are subject to the deliberative process privilege. In addition, because the deliberative process privilege is only a qualified privilege, the privilege in this case must yield to Wyeth's overwhelming need for the documents, which far outweighs any interest the FDA has in maintaining the confidentiality of those documents. For these reasons, Wyeth respectfully requests the court to compel the FDA to produce the subpoenaed documents.

**1. The FDA has Failed to Meet its Burden of Showing that the Subpoenaed Documents are Subject to the Deliberative Process Privilege**

Because the FDA has produced an inadequate Vaughn index, it has failed to meets its burden of showing that the documents are subject to the deliberative process privilege.

The "deliberative process privilege" is a qualified privilege that allows the government and its agencies to withhold only those predecisional documents that would reveal "advisory opinions, recommendations and deliberations comprising

part of the process by which governmental policies are formulated." *See In re Sealed Case*, 121 F.3d 729, 737 (D.D.C. 1997) (*quoting Carl Zeiss Stiftung v. V.E.B. Carl Zeiss, Jena*, 40 F.R.D. 318, 324 (D.D.C. 1966); *United States v. Ernstoff*, 183 F.R.D. 148, 152 (D.N.J. 1998). Although the privilege is often asserted in response to or in the context of a Freedom of Information Act ("FOIA") request or litigation (see 5 U.S.C. § 552), the privilege has its origin in common law. Distinguishing between the scope and extent of information obtainable through the FOIA as compared to normal discovery tools, one court has explained that:

> The FOIA furthers the public's general right to know and ensures government accountability. Discovery discourages unfair surprise and delay at trial. In the FOIA context, the requesting party's need for the information is irrelevant; the most urgent need will not overcome an applicable FOIA exemption. In the discovery context, when qualified privilege is properly raised, the litigant's need is a key factor. Whether the information is disclosed depends on the relative weight of the claimant's need and the government's interest in confidentiality.

*Friedman v. Bache Halsey Stuart Shields, Inc.*, 738 F.2d 1336, 1344 (1984)(emphasis added). The most fundamental concept relating to discovery and evidentiary issues, "relevance" to the litigation at issue, is of no consequence to the scope of information obtainable through the FOIA. *Id.* When governmental information is sought during civil litigation, the FOIA acts

only as a "floor." *Friedman v. Bache Haley Stuart Shields, Inc.*, 738 F.2d 1336, 1344 (1984). Information that is normally privileged from disclosure during litigation is also privileged from disclosure under the FOIA. *United States v. Weber Aircraft Corp.*, 465 U.S. 792, 801-802 (1984). Conversely, the fact that material is privileged under the FOIA does not necessarily preclude a litigant from compelling access to material through normal civil discovery mechanisms. *Parton v. United States Dept. of Justice*, 727 F.2d 774, 777 (8th Cir. 1984); *see also John Doe Agency v. John Doe Corporation*, 493 U.S. 146, 153 (1989) (noting that "FOIA was not intended to supplement or displace rules of discovery").

Thus, information available through the FOIA is likely to be obtainable in civil discovery. *Id.* On the other hand, information unavailable through the FOIA is not necessarily unavailable through civil discovery. *Id.*; *In re LTV Securities Litigation*, 89 F.R.D. 595, 618 (N.D. Tex 1981). To assert the deliberative process privilege, the government has the burden of showing that a withheld document is "predecisional" (i.e., was made before the adoption of agency policy) and "deliberative." (i.e., was part of the give and take of the consultative process). *In re Sealed Case*, 121 F.3d at 737; *Coastal States*

*Gas Corp. v, Dep't of Energy*, 617 F.2d 854, 868 (D.C. Cir. 1980).

The primary rationale for the privilege is to encourage the free flow of ideas and candid discussions among governmental decision-makers. *Id.* Therefore, the privilege does not protect purely factual information in nature. *Petroleum Info. Corp. v. U.S. Dep't of Interior*, 976 F.2d 1429, 1434 (D.C. Cir. 1992); *In re Sealed*, 121 F.3d at 737. Nor does it protect expert opinions that are generally discoverable, unless the expert's opinion somehow reflects the deliberative process. *Parke, Davis & Company v. Califano*, 623 F.2d 1, 6 (6th Cir. 1980). Notably, if a document was predecisional at one time, it can later lose that status if the agency adopts, whether formally or informally, the position taken in the document or if it is otherwise used by the agency in dealing with the public. *Coastal States Gas Corp.*, 617 F.2d at 866.

