

In the United States Court of Federal Claims

ORIGINAL

OFFICE OF SPECIAL MASTERS

(Filed: November 7, 2003)

FILED
NOV 7 2003
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 AND ORDER- -NOVEMBER 7, 2003

This Update describes a number of recent developments in the Omnibus Autism Proceeding that have occurred since the last Update dated September 24, 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 September 26, October 3, October 6, October 21, October 28, and November 3, 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 3350 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.

B. Discovery

1Counsel participating in those conferences included Michael Williams, Kathleen Dailey, Thomas Powers, and Ghada Anis for petitioners; Vincent Matanoski, Mark Raby, Linda Renzi, Traci Manning, and Ann Donohue for respondent.

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 more slowly, as detailed in my previous Autism Updates. The process of production of that material continues to move forward. Recently, the bulk of the Food and Drug Administration (FDA) file with respect to the Merck measles vaccine was submitted to the Petitioners' Steering Committee (hereinafter "the Committee"). Previously, the bulk of the files for the Merck MMR combined vaccine and the Merck mumps vaccine were submitted to the Committee. Large portions of the files pertaining to the Glaxo/SmithKline Hepatitis B vaccine, the North American Healthcare DtaP vaccine, and the Merck Hepatitis B vaccine will soon be submitted. And the files with respect to many additional vaccines are continuing to move at various stages through the arduous process toward disclosure.

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, they had chiefly focused their efforts on the goal of providing the Committee with pre-publication access to the data set of one particular study, known as the "Thimerosal Screening Analysis," but it was recently learned that the results of that study will in fact be published in early November of 2003, earlier than previously anticipated. The parties are currently working to see how they can enable the Committee to access the data promptly after the study is published.

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 Center for Disease Control and Prevention (“CDC”) relating to that study, respondent has filed a response,² and the parties are working to resolve the matter.

4. Organizational Depositions

The Committee has also recently filed an additional discovery request,³ seeking to depose a representative of the CDC. Respondent filed a response to that request on October 27 (again, into the file in *Taylor v. HHS*, No.02-699V). However, after discussion of that request at the status conferences held on October 28 and November 3, respondent sought and received permission to file a supplemental response on November 7, 2003. We will then further discuss the matter at a conference scheduled for November 10, 2003.

The Committee intends to later file a similar request for deposition of an FDA official.

5. Non-party discovery

On October 7, 2003, the Committee filed a 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 was discussed at status conferences on October 21 and October 28, 2003, with counsel from Merck participating in a portion of the latter conference. Merck’s counsel indicated that Merck opposes the request. On October 29, the Committee filed a revised request for subpoena authorization. On October 30, I filed an Order setting a briefing schedule concerning the request, with Merck and the Committee to file briefs between November 14 and December 15, and oral argument to follow soon thereafter. I will promptly rule on the request once briefing and argument are complete.

C. Issue of the proper date for issuing “§ 12(g)(1) notices”

As discussed in my Update of September 24, a controversy has arisen in the autism cases concerning when the special master should issue the notice pursuant to 42 U.S.C. § 300aa-12(g)(1) (hereinafter the “§ 12(g)(1) notice”), which notice triggers the right of a Vaccine Act petitioner to withdraw his petition pursuant to 42 U.S.C. § 300aa-21(b). On September 3, 2003, I filed, in the individual autism case of *Stewart v. Secretary of HHS*, No. 02-819V, an opinion ruling against the respondent’s proposed statutory interpretation concerning this controversy. (That published ruling was put into the Autism Master File by my Order of September 9, 2003, and thus can be accessed

²That response was filed into the file of the individual autism case of *Taylor v. HHS*, No. 02-699V, rather than into the Autism Master file.

³With that discovery request, the discovery request noted above for the Stehr-Green study, and the “non-party discovery” to be discussed immediately below, the Omnibus Autism Proceeding has now moved into the “second round” of discovery, discussed in the initial general plan for the Proceeding.

on this court's Internet website, along with all other materials filed in the Autism Master File, at www.uscfc.uscourts.gov/osm/osmautism.htm.) Further, at the status conference held on October 3, 2003, respondent's counsel indicated that respondent will not attempt at this time to obtain interlocutory appellate review of my ruling concerning this issue in the *Stewart* case. Accordingly, I am in the process of filing, in each autism case in which respondent filed a "Motion for Appropriate Relief" identical to respondent's Motion in *Stewart*, a denial of respondent's motion.

