

# In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS  
(Filed: January 19, 2007)

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IN RE: CLAIMS FOR VACCINE INJURIES \*  
RESULTING IN AUTISM SPECTRUM \*  
DISORDER OR A SIMILAR \*  
NEURODEVELOPMENTAL DISORDER \*                   AUTISM MASTER FILE  
\*  
VARIOUS PETITIONERS, \*  
\*  
v. \*  
\*  
SECRETARY OF HEALTH AND \*  
HUMAN SERVICES, \*  
\*  
Respondent. \*  
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## AUTISM UPDATE--JANUARY 19, 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 November 27, 2006. Since that Update, a number of important documents have been filed by the petitioners into the Autism Master File,<sup>1</sup> and much planning has occurred concerning the causation hearing to be held in June 2007. (See part D of this Update, below.) Unrecorded telephonic status conferences were held on November 29 and December 20, 2006, and on January 8, 2007. Further, two additional special

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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 nearly all of the complete File, with the exception of a few documents that are withheld from the website due to copyright considerations or due to § 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.

masters have been assigned to the OAP (see part C below); accordingly, this Update is being issued by the *three special masters* now presiding over the OAP.<sup>2</sup>

### ***A. Number of cases***

At this time, more than 5,100 petitions in autism cases have been filed, and about 4,750 remain pending, stayed (at the petitioners' own requests) until the conclusion of the Omnibus Autism Proceeding.<sup>3</sup> Additional petitions continue to be filed, although at a considerably 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, petitioners have 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. At this point, all of the petitioners' discovery requests have been resolved, except for the ongoing production discussed at point 2 below and the controversy discussed at point 4 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 217,000 pages.

#### ***2. The vaccine license application files***

One category of documents requested, pursuant to petitioners' original Requests for Production Nos. 10 and 12, involves the Food and Drug Administration (FDA) files that pertain to vaccine license applications. In this area, efforts to produce material have proceeded slowly, as detailed in previous Autism Updates, but the process of production of that material continues to move forward, and is now very near completion. Since the last update, respondent has submitted to the Petitioners' Steering Committee (hereinafter "the Committee") several small additional

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<sup>2</sup>Accordingly, use in these Autism Updates of the pronouns "we," "our," etc., will refer to the three undersigned special masters collectively.

<sup>3</sup>Of the petitions that are no longer pending, 255 were voluntarily dismissed or withdrawn by the petitioners; in 88 of those cases, the dismissal was due to the fact that, inadvertently, a second petition had been filed pertaining to the same autistic child. In addition, 117 cases have been dismissed by a special master because they were not timely filed.

portions of the FDA files pertaining to several vaccines. Prior to that, other portions of the files for those vaccines were submitted, and files for a number of additional vaccines were submitted. All told, files have been submitted for 22 vaccines, as enumerated in a number of previous Autism Updates. With respect to a few of those 22 vaccine files, we anticipate that a few more pages will be disclosed shortly.<sup>4</sup> That disclosure should complete the discovery process with respect to the vaccine license files.

### ***3. Discovery pursuant to resolution of the “2004 motion to compel”***

On April 14, 2005, Special Master Hastings filed a Discovery Order resolving the petitioners’ “motion to compel production” that was filed on March 9, 2004. The parties have proceeded with the discovery procedures described in that Order, concerning the study known as the “Thimerosal Screening Analysis” (“TSA”). During certain 2006 status conferences, the Committee disclosed that the Committee’s experts did, in fact, obtain access to certain data concerning the TSA. The written report of those experts, resulting from their evaluation of that data, was filed into the Autism Master File on December 13, 2006, as Petitioners’ Exhibit No. 91.

### ***4. Petitioners’ “2006 motion to compel”***

On December 8, 2006, the Committee file a second “motion to compel,” again relating to the TSA study. In this motion, the Committee seeks access to certain data from the Vaccine Safety Datalink (“VSD”) program, which is a program sponsored by the Centers for Disease Control in which data is collected from a number of managed care organizations (“MCO’s”) for use in reviewing vaccine safety issues. The motion requests that we issue subpoenas directing the CDC and the MCO’s to permit the Committee’s experts to access certain VSD data.