As mentioned, the FDA, as the party asserting the deliberative process privilege, has the burden of proving the existence of such a privilege. *In re Sealed Case*, 121 F.3d at 737; *Coastal States Gas Corp.*, 617 F.2d at 868. The purpose of a Vaughn index is to allow the requester an opportunity to challenge the assertion of privilege as to a particular document, as well as to provide the court with an adequate

foundation to make a ruling as to the legitimacy of the privilege. *Campaign for Responsible Transplantation v. U.S. Food and Drug Administration*, No. 00-2849, 2002 U.S. Dist. LEXIS 18004, at *16 (D.D.C. September 3, 2002). Therefore, in the present case, the FDA was required to provide "a relatively detailed justification *specifically identifying the reasons* why [the deliberative process privilege] is relevant [to each of the documents withheld or redacted]." *Id.* (emphasis in original) (*quoting Mead Data Cent., Inc. v. Dep't of Air Force*, 566 F.2d 242, 251 (D.C. Cir. 1977)); *Campaign for Responsible Transplantation*, 2002 U.S. Dist. LEXIS 18004, at *14-15.; *see also Sandgrund v. U.S. Sec. & Exch. Comm'n*, 215 F. Supp. 2d 178, 181 (D.D.C. 2002) (finding that government agency had duty to offer "as much detail as possible as to the nature of the document, without actually disclosing information that deserves protection").

Despite its burden, the FDA here has failed to provide the requisite level of specificity as to the reason why the deliberative process privilege is applicable to any of the documents withheld or redacted. Nor has it provided "as much detail as possible" as to the nature of those documents. Rather, the FDA's index provides only the bates label numbers, the dates of the documents, subject, attachment, disposition and

reason for withholding/redacting, and the number of pages. Under the guise of providing the "reason for withholding/redacting document," the FDA simply states that the document listed contains information relating to the "deliberative process," without providing any basis for that assertion.

This court has found that merely claiming, as the FDA does here, that a document was part of its decision-making process and therefore privileged is not enough to meet its burden. *Lurie v. Dep't of the Army*, 970 F. Supp. 19, 33-34 (D.D.C. 1997). Moreover, in the recent case of *Campaign for Responsible Transplantation*, this court found that the FDA's mere recitation of the legal standard for a privilege in the "reason for withholding column" of a Vaughn index was inadequate. *Campaign for Responsible Transplantation*, 2002 U.S. Dist LEXIS 18004, at *22; *see also In re: Diet Drugs Products Liability Litigation*, MDL Docket No. 1203, 2000 U.S. Dist. LEXIS 15170, at *8-10 (E.D. Pa. October 12, 2000) (finding as insufficient a Vaughn index which only provided the author, the person to whom it was addressed, the date, the type of document and a brief description of the document); *accord Coastal States Gas Corp.*, 617 F.2d 854, 861 (D.C. Cir. 1980).

In short, the case law makes clear that the FDA's Vaughn index relied upon here is legally inadequate to justify

withholding the documents. It does not provide Wyeth with an opportunity to determine whether each of the documents withheld or redacted on the basis of deliberative process was "predecisional" and "deliberative". It does not state the agency decision, or deliberative process, for which the claim is premised and it does not offer "as much detail as possible as to the nature of the document" as required. *Sandgrund*, 215 F. Supp. 2d at 181. Consequently, the FDA has not met its burden of showing, as a threshold matter, that the deliberative process privilege even applies. Therefore, Wyeth respectfully requests this court to compel production of the subpoenaed documents.

**2. Wyeth's Interest in the Subpoenaed Documents Outweighs The FDA's Interest in Keeping the Documents Confidential**

As mentioned, the deliberative privilege is only a qualified privilege that can be readily overcome when the need of private parties for the documents outweighs the government's need for confidentiality. *In re Sealed Case*, 121 F.3d at 729; *Coastal States Gas Corp*, 617 F.2d at 858; *United Farley*, 11 F.3d at 1389; *In re: Diet Drugs Products Liability Litigation*, MDL Docket No. 1203, 2000 U.S. Dist. LEXIS 15170, at *11-12; *Ernstoff*, 183 F.R.D. at 152-53. Therefore, even if the court were to conclude that the deliberative process privilege applies to any of the withheld or redacted documents, the privilege

should be overcome in this case because Wyeth's interest in obtaining the documents outweighs the government's interest in keeping them confidential. *Id.* Consequently, Wyeth respectfully submits that, under a balancing test it is entitled to the subpoenaed documents even if the privilege had been appropriately asserted and supported.

