

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
(Filed: March 14, 2007)

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 14, 2007

This Update describes a number of recent developments in the Omnibus Autism Proceeding (“OAP”) that have occurred since the last Autism Update, issued on January 19, 2007. Since that Update, a number of important documents have been filed into the Autism Master File,¹ and much planning has occurred concerning the causation hearing to be held in June 2007. (See part D of this Update, below.) Unrecorded telephonic status conferences were held on January 23 and 25, and February 9, 12, and 28, 2007.

¹The Autism Master File constitutes the record of the Omnibus Autism Proceeding. The complete File is maintained by the Clerk of this court, and is available for inspection by the parties. An electronic version of the File is maintained on this court’s website. This electronic version contains a complete list of all documents in the File, along with the full contents of most of those documents; the exception is that the content of a few documents has been withheld from the website due to copyright considerations or due to 42 U.S.C. § 300aa-12(d)(4)(A). To access this electronic version of the Autism Master File, visit this court’s website at www.uscfc.uscourts.gov. Click on the “Office of Special Masters” page, then on the “Autism Proceeding” page.

A. Number of cases

At this time, about 4,800 petitions in autism cases remain pending, stayed (at the petitioners' own requests) until the conclusion of the Omnibus Autism Proceeding. (The pending cases are now being divided among the three presiding special masters, as discussed at part C of this Update, below.) Additional petitions continue to be filed, although at a considerably reduced rate.

B. Discovery issues

As indicated in previous Autism Updates, a tremendous amount of work has been done by counsel for both parties concerning the petitioners' extensive discovery requests. We will not reiterate developments covered in previous updates, but will summarize below the discovery progress, and note certain new developments in the discovery area.

1. General progress concerning petitioners' discovery requests

As reported previously, the Petitioners' Steering Committee (hereinafter "PSC"), which is the committee of attorneys representing the petitioners in the Omnibus Autism Proceeding, has 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.² At this point, all of the PSC's discovery requests have been resolved, except for the controversy discussed at point 3 below. By our informal count, the total number of pages of documents provided by respondent to the petitioners (not counting the material available via website) now approximates 218,000 pages.

2. The vaccine license application files

One category of documents requested, pursuant to petitioners' original Requests for Production Nos. 10 and 12, involved the Food and Drug Administration (FDA) files that pertain to vaccine license applications. In this area, efforts to produce material proceeded slowly, as detailed in previous Autism Updates, but we are now very pleased to report that the production process was *completed* on February 12, 2007. We extend our thanks for the extensive work, performed by personnel of the FDA and Department of Justice, involved in this extensive production.

²I note that while the PSC'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 PSC. (See discussion in the Autism Update filed on June 23, 2004, pp. 4-6.)

3. Petitioners' "2006 motion to compel"

On December 8, 2006, the PSC filed a second "Motion to Compel." In this motion, the PSC seeks access to certain data from the Vaccine Safety Datalink ("VSD") program, which is a program sponsored by the Centers for Disease Control in which data is collected from a number of managed care organizations ("MCOs") for use in reviewing vaccine safety issues. The motion requests that we direct the CDC and the MCOs to permit the PSC's experts to access certain VSD data.

Respondent filed a response, opposing the motion, on January 19, 2007. The MCOs also filed a response opposing the motion, on February 26, 2007. The PSC is due to file a reply on March 16, 2007.

We note also that we have discussed this matter with the parties, and all agree that the resolution of this new discovery matter *will not* delay the presentation of the initial "test cases" to be discussed in part D of this Update, below.

C. Reassignment of cases

As reported in the last Autism Update, the Chief Special Master recently assigned two additional special masters to the Omnibus Autism Proceedings. Further, the Chief Special Master is in the process of reassigning some of the pending individual autism cases from the docket of Special Master Hastings to the dockets of Special Masters Vowell and Campbell-Smith. When this process is completed, the pending autism cases will be distributed roughly equally among the three special masters. In order to ease the burden on the court's administrative staff, the reassignment process will be taking place over a period of several weeks.

In the reassignment process, cases involving siblings will be assigned to the same special master. With respect to attorneys who are counsel of record in multiple cases, each such attorney will have approximately one-third of his/her cases assigned to each of the three masters. Cases filed *pro se*, or filed by attorneys who are counsel in only one case, will be assigned randomly. The reassignments are also being made so that the cases filed in each year (*e.g.*, 1999) will be divided equally among the three masters.

In addition, newly-filed autism petitions are also being randomly assigned among the three special masters.

