

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTER
(Filed: September 7, 2006)

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U.S. COURT OF
FEDERAL CLAIMS

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

AUTISM UPDATE--SEPTEMBER 7, 2006

This Update describes a number of recent developments in the Omnibus Autism Proceeding that have occurred since my last Update, dated May 16, 2000. *The most important development, the setting of a date for the evidentiary hearing concerning the general causation issue, will be discussed at part D of this update, below.* Unrecorded telephonic status conferences were held on June 22, July 27, and August 17, and September 6, 2006.

A. Number of cases

At this time, more than 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.¹ Additional petitions continue to be filed, although at a considerably reduced rate.

¹Many of the cases that are no longer pending were voluntarily dismissed or withdrawn by the petitioners; in many of those cases, the dismissal was due to the fact that, inadvertently, a second petition had been filed pertaining to the same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 216,000 pages.

2. The vaccine license application files

One category of documents requested, pursuant to petitioners' original Requests for Production Nos. 10 and 12, involves the Food and Drug Administration (FDA) files that pertain to 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. Soon after the last update, respondent submitted to the Petitioners' Steering Committee (hereinafter "the Committee") large portions of the FDA files pertaining to the Merck hepatitis B vaccine (3,007 pages) and the Merck mumps vaccine (407 pages). Prior to that, other portions of the files for those vaccines were submitted, and files for the following additional vaccines were submitted: the Merck MMR combined 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 Wyeth/Lederle DTaP vaccine, the Aventis DTP vaccine, Lederle HIB conjugate vaccine, the Lederle DTP/HIB conjugate vaccine, the Merck measles vaccine, the Merck rubella vaccine, the Aventis HIB conjugate vaccine, and the Lederle DT vaccine.

With respect to a few of the 22 vaccine files noted above, several small batches of additional pages have been disclosed within the last few days, and a few more batches are anticipated to be disclosed shortly.² That disclosure should complete the discovery process with respect to the vaccine license files.

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

On 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 have proceeded with the discovery procedures described in that Order, concerning the study known as the “Thimerosal Screening Analysis” (“TSA”). At the most recent status conference, the Committee informed me that the Committee’s experts have, in fact, obtained access to certain data concerning the TSA, and are in the process of analyzing such data.

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.³ The Committee has also submitted a *curriculum vitae* (“CV”) for each of those experts, and those CV’s are posted on this court’s website.

Respondent’s list of expert witnesses was filed on May 15, 2006, with an amendment on July 27, 2006.

D. Dates and planning for general causation hearing

On July 18, 2006, the Committee filed a proposal for scheduling the hearing concerning the “general causation issue”—*i.e.*, the issue of whether thimerosal-containing vaccines and/or MMR vaccines can cause autism and/or similar disorders, and, if so, in what circumstances. The Committee’s proposal, which is posted on the Autism Proceeding page of this court’s website, contains a number of suggestions by the Committee concerning procedures for the general causation hearing. The parties and I have already engaged in lengthy discussions concerning this proposal, during the status conferences held on July 27, August 17, and September 6, 2006. The most important news is that the Committee has proposed that the general causation hearing be held in June

²I 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.)

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

of 2007, and that proposal is acceptable to the respondent and to myself. Specifically, our plan at this time is for an evidentiary hearing lasting two to three weeks, commencing on June 11, 2007.

In conjunction with the scheduled hearing date of June 2007, the Committee has requested a change in the due date for the Committee's expert reports, which is currently set for December 31, 2006. The Committee has requested that the due date be extended to February 16, 2007, and, after discussion at our status conferences, I have agreed to that proposed extension.⁴ The respondent's expert reports will be due 60 days later, on April 17, 2007.

Another important item is that the Committee has determined that it will *not* seek 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. The Committee views these as closely related topics, and, at the 2007 hearing, the Committee will present its evidence concerning *both* topics.

Other procedures and details concerning the general causation hearing are still under discussion. I will be meeting regularly with the parties to iron out these details as soon as possible.

E. Judicial conference and Autism-related activities

As indicated in my previous Update, 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, at 10:00 a.m., 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 will be conducting its own meeting from 8:30 a.m. to 9:45 a.m. prior to the "in-person" status conference. Finally, during the afternoon, the OSM will present a program devoted to "causation-in-fact" issues in Vaccine Act proceedings *in general* (not specific to the autism cases). This program will involve law professors and judges of both the U.S. Court of Federal Claims and the U.S. Court of Appeals for the Federal Circuit, who will discuss the general process of how those courts approach causation issues in Vaccine Act cases.

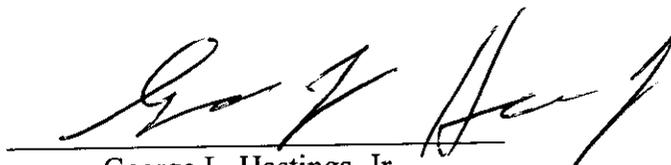
I will soon be placing into the Autism Master File, available on this court's website, a supplemental notice providing further details with respect to the Autism-related activities and the above-described "causation-in-fact" program to be presented by the OSM. In addition, the court's

⁴While granting this extension, I stressed at the status conference on August 17 that, in order for the hearing to actually take place as scheduled in June of 2007, each party's expert reports will need to *clearly* and *comprehensively* set forth that party's theory and evidence concerning the general causation issue.

website will also soon be posting registration information concerning the judicial conference. I look forward to seeing many Vaccine Act attorneys at that conference.

F. Future proceedings

As noted above, I will continue to meet regularly with counsel for both the Committee and respondent, to finalize details for the general causation hearing. I will continue to issue these Autism Updates describing the process. The next status conference in the Omnibus Autism Proceeding is scheduled for October 2, 2006.

A handwritten signature in black ink, appearing to read "George L. Hastings, Jr.", written over a horizontal line.

George L. Hastings, Jr.
Special Master