

In the United States Court of Federal Claims

ORIGINAL

FILED

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U.S. COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

(Filed: September 24, 2003)

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--SEPTEMBER 24, 2003

This Update describes a number of recent developments in the Omnibus Autism Proceeding that have occurred since the last Update dated June 27, 2003. I note that counsel for both parties and I have continued to work diligently on the Proceeding during that time period. Status conferences were held on July 7, July 24, August 12, August 28, September 3, and September 17, 2003,¹ while counsel were also working extensively with one another throughout this period, in order to keep the Proceeding moving forward.

A. Petitioners' Steering Committee

Substantial changes have taken place within the Petitioners' Steering Committee. Jeffrey Thompson has moved to a new law firm, and is no longer a lead participant in the autism cases. I thank him for his outstanding service, which greatly advanced the Omnibus Autism Proceeding. The

¹Counsel participating in those conferences included Jeffrey Thompson, Ghada Anis, Michael Williams, Kathleen Dailey, Thomas Powers, and Thao Ho for petitioners; Vincent Matanoski, Mark Raby, Gregory Fortsch, and Ann Donohue for respondent. In addition, a large number of additional members of the Petitioners' Steering Committee participated in the in-person conference held on August 12, 2003.

new co-chair of the Committee, in place of Mr. Thompson, is Michael Williams of Portland, Oregon. Remaining as the other co-chair is John Kim of Houston. The Committee's "liaison counsel" is still Ghada Anis, who can be reached at the Committee's office as follows:

Petitioners' Steering Committee
733 15th Street, N.W.
Suite 700
Washington, D.C. 20005

Phone: (202) 393-6411
Email: Ghada@AutismPSC.com
Fax: (202) 318-7518

A new complete roster of the Petitioners' Steering Committee is attached at the end of this Update.

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

Much material responsive to the petitioners' extensive 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. Many 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' 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, due in part to the massive amount of material involved, and in part to the cumbersome procedures required under federal law for disclosure of material submitted by vaccine-makers during the licensing process. The process of production of that material continues to move forward. Extensive Food and Drug Administration (FDA) files with respect to certain license applications for the MMR combined vaccination and the mumps vaccination have been disclosed to the Petitioners' Steering Committee (hereinafter "the Committee"), and the files with respect to many additional vaccinations are moving through the arduous process toward disclosure. This

process, however, involves not only review of these files by government lawyers to determine which materials are appropriate for disclosure, but also involves the vaccine manufacturers who submitted the licensing applications, giving such manufacturers an opportunity to object to disclosure. Despite many months of hard work by many government employees, there is still much work to be done in order to complete disclosure of the rest of the many files being sought. Further, after studying the files disclosed thus far, Committee members have asserted that because of redactions from the files made during the review process, the files as disclosed have been less helpful than anticipated.

Accordingly, while the parties will continue the process of review and disclosure of the FDA's vaccine license application files, Committee members have proposed a new discovery approach toward obtaining the same information, in the hopes of obtaining it more speedily. Committee members are currently preparing requests for third-party discovery from the vaccine manufacturers themselves, and are contacting counsel for such manufacturers to initiate that discovery process. The Committee expects to file very soon the first such formal request for discovery from a manufacturer.

3. Issue of access to unpublished study data

I have indicated in previous Autism Updates that the parties have been in disagreement concerning the issue of production of materials relating to certain "ongoing and proposed studies." As I have noted, the parties have engaged in extensive ongoing efforts to resolve that issue. Specifically, they have 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." After long negotiations, the two sides have at times apparently come close to agreement on a procedure for making that data set available to the Committee pursuant to a confidentiality agreement, but have not ever been able to reach complete agreement. At the status conference held on August 12, 2003, petitioners' counsel requested that a hearing be scheduled for late September, at which the parties would present to me any argument and/or evidence concerning the issue of whether I should compel disclosure of that data set under a confidentiality agreement. On August 12, the week of September 29 was set aside for that purpose, although the parties pledged to continue to attempt to settle the issue in the meantime. At the September 3 conference, it was agreed that the date of September 30 would be set aside for the hearing, and that briefs concerning the issue would be filed on September 23.

On August 28, respondent's counsel announced that the results of the study in question will in fact be published sometime in November of 2003, earlier than previously anticipated. The parties then attempted to determine what the procedures would be for petitioners to access the data set once the study is published, and to determine whether pre-publication access under a confidentiality agreement could still substantially speed up the Committee's access to the data set. At the conference held on September 17, 2003, petitioners' counsel indicated that according to the information available to them, the post-publication access process might be lengthy, and they wished to proceed with the existing plan to put before me, via briefs to be filed on September 23 and hearing to be held on September 30, the parties' positions concerning whether I should order pre-publication

disclosure via a confidentiality agreement. Therefore, at that September 17 conference, I directed that the parties file briefs concerning that issue by September 23, and that a hearing be held on September 30, if agreement was not reached.

On September 19, 2003, however, the Committee informed my office that after further discussions between the two sides, the petitioners no longer desired a hearing on September 30. Instead, the Committee will continue to work on settlement of the issue with respondent's representatives.

