

ORIGINAL

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

(Filed: April 23, 2008)

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APR 23 2008
OSM
U.S. COURT OF
FEDERAL CLAIMS

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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.
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AUTISM MASTER FILE<sup>1</sup>

AUTISM UPDATE--APRIL 23, 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 March 27, 2008. Since that last Update, unrecorded telephonic status conferences were held on April 4 and April 14, 2008.

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

***A. 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 2007 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 briefs on November 12, 2007, February 1, 2008, and February 11, 2008, and respondent filed briefs on January 11, 2008, and April 4, 2008. The petitioners are scheduled to file one additional brief. In *Hazlehurst*, petitioners’ filed briefs on January 4 and February 27, 2008, while respondent filed a brief on February 6, 2008. In *Snyder*, petitioners filed a brief on February 19, 2008, respondent’s brief was filed on April 1, 2008, and supplemental expert reports and medical literature were filed by both parties in March and April.

In each of these three cases, the presiding special master has already spent many hours analyzing the evidence and briefs presented by the parties. In each case, the presiding special master intends to issue a detailed written ruling in the case, as soon as possible, after the last of the post-hearing briefs is filed in the case.

However, at the present time we are simply required to wait, before completing our analysis of the three cases, until we see whether any *additional* evidence pertinent to these cases is obtained by Petitioners’ Steering Committee, as described in part B of this Update, immediately below. To be sure, we are disappointed by this delay, and each of us is eager to complete his or her analysis of the test case at hand. We have repeatedly urged the PSC, since the hearing in June of last year, to file their application with the British court as soon as possible. However, we believe that it is only fair to the petitioners that we wait, for a reasonable period of time, to see if this effort by the PSC produces any relevant evidence. We hope that this process will be completed soon, so that the analysis and ruling concerning the “entitlement” issue can be completed soon in each of the three test cases.

***B. 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 respondent 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. 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--namely, six particular expert reports--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 PSC asked the special masters to supply a document indicating support for the PSC's application. We supplied a letter, a copy of which was attached to our previous Autism Update filed on March 27, 2008.

We are informed that the PSC hopes to file the application with the U.K. court very soon. However, during the status conference on March 20, 2008, the PSC representative explained that the PSC prefers to first obtain consent from the experts in question, and was having difficulty in obtaining consent from some of those experts. We have urged the PSC to act as expeditiously as possible, even in the absence of a response from the experts in question, since we do not wish to have this matter delay the issuance of the rulings in the three test cases under the PSC's first theory.

### ***C. Upcoming evidentiary hearing concerning the petitioners' second theory 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. As we have previously reported, an evidentiary hearing concerning the PSC's *second* theory, that thimerosal-containing vaccines alone can cause autism, is scheduled to take place on May 12 through 30, in Washington, D.C.

#### ***1. General description of the May hearing***

Under the procedure adopted for the PSC's second causation theory, that thimerosal-containing vaccines alone can cause autism, the PSC filed into the Autism Master File, on August 28 and September 4, 2007, three *general causation* expert reports pertaining to that second theory. Later that fall, the PSC designated three "test cases" concerning that theory: *Mead v. HHS*, No. 03-215V; *Krakov v. HHS*, No. 03-632V; and *King v. HHS*, No. 03-584V. The PSC filed case-specific expert reports in each of those three cases, as did the respondent. An evidentiary hearing, encompassing both *general causation* concerning the second theory, and *specific causation* in each of the three cases, was scheduled for May 12 through 30, 2008, in Washington, D.C.

However, on or about April 1, 2008, the PSC informed us that the *Krakov* case is being withdrawn as a test case. The PSC is in the process of choosing a replacement test case. But it appears impossible that the replacement case could be ready for case-specific trial by the time of the second-theory hearing scheduled for May 12-30, 2008. Accordingly, the procedure for the May hearing will be slightly altered, as follows.

All three of the undersigned special masters will preside over the May hearing. Most of that hearing will be dedicated to the presentation of the *general causation* evidence pertaining to the PSC's second causation theory--*i.e.*, evidence relevant to the *general issue* of whether thimerosal-containing vaccines can cause autism, and, if so, in what circumstances. It will be the function of all three special masters to consider that *general causation* evidence, so that each of the three special masters can then apply that general causation evidence to the specific test case assigned to that special master.

