

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

(Filed: April 21, 2006)

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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. \*  
\*\*\*\*\*

### SECOND RULING CONCERNING ISSUE OF TIME FOR FILING EXPERT REPORTS

HASTINGS, *Special Master*.

The above-captioned proceeding is a special proceeding conducted pursuant to the National Vaccine Injury Compensation Program (hereinafter “the Program”).<sup>1</sup> As will be detailed below, this proceeding involves claims by numerous families, filed under the Program, alleging that their children’s neurodevelopmental disorders were caused by certain childhood vaccines. This document constitutes my ruling concerning a motion by the petitioners seeking more time in which to file the expert reports on petitioners’ behalf.

As set forth below, I hereby grant certain relief in this regard to the petitioners.

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<sup>1</sup>The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 *et seq.* (2000 ed.). Hereinafter, for ease of citation, all “§” references will be to 42 U.S.C. (2000 ed.). I will also at times refer to the statute that governs the Program as the “Vaccine Act.”

# I

## BACKGROUND

### A. *The “Omnibus Autism Proceeding”*

The dispute that is the subject of this opinion arises in the context of an unusual situation involving multiple cases filed under the Program that share a common issue of medical causation. Each of these cases involves an individual who suffers from a neurodevelopmental disorder known as an “autism spectrum disorder”--“autism” for short--or a similar neurodevelopmental disorder. In each case, it is alleged that such disorder was causally related to one or more vaccinations received by that individual--*i.e.*, it is alleged that the disorder was caused by measles-mumps-rubella (“MMR”) vaccinations; by the “thimerosal” ingredient contained in certain diphtheria-tetanus-pertussis (“DTP”), diphtheria-tetanus-acellular pertussis (“DTaP”), hepatitis type B, and hemophilus influenza type B (“HIB”) vaccinations; or by some combination of the two. To date, almost 5,000 such cases have been filed with this court, and additional cases continue to be filed each week.

To deal with this large group of cases involving a common factual issue--*i.e.*, whether these types of vaccinations can cause autism--in 2002 the Office of Special Masters (OSM) conducted a number of informal meetings with attorneys who represent many of the autism petitioners and with counsel for the Secretary of Health and Human Services, who is the respondent in each of these cases. At these meetings the petitioners’ representatives proposed a special procedure by which the OSM could process the autism claims as a group. They proposed that the OSM utilize a two-step procedure: first, conduct an inquiry into the *general causation issue* involved in these cases-- *i.e.*, whether the vaccinations in question can cause autism and/or similar disorders, and, if so, in what circumstances-- and then, second, apply the outcome of that general inquiry to the individual cases. They proposed that a team of petitioners’ lawyers be selected to represent the interests of the autism petitioners during the course of the general causation inquiry. They proposed that the proceeding begin with a period of discovery concerning the general causation issue, followed by the submission of expert reports by each side, an evidentiary hearing, and finally a ruling on the general causation issue by a special master. Then, the general causation conclusions, reached as a result of the general proceeding, would be applied to the individual cases.

As a result of the meetings discussed above, the OSM adopted a procedure generally following the format proposed by the petitioners’ counsel. On July 3, 2002, the Chief Special Master, acting on behalf of the OSM, issued a document entitled the *Autism General Order #1*.<sup>2</sup> That Order set up a proceeding known as the Omnibus Autism Proceeding (hereinafter sometimes

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<sup>2</sup>The *Autism General Order #1* is published at 2002 WL 31696785, 2002 U.S. Claims LEXIS 365 (Fed. Cl. Spec. Mstr. July 3, 2002). I also note that the documents filed in the Omnibus Autism Proceeding are contained in a special file kept by the Clerk of this court, known as the “Autism Master File.” Most of that file may be viewed on this court’s Internet website at [www.uscfc.uscourts.gov/osm/osmautism.htm](http://www.uscfc.uscourts.gov/osm/osmautism.htm).

“the Proceeding”). In that Proceeding, a group of counsel, selected from attorneys representing petitioners in the autism cases, was designated as the Petitioners’ Steering Committee, and began the process of obtaining and presenting evidence concerning the *general issue* of whether these vaccines can cause autism, and, if so, in what circumstances. Expert reports for the petitioners and the respondent will be filed, and an evidentiary hearing will be held. A special master will issue an analysis of that general issue, and the results of that analysis will then be applied to the individual cases. (2002 WL 31696785 at \*3; 2002 U.S. Claims LEXIS 365 at \*8.)

The *Autism General Order #1* assigned the responsibility for presiding over the Omnibus Autism Proceeding to the undersigned special master. In addition, I have also been assigned responsibility for all of the individual Program petitions in which it is alleged that an individual suffered autism or an autistic-like disorder as a result of MMR vaccines and/or thimerosal-containing vaccines. The individual petitioners in each of those cases have requested that, in general, no proceedings with respect to the *individual petitions* be conducted until after the conclusion of the Omnibus Autism Proceeding concerning the *general* causation issue.<sup>3</sup> The OSM will then deal specifically with the individual cases.

