

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

OFFICE OF SPECIAL MASTERS  
(Filed: December 22, 2005)

DEC 22 2005  
OSM  
U.S. COURT OF  
FEDERAL CLAIMS  
AUTISM MASTER FILE

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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. \*  
\*\*\*\*\*

**AUTISM UPDATE--DECEMBER 22, 2005**

This Update describes a number of recent developments in the Omnibus Autism Proceeding that have occurred since my last Update, dated September 29, 2005. Unrecorded telephonic status conferences were held on October 25 and December 16, and an "in person" status conference, involving numerous petitioners' attorneys, was held in Philadelphia on November 4, 2005, in conjunction with this court's annual judicial conference.

**A. Number of cases**

At this time, more than 5,000 petitions in autism cases have been filed, and more than 4,700 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Many of the cases that are no longer pending were voluntarily dismissed or withdrawn by the petitioners; in most of those cases, the dismissal was due to the fact that, inadvertently, a second petition had been filed pertaining to the same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 208,000 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 Aventis tetanus vaccine (6 pp.); Lederle HIB conjugate vaccine (157 pp.); the Lederle DTP/HIB conjugate vaccine (3,198 pp.); Aventis DTaP vaccine (231 pp.); the Merck HIB conjugate vaccine (749 pp.); the Merck hepatitis B vaccine (1,443 pp.); the Wyeth/Lederle DTaP vaccine (5,401 pp.); and the Aventis DTP vaccine (36 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 Merck measles vaccine, the Merck rubella vaccine, the Baxter/North American Healthcare DTaP vaccine, the Aventis HIB conjugate vaccine, the Lederle DT 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; and the Wyeth/Praxis tetanus 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>

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

In the Update of April 28, 2005, I described the resolution of the petitioners’ “motion to compel production” concerning petitioners’ second round of requested government discovery. The parties are now proceeding with the discovery procedures described. It appears that, in general, the procedures for providing the committee with access to the pre-2000 data concerning the “Thimerosal Screening Analysis” (“TSA”) study have proceeded satisfactorily. At the conference on November 4, 2005, however, I was informed by Committee members that some difficulties have arisen in the course of the committee’s attempt to access certain post-2000 data from the Vaccine Safety Datalink relating to the TSA. Respondent’s counsel have asserted that such data was not covered by the procedures set forth in my Discovery Order dated April 14, 2005. Nevertheless, the parties are continuing to work to see if this matter can be resolved between them.

I will continue to meet regularly with the parties in an effort to solve these discovery problems that have arisen, or, if necessary, to rule myself on any disputes that cannot be settled.

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

As previously noted, earlier this year, 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 late 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 provided that by January 31, 2006, petitioners must designate who their experts will be, and must also file at that time 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 representatives have informed me that the Committee will, in fact, be complying with those directives by the due date of January 31, 2006.

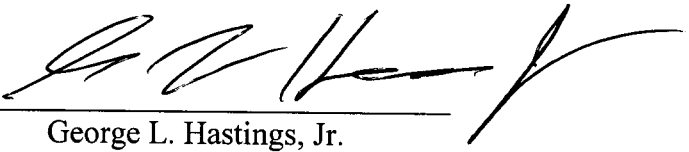
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<sup>2</sup>I note that while the Committee’s discovery *requests* have been filed into the Autism Master File, the respondent’s discovery *responses* have been filed into the file of an individual autism case, *Taylor v. HHS*, No. 02-699V. The latter 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. (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 once 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. As indicated above, while the discovery process now appears to be nearing completion, the Committee wishes to delay the filing of expert reports for an additional time period, in anticipation of the completion of a number of studies that may be relevant to the general causation issue. As also indicated, I will continue to monitor this process carefully, in order to give the Committee the time that it reasonably needs, but also move the Proceeding to completion at the earliest date that is reasonable under all the circumstances.<sup>3</sup>

The next status conference in the Omnibus Autism Proceeding is scheduled for January 19, 2006.

  
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George L. Hastings, Jr.  
Special Master

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<sup>3</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).