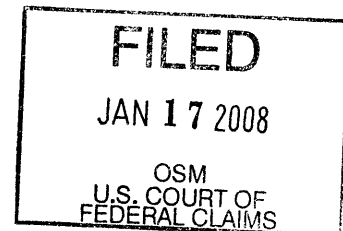


In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

(Filed: January 17, 2008)



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 FILE¹

AUTISM UPDATE--JANUARY 17, 2008

This Update describes a number of recent developments in the Omnibus Autism Proceeding ("OAP") that have occurred since the last Autism Update, issued on November 28, 2007. Since that last Update, unrecorded telephonic status conferences were held on December 17, 2007, and January 8, 2008.

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 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. From the home page, click on the "Vaccine Program" page, then on the "Autism Proceeding" page.

A. Number of cases

At this time, about 4,900 petitions in autism cases remain pending, stayed (at the petitioners' own requests) until the conclusion of the OAP. Additional petitions continue to be filed.

B. Post-hearing proceedings in the "test cases" concerning petitioners' first theory of general causation

As explained in previous Autism Updates, the Petitioners' Steering Committee (PSC) stated its desire to present *three different theories* of "general causation" in the Omnibus Autism Proceeding, and the undersigned special masters instructed the PSC to designate three "test cases" for *each* of the three theories. Accordingly, during recent months we conducted hearings in three "test cases" with respect to the PSC's *first* "general causation" theory, *i.e.*, the theory that MMR vaccines and thimerosal-containing vaccines can *combine* to cause autism. Specifically, in June we conducted an evidentiary hearing concerning the first "test case," *Cedillo v. HHS*, No. 98-916V, with Special Master Hastings presiding. In the second case, *Hazlehurst v. HHS*, No. 03-654V, a hearing was held before Special Master Campbell-Smith in October, and in the third case, *Snyder v. HHS*, No. 01-162V, a hearing was held in November before Special Master Vowell.

The parties are now in the process of preparing written briefs analyzing the evidence in each of the three cases. In *Cedillo*, the petitioners filed their opening brief on November 12, 2007, and respondent filed a responsive brief on January 11, 2008. In *Hazlehurst*, the petitioners' opening brief was filed on January 4, 2008. Additional briefs are due to be filed in each case. After the last of those briefs is filed in each case, the presiding special master will issue a written ruling.

C. The petitioners' additional theories of general causation

As noted previously, the PSC proposes to present *three different* theories of "general causation." As to the PSC's first theory, we have already heard the evidence in the three "test cases" described above. 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.

1. Second theory

Under the procedure and schedule that we have adopted, the PSC filed into the Autism Master File, on August 28 and September 4, 2007, three *general causation* expert reports pertaining to the PSC's second theory, that thimerosal-containing vaccines alone can cause autism. In recent weeks, the PSC has designated its three "test cases" concerning that theory: *Mead v. HHS*, No. 03-215V; *Krakow v. HHS*, No. 03-632V; and *King v. HHS*, No. 03-584V. The PSC has filed case-

specific expert reports in each of the three cases.² The respondent is scheduled to file respondent's expert reports concerning all three cases on February 25, 2008. An evidentiary hearing, encompassing both *general causation* concerning the second theory, and *specific causation* in each of the three cases, will take place on May 12 through 30, 2008, in Washington, D.C.

2. Third theory

The PSC's third theory, as noted above, is that the MMR vaccine alone can cause autism. The schedule for that theory is as follows. The PSC will designate three test cases and file all expert reports concerning that theory and those test cases by May 5, 2008. Respondent's expert reports are due on July 28, 2008. An evidentiary hearing will be held beginning on September 15, 2008, in Washington, D.C.