In balancing the interests of the parties, courts look to a variety of factors:

a. Interests of the private litigant;

b. Relevance of the evidence sought;

c. Availability of other evidence;

d. Seriousness of the litigation and issues involved;

e. Need for accurate judicial findings of fact;

f. Public's interest in learning how effectively the government is operating;

g. Role of Government in the litigation and issues involved; and

h. Impact on the effectiveness of government employees.

*In re Sealed Case*, 121 F.3d at 737-38; *First Eastern Corp. v. Mainwaring*, 21 F.3d 465, 468 n. 5 (D.C. Cir. 1994) (quoting *In re Subpoena Served Upon Comptroller of Currency*, 967 F.2d 630, 634 (D.C. Cir. 1992); *In re Diet Drugs Products Liability Litigation*, 2000 U.S. Dist. LEXIS 15170, at *11-12.

Under an analysis of the enumerated factors, as more fully explained below, any interest the government has in maintaining the confidentiality of the requested documents is substantially -- indeed overwhelmingly -- outweighed by Wyeth's to obtain those documents.

**a. Wyeth has a strong interest in obtaining the privileged documents**

As mentioned, hundreds -- and potentially thousands -- of plaintiffs have and will bring lawsuits against manufacturers of PPA-containing products, including Wyeth, in both state and federal courts across the country. Central to most, if not, all these PPA actions are claims that the manufacturers of PPA-containing products knew or should have known of side-effects of PPA, and had the FDA been timely warned of these side effects, PPA would never have been approved, or would have been approved only when accompanied by prominent warnings of these alleged side effects.

Therefore, obtaining the FDA's information concerning the safety and effectiveness of PPA and its investigation, studies, and deliberations concerning PPA are critical to the defense of these cases, especially considering that up until November of 2000, the FDA permitted manufacturers to market and distribute PPA medicines, had not requested manufacturers to voluntary

remove any of those products, and as late as 1996, had acknowledged that the ingredient did not pose a significant risk to public health. *See* 61 Fed. Reg. 5912, 5913 (1996).

**b. The documents sought are highly relevant as the FDA is and has been the governmental agency responsible for regulating products containing PPA**

The FDA regulates one of the most heavily regulated industries in the world, pharmaceutical products. As described earlier, the FDA consistently stated since the early 1970's and as late as 1996 that PPA did not pose a public health risk. Information relating to the safety and effectiveness of PPA, and the FDA's knowledge and evidence on that point, will provide direct evidence concerning the scientific and medical knowledge and the reliability of that information. That information is directly related to the defendants' knowledge about the safety and effectiveness of PPA-containing products and whether they knew, or should have known, based on then-existing scientific data, that PPA products constituted an unreasonable risk of harm. That information also bears substantially on the reasonableness of the manufacturers in continuing to market PPA-containing products until the FDA asked them to voluntarily remove the products from the market in late 2000.

The FDA has withheld documents that would demonstrate its position on PPA, which appear, based on the documents produced to date, to be contrary to the plaintiffs' allegations. For example,[13] the two entries on page one of the Vaughn index describing documents to William Gilbertson, dated August 1990, from Dr. Robert Temple (Bates Nos. 0170-1072) and Dr. Raymond Lipicky (Bates Nos. 0173-0201) are the same documents that are summarized in the "OTC Weight Control Chronology", which was previously produced as PPA 0386 to 0396.[14] The August 1990 entry in the "OTC Weight Control Chronology" at Bates No. PPA 0395 states that Drs. Temple and Lipicky's review of "IND blood pressure/response studies of PPA concluded that 25 mg immediate release dose and 75 mg controlled-release dose are safe for OTC

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[13] By providing examples of certain documents withheld or redacted by the FDA on the basis of deliberative process which Wyeth believes would reveal the FDA's position on PPA, Wyeth is by no means providing an exhaustive listing of all such documents, as such a task would be impossible given the vagueness and inadequacy of the FDA's Vaughn index. Rather, Wyeth provides these examples as illustrative of the numerous other documents it believes are directly relevant to FDA's position on PPA. As was discussed previously, by failing to provide an adequate Vaughn index, specifically detailing the reasons why the deliberative process privilege applies to each document withheld or redacted, the FDA has failed to properly invoke the deliberative process privilege in the first instance.