***B. The schedule for the Omnibus Autism Proceeding, and the petitioners’ request here at issue***

The *Autism General Order #1* contained an initial schedule for the anticipated activities in the Omnibus Autism Proceeding. (See Part D of that *Order*, and Exhibit E attached thereto.) The schedule anticipated a discovery period of fourteen months; petitioners’ expert reports to be filed in November 2003; an evidentiary hearing to commence in March 2004; and the special master’s ruling on the general causation issues to be issued by July 2004.

The actual course of the Omnibus Autism Proceeding, quite obviously, has deviated from that initial schedule. As detailed in my Autism Updates filed into the Autism Master File (and posted on this court’s website) regularly over the past three-plus years, the discovery process has taken much longer than initially anticipated. The Petitioners’ Steering Committee (hereinafter “the Committee”) made a very extensive initial request for production of materials from government files, and later an extensive second request. At a couple of points, disputes between that Committee and respondent’s representatives delayed production. However, respondent’s representatives have cooperatively worked with the Committee, and those disputes have eventually been resolved between the parties on each occasion. As a result, a massive amount of material from government files--well over 200,000 pages--has been provided to the Committee. Moreover, much of this material has been from the Food and Drug Administration’s (FDA) vaccine license application files, which means that production of each set of documents (with respect to each vaccine of each manufacturer) can occur

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<sup>3</sup>I note that it is up to each individual petitioner to determine whether to defer proceedings concerning his or her own case pending the completion of the Omnibus Autism Proceeding. If an individual petitioner has proof of causation in his own case that he wishes to put before a special master at any time, that petitioner will be allowed to do so.

only after a very lengthy and cumbersome procedure involving review of the material (1) by FDA personnel, (2) by Department of Justice personnel, and (3) by personnel of the vaccine manufacturer that originally submitted the material for the license application. Production of this huge amount of material, via such a complicated process, has simply taken a long time, despite conscientious efforts by all involved.

Further, the discovery process was additionally delayed due to efforts by the Committee to obtain records directly from the files of a vaccine manufacturer, an effort that proved unsuccessful. See *In Re Autism Claims*, 2004 WL 1660351 (Fed. Cl. Spec. Mstr. July 16, 2004).

Unsurprisingly, the Committee has desired to delay the filing of expert reports until after the completion of the discovery process. I have, accordingly, deferred the time for the Committee to submit the expert reports on behalf of petitioners. In early 2005, however, with the end of those discovery procedures apparently in sight, I instructed the Committee to propose a new date for the submission of the petitioners' expert reports. The Committee submitted a filing in that regard on June 14, 2005, and the respondent filed a response thereto on July 12, 2005.

In its filing, the Committee requested that it not be required to submit the petitioners' expert reports prior to the end of 2006. The Committee pointed to the existence a number of ongoing medical studies relevant to the general causation issue, some of which are scheduled to be completed or published in late 2006. The Committee argued that it makes sense that its experts be able to evaluate these studies before filing their expert reports.

Respondent, in reply, offered solely a legal argument, contending that under the statute I do not have the *legal authority* to delay the Omnibus Autism Proceeding any further.

On August 11, 2005, I issued my Ruling Concerning Issue of Time for Filing Expert Reports. In that document, I first dealt with respondent's argument concerning my legal authority, finding that argument to be without merit. I then addressed the issue of how much time I should allow the Committee in which to file its expert reports. I noted that the Committee had pointed to specific relevant ongoing studies relevant to the general causation issue. (Filing of June 14, 2005, p. 5.) For two of those studies there were anticipated publication dates later in 2005 (items 1, 5), and for three more studies, publication or completion was anticipated about September 2006 (items 2, 3, 9). I noted that seemed reasonable to wait for the results of those particular, identified studies. Accordingly, at that time I deferred indefinitely the due date for the petitioners' expert reports. I also required, however, that the Committee file a statement from an *expert*, giving the *expert's* views to whether it is necessary--and, if so, *why* it is necessary--to wait until the end of 2006 to file the expert reports.

In compliance with my direction, the Committee filed, on January 31, 2006, the report of Dr. Sander Greenland, a professor of epidemiology at the UCLA School of Public Health. Dr. Greenland analyzed certain aspects of the available evidence, and opined that it would be appropriate for me to allow additional time to the Committee to file its expert reports.

After the Committee filed Dr. Greenland's report, respondent's representatives informed me that respondent would present no evidence concerning this timing issue, and no argument beyond the legal argument presented in respondent's filing of July 12, 2005.

## II

### DISCUSSION

As I have stated on earlier occasions, it seems unfortunate to see delay in the resolution of the Omnibus Autism Proceeding. The Proceeding has already lasted for well over three years, when the original proposed schedule called for completion in two years. Further, ideally, I certainly would like to see these autism causation issues move to a conclusion as soon as possible--not for the sake of the respondent, the vaccine manufacturers, or myself, but for the sake of the many *families* who have pending Vaccine Act claims, who need help for their developmentally-impaired children, and who have voluntarily elected to stay proceedings concerning their own individual Vaccine Act petitions pending the completion of the Omnibus Autism Proceeding. For the sake of these families, I would *very much* like to reach a resolution of the Omnibus Autism Proceeding as soon as possible.

