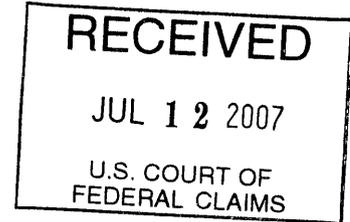


# In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS  
(Filed: July 12, 2007)



\*\*\*\*\*  
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<sup>1</sup>

## AUTISM UPDATE--JULY 12, 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 May 25, 2007. Since that last Update, telephonic status conferences were held on May 31, June 5, June 6, June 8,<sup>2</sup> and July 9,

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<sup>1</sup>The 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 some 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](http://www.uscfc.uscourts.gov). Click on the “Office of Special Masters” page, then on the “Autism Proceeding” page.

<sup>2</sup>All of the above-mentioned status conferences were unrecorded, except for the conference on June 8, 2007. That conference primarily concerned the individual case of Michelle Cedillo, but a few items concerning the Omnibus Autism Proceeding were also discussed. The transcript of that conference is contained in the record of the *Cedillo* case.

2007. In addition, on June 11 through June 26, 2007, we conducted the evidentiary hearing for the first “test case” in the Omnibus Autism Proceeding. (See part C of this Update, below.)

**A. Number of cases**

At this time, just over 4,800 petitions in autism cases remain pending, stayed (at the petitioners’ own requests) until the conclusion of the Omnibus Autism Proceeding. Additional petitions continue to be filed.

**B. Discovery issues**

As indicated in previous Autism Updates, a tremendous amount of work has been done over the last five years concerning the petitioners’ extensive discovery requests. We will not reiterate developments covered in previous updates, but will summarize below the discovery process, and note the latest development 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.<sup>3</sup> By the time of our last Update, all of the PSC’s outstanding discovery requests had been resolved, except for the controversy discussed at point 2 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) approximates 218,000 pages.

**2. Petitioners’ “2006 motion to compel”**

On December 8, 2006, the PSC filed a “Motion to Compel.” This motion concerned the Vaccine Safety Datalink (“VSD”) Project, 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. In that motion, the PSC requested that we direct the CDC and the MCOs to conduct an extensive study involving VSD Project data, in conjunction with the PSC’s experts. On May 25, 2007, we filed, into the Autism Master File, our 22-page ruling on the issue, denying the motion.

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<sup>3</sup>I 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.)

Thus, at this time there are no discovery issues pending before us in the Omnibus Autism Proceeding.

### *C. Hearing in the Cedillo “test case”*

On June 11 through June 26, 2007, we conducted an evidentiary hearing concerning a “test case” in the Omnibus Autism Proceeding. At that evidentiary hearing, the PSC and respondent presented testimony concerning both a “general causation issue”--*i.e.*, whether MMR vaccines and thimerosal-containing vaccines can *combine* to 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. All three of the undersigned special masters participated in that hearing. Special Master Hastings alone will decide the *specific causation* issue in that *Cedillo* case, while the other two special masters participated in order to hear the *general causation* evidence.

As noted in our last Update, both parties gave their consent to make that evidentiary hearing *completely open to the public*. The hearing was held in the largest courtroom that we could secure, enabling all those who wished to do so to attend in person. For those who could not attend in person, there were three different ways to follow the hearing. First, anyone interested was able to “dial in” to the proceedings through a “listen-in-only” telephone connection. Second, one could download the audio of each day of the hearing from the Internet. Third, transcripts of each day’s proceedings were posted on this court’s website the next day after each day’s proceedings.<sup>4</sup> In addition, there was considerable press coverage of the hearing.

The evidentiary hearing lasted 12 days, from June 11 through June 26, 2007. We heard moving testimony from Theresa Cedillo, mother of 12-year old Michelle Cedillo, the subject of the case. We also heard testimony from six expert witnesses for the petitioners, and nine expert witnesses for the respondent.<sup>5</sup> We acknowledge and thank the counsel for both sides, who presented their evidence very ably during the hearing. We know that they worked enormously hard in preparing and in conducting this hearing, and we appreciate that hard work.