[14] *See* MDL Plaintiffs' Exhibit # FDA0076 (attached as Exhibit "M").

use." These documents contributed to and were part of the FDA's position at the time and are far more accurate than Mr. Parker's declaration.

The plaintiffs also raised the issue of Dr. Lipicky's opinions during the October 9, 2002 deposition of Anthony Amitrano, Director of Regulatory Affairs for GlaxoSmithKline. Plaintiffs' counsel asked Mr. Amitrano if he "[w]ould be surprised if I [plaintiffs' counsel] were to tell you that in 1988 representatives of Menley and James were informed by Dr. Lipicky at the FDA that the available body of data regarding the safety of PPA did not support the safety of the drug."[15] Mr. Amitrano responded that he was "not aware of that information". Amitrano Decl.[16] The "OTC Weight Control Chronolgy" references documents that have been withheld and that would appear to demonstrate that Dr. Lipicky's opinion in 1990 was contrary to that alleged by plaintiffs' counsel.

**c. The documents subpoenaed are not otherwise available from other sources**

The documents sought are simply unavailable from any other source. As a review of the Vaughn index indicates, the

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[15] *See* Deposition of Anthony Amitrano, October 9, 2002, p. 325:12-16 (relevant portions attached as Exhibit "N").
[16] *Id.* at 325:18.

documents being withheld by the FDA principally consist of memoranda and studies prepared by various agency personnel. Absent compliance by the FDA with the present subpoena, those documents will not be accessible to the parties in the PPA litigation.

**d. The seriousness of this mass tort litigation is shown by the hundreds and potentially thousands of plaintiffs who claim to have suffered serious injury as a result of ingestion of PPA-containing product**

As mentioned, a large number of lawsuits have been filed across the country, both in federal and state courts, by claimants who allege to have suffered serious injury from ingestion of PPA products, the very products regulated by the FDA. Needless to say, the potential exposure to the defendants in these case can easily reach an enormous magnitude. Therefore, there can be no questions concerning the seriousness of this mass tort litigation.

**e. The documents subpoenaed will shed light on Wyeth's knowledge about the safety and effectiveness of the PPA-containing products manufactured by Wyeth and other manufacturers, and the reasonableness of the manufacturers in continuing to market these products, enabling a fact-finder to reach accurate findings**

Only by reviewing the subpoenaed documents will a fact-finder have sufficient knowledge and basis to make an assessment regarding the knowledge of the scientific community, the FDA and

the defendants regarding the safety and effectiveness of PPA-containing medicines.

**f. The public has a strong interest in learning about the information the FDA had concerning the safety and effectiveness of PPA Products during the relevant time periods**

As the regulating body for OTC and prescriptions drugs, the FDA is responsible for protection of the public's health. If the plaintiffs' allegations are believed, to the effect that there was mounting, publicly available evidence that PPA was a cause of hemorrhagic stroke, the public has a strong interest in finding out about the FDA's knowledge of the risks associated with PPA, especially in light of the FDA's inaction, its failure to request manufacturers to voluntary withdraw PPA products before November 2000, and its at least tacit approval of the marketing of the drug.

**g. As the governmental agency responsible for regulating one of the most regulated industries in the United States and the world, the FDA's knowledge and importance is of undeniable importance in this litigation**

As shown above, the FDA's analysis and regulatory intent regarding PPA is a central issue in this litigation. The plaintiffs have highlighted the importance of this issue by submitting the expert report of Mr. Parker, which spends more than twenty pages attempting to characterize the agency's

thinking historically, and by specifically deposing Mr. Amitrano on Dr. Lipicky's opinions. Mr. Parker's contention that the FDA's pronouncements put the industry on notice as early as 1985 does not accurately portray the FDA's position concerning PPA. *See* Exh. "E." The evidence of Dr. Lipicky's opinions in 1990 as summarized in the "OTC Weight Control Chronology" appear to be contrary to that alleged by plaintiffs' counsel during Mr. Amitrano's deposition.

