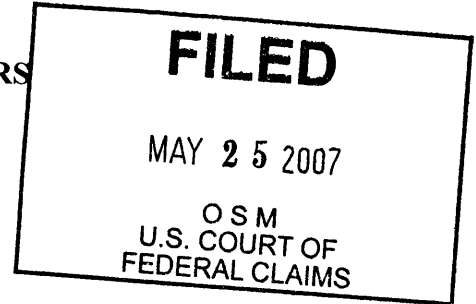


In the United States Court of Federal Claims
ORIGINAL

OFFICE OF SPECIAL MASTERS
(Filed: May 25, 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

AUTISM UPDATE--MAY 25, 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 March 14, 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 C of this Update, below.) Unrecorded telephonic status conferences were held on March 16; April 2, 13, and 25; and May 7, 11, 17, and 23, 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 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. Click on the “Office of Special Masters” page, then on the “Autism Proceeding” page.

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. The process of dividing the pending cases among the three presiding special masters has now been completed. Additional petitions continue to be filed, but at a very 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 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) now approximates 218,000 pages.

2. Petitioners' "2006 motion to compel"

On December 8, 2006, the PSC filed a "Motion to Compel." In this motion, the PSC seeks access to certain data from 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. The motion requests that we direct the CDC and the MCOs to permit the PSC's experts to access certain VSD Project data.

Extensive briefs and exhibits have been filed concerning the matter; the last of those was filed on March 28, 2007. We will file our ruling on the issue soon.

C. Planning for first "test case" on June 11, 2007

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.)

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. At that evidentiary hearing both the PSC and respondent will present 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 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.

The petitioners filed their expert reports into the *Cedillo* case file on February 20, 2007. Respondent’s expert reports were filed on April 24, 2007. The petitioners will present their expert testimony during the first week of the June hearing. The respondent will present expert testimony during the second week and possibly part of the third week, with any rebuttal evidence thereafter.

We are happy to report that both parties have now given their consent to make this 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 201 at the National Courts Building in Washington, D.C.³ 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, transcripts of each day’s proceedings will be posted on this court’s website about 24 hours after the conclusion of each day’s proceedings. (Details regarding each of these three methods appear below.)

On the first day of the hearing, June 11, we will start proceedings at 9:00 a.m. (Eastern time). On the days thereafter, we will likely begin either at 8:00 a.m. or 9:00 a.m., depending on the witness schedule for the day. On most days we will likely adjourn around 6:00 p.m., again 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.

Our courtroom will seat about 400 to 450 people, so we hope that all who wish to attend may be admitted. There will be designated seating near the front 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, letting us 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.)

³This 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, D.C. 20005. (There is limited parking in the area. The closest Metro stops are McPherson Square and Metro Center.)

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 (<http://registration.teleconferencingcenter.com/go/autismphoneaudio>) or by visiting this court's Autism Proceeding web page and clicking on the "*registration page for listening to the autism trial*" link. In either event, you will encounter a registration page. All you need to do is to check the boxes for the dates on which 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 web page. After each day's audio download and transcript is posted, visit that web page and click on the link for "*audio recordings and transcripts.*"

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

D. May 17 "phone conference"--outreach to all attorneys in the Autism cases

On May 17, 2007, we conducted a new type of event in the Omnibus Autism Proceeding--a telephonic conference in which we included not just the "lead counsel" for the PSC, but *all* attorneys with pending Vaccine Act autism claims. Notices about the conference went out via email to all counsel with pending Vaccine Act autism claims⁴ on May 9 and May 16, 2007. Due to the large number of attorneys involved, this was, unfortunately, a "one-way" conference, in which participants other than the special masters could listen, but not speak. Attorneys were, however, able to e-mail questions to us during the conference, which we then answered.

⁴We e-mailed the notices to all such counsel for whom we could locate an e-mail address (we utilized court docket information and a list supplied to us by the PSC). For a few attorneys, however, we could not locate an e-mail address. Any attorney with a pending Vaccine Act autism case, who did not receive the e-mails described above, please e-mail us at autism@ao.uscourts.gov, and provide us with an e-mail address for you.