D. Filing of medical records, and determinations concerning timeliness of filing, in pending autism cases

As previously reported, in recent months the Chief Special Master has been working with representatives of the respondent and the PSC concerning another issue relating to the 4,900 pending autism cases. That is, in many of the pending cases, medical records have not been filed (see *Autism General Order #1*, p. 7), and it is therefore not clear whether those petitions were timely filed. The Chief Special Master and those party representatives are working cooperatively on the issue of how to get enough records filed in the pending cases, so that determinations concerning the timeliness of filing can be made in such cases, even as the parties in the pending cases await the outcomes of the nine "test cases" described above.

We again stress that at this time we will NOT be ordering records to be filed in ALL of the pending autism cases. Rather, the Chief Special Master and the parties' representatives are organizing this process in a deliberate, step-by-step manner. Initially, the PSC chose about 50 cases in which selected records were filed, sufficient to permit a determination with regard to timely filing. The Chief Special Master and the party representatives have been working through those 50 cases, to see what types of issues arise.

In recent weeks, the Chief Special Master, working with the PSC and respondent's representatives, has begun a process of selecting about 200 cases per month in which the petitioner will be required to submit selected records. Petitioner's counsel (or a petitioner proceeding without counsel) will be specifically notified by written order if his or her case has been selected, and will be given detailed instructions concerning how to file the required records. ***Unless you receive specific notification from the court that your case has been selected for this process, there is no requirement to file medical records at this time.***

²The expert reports in *Mead* and *King* have been posted on the "Autism Proceeding" page of this court's website; the report in *Krakow* should be posted soon.

The Office of Special Masters issued the first batch of such orders on January 15, 2008. Similar batches will be issued in the coming months. We note that the Office of Special Masters, the PSC, and respondent are striving to structure this process in a way that will not overburden this court or counsel for either side. In this regard, we note that one way of limiting the burden of this process on both parties and the court is for petitioners' counsel to convert their cases to this court's ECF (electronic case filing) system. Our ECF system allows for "paperless" filing of documents into a case file, including even substantial filings consisting of hundreds of pages. The Office of Special Masters ("OSM") recently issued OSM General Order 13, which updated the procedures for electronic filing in Vaccine Act cases.³ ***We strongly urge petitioners' counsel that if your case is selected for the filing of medical records, you convert the case to the ECF system before filing the requested records, if at all possible.***⁴ Further, as to any cases not yet selected for the filing of records, we encourage counsel to consider converting such cases to the ECF format, in anticipation of the day, in the not-too-distant future, when the court will require the filing of medical records in those cases as well.

We will continue to report concerning this process in future Autism Updates.

E. Attempt to obtain documents from United Kingdom litigation file

A few days before the evidentiary hearing in the *Cedillo* case in June of 2007, the respondent filed certain documents that it had obtained from a United Kingdom ("U.K.") legal proceeding concerning the issue of whether the MMR vaccine causes autism. The respondent obtained such documents from the sealed U.K. court file by petitioning the presiding judge in that case for release of the documents. Within the last few weeks, the PSC has notified the respondent and the undersigned special masters that the PSC will petition that same U.K. court for disclosure of *additional* documents from the sealed file. On January 8, 2008, the PSC shared with the respondent and the undersigned special masters a draft of an application to be filed with the U.K. court. The undersigned special masters have authorized the PSC to state in the application that we support the PSC's application.

We expect that the PSC will file the application with the U.K. court very soon.

F. 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

³OSM General Order 13 is posted on this court's website. From the court's home page, click on the "Vaccine Program" page, then the "Court Orders" page.

⁴Procedures for conversion of a case to the ECF format will be set forth in the Order to File Medical Records issued in each case, and are also set forth in OSM General Order 13.

Autism Updates describing the process. The next status conference in the Omnibus Autism Proceeding is scheduled for January 31, 2008.

*Patricia Campbell Smith by
Geo Hastings*

Patricia Campbell-Smith
Special Master

Denise Vowell

Denise Vowell
Special Master

George L. Hastings, Jr.

George L. Hastings, Jr.
Special Master