The documents withheld by the FDA written by Drs. Temple and Lipicky, which state that PPA was safe for OTC use, are far more accurate of the status of the FDA's position in 1990 than either Mr. Parker's declaration or plaintiffs' counsel understanding of Dr. Lipicky's opinions. This information is clearly relevant and central to the manufacturers' response to the plaintiffs' allegations. The manufacturers will want to show that they acted reasonably in relying on the FDA's repeated statements that PPA did not present a public health hazard. Against this background, the agency's views toward PPA, and the thinking underlying those views, have become core issues in this litigation.

h. The impact on government employees caused by the disclosure of the information is minimal

It is difficult to ascertain how the disclosure of the limited number of documents sought by the subpoena could negatively impact the government or its employees. Over the years, the FDA maintained an open dialogue with scientists and manufacturers regarding PPA, and agency officials often expressed their views in those discussions. The plaintiffs have made assertions concerning the FDA's position and the opinions of a number of FDA employees, such as Dr. Lipicky. The documents subpoenaed contain information of both of these. It is sheer speculation to think that the disclosure of written reports of these views would somehow limit or inhibit the agency's discourse, particularly since much of the material sought was created many years ago.

B. WYETH'S SUBPOENA TO THE FDA IS NOT UNDULY BURDENSOME AND DOES NOT IMPOSE AN UNREASONABLE DEADLINE FOR COMPLIANCE

The MDL Subpoena directed to the FDA is not unduly burdensome and does not impose an undue burden. Most important, it seeks documents the FDA already has already gathered, reviewed, organized, bates labeled, and produced in redacted form in some cases, in responding to the Kerrigan Subpoena.

Generally, a party "may obtain discovery regarding any matter, not privileged, which is relevant to the claim or defense of any party." FED. R. CIV. P. 26(b)(1). The party opposing the subpoena has the burden to prove that the subpoena is unduly burdensome. *Linder v. Calero-Portocarrero*, 180 F.R.D. 168, 171-72 (D.D.C. 1998) (citing FED. R. CIV. P. 45(c)(3)(A)(iv)) ("*Calero-Portocarrero I*"); *Linder v. Calero-Portocarrero*, 183 F.R.D. 314, 318 (D.D.C. 1998) ("*Calero-Portocarrero II*"); *Northrop Corp. v. McDonnell Douglas Corp.*, 751 F.2d 395, 403 (D.D.C. 1984). Federal Rule of Civil Procedure 45 is to be read in light of Rules 25-37; thus, the factors to consider in analyzing whether a subpoena constitutes an undue burden include relevance, the need of the party for the documents, whether the request is cumulative, the time and expense required to comply, and the importance of the issues at stake in the litigation. *Calero-Portocarrero I*, 180 F.R.D. at 174; *see also* FED. R. CIV. P. 26(b). Whether complying with a subpoena is reasonable or unduly burdensome "must be determined according to the facts of the case." *Northrop Corp.*, 751 F.2d at 407 (remanding case for district court to determine whether searching 967 cubic feet of documents is reasonable).

### 1. It is Reasonable for the FDA to Comply with the Subpoena

The FDA should not have to spend an unreasonable amount of time and cost in order to comply with Wyeth's subpoena because the FDA has already searched for and organized the materials requested and had to review them to make the objections claimed in the Vaughn index. Further, the court should reject the FDA's argument that it will somehow require vast resources to defend the deliberative process privilege, when the FDA has not even shown the privilege applies to those documents in the first instance.

To determine whether compliance with a subpoena would be unduly burdensome, courts look at the volume of material requested and the ease of searching for the requested documents in the form presented. *Calero-Portocarrero II*, 183 F.R.D. at 320 (citing *Northrop Corp.*, 751 F.2d at 404). An additional factor is whether compliance threatens the normal operations of the responding agency. *Id.* (citing *United States v. Int'l Bus. Machs. Corp.*, 83 F.R.D. 97, 108 (S.D.N.Y. 1979)). For instance, in *Calero-Portocarrero I*, the court looked to affidavits submitted by the agency stating that over 1 million pages of records would have to be hand-searched, and it would take over 27 man-years to retrieve the records and review and redact the

records. 180 F.R.D. at 175. There, the court used that fact to support its conclusion that the subpoena was unduly burdensome. *Id.*

Conversely, in *IBM*, the government served a subpoena on *IBM* and its Chairman of the Board. 83 F.R.D. at 98. *IBM* estimated it would require 62,000 man-years and over $1 billion to comply with the subpoena and estimated that 5 billion pages in 120 countries would be responsive to the subpoena. *Id.* at 99 n.4. Nevertheless, the court found the subpoena was not unduly burdensome compared to *IBM's* size and resources. *Id.* at 109.

