ORIGINAL

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER, OR A SIMILAR NEURODEVELOPMENTAL DISORDER,

Various Petitioners,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

AUTISM MASTER FILE

Petitioners' Steering Committee's Request for the Production of Documents: Merck & Company, Incorporated

TO: MERCK & COMPANY, INC., ("MERCK") AND ITS ATTORNEYS

PLEASE TAKE NOTICE that pursuant to 42 USC §300aa-12(d), RCFC 34 and 45, and Vaccine Rule 7, you are directed to produce to the Petitioners' Steering Committee for inspection the following documents that are in your custody or control.

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

If a document is withheld by you on the grounds of attorney-client privilege or attorney work product, or any other privilege as provided by law, identify such document by date, author, recipient and subject matter (without disclosing its contents) sufficient to describe the document so that the Special Master may rule on your objection.

All of the categories of information described below relate to Merck's biologic product known as "MMR," consisting of the combined vaccines for measles, mumps and rubella.

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A. Product License Applications

Produce all of those documents contained in the Product License Applications ("PLAs") for the years 1990 to 2003 for MMR. This request is intended to encompass all documents responsive to petitioners' earlier discovery request to the FDA seeking PLA materials for this product. This request directly to Merck to produce PLA documents directly to petitioners is intended to include all documents or portions of documents that were withheld, redacted, or otherwise made unavailable to petitioners in those MMR PLA documents already delivered to petitioners by the respondent.

In addition to the PLA documents requested above, Merck is directed to deliver to petitioners any documents relating to the following categories. It is intended that the following requests seek only those documents not otherwise included in the PLAs requested above.

B. Product Safety Research Produce documents relating to:

1. Any research, survey, study, test or other investigation, whether published or not, conducted by Merck or any of its subdivisions or predecessor corporations, or any entity employed by Merck, under contract to Merck, or funded by Merck, regarding the human or animal health effects of MMR or the single-antigen measles component thereof.

2. Any research, survey, study, test or other investigation, whether published or not, conducted by Merck or any of its subdivisions or predecessor corporations, or any entity employed by Merck, under contract to Merck, or funded by Merck, regarding the neurological or neurodevelopmental human and animal health effects of the MMR or the single-antigen measles component thereof.

3. Any research, survey, study, test or other investigation, whether published or not, that was **not** conducted by Merck or any of its subdivisions or predecessor corporations, or any entity employed by Merck, under contract to Merck, or funded by Merck, but that Merck was aware of, regarding the neurological or neurodevelopmental human and animal health effects of the MMR or the single-antigen measles component thereof.

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C. Communications Between Merck and the U.S. Government:

Produce documents relating to any communications between Merck and any agency or division of the U.S. federal government, including but not limited to the Centers for Disease Control and Prevention, the Food and Drug Administration, and the Department of Health and Human Services, and any of the subdivisions of those entities, regarding the safety, or concerns about the safety, of MMR or the single-antigen measles component thereof.

D. Materials Created for, or Produced in, Litigation in the United Kingdom Involving the MMR Vaccine and its Alleged Link to Gastrointestinal Disease and Autism Spectrum Disorders.

It is petitioners' understanding that Merck's MMR vaccine product was the subject of litigation in Great Britain, that Merck was a party to that litigation, and that the gravamen of the litigation was that the MMR, or the measles component thereof, caused gastrointestinal disease and autism spectrum disorders. Based on that knowledge and understanding, petitioners request that Merck produce the following categories of documents related to the British litigation:

1. A copy of the entire set of documents that Merck produced pursuant to discovery requests from the plaintiffs, limited to those documents relating to issues of causation;

2. Copies of any expert reports, summaries, witness statements, and depositions prepared by or on behalf of Merck in that litigation, limited to those documents relating to issues of causation.

3. Copies of any expert reports, summaries, witness statements and depositions prepared by any other party to the UK MMR litigation and served on Merck.

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DATED this 25th day of February, 2003.

Respectfully submitted,

By: _____

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