



ORIGINAL

In the United States Court of Federal Claims

FILED
OCT 28 2004
U.S. COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

(Filed: October 28, 2004)

IN RE: CLAIMS FOR VACCINE INJURIES *
RESULTING IN AUTISM SPECTRUM *
DISORDER OR A SIMILAR *
NEURODEVELOPMENTAL DISORDER *

AUTISM MASTER FILE

VARIOUS PETITIONERS, *

v. *

SECRETARY OF HEALTH AND *
HUMAN SERVICES, *

Respondent. *

AUTISM UPDATE--OCTOBER 28, 2004

This Update describes a number of recent developments in the Omnibus Autism Proceeding that have occurred since my last Update, dated August 30, 2004. 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 September 15 and October 18, 2004,¹ and, as will be detailed below, an evidentiary hearing was held on September 23, 2004.

A. Number of cases

At this time, more than 4,400 petitions in autism cases have been filed, and about 4,250 remain pending, stayed (at the petitioners' own request) until the conclusion of the Omnibus Autism Proceeding.² Additional petitions continue to be filed regularly.

¹Counsel participating in those conferences and the hearing included Michael Williams, John Kim, Thomas Powers, Ghada Anis for petitioners, along with Vincent Matanoski and Mark Raby for respondent.

²Almost all of the cases that are no longer pending were voluntarily dismissed or withdrawn by the petitioners; in most of those cases, the dismissal was due to the fact that, inadvertently, a

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 initial 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' initial set of Requests for Production, except for the ongoing production discussed at point 2 below and the items concerning finished and ongoing studies mentioned at point 4 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 147,000 pages.)

2. The vaccine license application files

One category of documents requested, pursuant to petitioners' 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. Since my last Update, respondent submitted to the Petitioners' Steering Committee (hereinafter "the Committee") a third portion (1781 pages), a fourth portion (2696 pages), and a fifth portion (232 pages) of the Food and Drug Administration (FDA) file that pertains to the Wyeth/Lederle DTaP vaccine, along with the first portion of the file pertaining to the Aventis HIB conjugate vaccine (4,045 pages). Prior to that, large portions of the files for 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, and the Aventis DTaP vaccine were submitted to the Committee. And the files with respect to several additional vaccines are continuing to move at various stages through the arduous process toward disclosure.³

second petition had been filed pertaining to the same autistic child.

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. Organizational depositions

As previously reported, the Committee has filed a request to depose certain government officials. Two representatives of the Centers for Disease Control and Prevention (“CDC”) were deposed on December 9, 2003; a representative of the Agency For Toxic Substances and Disease Registry was also deposed on December 9, 2003; and a FDA official was deposed on May 27, 2004. The respondent has declined, however, to provide an official of the National Institutes of Health (“NIH”) for deposition, however, and the Committee has recently requested that I order the respondent to provide such an official for deposition as part of the “motion to compel” discussed immediately below.

4. Motion to compel discovery from respondent

As indicated in previous Autism Updates, the parties have been in disagreement concerning the issue of production of materials relating to certain studies, particularly those related to one recently-completed study known as the “Thimerosal Screening Analysis” (“TSA”). After extensive 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 NIH for deposition. The motion seeks, *inter alia*, documents relating to (1) the TSA; (2) other completed and published studies; and (3) studies in progress. It also seeks documents from the vaccine license application files in addition to those that have been disclosed as discussed above in paragraph (B)(2) of this update.

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. An evidentiary hearing concerning that motion was originally tentatively scheduled to be held in June, but, as explained in my Autism Update filed on June 23, 2004, that hearing had to be delayed. On September 23, 2004, petitioners’ counsel presented the testimony of two expert witnesses, Dr. Harland D. Austin and Ms. Cathy Lally, in support of their motion. A second evidentiary hearing has been scheduled for November 1, 2004, at which I will hear responsive testimony from respondent’s experts.

C. Judicial Conference

As noted in the previous Update, the U.S. Court of Federal Claims, the court whose judges review the special masters’ decisions in Vaccine Act cases, is hosting its annual judicial conference on November 9 and 10, 2004, in Washington, D.C. The general purpose of the conference, like all judicial conferences, is to provide a forum interaction between the courts’ judges and its bar members. The Vaccine Act special masters will be participating in the conference as well as the court’s judges. In an effort to make this particular conference especially relevant to Vaccine Act attorneys, during the afternoon of November 9 there will be two special panels devoted to the topic of “causation-in-fact” issues in Vaccine Act cases. Then, on the morning of November 10 at 10:00 a.m., I will be conducting an in-person status conference concerning the Omnibus Autism

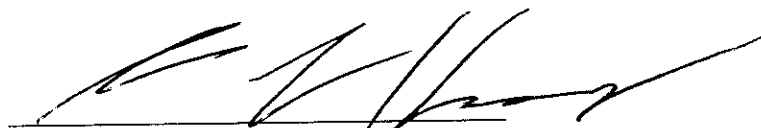
Proceeding. Any attorney with a pending autism case will be invited to participate in that status conference, with ample time provided for asking questions.

I hereby once again cordially invite all attorneys with pending autism claims to participate in the Omnibus Autism Proceeding status conference on November 10.

D. 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 anticipated. However, it is the strategic decision of the Committee to pursue further discovery before presenting the petitioners' causation case. While I am eager to proceed to the presentation of the petitioners' causation case, I will leave this strategic decision to the Committee. If the Committee believes that it will be of advantage to the autism petitioners that the Committee pursue additional discovery before presenting that case, I will defer to the Committee. My role, instead, will be assist in facilitating the discovery process in any way that I can, to promptly resolve any discovery disputes between the parties when such disputes are presented to me, and to be ready to promptly hear and rule upon the petitioners' causation case as soon as the petitioners are ready to present it.⁴

The next evidentiary hearing in the Omnibus Autism Proceeding is scheduled for November 1, 2004, and the next status conference is scheduled for November 22, 2004.



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).