One court even offered the solution that the agency could allow the requester to look through the documents in order to relieve the agency of expending their own man-power. *Flatow v. Islamic Republic of Iran*, 196 F.R.D. 203, 207-08 (D.D.C. 2000), *superceded by statute on other grounds*, *Elahi v. Islamic Republic of Iran*, 124 F. Supp. 2d 97 (D.D.C. 2000), *affirming narrowing of* subpoena, *Flatow v. Islamic Republic of Iran*, 2002 U.S. App. LEXIS 21031 (D.C. Cir. October 8, 2002). The court recognized there could be confidentiality concerns associated with such a procedure, but a protective order could provide any needed safeguards. *Id.*

Moreover, in *Northrop Corp.*, the state, in opposing a subpoena, conceded that its files were organized topically and

geographically, but claimed that the subpoena was oppressive because a privilege protected "a high proportion of the documents." 751 F.2d at 404. The court rejected that argument and found that the district court had abused its discretion in quashing the subpoena directed to the state. *Id.* at 403-04. The court rejected the state's reasoning because the state had not met its burden of proving that a privilege, including the deliberative process privilege, protected many of the documents. *Id.* at 404; *see also Campaign for Responsible Transplantation*, 2002 U.S. Dist. LEXIS 18004, at *14-26 (discussing importance of the Vaughn index in determining whether a privilege applies).

Here, the volume of documents being requested is not as great as that at issue in either *IBM* or *Calero-Portocarrero I*, and in *IBM* the court allowed the subpoena to stand despite the volume and cost. Here, Wyeth has very narrowly tailored its subpoena to require production of only a subset of the documents requested. By the FDA's own count, Wyeth is seeking only 281 documents totaling a mere 1993 pages. *See* the FDA Letter, Exh. "I", p. 3. This number is obviously manageable and nowhere near the 1 million pages the court found was unduly burdensome in *Calero-Portocarrero I*. As a consequence, a minimum amount of searching for these documents would be required because the FDA

has already had to organize, bates label, and review them in asserting the privilege in the first instance.

The FDA has also stated that the subpoena is unduly burdensome because the agency will have to defend its claims of deliberative process privilege, just as the state argued in *Northrop*. The FDA stated in its letter, "[i]n order to defend claims of deliberative process privilege, the government must prepare declarations that describe each document or individual page withheld, and each partial redaction made, and explain the basis for the assertions of privilege." Exh. "I", p. 3. That argument turns the concept of "undue burden" on its head, as the agency attempts to portray its legal obligation to justify its privilege claim as itself burdensome. As previously discussed, the FDA has not met its burden that the privilege even applies. Thus, the court must reject this argument, just as the court did in *Northrop*.

The Vaughn index itself is an affidavit, and it should already adequately describe the documents being withheld and state the justification for claiming the deliberative process privilege. *See Campaign for Responsible Transplantation*, 2002 U.S. Dist. LEXIS 18004, at *14-17. Just because the FDA has not produced an adequate Vaughn index as this Court requires and therefore still faces the job of justifying its privilege

The MDL Subpoena is not overbroad. The search is confined to documents already identified in the Vaughn index that the FDA produced in response to the Kerrigan Subpoena. While the FDA categorizes the subpoena as "all documents withheld, redacted, or released only in part based on a claim deliberative process," (see FDA Letter Exh. "I," p. 3), Wyeth is only seeking a sub-category of documents listed in the Vaughn index -- documents categorized under the deliberative process privilege without justification. The FDA itself, by responding to and categorizing documents responsive to the Kerrigan Subpoena, has already narrowed the universe of documents sought.

**3. Wyeth Has a Particularized Need for the Documents Subpoenaed**

As mentioned earlier, Wyeth needs these documents to be able to defend against the hundreds and possibly thousands of claimants in this multi-district litigation, as well as the related claims pending in state courts across the country. Courts will consider the need of the requester for the documents sought by the subpoena, which includes the importance of the issues at stake in the litigation. *Westinghouse Elec. Corp. v. City of Burlington,* 351 F.2d 762, 767 (finding that the importance of the case and the large amount of money at stake are relevant to determining the reasonableness of the subpoena).

