

In the United States Court of Federal Claims

ORIGINAL

OFFICE OF SPECIAL MASTERS
(Filed: November 27, 2006)

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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--NOVEMBER 27, 2006

This Update describes a number of recent developments in the Omnibus Autism Proceeding that have occurred since my last Update, dated September 7, 2006. *The most important developments, related to the upcoming evidentiary hearing concerning the general causation issue, will be discussed at part D of this update, below.* Unrecorded telephonic status conferences were held on October 2, October 20, and November 8, 2006, and an "in person" status conference was held on October 25. (See part C of this Update, below.)

A. Number of cases

At this time, more than 5,100 petitions in autism cases have been filed, and about 4,750 remain pending, stayed (at the petitioners' own requests) until the conclusion of the Omnibus

Autism Proceeding.¹ Additional petitions continue to be filed, although at a considerably reduced rate.

B. Discovery issues

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 note certain new developments in the discovery area.

1. General progress concerning petitioners' discovery requests

As reported previously, petitioners have made two extensive discovery requests for materials from government files, and as a result many thousands of pages of material have been copied from government files and supplied to petitioners. At this point, all of the petitioners' discovery requests have been resolved, except for the ongoing production discussed at point 2 below and the ongoing procedures discussed at point 3 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 217,000 pages.

2. The vaccine license application files

One category of documents requested, pursuant to petitioners' original Requests for Production Nos. 10 and 12, involves the Food and Drug Administration (FDA) files that pertain to 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, and is now very near completion. Since the last update, respondent has submitted to the Petitioners' Steering Committee (hereinafter "the Committee") another portion of the FDA file pertaining to the Wyeth/Lederle DTaP vaccine (218 pages). Prior to that, other portions of the file for that vaccine were submitted, and files for the following additional vaccines were submitted: the Merck MMR combined vaccine, the Baxter/North American Healthcare DTaP vaccine, the Wyeth/Praxis DPT vaccine, the Wyeth/Praxis DT vaccine, the Lederle DTP vaccine, the Lederle tetanus vaccine, the GlaxoSmithKline hepatitis B vaccine, the Aventis DT vaccine, the Wyeth/Praxis tetanus vaccine, the Aventis tetanus vaccine, the Aventis DTaP vaccine, the Merck HIB conjugate vaccine, the Aventis DTP vaccine, Lederle HIB conjugate vaccine, the Lederle DTP/HIB conjugate vaccine, the Merck measles vaccine; the Merck rubella vaccine, the Aventis HIB conjugate vaccine, the Lederle DT vaccine, the Merck hepatitis B vaccine, and the Merck mumps vaccine.

¹Many of the cases that are no longer pending were voluntarily dismissed or withdrawn by the petitioners; in many of those cases, the dismissal was due to the fact that, inadvertently, a second petition had been filed pertaining to the same autistic child. A number of other cases have been dismissed by me because they were not timely filed.

With respect to a few of the 22 vaccine files noted above, a few more small groups of pages are anticipated to be disclosed shortly.² That disclosure should complete the discovery process with respect to the vaccine license files.

3. Discovery pursuant to resolution of “motion to compel”

On April 14, 2005, I filed a Discovery Order resolving the petitioners’ “motion to compel production,” concerning petitioners’ second round of requested government discovery. The parties have proceeded with the discovery procedures described in that Order, concerning the study known as the “Thimerosal Screening Analysis” (“TSA”). At the most recent status conferences, the Committee informed me that the Committee’s experts have, in fact, obtained access to certain data concerning the TSA, and are nearing completion of their analysis of such data. The written report of those experts is expected to be filed within the next few days.

During our regular Autism Omnibus Proceeding status conference on October 2, 2006, however, the Committee notified me that the Committee intends to file another “motion to compel” discovery of data. This motion will seek access to certain post-2000 follow-up data, concerning those children who were the subjects of the TSA. The Committee expects to file that motion within the next few days.

C. Recent judicial conference

On October 25, 2006, the U.S. Court of Federal Claims held its annual judicial conference in Washington, D.C. In conjunction with the conference, I conducted an “in-person” status conference in the Omnibus Autism Proceeding, and attendance was substantial. Most of those in attendance were petitioners’ attorneys who do not participate in the regular telephonic status conferences in the Omnibus Autism Proceeding, so I attempted at the conference to provide these attorneys with as much information as possible concerning the day-to-day activities in the Proceeding. I thank all those who attended and participated in that status conference and the court’s judicial conference.

D. Planning for general causation hearing

As reported in my last Autism Update, acting on a proposal of the Committee, I have scheduled the hearing concerning the “general causation issue”--*i.e.*, the issue of whether thimerosal-containing vaccines and/or MMR vaccines can cause autism and/or similar disorders, and, if so, in what circumstances--for next June 11-29, 2007. The Committee will file its expert reports by

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. (See discussion in my Autism Update filed on June 23, 2004, pp. 4-6.)

February 14, 2007, and the respondent's expert reports will be due on April 17, 2007. Additional procedures and details concerning the general causation hearing, such as the location of the hearing, have yet to be finalized, but counsel for both sides and I are working diligently to resolve them. The Committee on July 18, 2006, filed a preliminary proposal concerning certain details (now posted on the Autism Proceeding page of this court's website³), and the Committee will file a second proposal within the next few days. The respondent's response will be filed about two weeks after the Committee's second filing. I will then rule on any disputes between the parties.