D. Planning for causation hearings, and related issues

As reported in the most recent Updates, we have scheduled an evidentiary hearing, for a "test case" in the Omnibus Autism Proceeding, for June 11-29, 2007. Since the last Update, a number of developments have taken place concerning that hearing. Further, additional discussions have taken place, concerning the issue of how the June hearing fits into an *overall plan* for resolving all

of the pending autism cases. We discuss below our current “working plan,” and issues arising therefrom.

1. The June hearing, and the plan for additional “general causation” hearings

As reported previously, at the June evidentiary hearing both the PSC and respondent will present testimony concerning both the “general causation issue”--*i. e.*, whether MMR vaccines and/or thimerosal-containing vaccines can cause autism--and *also* the specific causation issue in the particular case selected by the PSC, which is the case of *Cedillo v. Secretary of HHS*, No. 98-916V.³ All three special masters will preside over that hearing. Special Master Hastings alone will decide the *specific causation* issue in that *Cedillo* case, while the other two special masters will participate in order to hear the *general causation* evidence. Further, the PSC will also select *two more* individual cases, in addition to the *Cedillo* case, which would fall within the same general causation theory to be presented by the PSC at the June hearing. Those two cases will be assigned to Special Masters Campbell-Smith and Vowell, and case-specific hearings in each of those cases will be held either in June of 2007 or during the following three months. Each of those two special masters, then, will be able to apply the evidence concerning the *general* causation issue, presented at the June 2007 hearing, to the *individual case* assigned to that special master.

Thus, by the early fall of this year, three different special masters will have heard the evidence concerning the petitioners’ “general causation” theory that is to be presented in June 2007, and will be ready to apply that evidence to the three *individual cases* that will also have been presented to those special masters. Soon thereafter, three rulings, each evaluating that general causation theory, will be issued. And those three special masters will then be ready to evaluate the specific causation issues in the *other* autism cases, to the extent that such cases fall within the general causation theory to be presented in June, as swiftly and efficiently as possible.

To explain the rest of the plan that we have adopted for advancing the Omnibus Autism Proceeding, we need to return to a term used above, the term “general causation issue.” As explained previously in the Chief Special Master’s *Autism General Order #1*⁴ and in the Autism Updates regularly issued by Special Master Hastings, the common goal of all participants, since the beginning of the Omnibus Autism Proceeding in 2002, has been to process this large group of cases as efficiently as possible. All participants have recognized that while in each case the ultimate question would be whether a vaccination or vaccinations injured the *specific vaccinee*--*i. e.*, the “specific causation” issue in the case--in virtually every case the answer to the “specific causation” issue would depend, in part, on the answer to a “general causation issue”--*i. e.*, the general question

³We note that the petitioners filed four expert reports into the *Cedillo* case file on February 20, 2007. Respondent’s expert reports will be filed by April 24, 2007.

⁴The *Autism General Order #1* and the previous Autism Updates are available on the court’s website. (See page 1, footnote 1, above.) The *Autism General Order #1* is also published at 2002 WL 31696785, 2002 U.S. Claims LEXIS 365 (Fed. Cl. Spec. Mstr. July 3, 2002).

of whether MMR vaccines or thimerosal-containing vaccines, or both combined, *can cause* neurodevelopmental disorders. All have agreed that because the evidence concerning that “general causation issue” would be relevant to many individual cases, it made sense from an efficiency standpoint that the parties not be required to present their evidence concerning that “general causation issue” repetitively in every individual case. Instead, evidence concerning “general causation,” once presented at a “general causation hearing” or a “test case” hearing, and recorded via transcript, could then be applied to *many* individual cases. That would eliminate the need for the parties to repeatedly present the same general causation testimony, by the same expert witnesses, in one individual case after another.

However, both the Chief Special Master and Special Master Hastings also understood from the beginning of the Omnibus Autism Proceeding (OAP) that use of the term “general causation issue” did *not* guarantee that, ultimately, the “specific causation issues” in *all* of the individual cases involved in the OAP would be finally resolved after just a *single* general evidentiary hearing. They understood that, as the science developed and the parties developed their causation evidence, the “general causation issue” might eventually be *divided* into two or more categories. For example, it always seemed quite possible that the theory that *MMR vaccines* can cause autism might eventually be tried separately from the theory that *thimerosal-containing vaccines* can cause autism. Note the following discussion by the Chief Special Master in the *Autism General Order #1* (2002 WL 31696785 at *6):