During the conference we covered two main topics. First, we provided information concerning the “test case” hearing to be held next week, chiefly the information provided at part C of this Update above. Secondly, we discussed our future plans for the Omnibus Autism Proceeding and the “crisis point” at which we find the OAP, as we will discuss below at part E of this Update.

We are pleased to report that approximately 90 counsel dialed in and listened to the conference. We hope that the conference provided valuable information.

We note that the May 17 telephonic conference was part of our continuing effort to communicate as best we can with the petitioners in these nearly 5,000 pending Vaccine Act autism cases, and their counsel. Due to this huge number of people involved, our primary method of communication, to let people know what is going on in the Omnibus Autism Proceeding, has been our “Autism Proceeding” section of the court’s Internet website. We have also, however, conducted a number of in-person conferences open to all counsel, in conjunction with this court’s annual Judicial Conferences. The May 17 conference was an effort on our part to try a *different* form of communication, with the goal of including as many persons as possible. We thank those who participated, and we continue to solicit suggestions concerning how we can best communicate with the autism petitioners and their counsel.

E. “Crisis point” in Omnibus Autism Proceeding

We will now discuss a difficult topic--the fact that we now find ourselves at a *crisis point* in the Omnibus Autism Proceeding. To explain that statement, we need to begin by reviewing some of the *history* of the Omnibus Autism Proceeding.

On July 3, 2002, the Chief Special Master, Gary Golkiewicz, issued the *Autism General Order #1*,⁵ to address a method for handling an unprecedented number of Vaccine-Act petitions alleging that vaccines, either MMR vaccines or thimerosal-containing vaccines, cause autism.

The *Autism General Order #1* grew out of meetings with an informal advisory committee comprised of members of the petitioners’ bar, and representatives of the Secretary of Health and Human Services. The General Order acknowledged that the large number of petitions already filed, and the even larger number of petitions anticipated, would stretch the resources of bench and bar. The Order formally established the Omnibus Autism Proceeding (“OAP”), as a consolidated proceeding to deal with those cases. The Order established the PSC to represent the interests of petitioners in the OAP. The membership of the PSC was to be determined by the petitioners’ bar, with two attorneys selected by the committee to serve as “lead counsel.” The PSC has continued to represent the interests of autism petitioners since the inception of the OAP. Petitioners’ representatives proposed a timetable for resolving the general causation issues involved in these

⁵The *Autism General Order #1* is published at 2002 WL 31696785, 2002 U.S. Claims LEXIS 365 (Fed. Cl. Spec. Mstr. July 3, 2002). It can also be found on this court’s website as the first document in the Autism Master File.

cases. In the *Autism General Order #1*, the Chief Special Master adopted most of the petitioners' proposals, establishing a discovery period, followed by a hearing on the general issue of causation within two years.

All persons with pending Vaccine Act claims involving autism, or who filed claims thereafter, were permitted to "opt in" to the OAP. Any petitioner also retained the right to "opt out" of the OAP and to request that his or her case be heard separately. Over the years since the OAP was established, virtually every autism petitioner has elected to "opt in" to the OAP, and to wait for the outcome of the OAP.

In January 2004, Special Master Hastings reluctantly delayed the initially-scheduled hearing date of March 2004, while various discovery issues were resolved. Over the following 2 ½ years, he urged the PSC lead attorneys to try to prepare their general causation case for trial as soon as possible. He deferred to those PSC attorneys, however, when they said that they needed more time to complete discovery, and to wait for the results of certain studies. Special Master Hastings was reluctant to press any petitioners to try their cases before they were ready to do so, and took that approach to the autism cases, granting a number of extensions of the date for the general causation hearing.

On July 18, 2006, the PSC filed a proposal for the conduct of general causation proceedings, proposing a hearing in June 2007, conducted over a two-to-three-week period, in which petitioners would present evidence regarding *all* of their theories of *general causation*. In accordance with the PSC's request, a general causation hearing was scheduled to commence on June 11, 2007, with petitioners to file expert reports on February 16, 2007, and respondent's expert reports to be filed 60 days later.