The parties have agreed that the respondent will file a response to the motion on January 19, 2007. Respondent’s counsel is also in contact with counsel for the MCO’s, to determine how counsel for the MCO’s will desire to participate in whatever procedures are conducted concerning this discovery request.

We note also that we have discussed this matter with the parties, and all agree that the resolution of this new discovery matter *will not* delay the presentation of the “test cases” to be discussed in part D of this Update, below.

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<sup>4</sup>I note that while the Committee’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 Committee. (See discussion in the Autism Update filed on June 23, 2004, pp. 4-6.)

### ***C. Additional special masters added to Omnibus Autism Proceeding***

During the Omnibus Autism Proceeding status conferences from mid-summer through November of 2006, the parties discussed the issue of whether one or more additional special masters should become involved in the OAP. Specifically, at the conference held on July 27, Special Master Hastings notified the parties that the Chief Special Master had raised the possibility of assigning additional special masters to the OAP. Under this proposal, the pending cases would be divided in a random fashion among Special Master Hastings and the additional masters, and the additional special masters would jointly preside with Special Master Hastings over the general causation hearing to be held in June 2007. All such special masters, jointly or individually, would issue analyses of the evidence presented at the general causation hearing. Then, each of those special masters would turn to the task of applying the knowledge gained from that general causation hearing to the *individual cases* assigned to that master. Special Master Hastings invited the parties to consider the possibility of adding additional special masters, and to present discussion of that subject at the next OAP status conference.

The next OAP status conference was held on August 17, 2006. Both the Chief Special Master and Special Master Hastings participated. The two participating representatives of the Committee, attorneys John Kim and Thomas Powers, expressed opposition to the idea of adding additional special masters to the OAP at this time. At the conclusion of that conference, the special masters requested that the Committee file a memorandum setting forth the Committee's reasoning; the Committee representatives agreed to do so. At subsequent status conferences held on September 6, October 2, October 20, November 8, and November 19, 2006, however, the Committee's representative on each occasion sought additional time in which to file the Committee's views concerning this matter. The written views of the Committee were finally presented in a document that was "e-mailed" to the Court on January 5, 2007, and formally filed on January 9, 2007.

As to this issue of adding additional special masters to the OAP, the Chief Special Master carefully considered the views advanced by the Committee's representatives during the OAP status conference held on August 17, 2006, and in the Committee's memorandum filed on January 9, 2007. He discussed the matter extensively with other special masters. After such consultation, the Chief Special Master, along with the undersigned special masters, reached the conclusion that it is appropriate that additional special masters begin to participate in the OAP at this time. The Chief Special Master set forth his reasoning in a document filed into the Autism Master File on January 11, 2007. In that document, he formally designated that Special Master Denise Vowell and Special Master Patricia Campbell-Smith would be added to the OAP.

We briefly summarize the Chief Special Master's reasoning as follows. First, it simply seems highly unlikely that a single special master would ever be able to finally dispose of nearly 5,000 separate individual cases. In the period from 2002 to the present, during which the petitioners did *not* seek to put forward their causation case, but concentrated on discovery matters only, it made sense to utilize a single special master. During that period, Special Master Hastings was able to manage the discovery issues in the OAP, and also deal with procedural matters in the individual

cases, such as motions to dismiss for untimely filing, etc. However, since the petitioners are now ready to present their general causation evidence and to present their specific causation evidence in some specific cases, it seems inevitable that more than one special master will soon be needed to decide the specific causation issues in so many cases. In each individual case, a special master will need to apply the evidence introduced in the *general* causation hearing to the *specific* facts of that individual case. It is quite unlikely that a single special master will be able to do that in each of nearly 5,000 cases. Therefore, since it seems inevitable that additional special masters will become involved in these cases, it seems that *now* is the appropriate time to get additional special masters involved. That is, the additional special masters will be able to witness “in person” the presentation of all the witnesses concerning *general* causation in June 2007, so that they will be ready to apply that evidence to *individual* cases as soon as that is necessary.