We again thank the Cedillo family for coming to Washington, and being with us throughout the hearing. We thank them, as well, for generously agreeing to have Michelle’s case designated as the first “test case” in the Omnibus Autism Proceeding. Further, as we did during the hearing, we extend our sympathy to Michelle and her family for all they have been through. And, we reaffirm our admiration for the way that the Cedillo family has coped with Michelle’s illness.

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<sup>4</sup>Access to the audio downloads and the transcripts is still available through this court’s website, via the “Autism Proceeding” page.

<sup>5</sup>We also heard extremely brief telephonic testimony from Nicholas Chadwick, who testified for respondent as a factual witness concerning his personal knowledge of circumstances concerning certain testing procedures arguably relevant to the case of Michelle Cedillo.

In addition, as we did at the hearing, we acknowledge the families of all the other 4,800 Vaccine Act claimants who have been diagnosed with autism or similar conditions. Some members of those families attended the hearing in person; many hundreds listened in by means of our teleconferencing system; and others followed the hearing by downloading the audio or reading the hearing transcripts from the Internet. To all such family members, as to the Cedillo family, we three special masters pledge that we will consider very carefully the evidence put before us during the June hearing, and give that evidence our very complete and thorough study. We realize the tremendous importance of the task assigned to us in deciding these cases, and we will give our greatest effort in carrying out that heavy responsibility.

Of course, now that the evidentiary hearing in this first “test case” hearing is finished, many will want to know when the *ruling* in the case will be issued. The answer is in two parts, as follows.

First, as to the specific case of *Michelle Cedillo*, Special Master Hastings alone will consider the evidence and issue a written ruling. That will happen, however, only after both parties file written briefs analyzing the evidence in the case. The following schedule has been established for that briefing process. The petitioners will file their opening brief by October 15, 2007; the respondent will file a brief by December 15, 2007; and the petitioners will file a reply brief by January 15, 2008. Once the last of those briefs are filed, Special Master Hastings will analyze those briefs. He will study not only the 3,000-page transcript of the hearing, but also the other evidence in the record, including thousands of pages of Michelle’s medical records; approximately 20 expert reports specific to Michelle’s case; and the approximately 800 articles from medical journals and medical text excerpts, filed by the parties. He will then issue a ruling in the *Cedillo* case as soon as possible.

However, the June hearing, of course, concerned more than just Michelle Cedillo. For a discussion of how the *other two* special masters will apply the evidence presented at the June hearing, see the next section of this Update, immediately below.

#### ***D. The next two “test cases” concerning the PSC’s first general causation theory***

As explained in previous Autism Updates, the PSC has stated its desire to present three different theories of “general causation” in the Omnibus Autism Proceeding. And we, the presiding special masters, have instructed the PSC to designate three test cases for *each* of the three theories. Michelle Cedillo’s case, then, is part of an initial group of three “test cases” with respect to the PSC’s *first* “general causation” theory. Therefore, during the June hearing, the parties presented evidence not only about the particulars of Michelle’s claim, but also about the first *general causation* theory of the Petitioners’ Steering Committee--that is, the *general* theory that MMR vaccines and thimerosal-containing vaccines can *combine* to cause autism.

We are pleased to report that since our last Autism Update, the PSC has designated the two additional “test cases” concerning that first “general causation” theory. One of those cases has been assigned to Special Master Campbell-Smith, the other to Special Master Vowell. Therefore, having

heard that “general causation” testimony during the June hearing, Special Masters Campbell-Smith and Vowell have begun the process of *applying* that evidence to the *other two* initial test cases. Case-specific evidentiary hearings will be conducted concerning each of those two cases this fall. Those evidentiary hearings will be much more limited in scope than the June hearing, because in each case the special master can apply the *general causation* evidence from the June hearing to the particular case. Special Masters Campbell-Smith and Vowell will then each issue a written ruling in their respective “test cases.”

