

In the United States Court of Federal Claims

ORIGINAL

OFFICE OF SPECIAL MASTERS

(Filed: April 23, 2004)

FILED
APR 23 2004
U.S. COURT OF
FEDERAL CLAIMS

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IN RE: CLAIMS FOR VACCINE INJURIES
RESULTING IN AUTISM SPECTRUM
DISORDER OR A SIMILAR
NEURODEVELOPMENTAL DISORDER
VARIIOUS PETITIONERS,
v.
SECRETARY OF HEALTH AND
HUMAN SERVICES,
Respondent.
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AUTISM MASTER FILE

AUTISM UPDATE-APRIL 23, 2004

This Update describes a number of recent developments in the Omnibus Autism Proceeding that have occurred since my last Update, dated March 12, 2004. I note that counsel for both parties and I have continued to work diligently on the Proceeding during that time period. Unrecorded telephonic status conferences were held on March 17, March 24, March 29, April 9, and April 16, 2004.<sup>1</sup>

A. Number of cases

At this time, more than 3900 petitions in autism cases have been filed, and more than 3800 remain pending, stayed until the conclusion of the Omnibus Autism Proceeding. Additional petitions continue to be filed regularly.

<sup>1</sup>Counsel participating in those conferences included Michael Williams, Thomas Powers, and Ghada Anis for petitioners; Vincent Matanoski, Mark Raby, Linda Renzi, and Ann Donohue for respondent.

## ***B. Discovery***

As indicated in my previous Autism Updates, a tremendous amount of work has been done by counsel for both parties concerning the petitioners' extensive discovery requests. I will not reiterate developments covered in my previous updates, but I will summarize below our progress and certain new developments in the discovery area.

### ***1. General progress concerning initial Requests for Production***

Certain material responsive to the petitioners' extensive initial set of Requests for Production was made available to petitioners during the fall of 2002 via various government web sites, and petitioners' counsel have analyzed that data. Many thousands of pages of additional material have been supplied to petitioners since December of 2002, and petitioners' counsel have analyzed those documents as well. At this point, the respondent has now substantially complied with all of the petitioners' initial set of Requests for Production, except for the item discussed at point 2 below and the item concerning "ongoing studies" mentioned at point 4 below.

### ***2. The vaccine license application files***

One category of documents requested, pursuant to petitioners' Requests for Production Nos. 10 and 12, involves vaccine license applications. In this area, efforts to produce material have proceeded slowly, as detailed in my previous Autism Updates, but the process of production of that material continues to move forward. Since my last Update, the first portion of the Food and Drug Administration (FDA) file that pertains to the Aventis DTaP vaccine was submitted to the Petitioners' Steering Committee (hereinafter "the Committee"), along with second portions of the files pertaining to the GlaxoSmithKline hepatitis B vaccine and the North American Healthcare DTaP vaccine. Prior to that, the bulk of the files for the Merck MMR combined vaccine, the Merck mumps vaccine, the Merck measles vaccine, the Merck rubella vaccine, and the Merck hepatitis B vaccine were submitted to the Committee. And the files with respect to several additional vaccines are continuing to move at various stages through the arduous process toward disclosure.<sup>2</sup>

### ***3. Organizational depositions***

As previously reported, as part of the petitioners' "second round" of discovery, initiated in the fall of 2003, the Committee has filed a request to depose certain government officials. Three representatives of the Centers for Disease Control and Prevention ("CDC") were in fact deposed on December 9, 2003, and the respondent has agreed to provide an FDA official for deposition (the

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<sup>2</sup>I note that while the Committee's discovery *requests* have been filed into the Autism Master File, the respondent's discovery *responses* have been filed into the file of an individual autism case, *Taylor v. HHS*, No. 02-699V. The latter file is available to autism petitioners and their counsel, via special procedures set up by the Committee, but not to the general public, as mandated by the Vaccine Act.

parties are still trying to agree on a deposition date). The respondent has declined to provide an official of the National Institutes of Health ("NIH") for deposition, however, and the Committee has recently requested that I order the respondent to provide such an official for deposition as part of the "motion to compel" discussed immediately below.

#### ***4. Motion to compel discovery from respondent***

As indicated in previous Autism Updates, the parties have been in disagreement concerning the issue of production of materials relating to certain studies, especially those related to one recently completed study known as the "Thimerosal Screening Analysis" ("TSA"). After extensive efforts to settle this issue were unsuccessful, the Committee on March 9, 2003, filed a "Motion to Compel," requesting that I order respondent both to produce certain documents and to provide a witness from the NIH for deposition. The motion seeks, *inter alia*, documents relating to (1) the TSA; (2) other completed and published studies; and (3) studies in progress. It also seeks documents from the vaccine license application files in addition to those that have been disclosed as discussed above in paragraph (B)(2) of this update.

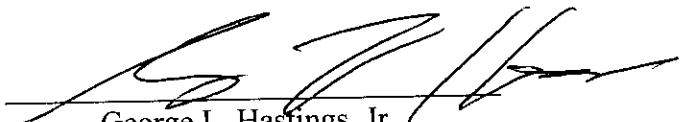
The parties have agreed that respondent will file a written response to that motion by May 14, 2004; that the Committee will file a reply brief by June 4, 2004; and that an evidentiary hearing concerning that motion will be held sometime between June 21 and 29, 2004.

#### ***5. Non-party discovery***

As previously noted, in February of this year the Committee announced that it intended to redirect its initial effort to obtain discovery from the vaccine manufacturer, Merck and Company. The Committee filed a request for documents from Merck concerning its MMR and measles vaccines on February 26, 2004, and then filed the Committee's initial documentation and argument supporting that request on March 23, 2004. The participants have agreed to a briefing schedule concerning that discovery request, by which Merck will respond by April 23, the Committee will reply by May 7, and oral argument will be held on May 26.

#### ***C. Future proceedings***

The next status conference in the Omnibus Autism Proceeding is scheduled for May 6, 2004.



George L. Hastings, Jr.  
Special Master