

**ORIGINAL**  
**In the United States Federal Claims**

**OFFICE OF SPECIAL MASTERS**  
**(Filed: May 16, 2006)**

<b>FILED</b>
MAY 16 2006
O S M 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--MAY 16, 2006**

This Update describes a number of recent developments in the Omnibus Autism Proceeding that have occurred since my last Update, dated December 22, 2005. Unrecorded telephonic status conferences were held on January 19, February 16, March 16, April 12, and May 10, 2006.

*A. Number of cases*

At this time, nearly 5,100 petitions in autism cases have been filed, and about 4,750 remain pending, stayed (at the petitioners' own requests) until the conclusion of the Omnibus Autism Proceeding.<sup>1</sup> Additional petitions continue to be filed regularly.

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<sup>1</sup>Many of the cases that are no longer pending were voluntarily dismissed or withdrawn by the petitioners; in most of those cases, the dismissal was due to the fact that, inadvertently, a second petition had been filed pertaining to the same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. A number of other cases have been dismissed by me because they were not timely filed.

## ***B. Discovery issues***

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 note certain new developments in the discovery area.

### ***1. General progress concerning petitioners' discovery requests***

As reported previously, petitioners have made two extensive discovery requests for materials from government files, and as a result many thousands of pages of material have been copied from government files and supplied to petitioners. At this point, all of the petitioners' discovery requests have been resolved, except for the ongoing production discussed at point 2 below and the ongoing procedures discussed at point 3 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 212,000 pages.

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

One category of documents requested, pursuant to petitioners' original 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, and is now very near completion. In recent weeks, respondent submitted to the Petitioners' Steering Committee (hereinafter "the Committee") portions of the Food and Drug Administration (FDA) files that pertain to the Lederle HIB conjugate vaccine (3,171 pp.); the Lederle DTP/HIB conjugate vaccine (114 pp.); the Merck measles vaccine (381 pp.); the Merck rubella vaccine (270 pp.); the Aventis HIB conjugate vaccine (252 pp.); and the Lederle DT vaccine (72 pp.). Prior to that, other portions of the files for all of those vaccines were submitted, and files for the following additional vaccines were submitted: the Merck MMR combined vaccine, the Merck mumps vaccine, the Baxter/North American Healthcare DTaP vaccine, the Wyeth/Praxis DPT vaccine, the Wyeth/Praxis DT vaccine, the Lederle DTP vaccine, the Lederle tetanus vaccine, the GlaxoSmithKline hepatitis B vaccine, the Aventis DT vaccine, the Wyeth/Praxis tetanus vaccine, the Aventis tetanus vaccine, the Aventis DTaP vaccine, the Merck HIB conjugate vaccine, the Merck hepatitis B vaccine, the Wyeth/Lederle DTaP vaccine, and the Aventis DTP vaccine.

With respect to a few of the 22 vaccine files noted above, small additional portions of the files are continuing to move through the final stages toward disclosure. The parties anticipate that very soon, this process will be complete.<sup>2</sup>

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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

### ***3. Discovery pursuant to resolution of “motion to compel”***

In the Update of April 14, 2005, I filed a Discovery Order resolving the petitioners’ “motion to compel production,” concerning petitioners’ second round of requested government discovery. The parties are now proceeding with the discovery procedures described in that Order, concerning the study known as the “Thimerosal Screening Analysis” (“TSA”). At the status conference held on March 16, 2006, I strongly urged the Committee to substantially *speed up* the pace of those efforts, and the Committee representatives assured me that they would do so.

I will continue to meet regularly with the parties, and closely monitor the progress of these efforts. If necessary, I will rule on any disputes that cannot be settled.

#### ***C. Filing of expert witness lists***

On February 16, 2006, the Committee filed its list of 16 expert witnesses that the Committee may present at the eventual hearing concerning the general causation issue.<sup>3</sup> The Committee has also submitted a *curriculum vitae* (“CV”) for each of those experts, and those CV’s will soon be posted on this court’s website.

Respondent’s list of expert witnesses is due to be filed on June 15, 2006.

#### ***D. Issue of time for filing expert reports***

As previously noted, in mid-2005 the Committee filed a motion seeking more time in which to file the *expert reports* on petitioners’ behalf in the Omnibus Autism Proceeding. The Committee requested that the due date for its expert reports be extended until the end of 2006. I filed a written ruling, addressing the request, on August 11, 2005. In that ruling, I deferred indefinitely the due date for the petitioners’ expert reports, but I stated that the petitioners would need to file a statement from an *expert*, giving the *expert’s* view as to whether it is necessary to wait until late 2006 to file the expert reports.

The Committee filed such an expert report on January 31, 2006. After reviewing that report, I issued a second ruling addressing the issue of the due date for the petitioners’ expert reports. As the petitioners requested, I deferred the due date until December 31, 2006. My reasoning for granting the request is detailed in that ruling, which was filed on April 21, 2006, and is posted on this court’s website.

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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.)

<sup>3</sup>One Committee representative cautioned, however, that it is likely that only *some* of those experts, perhaps 6 to 8, will actually testify at the hearing.

### ***E. Judicial conference and Autism-related activities***

The U.S. Court of Federal Claims will host its annual judicial conference on October 25, 2006, in Washington, D.C. Vaccine Act attorneys should be aware that the Office of Special Masters (OSM) is scheduling certain Vaccine Act-related and Autism-related activities in conjunction with that judicial conference.

Specifically, I will conduct an “in-person” status conference concerning the Omnibus Autism Proceeding. Any attorney with a pending autism case will be invited to participate in that status conference, with ample time provided for asking questions. Further, the Petitioners’ Steering Committee in the Omnibus Autism Proceeding is considering whether to conduct its own meeting in conjunction with the judicial conference. Finally, the OSM will also present a program devoted to “causation-in-fact” issues in Vaccine Act proceedings in general (not specific to the autism cases).

In the following months I will be working with the attorneys in the Omnibus Autism Proceeding to finalize details with respect to the Autism-related activities, and the OSM will be working to finalize details with respect to the above-described “causation-in-fact” program. I will post further details on the Omnibus Autism Proceeding portion of the court’s website. In addition, the court’s website will also soon be posting general information concerning the judicial conference.

### ***F. Planning for general causation hearing***

As indicated in my previous Updates, the general plan for the Omnibus Autism Proceeding is that once the Committee is done with its discovery process, both sides will file expert reports, and then I will conduct an evidentiary hearing (or hearings) concerning the “general causation issue.” At our regular conferences, counsel and I have continued to discuss the issue of the format, procedures, etc., for such an evidentiary hearing or hearings. A couple of points that we recently discussed are worthy of mention here.

First, I note that Committee representatives have explained that Committee members are considering whether to divide what we have been calling the “general causation issue” into *more than one* issue. Specifically, the Committee may propose *separate* hearings concerning (1) the issue of whether thimerosal-containing vaccines can cause autism, and (2) the issue of whether MMR vaccines can cause autism.

Second, I note that Committee representatives have been working on a written proposal addressing issues concerning the general causation hearing or hearings. The Committee hopes to file such proposal within the next several weeks.

### ***G. Future proceedings***

I will continue to meet regularly with counsel for both the Committee and respondent, monitoring the discovery process and working toward the goal of moving the Proceeding to

completion at the earliest date that is reasonable under all the circumstances.<sup>4</sup> I will continue to issue these Autism Updates describing the process. The next status conference in the Omnibus Autism Proceeding is scheduled for June 22, 2006.



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 or her own case that the petitioner 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).