

**ORIGINAL**

**In the United States Court of Federal Claims**

**OFFICE OF SPECIAL MASTERS**

**(Filed: December 23, 2004)**

**FILED**  
**DEC 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** \*  
  
VARIOUS PETITIONERS, \*  
  
v. \*  
  
SECRETARY OF HEALTH AND \*  
HUMAN SERVICES, \*  
  
Respondent. \*  
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**AUTISM MASTER FILE**

**AUTISM UPDATE--DECEMBER 23, 2004**

This Update describes a number of recent developments in the Omnibus Autism Proceeding that have occurred since my last Update, dated October 28, 2004. I note that counsel for both parties and I have continued to work diligently on the Proceeding during that time period. An "in-person" status conference involving numerous petitioners' counsel was held on November 10, 2004; unrecorded telephonic status conferences were held on November 23, December 6, and December 20, 2004;<sup>1</sup> and, as will be detailed below, an evidentiary hearing was held on November 1, 2004.

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<sup>1</sup>Counsel participating in those conferences and the hearing included Michael Williams, John Kim, Thomas Powers, and Ghada Anis for petitioners, along with Vincent Matanoski and Mark Raby for respondent.

### ***A. Number of cases***

At this time, approximately 4,500 petitions in autism cases have been filed, and more than 4,300 remain pending, stayed (at the petitioners' own request) until the conclusion of the Omnibus Autism Proceeding.<sup>2</sup> Additional petitions continue to be filed regularly.

### ***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 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 since then many thousands of pages of additional material have been copied from government files and supplied to petitioners. At this point, the respondent has now substantially complied with all of the petitioners' initial set of Requests for Production, except for the ongoing production discussed at point 2 below and the items concerning finished and ongoing studies mentioned at point 4 below. (By my informal count, the total number of pages of documents provided by respondent to the petitioners (not counting the material available via website) now approximates 164,000 pages.)

#### ***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, respondent submitted to the Petitioners' Steering Committee (hereinafter "the Committee") a sixth portion (3770 pages) of the Food and Drug Administration (FDA) file that pertains to the Wyeth/Lederle DTaP vaccine, along with a fourth portion of the Aventis DTaP file (1000 pages), and the first portion of the Merck HIB conjugate file (12,000 pages). Prior to that, large portions of the files for the Merck MMR combined vaccine, the Merck mumps vaccine, the Merck measles vaccine, the Merck rubella vaccine, the Merck hepatitis B vaccine, the GlaxoSmithKline hepatitis B vaccine, the North American Healthcare DTaP vaccine, and the Aventis HIB conjugate vaccine were submitted to the Committee. And the

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<sup>2</sup>Almost all of the cases that are no longer pending were voluntarily dismissed or withdrawn by the petitioners; in most of those cases, the dismissal was due to the fact that, inadvertently, a second petition had been filed pertaining to the same autistic child.

files with respect to several additional vaccines are continuing to move at various stages through the arduous process toward disclosure.<sup>3</sup>

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

As indicated in previous Autism Updates, the parties have been in disagreement concerning the issue of production of certain materials from government files, particularly 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, 2004, filed a “Motion to Compel,” requesting that I order respondent both to produce certain documents and to provide a witness from the National Institute of Health for deposition. The motion seeks, *inter alia*, documents relating to (1) the TSA; (2) other completed and published studies; and (3) studies in progress.

Respondent filed a written response to that motion (into the *Taylor* file) on May 14, 2004, and the Committee filed a reply brief on June 7, 2004. Two evidentiary hearings concerning that motion have been held on September 23, 2004, and November 1, 2004. At the conclusion of the second hearing, counsel for both parties and I conferred informally to discuss a proposal submitted by respondent’s counsel to resolve outstanding discovery issues regarding the material respondent will voluntarily provide to the committee. Since that time, counsel for the parties have made progress toward narrowing the disputed issues, as reported in status conferences held on November 23, December 6, and December 20, 2004. Counsel will report their progress in narrowing the issues by the next status conference, to be held on January 4, 2005. Counsel are hopeful that their discussions will result in resolution of nearly all discovery issues. After that, I will promptly resolve any remaining unresolved discovery issues.

#### ***C. Judicial conference and “in-person” status conference***

I note that a large number of Vaccine Act attorneys with pending autism cases participated in the U.S. Court of Federal Claims’ annual judicial conference on November 9 and 10, 2004, in Washington, D.C. During the afternoon of November 9 there were two special panels devoted to the topic of “causation-in-fact” issues in Vaccine Act cases. Then, on November 10, I conducted an in-person status conference concerning the Omnibus Autism Proceeding, with participation by several dozen attorneys who have pending autism cases.

On behalf of the entire court, I extend the court’s thanks to those Vaccine Act attorneys for their participation in those events.

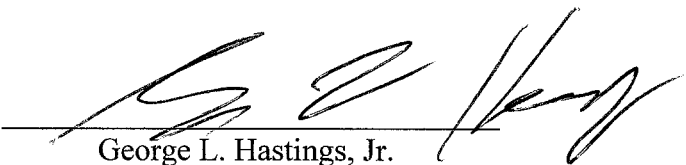
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<sup>3</sup>I note that while the Committee’s discovery *requests* have been filed into the Autism Master File, the respondent’s discovery *responses* have been filed into the file of an individual autism case, *Taylor v. HHS*, No. 02-699V. The latter 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. (See discussion in my Autism Update filed on June 23, 2004, pp. 4-6.)

***D. Future proceedings***

As indicated in my previous Updates, the general plan for the Omnibus Autism Proceeding is that as soon as the Committee is done with its discovery process, both sides will file expert reports, and then I will conduct an evidentiary hearing concerning the general causation issue. Obviously, the discovery process has taken longer than anticipated. However, it is the strategic decision of the Committee to pursue further discovery before presenting the petitioners' causation case. While I am eager to proceed to the presentation of the petitioners' causation case, I will leave this strategic decision to the Committee. If the Committee believes that it will be of advantage to the autism petitioners that the Committee pursue additional discovery before presenting that case, I will defer to the Committee. My role, instead, will be assist in facilitating the discovery process in any way that I can, to promptly resolve any discovery disputes between the parties when such disputes are presented to me, and to be ready to promptly hear and rule upon the petitioners' causation case as soon as the petitioners are ready to present it.<sup>4</sup>

The next status conference in the Omnibus Autism Proceeding is scheduled for January 4, 2005.

  
George L. Hastings, Jr.  
Special Master

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<sup>4</sup>I note, as I have in the past, that it is up to each individual petitioner to determine whether to defer proceedings concerning his or her own case pending the completion of the Omnibus Autism Proceeding. If an individual petitioner has proof of causation in his own case that he wishes to put before a special master at any time, that petitioner will be afforded a prompt hearing. Or, a petitioner whose petition has been pending for 240 days has the option of electing to withdraw from the Program under the procedure of 42 U.S.C. § 300aa-21(b), during the 30-day period after I issue the notice required under 42 U.S.C. § 300aa-12(g).