In addition, during the May hearing, the PSC attorneys will also present the *specific causation* evidence in two of the three cases, the *Mead* case and the *King* case. At a later date, yet to be specified, the PSC will present the *specific causation* evidence in the third test case.

Thereafter, Special Master Campbell-Smith will resolve the *Mead* case, Special Master Hastings will resolve the *King* case, and Special Master Vowell will resolve the third test case.

## ***2. Complete public access to the May hearing***

We are happy to report that both parties have given their consent to make this May hearing *completely open to the public*. Given the apparent considerable interest in the issues, we appreciate the willingness of both sides to make the hearing public. The hearing will be held in the largest courtroom that we could secure, Courtroom 402 at the National Courts Building in Washington, D.C.<sup>2</sup> For those who will not be attending in person, there will be three different ways to follow the hearing. First, one may "dial in" to the proceedings through a "listen-in-only" telephone connection. Second, one may download the audio of the hearing from the internet, about one day after the hearing. Third, the transcript of the proceedings will at some time (yet to be determined) be posted on this court's website. (Details regarding each of these three methods appear below.)

On the first day of the hearing, May 12, we will start proceedings at 10:00 a.m. (Eastern time). On the days thereafter, we will begin at 9:00 a.m. On most days we will likely adjourn sometime during the late afternoon or early evening, depending on the witness schedule. For those who anticipate attending in person, we caution that you must allow sufficient time to pass through court security each time you enter the National Courts Building.

If public attendance is similar to the attendance at the hearing in the *Cedillo* test case, last year, then all who wish to attend may be seated. However, our courtroom's seating capacity is only about 100, so we cannot guarantee seating for all. There will be designated seating for attorneys with pending Vaccine Act autism cases. Accordingly, to help us determine the proper number of seats to designate for counsel, we request that counsel e-mail us at [autism@ao.uscourts.gov](mailto:autism@ao.uscourts.gov), letting us

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<sup>2</sup>This is the building that houses both the United States Court of Federal Claims and the United States Court of Appeals for the Federal Circuit. The address is 717 Madison Place, N.W., Washington, DC 20005. (There is limited parking in the area. The closest Metro stops are McPherson Square and Metro Center.)

know on which days you expect to attend in person, and how many counsel from your firm will attend. (State in the email that you are an attorney with a pending autism case.)

In addition, for those, attorneys or others, who plan on *listening* to the hearing on the *dial-in phone* connection mentioned above, we need your cooperation to ensure that an adequate number of phone lines will be available. We need you to *register ahead of time*, letting us know on what days you expect to listen. Registration will be on-line, and is *very* quick and easy. You can register either by typing the following website address ([https://registration.teleconferencingcenter.com/menu.php?short\\_name=autismphoneaudio](https://registration.teleconferencingcenter.com/menu.php?short_name=autismphoneaudio)) or by visiting this court's Autism Proceeding webpage and clicking on the "*Registration for Listen-in Thimerosal/Autism test trial*" link. In either event, you will encounter a registration page. All you need to do is to check the boxes for the dates when you want to listen. To listen for a single day, check the box for that day, and then select the "*Register*" button located to the right for that day. For multiple days or to listen to the entire trial, you must check the boxes for the specific days you are interested in; to listen for the entire trial, you must check the boxes for all of the individual days. After checking the boxes for the days in which you are interested, select the "*Register for Selected Events*" button located at the bottom of the page. *Please register as soon as possible*, so that we will be sure to have enough telephone lines available. However, you may be able to register up to the day of the trial to which you wish to listen. When you register, you will receive a confirmation statement, which will list the phone number to call on the hearing day (888-638-9716), and the "Conference ID" number for each day's hearing.

For those who would like to *download the audio* of the hearing or *read the transcript*, those services will also be accessible through our Autism Proceeding webpage.

Finally, we advise interested parties *to keep checking our Autism Proceeding webpage*. We will continue to post information that will allow you to follow the hearing closely.

