

In the United States Court of Federal Claims

ORIGINAL

OFFICE OF SPECIAL MASTERS

(Filed: June 27, 2005)

FILED
JUN 27 2005
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-JUNE 27, 2005

This Update describes a number of recent developments in the Omnibus Autism Proceeding that have occurred since my last Update, dated April 28, 2005. 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 May 4, June 2, and June 23, 2005.

A. Number of cases

At this time, approximately 4,800 petitions in autism cases have been filed, and about 4,500 remain pending, stayed (at the petitioners' own request) until the conclusion of the Omnibus Autism Proceeding. Additional petitions continue to be filed regularly.

1Counsel participating in those conferences included Thomas Powers and Ghada Anis for petitioners, along with Vincent Matanoski and Mark Raby for respondent.

2Many of the cases that are no longer pending were voluntarily dismissed or withdrawn by the petitioners; in most of those cases, the dismissal was due to the fact that, inadvertently, a second petition had been filed pertaining to the same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

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 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, nearly 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 196,000 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 at last nearing 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 DTP vaccine (463 pp.); the Lederle tetanus vaccine (472 pp.); the GlaxoSmithKline hepatitis B vaccine (2,563 pp.); the Aventis DT vaccine (1,131 pp.); the Wyeth tetanus vaccine (566 pp.); and the Lederle DT vaccine (3,135 pp.). Prior to that, large portions of the files for the following vaccines were submitted: the Merck MMR combined vaccine, the Merck mumps vaccine, the Merck measles vaccine, the Merck rubella vaccine, the Merck hepatitis B vaccine, the North American Healthcare DTaP vaccine, the Aventis HIB conjugate vaccine, the Aventis DTaP vaccine, the Merck HIB conjugate vaccine, the Aventis DTP vaccine, the Wyeth/Lederle DTaP vaccine, the Wyeth/Praxis DPT vaccine, the Wyeth/Praxis DT vaccine, the Lederle HIB conjugate vaccine, and the Lederle DPT/HIB conjugate vaccine. Finally, the files with respect to just a few additional vaccines are

dismissed by me because they were not timely filed.

continuing to move through the final stages of the arduous process toward disclosure. The parties anticipate that within a few weeks, this process will be complete.³

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

In the Update of April 28, 2005, I described the recent 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.

C. 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 originally anticipated. However, it has been the strategic decision of the Committee to pursue discovery before presenting the petitioners’ causation case. While I am eager to proceed to the presentation of the petitioners’ causation case, I have left this strategic decision to the Committee.

As explained above, the process of obtaining discovery from respondent appears to be nearing completion. With respect to the vaccine license application files (see part B(2) above), we are close to the end of that arduous process. And, as explained in my Update of April 28, 2005, we have recently achieved a resolution of the petitioners’ more recent request for discovery from government files, although some work remains to be done by the parties in order to implement that resolution.

Therefore, at my request, the Committee on June 13, 2005, made a written filing explaining the Committee’s intentions concerning future proceedings. In that document, the Committee asserted that a number of studies relevant to the general autism causation issue are still underway, and stated that the Committee wishes to defer the filing of the Committee’s expert reports concerning

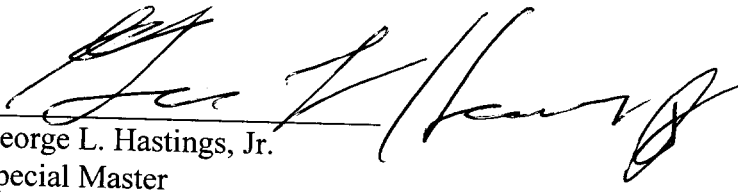
³I note that while the Committee’s discovery *requests* have been filed into the Autism Master File, the respondent’s discovery *responses* have been filed into the file of an individual autism case, *Taylor v. HHS*, No. 02-699V. The latter file is available to autism petitioners and their counsel, via 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.)

that causation issue until after the completion of those studies. The Committee would like to wait until at least late 2006, and possibly later, before filing the Committee's expert reports.

The respondent will file a response to that Committee filing by July 12, 2005, and we will discuss the matter at the next status conference in the Omnibus Autism Proceeding.

Meanwhile, as previously noted, I remain ready to assist in facilitating the remaining information-gathering and expert-identification process in any way that I can, and to promptly hear and rule upon the petitioners' causation case as soon as the petitioners are ready to present it.⁴

The next status conference in the Omnibus Autism Proceeding is scheduled for July 15, 2005.


George L. Hastings, Jr.
Special Master

⁴I 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).