One detail which will likely be of considerable interest is the issue of *access* to the evidentiary hearing and to the evidence to be supplied by both parties concerning the general causation issue. We have had informal discussions for many weeks concerning this topic, and the respondent has submitted an informal written proposal for purposes of discussion, but ***neither side as yet has submitted a formal full statement of its position.***⁴

This issue is complicated by 42 U.S.C. § 300aa-12(d)(4)(A), which states that "information submitted" in a Vaccine Act proceeding "may not be disclosed to a person who is not a party to the proceeding without the express written consent of the person who submitted the information." Pursuant to that statutory provision, hearings in Vaccine Act cases have generally been closed to anyone but the parties themselves. The question before us now is whether the upcoming evidentiary hearing in the Omnibus Autism Proceeding, which will affect not just one family but nearly 5,000 families, should be handled differently from previous Vaccine Act proceedings. Both parties and I agree that this Proceeding *should be handled quite differently*, that access *should* be provided to more than just those individuals who will be able to attend in person, by extraordinary means such as some type of webcasting of the hearing. The question which has not yet been determined, but will be decided over the next several weeks, is *exactly what procedures* we will utilize to provide extraordinary access to the hearing and to the documentary evidence to be submitted.

At this point, I reiterate, *neither party has as yet filed its formal written position* concerning this access issue. Respondent's formal written position will be filed shortly, likely within the next two weeks, and then the Committee will have a chance to formally respond in writing. ***I have as yet made no ruling concerning this issue, nor will I make any ruling until both sides have had a chance to fully consider and present their positions in writing.*** Accordingly, any speculation at this time concerning the outcome of this issue is completely premature.

³This court's Internet website is located at www.uscfc.uscourts.gov. Click on the "Office of Special Masters" page, then on the "Autism Proceeding" page.

⁴I note that in the Committee's above-mentioned initial general proposal concerning the general causation hearing, filed on July 18, 2006, the Committee did summarily state the view that the hearing "should be as open and transparent as possible," and should be "open to the media and the public generally." Neither party has as yet, however, filed a formal position as to the meaning of 42 U.S.C. § 300aa-12(a)(4)(A), discussed above, and how that position applies to the upcoming hearing.

I also stress that under no circumstances will the upcoming evidentiary hearing be a “secret” or “nontransparent” proceeding. At a *minimum*, under the respondent’s preliminary discussion proposal, the entire hearing will be completely open and accessible to the nearly 5,000 petitioners’ families and their counsel, either in person or via password-protected Internet access. Similarly, any documentary evidence submitted by *either* side, as well as the *complete* transcript of the hearing, would also be fully available to all petitioners and their counsel. Further, under *any* outcome, the petitioners will be absolutely free to make all of their *own* evidence concerning the causation issue *completely available to the general public*, and any special master’s ruling concerning the causation issue will also be made publicly available. Thus, under no circumstances will the general causation hearing be a “secret” hearing.

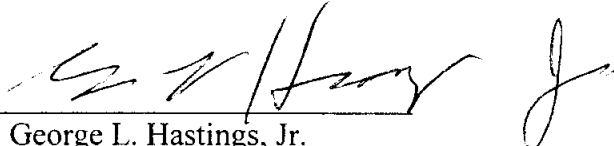
Moreover, I note that I fully understand that the Omnibus Autism Proceeding is hardly an ordinary proceeding of the type that the Court of Federal Claims special masters have conducted concerning most of the individual Vaccine Act cases over the life of this compensation program. The vast majority of Vaccine Act proceedings, of course have concerned only a single injured party, and so, in each proceeding, for reasons of the petitioner’s privacy and to conform with the above-cited § 300aa-12(d)(4)(A), the case file, and any hearing in the case, has been closed to the public. The Omnibus Autism Proceeding, on the other hand, is obviously *quite different*, because it may potentially affect the Vaccine Act claims of nearly 5,000 families. Therefore, since the very inception of the Proceeding in 2002, I have treated the question of access to the file of the Proceeding in a manner *far different* from that of any prior Program proceeding. My instinctual inclination, from the beginning of the Omnibus Autism Proceeding, has been to make all aspects of the Proceeding as *open and available* to the public as is possible within the provisions of the controlling statute. For example, at the very beginning of the Program, I established a publicly-accessible Internet website, on which I have posted the vast majority of the documents that have been filed by both sides into the Omnibus Autism Proceeding file during the ensuing four years.

It is, of course, my duty to comply with the provisions of § 300aa-12(d)(4)(A), and to carefully consider any arguments made by either party as to how that statutory provision should be applied to the Omnibus Autism Proceeding. I will do so. As of this time, I do not even know exactly what arguments the parties will make in this regard, so I certainly do *not* know how I will resolve any disputes between the parties in this regard. However, I certainly can guarantee unequivocally that *all* petitioners will be afforded *complete access* to *all* evidence that is submitted by both sides. Further, I can assure all concerned that I will do everything in my own power, within the provisions of the statute, to make sure that the Omnibus Autism Proceeding also is as open and accessible as possible to the general public.

E. Future proceedings

I will continue to meet regularly with counsel for both the Committee and respondent, to finalize details for the general causation hearing. I will continue to issue these Autism Updates

describing the process. The next status conference in the Omnibus Autism Proceeding is scheduled for November 29, 2006.



George L. Hastings, Jr.
Special Master