In the United States Court of Federal Claims

ORIGINAL

OFFICE OF SPECIAL MASTERS

(Filed: March 9, 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--MARCH 9, 2004

This Update describes a number of recent developments in the Omnibus Autism Proceeding that have occurred since my last Update, dated January 12, 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 January 15, February 5, February 12, and February 17, 2004,[1] while counsel were also working extensively with one another throughout this period, in order to keep the Proceeding moving forward.

A. Number of cases

At this time, more than 3700 petitions in autism cases have been filed, and are stayed pending the conclusion of the Omnibus Autism Proceeding. Additional petitions continue to be filed regularly.

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[1]Counsel participating in those conferences included Michael Williams, Thomas Powers, and Ghada Anis for petitioners; Vincent Matanoski and Mark Raby for respondent.

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 petitioners' counsel have analyzed that data. Thousands of pages of additional material has been supplied to petitioners since December of 2002, and petitioners' counsel have analyzed those documents as well. At this point, the respondent has now finished compliance with all of the petitioners' initial set of Requests for Production, except for the items discussed at points 2 and 3, immediately following.

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, voluminous additional portions of the Food and Drug Administration (FDA) files pertaining to the GlaxoSmithKline hepatitis B vaccine, the North American Healthcare DTaP vaccine, the Merck rubella vaccine, and the Merck hepatitis B vaccine have been submitted to the Petitioners' Steering Committee (hereinafter "the Committee"). Prior to that, the bulk of the files for the Merck MMR combined vaccine, the Merck mumps vaccine, and the Merck measles vaccine were submitted to the Committee. And the files with respect to many additional vaccines are continuing to move at various stages through the arduous process toward disclosure.[2]

3. Issue of access to study data

As indicated in previous Autism Updates, the parties have been in disagreement concerning the issue of production of materials relating to certain studies. As previously indicated, the parties have chiefly focused their efforts on the goal of providing the Committee with access to the data set of one particular study, known as the "Thimerosal Screening Analysis" ("TSA"). As also previously

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[2]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.

indicated, at times the parties have reported that they were close to settling this issue, but at the most recent conferences they indicated that a fundamental dispute remains. The Committee recently supplied to respondent a notice of its latest demands for materials concerning the TSA. The parties have agreed that the Committee will file by March 8, 2004, a motion requesting that I compel respondent to provide access to the data set. Respondent will respond by April 23, and the Committee will reply by May 7. The parties have set aside the week of June 7 for an evidentiary hearing concerning the dispute.

The parties have also recently focused on a second recently-published study, known as the Stehr-Green study. The Committee has submitted a request for production of documents in the files of the Centers for Disease Control and Prevention ("CDC") relating to that study, and respondent's representatives have located certain materials concerning the study. The parties are still working to resolve the matter, but the Stehr-Green study may also become an additional subject of the above-described "motion to compel." Committee representatives have also indicated that additional issues relating to ongoing studies may also be subjects of the motion to compel.

4. Organizational depositions

As previously reported, on September 30, 2003, the Committee filed a request to depose representatives of the CDC, and three representatives of the CDC were in fact deposed on December 9, 2003. As also previously reported, on December 17, 2003, the Committee filed requests to depose officials of the FDA and the National Institutes of Health ("NIH"). The respondent has recently agreed to provide an FDA official for deposition, and the parties are trying to agree on a deposition date. The respondent has declined to provide an NIH official for deposition. The issue of depositions may also be a subject of the above-described motion to compel.

5. Non-party discovery

As previously noted, on October 29, 2003, the Committee filed a revised request for authorization to issue a subpoena to the vaccine manufacturer, Merck and Company, for certain documents pertaining to that company's vaccination for Hepatitis B, known as "Recombivax." That request has been discussed at a series of status conferences, with participation by counsel from Merck. The Committee has noted that it intends in the future to request subpoenas pertaining to other vaccine manufacturers, and therefore counsel for four other manufacturers--*i.e.*, Wyeth, Baxter, GlaxoSmithKline, and Aventis Pasteur--have requested to participate in the proceedings pertaining to Merck, and, without opposition from the Committee, I have permitted those counsel also to participate in the status conferences and briefing. As previously reported, the Committee, Merck, and the other vaccine manufacturers have filed a number of briefs relating to the Committee's request. Originally, oral argument concerning that matter was scheduled for January 6, 2004, then rescheduled for March 2, 2004.

In mid-February, however, the Committee announced that it intended to redirect its initial effort to obtain discovery from Merck. The Committee noted that while production of the FDA file

concerning the Merck *Recombivax vaccine* is still ongoing, the government's production of the FDA files concerning the Merck *MMR and measles vaccines* has already been completed. (See paragraph No. 2 at p. 2 above.) Therefore, the Committee has temporarily withdrawn its discovery request concerning the Merck *Recombivax* vaccine (reserving the right to reinstate that request in the future), and instead has submitted a request for documents from Merck concerning its *MMR* and *measles* vaccines. The participants have agreed to a briefing schedule concerning that discovery request, by which the Committee will file its documentation and argument supporting that request by March 22, Merck will respond by April 21, the Committee will reply by May 5, and oral argument will be held on May 26.

I note that the Committee's requests for discovery from the vaccine manufacturers raise issues that are complicated, difficult, and wholly new to the National Vaccine Injury Compensation Program. I am devoting, and will continue to devote, extensive efforts to these issues. Once the participants have completed the presentation of their arguments, I will promptly rule on the Committee's pending request pertaining to Merck. In the meantime, the parties and I will simultaneously be working upon the remaining issues with respect to the Committee's discovery requests from *respondent.*

It is, of course, unfortunate that these discovery disputes are delaying the progress of the Omnibus Autism Proceeding toward an eventual hearing concerning the petitioners' causation claims. 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 to assist in facilitating the discovery process in any way that I can, and to be ready to promptly hear and rule upon the petitioners' causation case as soon as the petitioners are ready to present it.

C. Future proceedings

The next status conference in the Omnibus Autism Proceeding is scheduled for March 15, 2004.

George L. Hastings, Jr.
Special Master