Second, it also seems desirable, in the overall scheme of the Vaccine Act, to have more than one special master hear the general causation evidence and offer an evaluation of the general causation issue. If only one special master were to evaluate the general causation issue, 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 is subject to appellate review by (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 courts 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 these reasons, the two additional special masters have now been added to the Omnibus Autism Proceeding, and will participate in deciding the individual cases, as detailed in the next section of this Update. The currently-pending cases will be divided by the Chief Special Master randomly among those two masters and Special Master Hastings.

#### ***D. Planning for causation hearing***

The two most recent Updates reported that, acting on a proposal of the Committee, Special Master Hastings scheduled an evidentiary hearing concerning the “general causation issue”--*i.e.*, the issue of whether thimerosal-containing vaccines (“TCV’s”) and/or MMR vaccines can cause autism and/or similar disorders, and, if so, in what circumstances--for next June 11-29, 2007. Since the last Update, however, the Committee has changed its proposal somewhat, so that the exact focus of the June 2007 hearing will change slightly. We will discuss this change below.

To explain this change, we begin by noting that since the beginning of the Omnibus Autism Proceeding in 2002, all participants have shared the goal of processing this large group of cases as efficiently as possible. All participants have recognized that while in each case the ultimate question

would be whether a vaccination or vaccinations injured the *specific vaccinee*--i.e., the “specific causation” issue in the case--in virtually every case the answer to the “specific causation” issue would depend, in part, on the answer to a “general causation issue”--i.e., the general question of whether TCV’s, or MMR vaccines, or both together, *can cause* neurodevelopmental disorders. All have agreed that because the evidence concerning that general causation issue would be relevant to many individual cases, it made sense from an efficiency standpoint that the parties would present their evidence concerning that general causation issue at a single initial evidentiary hearing. That evidence, once presented at such a hearing, and recorded via transcript or other format, could then be applied to *many* individual cases. That would eliminate the need for the parties to repeatedly present the same general testimony, by the same expert witnesses, in one individual case after another.

To be sure, the participating counsel did disagree on one point. The respondent’s counsel suggested that the evidence relevant to the “general causation issue” be presented in the context of a “test case”--that is, we would conduct a hearing regarding *one particular Vaccine Act vaccinee*, at which both sides would present all the “general causation issue” evidence in that hearing; a special master would resolve that particular case; and the “general causation issue” evidence presented and recorded in that test case would then be available to be applied to *other* individual Vaccine Act petitioners. (I will refer to this suggestion as the “test case method” of proceeding). The petitioners’ counsel, on other hand, proposed a slightly different method of proceeding. They noted that with respect to a previous group of Vaccine Act cases involving a common question of general causation, the “rubella/arthropathy” cases, one special master had conducted a hearing which was *not* specific to a particular case, but instead addressed the *general causation issue* of whether the rubella vaccine can cause chronic arthropathy. The special master had then published an analysis of that general causation issue, which analysis prompted most of the individual cases to be resolved without further hearing, either settling on the basis of an award in the petitioner’s favor, or voluntarily dismissing.

In the “Autism General Order #1,” which initiated the Omnibus Autism Proceeding, the Chief Special Master in effect adopted the petitioners’ proposal, rather than the respondent’s “test case” model. (See discussion at pp. 3-4 of that order.<sup>5</sup>) However, the important point is that under *either* proposed method of proceeding, we would initiate the resolution of the individual autism cases by conducting a lengthy evidentiary hearing involving a substantial amount of evidence concerning the “general causation issue,” thereby creating a substantial body of evidence that could thereafter be applied to *many individual cases*.