The FDA's contention that the subpoena is unduly burdensome because it is the subject of a pre-existing subpoena in the *Kerrigan* case is likewise without merit. Although the *Kerrigan* case is now pending in the MDL, originally and at the time of issuance of the Kerrigan Subpoena, the case was pending in the United States District Court of Massachusetts. Moreover, the *Kerrigan* plaintiffs have never contested the FDA's assertion of privilege. Further, in negotiating with the FDA, plaintiff's counsel agreed to accept the FDA's response to outstanding FOIA request as being responsive to the Kerrigan Subpoena.[17] As previously noted, courts have found that information obtainable through the FOIA is different from information obtainable through a subpoena. The most fundamental concept relating to discovery and evidentiary issues, "relevance" to the litigation at issue, is of no consequence to the scope of information obtainable through the FOIA. *Friedman v. Bache Haley Stuart Shields, Inc.*, 738 F.2d 1336, 1344 (1984). When governmental information is sought during civil litigation, the FOIA acts as a "floor." *Id.* Thus, besides the fact that Wyeth was not the party who served the Kerrigan Subpoena, and therefore arguably

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[17] *See* July 26, 2001, letter from Edward J. Parr, Jr., attorney for the Kerrigan plaintiffs to Patricia J. Kaeding, attorney for the FDA (attached as Exh. "O").

did not have standing to compel production of those documents with regard to that specific subpoena, Wyeth would not have had the same right to compel production of the deliberative process documents through the Kerrigan Subpoena as it has with the MDL Subpoena, because the Kerrigan plaintiff had agreed to accept only those documents responsive to certain outstanding FOIA requests.

In summary, if the FDA complies with the MDL Subpoena, the agency will not be faced with having to conduct the same review in response to other subpoenas regarding PPA. Thus, compliance with this subpoena would actually decrease the burden on the FDA later.

**4. Wyeth's Subpoena Seeks Documents Relevant to Its Defense**

Wyeth's subpoena seeks documents that are relevant to defending plaintiffs' allegations. The pertinent inquiry focuses on the relevance of the documents sought to the purpose of seeking the documents. *IBM*, 83 F.R.D. at 104-05. The purpose of Wyeth in seeking the requested documents from the FDA is so that the company can defend itself against plaintiffs' allegations that Wyeth had knowledge that PPA was unsafe, but was still manufacturing and distributing the drug. Although it is difficult to assess the relevance of each document in the

Vaughn index because of the inadequate descriptions provided by the agency, the FDA has already produced redacted versions of these documents in response to the Kerrigan Subpoena.

The Kerrigan Subpoena sought documents "that refer or relate to the risk or occurrence of stroke associated with the use of phenylpropanolamine ('PPA') . . . and any and all documents that refer or relate to the safety, effectiveness, advertising, marketing, or promotion of PPA . . ." *See* Exh. "G." The FDA has never refused production of these documents on the basis of relevance. Moreover, by listing these documents as part of the Vaughn index, the FDA conceded, at least implicitly, that the documents were relevant and responsive to the Kerrigan Subpoena.

C. **WYETH'S SUBPOENA WAS PROPERLY SERVED**

As its final objection to the subpoena, the FDA claims that the subpoena does not comply with agency's regulations for the production of documents, citing to 21 C.F.R. Part 20 and specifically 21 C.F.R. § 20.2. Apparently, the FDA is asserting that its regulations require it to treat all subpoenas as requests under the FOIA. The FDA does not, however, provide any statutory or case law support for the bald assertion that its regulations can supplant the enforceability of a judicial subpoena. Moreover, the FDA's regulations provide that the

agency will comply with any court order to disclose documents. 21 C.F.R. § 20.83. Further, courts have consistently enforced subpoenas served on governmental agencies which were nonparties to litigation for which the subpoena was served. *See generally Friedman*, 738 F.2d at 1344 (noting difference between the FOIA and subpoena, and ordering Commodities and Futures Trading Commission as well as Securities and Exchange Commission to comply with subpoenas duces tecum); *The Committee for Nuclear Responsibility, Inc. v. Searborg*, 463 F.2d 788 (D.C. Cir. 1971) (enforcing subpoena against government agencies); *Exxon Shipping Co. v. U.S. Dep't of* Interior, 34 F.3d 774 (9th Cir. 1994) (enforcing subpoena against government despite housekeeping regulations to contrary); *In re: Diet Drugs Products Liability Litigation*, 2000 U.S. Dist. LEXIS 15170, at *5-8 (enforcing subpoena served on the FDA); *see also In re: Sealed* Case, 121 F.3d at 734 (enforcing subpoena served on White House counsel); *Chemical Weapons Working Group v. EPA*, 185 F.R.D. 1 (D.D.C. 1999) (deciding whether subpoena on EPA was subject to deliberative process privilege).