In each of those two additional test cases, the parties and the special master are already working on the cases. At this time, however, in neither case have we secured the permission of the petitioners to release their names to the public. We will present more details concerning these cases in our next Update.<sup>6</sup>

### ***E. The petitioners’ additional theories of general causation***

As noted above, the PSC proposes to present three different theories of “general causation.” The first is the theory that MMR vaccines and thimerosal-containing vaccines can *combine* to cause autism. The additional two theories are (2) that thimerosal-containing vaccines alone can cause autism, and (3) that MMR vaccines alone can cause autism. We have previously instructed the parties that evidentiary hearings in three test cases in *each* of these additional two theories are to be completed by September 30, 2008.

On June 25, 2007, the PSC filed, into the Autism Master File, a proposal concerning the timing of the test cases as to the *second* theory, that thimerosal-containing vaccines alone can cause autism. However, at the status conference held on July 9, 2007, the PSC modified that proposal, and an extensive discussion was held. Respondent will soon file a written response concerning the scheduling of the second theory, and the issue will be revisited at our next status conference, scheduled for July 20, 2007. We intend to designate a detailed schedule, for both the second and third theories, soon after that July 20 conference.

As we did in our last Autism Update, we urge all petitioners’ counsel with pending autism cases to help the PSC lead counsel in selecting and preparing the “test cases” for the next two “general causation” theories. If you believe that one of your cases might make an appropriate test case for either the second or third causation theories, please contact the PSC lead attorneys promptly.

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<sup>6</sup>At the July 9 conference, we also discussed the issue of the United Kingdom litigation file, from which the respondent recently obtained four documents. During the conference, the undersigned special masters stated that if the PSC elects to try to obtain any additional documents from that file, we will be very willing to consider any steps that we can take to assist in that attempt. As we noted, however, if the PSC wishes to have any such documents considered with respect to the *Cedillo* case and the other two initial “test cases,” then the PSC should *act soon* in initiating any such request.

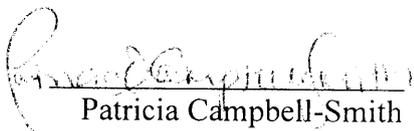
The current roster of members of the Executive Committee of the PSC, with contact information, was posted on the OAP website on March 9, 2007.

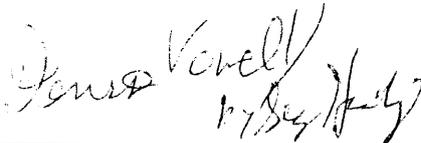
***F. Recent filings***

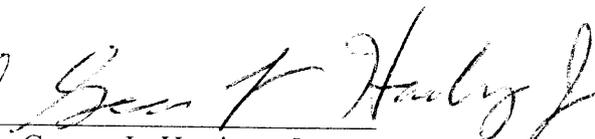
We note that new autism cases filed during the last several weeks have been assigned to the docket of the Chief Special Master, Gary Golkiewicz, rather than to the docket of any of the three undersigned special masters. That decision was made, by the Chief Special Master, in order to ensure that the undersigned can focus our efforts in the next few months on resolving the causation-in-fact issues in the “test cases” now before us. Under this approach, any procedural issues in the newly-filed cases can be addressed by the Chief Special Master. However, this initial assignment does not mean that those cases will necessarily remain on the Chief Special Master’s docket to the point of final decision. To the extent that such cases are not resolved on procedural issues, the Chief Special Master may at some future time reassign such cases to the dockets of the undersigned, for rulings concerning causation-in-fact or other issues.

***G. Future proceedings***

We will continue to meet regularly with the representatives of both the PSC and respondent, to plan the additional stages of the Omnibus Autism Proceeding. We will continue to issue these Autism Updates describing the process. The next status conference in the Omnibus Autism Proceeding is scheduled for July 20, 2007.

  
Patricia Campbell-Smith  
Special Master

  
Denise Vowell  
Special Master

  
George L. Hastings, Jr.  
Special Master