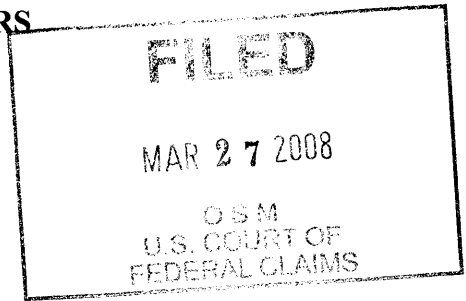


ORIGINAL

# In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

(Filed: March 27, 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 FILE<sup>1</sup>**

## **AUTISM UPDATE--MARCH 27, 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 January 17, 2008. Since that last Update, unrecorded telephonic status conferences were held on January 31, February 4, February 28, March 6, and March 20, 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](http://www.uscfc.uscourts.gov). From the home page, click on the “Vaccine Info” 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 briefs on November 12, 2007, February 1, 2008, and February 11, 2008, and respondent filed a brief on January 11, 2008. Each party is scheduled to file one additional brief. In *Hazlehurst*, petitioners' filed briefs on January 4 and February 7, 2008, while respondent filed a brief on February 6, 2008. In *Snyder*, petitioners filed a brief on February 19, 2008, and respondent's brief is due to be filed on April 1, 2008. After the last of the post-hearing briefs is filed in each case, and after any additional evidence is filed pursuant to the effort detailed below at part C of this Update, the presiding special master will issue a written ruling in each case.

### ***C. 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, and the PSC now has a final draft ready to be filed. 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 is attached as Exhibit A to this Update.

We are told 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 needs to first obtain consent from the experts in question, and is having difficulty in obtaining consent from some of those experts. We have urged the PSC to act as expeditiously as possible, 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.

#### ***D. 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. Since then, the PSC has designated its 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 has filed case-specific expert reports in each of the three cases, as has the respondent. 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.

#### ***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 weeks, 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 three batches of such orders (about 200 orders each month) on January 15, February 15, and March 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>2</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>3</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.

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

---

<sup>2</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>3</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.


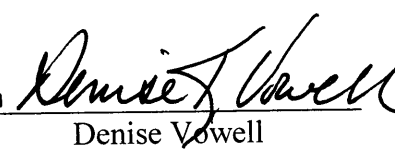
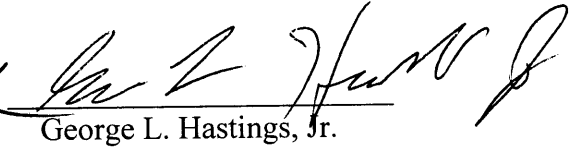
***F. Recent media reports***

In recent weeks, there have been a number of reports in the media concerning a certain Vaccine Act case, currently pending before the court. Some of those reports have erroneously stated that the Office of Special Masters has recently issued a “decision,” “opinion,” or “ruling” concerning the issue of whether a Vaccine Act claimant’s autism symptoms were caused by one or more vaccinations. The OSM has *not* issued any such decision, ruling, or opinion. (All Vaccine Act decisions and opinions are posted on the Court’s web site at: [www.uscourts.gov/vaccine-opinions-decisions](http://www.uscourts.gov/vaccine-opinions-decisions).) Pursuant to 42 U.S.C. § 300aa-12(d)(4)(A), officials of this court are generally prohibited from revealing any information concerning any Vaccine Act case, until a written decision concerning the case has been issued. Accordingly, we cannot provide any details concerning this matter at this time.

We do note, however, that under the statutory provision in question, information from a Vaccine-Act proceeding may be disclosed *if* the person who supplied such information provides “express written consent” for such disclosure. 42 U.S.C. § 300aa-12(d)(4)(A). Thus, for example, in the six autism “test cases” discussed above, we are able to disclose the names of the cases in this Update, because the families in question have provided such “express written consent.” Therefore, in the case that is the subject of the media reports, if the parties who supplied documents and information in the case provide their written consent, we may then be able to appropriately disclose documents in the case. Until such consent is provided, however, we cannot disclose any information. *We reiterate that this court has issued no decision on the issue of vaccine causation of autism.*

***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 April 14, 2008.

		
Patricia Campbell-Smith Special Master	Denise Vowell Special Master	George L. Hastings, Jr. Special Master

March 4, 2008

Justice Keith  
High Court of Justice  
Queen's Branch Division  
The Strand  
London WC2A 2LL

To The Honorable Mr. Justice Keith:

The Office of the Special Masters is a division within the United States Court of Federal Claims responsible for deciding vaccine injury claims pursuant to a federal statute, the National Vaccine Injury Compensation Act, 42 U.S.C. § 300aa. In resolving these claims, the Special Masters consider evidence presented by both sides in vaccine injury compensation proceedings in order to determine whether the party alleging a vaccine injury (the petitioner, represented by a private attorney) is entitled to compensation payable from a fund administered by the U.S. Department of Health and Human Services (the respondent, represented by attorneys from the U.S. Department of Justice). The three undersigned Special Masters are considering approximately 4800 claims in the Omnibus Autism Proceeding (OAP) within the vaccine injury program, where petitioners allege, among other things, that the MMR immunization was a substantial contributing cause of their autistic symptoms.

Respondent's counsel from the Department of Justice has presented certain evidence in these proceedings which was presented originally in litigation in the United Kingdom involving allegations by claimants that the MMR immunization caused their autism injuries. As the U.S. petitioners describe in their application, the evidence presented to the Special Masters by respondent was generated by the defense side (that is, by the pharmaceutical companies) in the U.K. litigation and unsealed upon petition by the respondent in early 2007. The U.S. petitioners, represented by a group of attorneys, known as the Petitioners' Steering Committee (PSC), coordinating the OAP litigation, seek additional evidence from the claimants' side in the U.K. matter.

The undersigned Special Masters join in the PSC petition to unseal certain documents on file in the U.K. matter. The evidence requested is related to the role of the Unigenetics laboratory in conducting tests, analyzing data, and generating reports that are the bases for a significant portion of the scientific expert testimony at issue in the OAP. The reports and testimony of Drs. Rima, Bustin and Simmonds presented by the respondent here (and on behalf of the pharmaceutical defendants in the U.K.) all take issue in various ways with the work of the Unigenetics laboratory. The undersigned

believe this evidence will be of significant assistance in evaluating the PSC's arguments and evidence in support of the Unigenetics work and data. Resolving the conflicting evidence and arguments related to the Unigenetics laboratory is important, ultimately, in our decision of the MMR-related compensation claims pending before us.

We therefore respectfully request that you favorably consider the PSC petition to unseal documents for use as evidence in the Omnibus Autism Proceeding in the U.S. National Vaccine Injury Compensation Program. To that end, we have authorized the PSC to append this letter to their petition to unseal these documents.

---

Denise K. Vowell  
Special Master

---

Patricia Campbell-Smith  
Special Master

---

George L. Hastings, Jr.  
Special Master