What is obvious here is that regardless how the request is made, the FDA will not produce the requested documents without a court order. After all, the plaintiff's counsel in the *Kerrigan* case agreed to accept as the FDA's primary production, those

documents which the agency itself deemed responsive to a pending request for production of documents which had been submitted to the agency under FOIA. *See* Exh. "O". In response, the FDA produced the Vaughn index that is the subject of this motion, whereby it asserted the deliberative process as grounds for withholding certain documents. Similarly, the FDA now refuses to produces the same documents requested through a subpoena. The FDA has made it clear that it will not produce the withheld documents whether the request is made pursuant to a FOIA request or through a subpoena. As a consequence, the FDA's argument that the subpoena does not comply with agency regulations is disingenuous at best and should be rejected by this court.

**III. CONCLUSION**

The FDA has failed to timely and adequately respond to a subpoena that was properly served on it. As a consequence, Wyeth respectfully requests this court to compel production of the narrowly defined documents sought in that subpoena.

This 12th day of December, 2002.

Matthew B. Lerner

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

| | |
|---|---|
| IN RE: PHENYLPROPANOLAMINE (PPA) PRODUCTS LITIGATION | CIVIL ACTION FILE NO. MDL Docket No.: 1407 Case Pending in the United States District Court of the Western District of Washington, Seattle |

**CERTIFICATE OF SERVICE**

I hereby certify that I have this day served the within and foregoing **WYETH'S BRIEF IN SUPPORT OF ITS MOTION TO COMPEL DOCUMENTS FROM THIRD PARTY, UNITED STATES FOOD AND DRUG ADMINISTRATION** by depositing a copy of same in the United States Mail in a properly addressed envelope with sufficient postage affixed thereto to ensure delivery to the following:

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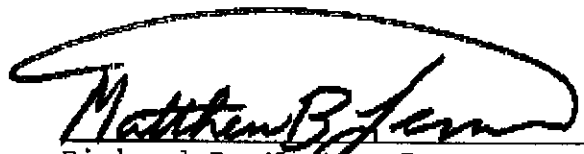
This 12th day of December, 2002.



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ORIGINAL

**IN THE UNITED STATES COURT OF FEDERAL CLAIMS**

**OFFICE OF SPECIAL MASTERS**

| | |
|---|---|
| IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER, OR A SIMILAR NEURODEVELOPMENTAL DISORDER,<br><br>Various Petitioners,<br><br>v.<br><br>SECRETARY OF HEALTH AND HUMAN SERVICES,<br><br>Respondent. | AUTISM MASTER FILE<br>Special Master George Hasting |

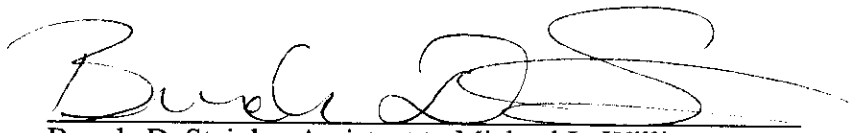
**CERTIFICATE OF SERVICE EXHIBITS A-G**

I hereby certify that on March 8, 2004, I served the foregoing **EXHIBITS A-G mentioned in Petitioners' Motion To Compel Discovery In The Autism Omnibus Proceeding; And Memorandum In Support Of Petitioners' Motion To Compel Discovery In The Autism Omnibus Proceeding** on the following individuals:

Vincent Matanoski
U.S. Department of Justice
Torts Branch, Civil Division
P.O. Box 146, Benjamin Franklin Station
Washington, D.C. 20044-0416

by United Parcel Service, next morning delivery

WILLIAMS DAILEY O'LEARY CRAINE & LOVE, P.C.



Brenda D. Steinle , Assistant to Michael L. Williams
Of Attorneys for Petitioners' Steering Committee

cc: George Hastings