Since the time of that *Autism General Order #1*, the participants in the Omnibus Autism Proceeding have been working under the assumption that we would follow the procedure proposed by the petitioners in 2002--i.e., conduct an evidentiary hearing concerning the “*general causation issue*,” have a special master issue a written analysis of the evidence concerning that general

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<sup>5</sup>The *Autism General Order #1*, issued on July 3, 2002, appears as the first document on the autism website mentioned above.

causation issue, and then turn to resolution of the *individual* cases. We continued to follow that assumption during mid-2006, as we began specific planning for a general causation hearing in June 2007.

However, at the OAP status conference held on December 20, 2006, the Committee representative announced that the Committee was changing its proposal concerning the initial evidentiary hearing to be held in June 2007. The Committee's new proposal was that we change to a "test case" method of proceeding. That is, at the June 2007 hearing the parties would present not only evidence concerning the "general causation issue," but *also* evidence concerning *one particular vaccine case*, so that a ruling concerning "specific causation" in that vaccinee's case could be issued at the conclusion of the hearing. The Committee confirmed this new proposal in a written document filed on January 5, 2007.

We, the undersigned special masters, have considered this proposed change to the format of the June 2007 hearing, and have determined that we will permit the Committee to follow its newly-proposed format.<sup>6</sup> Therefore, as proposed by the Committee, we will conduct an evidentiary hearing commencing on June 11, 2007, at which both parties will present testimony concerning the general causation issue and *also* the specific causation issue in the particular case selected by the Committee, which is the case of *Cedillo v. Secretary of HHS*, No. 98-916V. All three special masters will preside over that hearing, but Special Master Hastings alone will decide the *specific causation* issue in that *Cedillo* case. Further, we have also instructed the Committee to select *two* more individual cases, in addition to the *Cedillo* case, which would fall within the same general causation theory to be presented by the Committee at the June hearing. The Committee was instructed to be ready to present each of those two cases for specific causation rulings either in June of 2007 or within the following three months. Those two cases will be assigned to Special Masters Campbell-Smith and Vowell. Each of those special masters, then, will be able to apply the evidence concerning the *general* causation issue, presented at the June 2007 hearing, to the *specific* case assigned to that special master.

Thus, by the early fall of this year, three different special masters will have heard the petitioners' theory concerning the general causation issue, to be presented in June 2007, and will be ready to apply that evidence to the *individual cases* that will also have been presented to those special masters. Soon thereafter, three rulings, each evaluating that general causation theory, will be issued. And those three special masters will then be ready to evaluate the specific causation issues in the *other* autism cases as swiftly and efficiently as possible.

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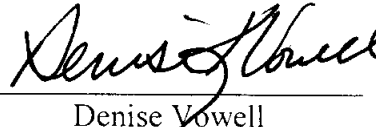
<sup>6</sup>At the OAP status conference held on January 8, 2007, respondent's counsel expressed concern that this change in format could delay the ultimate resolution of some of the autism cases. Respondent will describe these concerns in a brief to be filed on January 26, 2007. We will carefully study that brief, and, if appropriate, make alterations in our hearing plan.

***E. Future proceedings***

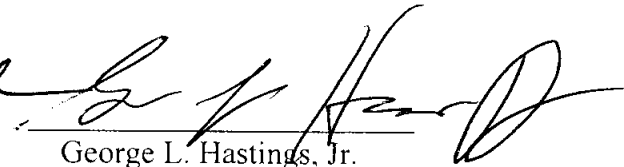
We will continue to meet regularly with counsel for both the Committee and respondent, to finalize details for the extensive hearing to be held in June 2007, and the additional case-specific hearings to be held in June or soon thereafter. We will continue to issue these Autism Updates describing the process. The next status conference in the Omnibus Autism Proceeding is scheduled for January 25, 2007.



Patricia Campbell-Smith  
Special Master



Denise Vowell  
Special Master



George L. Hastings, Jr.  
Special Master