Third, the above pages have referenced the “general causation issues.” The OSM recognizes that the Omnibus Autism Proceeding is in its earliest phase. While petitioners’ representatives have mentioned multiple potential theories of causation, until discovery is completed and expert reports are filed it will not be known whether one or more causation theories are at issue. As noted above, there have been suggestions that autistic disorders can be caused by (1) MMR vaccinations; (2) the thimerosal component of the DTP, DTaP, Hepatitis B, and HIB vaccinations; and/or (3) a combination of (1) and (2). Accordingly, the presiding special master, working with the parties’ representatives, will decide at a later date the most efficient procedure for resolving the causation issues, depending upon the development of the causation theories put forth by Petitioners’ Steering Committee.

Thus, it is not surprising to us that, in recent months, the PSC has proposed to divide its evidence concerning “general causation” into *three different theories*. First, the PSC wishes to present evidence concerning its first theory, (1) that MMR vaccines and thimerosal-containing vaccines can *combine* to cause autism; this is the theory to be presented at the hearing in June of this year. Then, at a later time, the PSC will present two *additional* theories: (2) that MMR vaccines alone can cause autism, and (3) that thimerosal-containing vaccines alone can cause autism.

Accordingly, during the last two OAP status conferences, we have directed that the PSC prepare to proceed to evidentiary hearings concerning the *two additional theories*, described in the

previous sentence, by no later than September 30, 2008. That is, the PSC will select three test cases for *each* of the two additional theories, and be ready to try such cases by September 30, 2008.

2. Respondent's objections to the plan

In a brief filed on January 26, 2007 (hereinafter "Br."), respondent has voiced certain objections to the general plan enumerated above. We will respond briefly to those objections, below.

First, respondent protests that dividing "general causation" into three theories is a "radical departure from the process that was in place" for the Omnibus Autism Proceeding. (Br. at 4.) Respondent asserts that the "court has always planned on one trial to hear all theories of causation." * * * There was never any doubt that the general causation trial would encompass all causation theories. (*Id.*) Respondent, however, is simply mistaken in this regard. As the lengthy quotation from the *Autism General Order #1*, set forth on the previous page, makes clear, it has long been anticipated that the PSC might wish to divide the general causation issue into separate theories. Indeed, that quotation seems to suggest exactly the same division, into three categories, that the PSC has now proposed.

Second, respondent has argued that, prior to the June hearing, the PSC should be required to specifically designate those cases of the 4,800 pending cases "whose outcome will hinge on the final decision" in the *Cedillo* case. (Br. at 9.) This suggestion, however, simply is impractical given the available time frame, as the PSC argued in its reply filed on February 26, 2007. Moreover, respondent may possibly be implying that the petitioners in such designated cases should be *bound* by the outcome of the *Cedillo* case, if the *Cedillos* *fail* to demonstrate that their daughter's autism was vaccine-caused. If so, that suggestion would seem to be quite one-sided. Respondent does not seem to be pledging that if the petitioners are *successful* in showing vaccine-causation in *Cedillo*, respondent would then automatically compensate all petitioners whose cases were designated by the PSC to have their outcomes "hinge on" the *Cedillo* outcome. It is not clear why one side should be "bound" by the outcome, but not the other.

Third, respondent argues that the *Cedillo* case seems not to be "representative of a great many of the cases in the OAP, and that, therefore, use of that case as the first "test case" may not significantly advance the resolution of a great many of the pending cases. This concern of respondent, we think, has some validity. The general fact pattern of the *Cedillo* case,⁵ indeed, does seem to be representative of only a relatively small number of cases out of the 4,800 pending. However, we have determined that it is appropriate, despite this concern, to proceed with the general plan set forth above, beginning with the "test case" hearing of *Cedillo* in June of this year. There are several reasons for this determination.

⁵At this point, in this public document, we are not at liberty to divulge details of the *Cedillo* case. See § 300-12(d)(4)(A).

First, it seems absolutely clear that we should hear the *Cedillo* case on the date proposed by the Cedillos themselves, whether that case is representative of other cases or not. If the Cedillos are ready to present their evidence, then a special master should be ready to hear that evidence and to make a ruling in the case.

