

In the United States Court of Federal Claims

ORIGINAL

OFFICE OF SPECIAL MASTERS

(Filed: April 28, 2005)

FILED
APR 28 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--APRIL 28, 2005

This Update describes a number of recent developments in the Omnibus Autism Proceeding that have occurred since my last Update, dated February 24, 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 March 7, March 22, and April 6, 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2Many of the cases that are no longer pending were voluntarily dismissed or withdrawn by the petitioners; in most of those cases, the dismissal was due to the fact that, inadvertently, a second petition had been filed pertaining to the same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 dismissed by me because they were not timely filed.

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' extensive discovery requests, except for the ongoing production discussed at point 2 below and the items 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 188,000 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 (694 pp.); the Wyeth/Praxis DPT vaccine (222 pp.); the Wyeth/Praxis DT vaccine (505 pp.); the Lederle HIB conjugate vaccine (4396 pp.); and the Lederle DPT/HIB conjugate vaccine (2208 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 GlaxoSmithKline 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, and the Wyeth/Lederle DTaP vaccine. Finally, the files with respect to just a few additional vaccines are 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

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.)

3. Motion to compel discovery from respondent

As indicated in previous Autism Updates, the parties had 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 initial 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 sought, *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 were held on September 23, 2004, and November 1, 2004. At the conclusion of the second hearing, however, counsel for both parties and I conferred informally to discuss a proposal submitted by respondent’s counsel to resolve outstanding discovery issues. Since that time, counsel for the parties have made progress toward narrowing the disputed issues, as reported in the many status conferences held since then. In recent weeks, the parties reached an agreement that has resulted in resolution of all of petitioner’s outstanding discovery requests. On April 8, the Committee filed into the Autism Master File a written document reflecting that agreement. Some of the Committee’s outstanding discovery requests were withdrawn, while the parties proposed a Discovery Order for my signature which would provide the Committee with some of the other discovery items desired. I signed and filed the Discovery Order, as proposed by the parties, into both the Autism Master File and the *Taylor* file on April 14, 2005.

I salute all counsel for both sides for their hard work in achieving this resolution of the Committee’s motion to compel.

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.

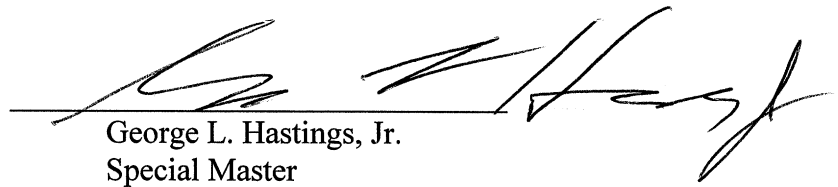
As explained above, the process of obtaining discovery from respondent appears to be nearing completion. With respect to the vaccine license application files (see part B(2) above), we are close to the end of that arduous process. And, as also explained above (part B(3)), we are also close to final resolution of the petitioners’ more recent request for discovery from government files.

With the above-described recent Discovery Order in place, the parties are in position for the Committee to obtain from respondent the remaining discovery items.

Therefore, at my request, the Committee has been working on a written filing explaining the Committee's intentions concerning future proceedings. Specifically, that filing will state the Committee's position concerning (1) what additional procedures the Committee desires to complete before the Committee files its expert reports, and (2) *when* the Committee estimates that it will be able to file those expert reports. At the next status conference, the Committee's representatives will explain the Committee's progress toward making that filing.

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 May 4, 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).