

In the United States Court of Federal Claims

A

OFFICE OF SPECIAL MASTERS

(Filed: January 12, 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 AND ORDER--JANUARY 12, 2004

This Update describes a number of recent developments in the Omnibus Autism Proceeding that have occurred since my last Update, dated November 7, 2003. I note that counsel for both parties and I have continued to work diligently on the Proceeding during that time period. Unrecorded status conferences were held on November 10, November 25, and December 19, 2003, 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 3500 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.

1Counsel participating in those conferences included Michael Williams, Kathleen Dailey, 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

Much 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 essentially 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. Recently, large portions of the Food and Drug Administration (FDA) files pertaining to the GlaxoSmithKline Hepatitis B vaccine, the North American Healthcare DTaP vaccine, and the Merck Hepatitis B vaccine were submitted to the Petitioners' Steering Committee (hereinafter "the Committee"). Previously, 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 "ongoing and proposed 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." As also previously indicated, at times they have reported that they were close to settling

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.

this issue, but at the most recent conference they indicated that a fundamental dispute remains. The Committee expects to file by mid-January a motion requesting that I compel respondent to provide access to the data set. The parties anticipate that an evidentiary hearing concerning the dispute will likely be necessary.

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, respondent has filed a response, and the parties are working to resolve the matter.

4. Organizational depositions

On September 30, 2003, the Committee filed an additional discovery request,³ seeking to depose representatives of the CDC. After considerable efforts, three representatives of the CDC were in fact deposed on December 9, 2003. On December 17, 2003, the Committee filed requests to depose officials of the FDA and the National Institutes of Health. The respondent will file responses to those requests in mid-January.

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. Merck and the other vaccine manufacturers filed briefs, in opposition to the Committee's request, on November 14 and December 3, 2003. The Committee filed a brief on December 10, 2003, and the vaccine manufacturers filed reply briefs on December 29 and 30, 2003. Originally, oral argument concerning the matter was scheduled for January 6, 2004, but at a status conference held on December 19, 2003, I informed the participants that to reasonably decide the issue, I would need additional information from both the Committee and Merck. I also suggested a possible compromise. The Committee and Merck, in response to my statements, both requested that the argument be postponed in order to give them an opportunity to consider my suggestions. They agreed that the next status conference be scheduled for January 15, 2004, to discuss whether a compromise can be reached, or, if not, to schedule procedures for taking additional evidence and argument concerning the issue.

³With that discovery request, the Omnibus Autism Proceeding has now moved into the "second round" of discovery, discussed in the initial general plan for the Proceeding.

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 Compensation Program. I am devoting, and will continue to devote, extensive efforts to these issues. If the parties are unable to settle their differences, I will promptly rule on the Committee's pending request pertaining to Merck, and any additional Committee requests, once the parties have had an opportunity to provide the information that I have requested. 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. Issue concerning "judgments"

As noted in previous Autism Updates, I have been considering the overall issue concerning when "judgments" should be entered in Vaccine Act cases. I issued a published ruling concerning this issue on November 26, 2003, in the case of *Currie v. Secretary of HHS*, No. 02-838V (published citation not yet available). On January 6, 2004, I placed that opinion into the Autism Master File, where it can be viewed on this court's website.

D. Issue of timeliness of petition filing

As noted in my last Autism Update, in several autism cases there are pending motions by respondent seeking dismissal on the ground that the petitions were not timely filed. On November 26, 2003, I published a ruling concerning one such case, *Wood v. Secretary of HHS*, No. 02-1317V (published citation not yet available). On January 6, 2004, I placed that opinion into the Autism Master File.

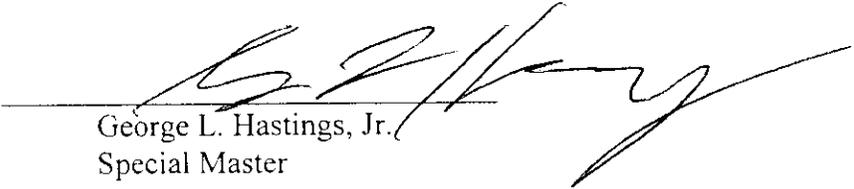
E. Filing records via compact disc

A committee, including a representative of the Petitioners' Steering Committee, a representative of respondent, and personnel from the Office of the Clerk of this court, recently developed a procedure by which, in autism cases, voluminous records could be filed with this court via compact disc rather than via a "paper copy." On December 16, 2003, I placed into the Autism Master File an order permitting the filing of records in autism cases via such method. In autism

cases in which the petitioners intend to file voluminous medical records, I strongly encourage the use of compact discs to file such records, as described in that order filed on December 16.

F. Future proceedings

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



George L. Hastings, Jr.
Special Master