Second, while admittedly not *completely* representative of a huge number of cases, the *Cedillo* case will likely, we believe, substantially advance the cause of moving the pending autism cases. The *Cedillo* case does appear to address causation issues that will at least have *relevance* to most, if not all, of the 4,800 pending cases. That is, the expert reports filed in *Cedillo* indicate that the petitioners will attempt in that case to demonstrate how, as a general matter, both MMR vaccines and thimerosal-containing vaccines can act on a child to result in autism. Therefore, the “general causation” presentation will likely bring to light evidence that will be potentially applicable to *all* of the pending cases in the OAP, which all, of course, involve MMR vaccines, thimerosal-containing vaccines, or both.

Third, it is important to note that the *Cedillo* case is only *one part* of our overall plan, set forth above, to process the autism cases. As explained above, *two other* individual cases, involving the same general causation theory to be presented in the *Cedillo* case, are to be tried by September 30 of this year. In addition, “test cases” involving the PSC’s *other two* general causation theories are to be tried by September 30, 2008. If we can adhere to this schedule, completing three hearings with respect to *each* of the PSC’s causation theories by September 30, 2008, then the cause of processing the autism cases will be well-served, in our view.

3. Matters raised by petitioners

The PSC’s brief filed on February 26, 2007, also raises two points that merit a brief discussion here.

First, petitioners indicate a concern that the general causation inquiries in the Omnibus Autism Proceeding *not* be strictly limited to cases that fall squarely within the category of “autism spectrum disorders.” (Br. at 1-2.) We note that beginning with the *Autism General Order #1*, all of this court’s documents filed in the OAP have borne a caption referring to injuries resulting in an “autism spectrum disorder, *or a similar neurodevelopmental disorder*” (emphasis added). Therefore, the simple answer to the PSC’s concern is that in the OAP we will be willing to consider causation theories that apply to not only the autism spectrum disorders, but also to neurodevelopmental disorders that are “similar” to autism spectrum disorders. The parameters of the similarity required is a matter to be addressed at a later time.

Second, the PSC raises a concern over one aspect of the *timing* of the special masters’ plan. (Br. at 3-5.) The PSC notes that the “Motion to Compel” discussed above is currently pending before the special masters. The PSC expresses concern that if it successfully obtains new evidence via that motion, the petitioners may need extra time to process that evidence, and thus may not be

able to proceed to hearing by September 30, 2008, concerning the petitioners' *two additional* theories described above.

We understand the PSC's concern in this regard, but we do not believe that it is necessary at this time to consider any specific change to the general schedule set forth above. If the PSC does gain new evidence via the motion to compel, we can *then* evaluate the extent and potential importance of such evidence, and decide whether a delay in the general plan is warranted. If, on the other hand, the motion to compel does not result in the production of new evidence, then there would be no need to deviate from the current schedule.

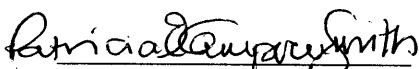
4. Issue of access to the June hearing

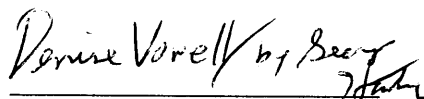
Another issue with respect to the June hearing concerns the question of *access* to the evidentiary to be held in June. As previously noted in these Updates, this issue is complicated by 42 U.S.C. § 300aa-12(d)(4)(A), which states that "information submitted" in a Vaccine Act proceeding "may not be disclosed 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 *Cedillo* should be handled differently from previous Vaccine Act proceedings. In prior informal discussions, both sides have indicated the preliminary view that this *Cedillo* hearing *should* be handled somewhat differently, that access *should* be provided to more than just the parties, 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.

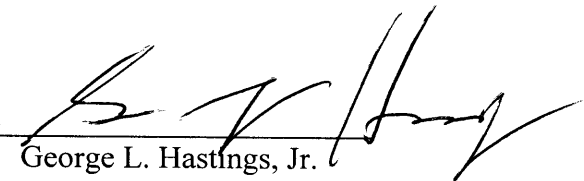
On March 5, 2007, the Cedillos filed, into the record of that *Cedillo* case, a document indicating that the Cedillos wish to open the hearing to the public at large. Respondent is due to file respondent's formal position concerning this issue on March 20, 2007. The PSC will then be afforded the opportunity to file a reply, if desired. We will then rule upon the issue, if the parties disagree.

E. Future proceedings

We will continue to meet regularly with the representatives of both the PSC and respondent, to finalize details for the June hearing, and to pursue other matters. We will continue to issue these Autism Updates describing the process. The next status conference in the Omnibus Autism Proceeding is scheduled for March 16, 2007.


Patricia Campbell-Smith
Special Master


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George L. Hastings, Jr.
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