However, it must be kept in mind that one primary purpose of the Vaccine Act is to *benefit the petitioners*, and in these autism cases the petitioners are families with children suffering from devastating disorders. I believe that it is appropriate to give the petitioners' representatives the time that they reasonably need in order to develop their causation case to the greatest extent possible. All of us involved in the Omnibus Autism Proceeding would like to see it conclude soon, but it is also important to give these families the chance to present the best case that they can. It is true that this process is taking longer than Congress ideally envisioned for most Vaccine Act cases, but the length of the process is simply the result of the fact that these cases involve novel and difficult scientific issues of medical causation. And, as pointed out in my Ruling filed on August 11, 2005, Congress clearly understood that *some* Vaccine Act cases *would* take longer than the ideal, as shown by the fact that Congress gave each petitioner the option under 42 U.S.C. § 300aa-21(b) of staying in the Program even after the initial time period for decision had expired. Accordingly, it does not seem necessary or desirable to arbitrarily force the Committee to present its evidence in the Omnibus Autism Proceeding before that Committee deems itself ready to do so. Instead, while I have encouraged the Committee to proceed as swiftly as possible, I must consider carefully the arguments of the Committee in seeking more time.

I note that three factors are important. First, while the Committee's discovery efforts seem to be *nearing* the end, they are not yet complete. In this regard, I note that on April 14, 2005, I issued a "Discovery Order." That order essentially memorialized an agreement between the parties designed to permit experts retained by the Committee to obtain certain data relevant to a study known as the "Thimerosal Screening Analysis" ("TSA"), which is also described in Dr. Greenland's report (p. 12) as the "Verstraeten 2003" study. Some progress has been made in implementing those procedures, but much additional work remains to be done. At an unrecorded status conference concerning the Omnibus Autism Proceeding held on March 16, 2006, I strongly urged the

Committee to substantially speed up the pace of these procedures, and the Committee representatives assured me that they would do so. However, the TSA does appear to me to be an extremely important study concerning the general causation issue that I face in the Omnibus Autism Proceeding, and, as described in Dr. Greenland's report (p. 12) and in testimony that was presented to me on September 23, 2004, there seems to be good reason to allow the Committee's experts to fully analyze the data from that study. Therefore, it seems quite appropriate to grant the time that the Committee now seeks, in order for the Committee's experts to complete their analysis of this very important data.

Second, as noted above, the Committee has identified three specific studies, relevant to the general causation issue that I must decide, in which completion or publication is scheduled for around September of 2006. It seems appropriate to allow the requested time so that the results of these studies may be incorporated in the experts' analysis.

Third, as explained above, the Committee has now filed the report of Dr. Greenland, an expert in epidemiology with excellent credentials relevant to the issue of how I should approach the causation issue before me. Dr. Greenland has opined that it would be prudent to grant the time requested. In contrast, respondent has *not* provided any expert report concerning this issue. Indeed, respondent's only filing concerning this issue (filed on July 12, 2005) offered only a legal contention which I found to be without merit; respondent has failed even to offer any *argument* as to why, as a matter of discretion, I should *not* allow the time that the Committee has requested.

Accordingly, for the three reasons set forth above, I will defer the due date for the Committee's expert reports until December 31, 2006.<sup>4</sup>

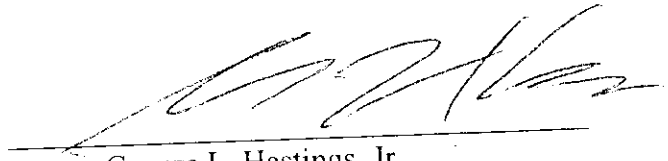
In so doing, however, I caution the Committee that the resolution of the general causation issue in the Omnibus Autism Proceeding *cannot be deferred indefinitely*. In this regard, I note that it seems likely that for *years* into the future, there will be ongoing studies as to the possible causes of autism. Therefore, it seems doubtful that it will be appropriate to wait for every last conceivably relevant study to conclude. Rather, I would not be inclined to consider any further delay unless an *expert or experts* were to analyze the many existing studies *in detail*, and to explain very specifically *why* any *particular* ongoing studies are important enough, *in the context of the existing studies*, to warrant further delay of the Omnibus Autism Proceeding.

Finally, I note that in my Ruling issued on August 11, 2005, I notified the parties that even though I was extending the due dates for the filing of the parties' *expert reports*, I would nevertheless require the parties to *designate their experts* in early 2006. Petitioners in fact filed their designation in February of 2006, and respondent's designation is to be filed very soon. As I indicated in that Ruling, the parties' experts clearly have much material *already available* concerning the general

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<sup>4</sup>The original schedule for the Omnibus Autism Proceeding contemplated that the evidentiary hearing concerning the general causation issue would commence about four months after the filing of the petitioners' expert reports.

causation issue, so that there is no reason that both parties' experts cannot begin work already. Then, once the ongoing studies mentioned above have been completed, such experts can incorporate the results of those studies into those experts' already-in-progress reports.

A handwritten signature in black ink, appearing to read "G. L. Hastings, Jr.", written over a horizontal line.

George L. Hastings, Jr.  
Special Master