4. Future schedule for discovery and other aspects of Omnibus Autism Proceedings

Quite obviously, the discovery process in the Omnibus Autism Proceedings has not gone as speedily as anticipated. I do not lay blame or fault on anyone for this occurrence. As I have observed in previous Autism Updates, I believe that all parties involved have been working very hard on this discovery process. It is clear that a huge effort involving a number of government agencies has taken place, in an effort to provide a thorough response to the discovery requests. A large amount of material has already been provided, and I continue to perceive that both sides are acting diligently, and in good faith. I note that in those areas where discovery is not yet complete, opposing counsel have worked amicably with each other with the goal of completing production cooperatively. The parties have not yet reached an impasse concerning any issue that they have needed to present to me for formal resolution, although I have always been ready to resolve any dispute if so requested. Indeed, I reiterate my thanks to all counsel involved for their tremendous efforts, in these difficult matters.

One chief reason for delay, however, has been the cumbersome process of discovery of the vaccine license applications, as explained above. It is the hope of all involved that by proceeding at this time directly to third-party discovery from the vaccine manufacturers, we may be able to more quickly obtain the same basic material that the petitioners' representatives had hoped to obtain from the vaccine license application files. This strategy, we hope, will speed the discovery process to a conclusion. I note, as a caution, however, that there has been very little experience with such third-party discovery from vaccine manufactures during the history of the Vaccine Act, so it is difficult to predict exactly how long such a process will take.

Accordingly, since we are only now proceeding to the "second round" of discovery, from the manufacturers, it is now clear that we will not be able to comply with all the dates for the final activities of the Omnibus Autism Proceeding--*i.e.*, the dates for the designations of experts, the filing of expert reports, and the hearing on the general causation issue--as set forth in the "Master Scheduling Order" attached to the *Autism General Order # 1* filed on July 3, 2002. At the joint request of the parties, I hereby formally modify that Master Scheduling Order by suspending those activity dates for an indefinite period of time. I will set new dates for those stages of the Omnibus Autism Proceeding at a future time.

I do promise, however, that I and counsel for both sides in the Omnibus Autism Proceeding will devote vigorous effort toward completing the remaining discovery as soon as is humanly possible. I reiterate that all counsel, as well as myself, have been doing, and will continue to do, everything in our power to expeditiously conclude discovery matters so that we can move forward toward the conclusion of the Omnibus Autism Proceeding.²

C. Number of cases

At this time, more than 3,200 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.

D. Inclusion of documents from individual autism cases in the Autism Master File

Occasionally, procedural issues came up in an individual autism case which may be of general interest to the autism petitioners. At the suggestion of the Petitioners' Steering Committee, I have begun to place copies of select documents respecting such issues into the Autism Master File, so that such documents may be easily accessed by persons interested in the autism cases. For example, on September 9, 2003, I filed, into the Autism Master File, an Order to which I attached two rulings concerning procedural issues that I made in the individual autism case of *Stewart v. Secretary of HHS*, No. 02-819V. I will continue, from time to time, to file copies of similar documents from individual autism cases into the Autism Master File.

E. Issue of the proper date for issuing "§ 12(g)(1) notices"

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). Previously, the practice under the Vaccine Act has been for the special master to issue such a notice 240 days after the date upon which the petition was *filed*. The respondent has now taken the position, however, that if a petition is filed that is not accompanied by all of the materials specified under 42 U.S.C. § 300aa-11(c), then the "§ 12(g)(1) notice" should not be issued until 240 days after the petitioner files the *last of those specified materials*. Respondent has filed motions asserting that statutory interpretation in many of the autism cases in which "short-form petitions" have been filed since July of 2002.

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

²Of course, no individual petitioner is *obligated* to wait for the outcome of the Omnibus Autism Proceeding. Any petitioner who at any time wishes to introduce evidence in order to attempt to prove his or her own case will be permitted to do so.

September 9, 2003, and thus can be accessed 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.) Since the above-described motions filed by respondent in all of the "short-form petition" cases raise the identical legal issue, that ruling in *Stewart* would seem to mean that I would begin to issue the "§ 12(g)(1) notices" in the "short-form petition" cases as the appropriate date arrives in each such case. However, respondent's counsel have indicated that they are considering whether to attempt to obtain interlocutory appellate review of my ruling concerning this issue by means of seeking a writ of mandamus in the *Stewart* case. Respondent's counsel anticipate that a decision whether to seek such appellate review will likely be made by October 3, 2003. Further, respondent's counsel have requested that, if respondent elects to seek such appellate review, I then refrain from issuing "§ 12(g)(1) notices" in *Stewart* and in the other "short-form petition" cases until the appellate review process in *Stewart* is complete. We should know very soon whether respondent will elect to seek appellate review concerning this controversy. Meanwhile, I am currently considering the above-described request by respondent that I refrain from issuing "§ 12(g)(1) notices" if respondent does seek such review. Once I know whether such review will be sought, I will promptly issue another of these "Autism Updates," to inform the autism petitioners of the status of developments concerning this issue.

F. 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 have since requested the parties' views on additional points with respect to that general issue, with briefs on those points to be filed by October 15, 2003.

Soon after those briefs are filed, I will file an opinion discussing this topic, in an individual autism case. I will place that opinion into the Autism Master File.

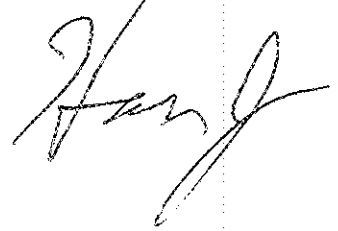
G. Issue of timeliness of petition filing

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 by October 6, 2003. After that brief is filed, I intend to rule 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.

H. Future proceedings

The next status conference in the Omnibus Autism Proceeding is scheduled for September 26, 2003.

George L. Hastings, Jr.
Special Master



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