#### ***D. PSC's third theory of general causation***

The PSC's third stated theory, as noted above, is that the MMR vaccine alone can cause autism. Under our original schedule for that theory, the PSC would designate three test cases and file all expert reports by May 5, 2008, with an evidentiary hearing to begin on September 15, 2008. However, on April 14, 2008, the PSC proposed a revision of the procedure concerning this theory. That proposal is under consideration, and further discussions concerning that proposal will take place on May 2, 2008.

#### ***E. 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 months, the Chief Special Master, working with the PSC and respondent’s representatives, has begun 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.***

The Office of Special Masters issued the first four batches of such orders (about 200 orders each month) on January 15, February 15, March 15, and April 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.<sup>3</sup> ***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.***<sup>4</sup> 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.

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<sup>3</sup>OSM General Order 13 is posted on this court’s website. From the court’s home page, click on the “Vaccine Info” page, then the “Court Orders” page.

<sup>4</sup>Procedures 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.

Once the first batch of selected medical records is filed in each case--the intent is that the appropriate records be filed in order to determine whether the case was timely filed--the respondent will analyze the records to determine whether, in respondent's view, the case was timely filed. If the respondent takes the position that the case was *not* timely filed, and the petitioner disagrees, then the petitioner will be given a *full chance* to offer evidence and/or argument on the issue. The special master will then make a determination concerning the timeliness issue.

If a case is determined *not* to have been timely filed, the case will be dismissed. If a case is determined to be *timely* filed, then the petitioner will be instructed to file any further medical records pertaining to the injured vaccinee, so that the case will be in a position to be promptly resolved once the "test cases" concerning causation are finally resolved. Of course, we recognize that it may be many months from now until all of the test cases are *finally* resolved, assuming that the losing party appeals the special masters' rulings in those test cases up to the level of the U.S. Court of Appeals for the Federal Circuit. However, the general plan of the Office of Special Masters is that during the time period of any appellate proceedings in the test cases, in the other 4900 autism cases we will either (1) dismiss the case if not timely filed, or (2) if the case is timely filed, get all relevant medical records filed, so that such cases can be promptly processed as to "causation" once the test case results become final.

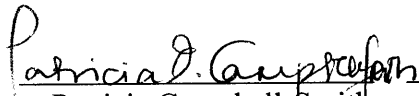
Finally, we offer an explanation concerning the assignment of the pending autism cases to the various special masters. During early 2007, the then-pending autism cases were split between the three undersigned special masters. New autism cases filed since June of 2007 have been assigned to the Chief Special Master. Thus, at this time most of the approximately 4900 pending autism cases are assigned to one of those four special masters. However, since the commencement of the above-described review of the 4900 cases concerning timeliness issues, a few cases have been assigned to one of the *other* four special masters (*i.e.*, Special Masters Abell, Edwards, Millman, and Moran). Those are cases in which timeliness is contested, and it appears that review of the timeliness issue may require a substantial time expenditure by a special master. Of course, as more of the above-described 200-cases-per-month move through the review process, we can expect that timeliness disputes in more cases will arise, and that additional cases will be reassigned, for resolution of *timeliness* issues, from the dockets of Special Masters Vowell, Campbell-Smith, Hastings, and Golkiewicz, to the dockets of the other four special masters.

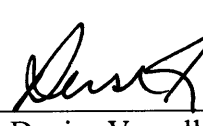
We will continue to report concerning this general process in future Autism Updates.

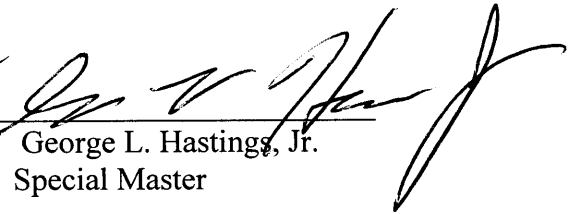
#### ***F. Future proceedings***

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

Autism Updates describing the process. The next status conference in the Omnibus Autism Proceeding is scheduled for May 2, 2008.

  
Patricia Campbell-Smith  
Special Master

  
Denise Vowell  
Special Master

  
George L. Hastings, Jr.  
Special Master