Numerous status conferences were conducted with the PSC and respondent's counsel between September and December 2006. During a status conference held on December 20, 2006, the PSC proposed a substantial change in the general causation hearing format. The PSC proposed that, rather than a general causation hearing, presenting *all* of the petitioners' causation theories, the PSC would instead present an actual case as a "test case" to test *one* of the PSC's *three* general causation theories; namely, the theory that a *combination* of the MMR vaccine and thimerosal-containing vaccines can cause autism. The PSC represented that this combination theory would cover "most" of the cases in the OAP. The PSC proposed that we later conduct subsequent hearings to address the PSC's two other theories: one, that *thimerosal-containing vaccines alone* can cause autism, and two, that the *MMR vaccine alone* can cause autism.

At about the same time that the PSC proposed this change of format for the general causation hearings, the Chief Special Master assigned two additional special masters, Special Masters Campbell-Smith and Vowell, to co-manage the autism docket along with Special Master Hastings. The three special masters jointly evaluated the PSC's proposal, and agreed to it, but added one major condition. We determined that for the "test case" approach to be useful, the PSC would need to designate *two additional* cases, in addition to the *Cedillo* case, as "test cases" with respect to the

PSC's first general causation theory. The "general causation" testimony to be presented at the June hearing could be applied to *all three cases*, but the PSC would also need to present "specific causation" evidence as to the other two cases by September 30 of this year. Then, Special Master Hastings would decide the *Cedillo* case, and the two other special masters would decide the other two cases.

Thereafter, under the plan that we adopted, a similar "test case approach" would be applied to each of the *other two* general causation theories of the PSC. That is, the PSC would designate three test cases as to each theory, and the three cases would be decided by the three special masters.

This plan, in our view, is the best method by which to move the bulk of the autism cases toward final resolution. In our estimation, it seems quite important to have *more than one* special master hear the general causation evidence and offer an evaluation of the general causation issues. If only one special master were to evaluate the general causation issues, there might be concern that the fate of so many families would be determined based upon the analysis of a single person. Having more than one special master evaluate the general causation evidence might alleviate that concern, and give people greater assurance that ultimately the correct evaluation will prevail. Moreover, under the Vaccine Act scheme each decision of a special master may be appealed to (1) a judge of the Court of Federal Claims, and (2) a panel of the United States Court of Appeals for the Federal Circuit. Only the Federal Circuit's rulings are *binding* on all special masters. It seems likely, therefore, that, ultimately, rulings by one of those higher courts, particularly the Federal Circuit, will finally determine, or strongly influence, the outcome of these autism cases. Accordingly, it may be very helpful to the judges of those courts to have available the evaluations of *more than one special master* concerning the general causation issue.

For that reason, we special masters have been consistent in requiring that the PSC designate *additional* test cases beyond the *Cedillo* case. At that first status conference on December 20, 2006, when the PSC *first* proposed moving to a "test case" format, Special Master Hastings advised the PSC attorneys that for a "test case" approach to be effective, the PSC would need to offer additional cases, rather than a single test case, for trial. Since that time, the PSC has stated that it would select two such cases, and has represented that it is working diligently on selecting the two cases. At the status conference held on January 25, 2007, the PSC was orally instructed to designate such cases within 30 days--*i.e.*, by February 24, 2007. The PSC did not do so. At the status conference held on February 28, 2007, the PSC representative stated that the two cases would be designated within seven to ten days. That did not happen. After further discussion, we extended the deadline for designation until March 30, 2007. That date, too, passed without any designation. At the status conference held on April 2, 2007, the PSC attorney stated that the two cases would be designated on April 6, 2007, but no designation was made by that date either. We then extended the deadline to April 30, then again to May 10, but, still no additional test cases have been designated.

Accordingly, we now find ourselves in a position where we have a hearing date and expert reports in only *one* of the 4800 pending autism cases. And, without going into detail, we note that

the facts of that one “test” case are fairly unusual, and do not appear to be representative of the majority of the cases in the OAP.