Of course, when I file a "§12(g)(1) notice" (also known as a "Formal Notice") in a case, that does *not* end the case, but merely gives the petitioner the *option* of withdrawing the petition if desired. As I have noted in such notices, I stress that the parties to the Omnibus Autism Proceeding and I are working diligently to resolve the general causation issues as quickly as possible. Regular updates on the progress of that proceeding will be available at the Office of Special Masters' page on the court's website. I encourage all of the autism petitioners to remain in the Program until the conclusion of the Omnibus Autism Proceeding, to see if that proceeding develops a theory of proof that might be applicable to this case.

D. Issue of "judgments"

As noted in a previous Autism Update, I and other special masters are considering the overall issue when "judgments" should be entered in Vaccine Act cases. To assist in this review, the parties to the Omnibus Autism Proceeding filed briefs concerning this topic on July 30, 2003, and August 22, 2003, respectively. I then requested the parties' views on additional points with respect to that general issue, and briefs concerning those points were recently filed.

I will soon file an opinion discussing this topic, in an individual autism case. I will place that opinion into the Autism Master File.

E. Issue of timeliness of petition filing

In several autism cases, there are pending motions by respondent seeking dismissal on the ground that the petitions were not timely filed. Such motions may be more complicated in autism cases than in previous Vaccine Act cases, due to the fact that in most of the autism cases it is alleged that the vaccinee was injured by a *series* of vaccinations, rather than a single vaccination. These motions have also been potentially made more complex by a recent ruling in *Setnes v. Secretary of HHS*, 57 Fed. Cl. 175 (2003). In one case in which a dismissal motion is pending, *Wood v. Secretary of HHS*, No. 02-1317V, I have invited the Petitioners' Steering Committee to file a brief, which was recently filed. I intend to rule soon on the dismissal motion in that case, and thereafter turn to the other pending dismissal motions. At the request of the Committee, I will consider placing certain documents from that *Wood* case--certainly including my ruling on the motion--into the Autism Master File.

F. Filing records via compact disc

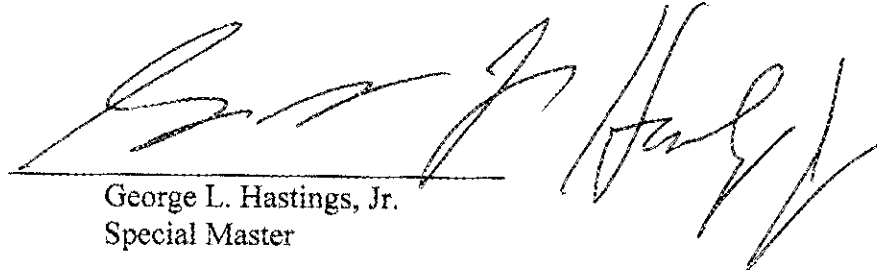
A committee, including a representative of the Petitioners' Steering Committee, a representative of respondent, and personnel from the Office of the Clerk of this court, is currently developing a procedure by which, in autism cases, voluminous records could be filed with the court via compact disc rather than via a "paper copy." That Committee will soon report to me, and I will then file into the Autism Master File an order permitting the filing of records in autism cases via such method.

G. Attorneys' fees

The Petitioners' Steering Committee has recently forwarded to me a memorandum that outlines the Committee's proposed procedures concerning the eventual application for attorneys' fees and costs with respect to this Omnibus Autism Proceeding. At the status conference on October 28, respondent's counsel noted concerns about the proposed procedures and the notion that fees and costs could be compensated in any proceeding that was not a "proceeding on a petition." Respondent's counsel indicated that these views would be submitted in writing. On October 29, 2003, I filed into Autism Master File a Notice concluding that the memorandum presents an appropriate method for accounting for attorney time and expenditures in the Proceeding.

H. Future proceedings

The next status conference in the Omnibus Autism Proceeding is scheduled for November 10, 2003.


George L. Hastings, Jr.
Special Master