Therefore, we wish to make it clear to all, particularly the petitioners’ counsel with autism cases, that the PSC has been unable, for whatever reason, to designate other “test cases” for trial. The PSC lead attorneys say that they are still trying to find and designate cases, but they have not been able or willing to do so as yet. So, we now ask for the assistance of other autism counsel in finding additional cases for all three theories currently advanced. We are still looking for two additional test cases on the theory that thimerosal-containing vaccines and the MMR vaccine, acting *together*, cause autism. We still wish to try the two additional cases on this combination theory, in individual proceedings, by September 30, 2007. Of course, all of the *general causation* evidence developed in the June 2007 hearing could be applied to those two cases.

Additionally, we are seeking three test cases on each of the two remaining theories of causation, with trial contemplated on one theory in early 2008 and trial on the second theory in mid-2008.

We want to stress that we believe that we are at a *crisis point* in the efforts to move the autism cases toward decision. The Office of Special Masters has adopted the approach toward these cases originally suggested by *petitioners’* counsel, and we have patiently waited for almost *five years* to give that approach a chance to succeed. We acknowledge that the PSC lead attorneys have put in a lot of hard and good work during those years, and we appreciate that work. But, after five years, we still have only *one* case ready for trial, and one that may be factually too unusual to give much guidance concerning the general causation issues. Either something must change, or we will be required to go to a new approach.

We note that perhaps many of the petitioners’ counsel have been waiting on the sidelines themselves, waiting to see what results the OAP might bring. That is understandable, but the time for waiting is now *over*. We hereby urge other autism counsel at this time, to *get more involved* with the PSC and the OAP. If you believe that one of your cases might make an appropriate test case for any of the three causation theories, please *contact* the PSC lead attorneys promptly. 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. Further, if you believe that one of your test cases might make an appropriate test case for the PSC’s *first* theory, that the MMR vaccine and thimerosal-containing vaccines can *combine* to cause autism, we ask that, in addition to contacting the PSC, you also e-mail our autism account, autism@ao.uscourts.gov, to let us know about the case as well.⁶

In the event that petitioners do not promptly come forward with additional test cases, to allow us to pursue the “test case” approach described above for handling the autism cases, it appears that

⁶If you are unsure whether your case might make an appropriate test case, contact the PSC, and/or contact the office of the assigned special master, to request a status conference concerning the case.

the “omnibus approach” to the autism cases may have to be declared a failure. In that case, we special masters anticipate that we would then move to a “case-by-case” approach. That is, we would begin to issue orders in the cases on our individual dockets, with a view toward moving as many cases as possible toward trial. Counsel should anticipate orders to file the documents required by Section 300aa-11(c), to include amended petitions, medical records, and expert opinions.

We believe that there still is time to revive the “test case” approach. But it will require that petitioners’ counsel promptly come forward with additional test cases. We hope that such cases will be brought forward very soon, so that we will not need to abandon the omnibus approach to resolving these autism cases.

F. Notice to petitioners’ attorneys about updating attorney information

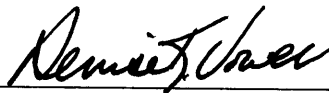
It is imperative that the Clerk’s office and respondent be provided with up-to-date service addresses, email addresses, and phone numbers of petitioners’ counsel. See RCFC 83.1(c)(3). Therefore, if any of this information has changed since a petitioners’ attorney filed a petition, counsel should file with this Court a notice supplying the updated information. Further, keep in mind that the Rules of the Court of Federal Claims do not provide for representation by a firm, but rather by a single counsel of record. Therefore, if a *counsel of record* for an autism petitioner leaves a firm, the firm and counsel should take care to file, depending on the client’s wishes, either (1) a motion to substitute another attorney in the firm as counsel of record, or (2) a notice of change of address for the counsel of record. See RCFC 83.4(c)(4).

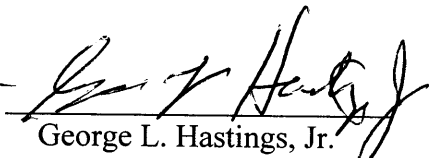
If a petitioner’s counsel has doubt about whether the information about the attorney of record currently on file with the Clerk is accurate, counsel should contact the Clerk’s office at (202) 357-6366.

G. 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 June 1, 2007.


Patricia Campbell-Smith
Special Master


Denise Vowell
Special Master


George L. Hastings, Jr.
Special Master