In the United States Court of Federal Claims

ORIGINAL

OFFICE OF SPECIAL MASTERS (Filed: September 27, 2007)

SEP 2 7 2007

IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER OR A SIMILAR NEURODEVELOPMENTAL DISORDER

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VARIOUS PETITIONERS,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

AUTISM MASTER FILE¹

ORDER CONCERNING SCHEDULE FOR PSC'S "SECOND THEORY" OF CAUSATION

A. Background

As we have noted in recent "Autism Updates," the Petitioners' Steering Committee (PSC) intends to present three different theories of "general causation" in this Omnibus Autism Proceeding (OAP). The first is the theory that MMR vaccines and thimerosal-containing vaccines can combine to cause autism. The additional two theories are (2) that thimerosal-containing vaccines alone can cause autism, and (3) that MMR vaccines alone can cause autism.

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.

On June 25, 2007, the PSC filed, into the Autism Master File, a proposal concerning the scheduling of the test cases as to the *second* theory, that thimerosal-containing vaccines alone can cause autism. Under that proposal, the PSC offered to designate three test cases, and to file the petitioners' expert reports concerning those cases, by August 31, 2007. On July 6, 2007, respondent sent a letter containing respondent's own scheduling proposal. (That letter was later filed into the Autism Master File on August 16, 2007.) Then, at the status conference held on July 9, 2007, the PSC orally modified its original proposal. At that time the PSC proposed that it would file several *general causation* expert reports by August 31, 2007, but that its deadline for *specifically identifying* the three test cases, and filing *case-specific expert reports* concerning those three cases, be set for October 31, 2007, instead of the originally-proposed August 31.

Pursuant to the parties' proposals and a lengthy discussion at the July 9 status conference, the undersigned special masters considered the scheduling issue. Prior to the next OAP status conference, on July 20, 2007, we "faxed" to all counsel a proposed schedule for the resolution of the petitioners' second-theory test cases. Under that proposal, we allowed the PSC until November 5, 2007, to designate the three test cases and file the case-specific expert reports. During the July 20 conference, all participants, including the PSC representatives, agreed to that schedule.

B. The PSC's current request for schedule change

During our OAP status conference on September 24, 2007, the PSC representative made a request for a change in the schedule to which all agreed during the July 20 conference. Specifically, counsel requested that the PSC deadline for designating the test cases and filing case-specific expert reports be extended from November 5 to December 3, 2007. Counsel explained that the PSC is using two physicians to analyze the medical records in a number of cases, select the three test cases, and write an expert report in each of the three cases. It is taking these physicians, he explained, longer than they expected to analyze the extensive medical records in those cases. Both physicians, he said, have clinical practices, which limit the time that can be devoted to reviewing those case files.

Respondent's counsel, in response, indicated misgivings about the PSC's proposed schedule change. Counsel noted that any change in the pretrial schedule could reduce the allotted period at the end of the pretrial period, between the filing of the respondent's expert reports and the scheduled evidentiary hearing date of May 12, 2008. Any reduction in that period, counsel noted, would make it more difficult for the special masters and the parties to complete their final preparation for trial.

We indicated that we would take the matter under advisement and issue a written ruling.

C. Discussion

Initially, we note that we do have sympathy for the difficult task facing the petitioners' experts in reviewing voluminous medical files and selecting the test cases. We understand that adding such a task to a physician's usual clinical practice would be highly challenging. We also note

that special masters in Vaccine Act cases are usually willing to grant a petitioner's reasonable requests for extensions of the time in which to file that petitioner's expert report or reports. The situation here, however, differs from those types of routine extension requests in two significant respects. First, in the ordinary case the requested delay would affect only the single petitioner involved in the case. Here, in contrast, we have nearly 5,000 families who have filed autism-related Vaccine Act claims, who are awaiting the outcome of these OAP test cases. Moreover, some of those claims have been pending for nearly ten years, and the PSC itself has had more than five years, since the inception of the OAP in July of 2002, to develop its proof concerning the causation question now at issue. In these circumstances, we believe that, in presiding over the OAP, we have an obligation to the 5,000 families to try to move the test cases toward completion as swiftly as reasonably possible.

Second, and even more importantly, in this case we already have in place a *trial schedule*, for May 12-30, 2008. It is not feasible to change that trial schedule. We have planned our own schedules around those dates, as have all of the many counsel, expert witnesses, and others involved. Moreover, based on the PSC's *own proposal*, we scheduled the *pretrial* deadlines, which the PSC now wishes to alter, based upon that trial schedule. We deliberately built into that overall schedule a substantial period between the due date for the respondent's expert reports and the start of trial. Our experience with our first test case pursuant to the PSC's first causation theory, the *Cedillo* case tried earlier this year, convinces us that there is need for such a period between the date for respondent's expert reports and the trial date, in order to allow the parties and the special masters to adequately prepare for the trial, and to allow for dealing with unexpected developments. The PSC's current proposal, however, could result in a substantial reduction in that planned time period.

In this regard, we also note that we are surprised by the swift change in the PSC's position concerning the timing of these cases. As noted above, on June 25, 2007, the PSC itself offered to designate the three test cases and file all expert reports by August 31, only 67 days later. Only two weeks later, the PSC changed its proposal to add another 61 days onto the time period, and we in fact granted the PSC an extra 66 days, nearly doubling the originally-requested period for completing those tasks. But now, the PSC seeks yet another 28 days.

Carefully considering all the circumstances discussed above, we do not believe that it would be prudent to grant the entire 28-day enlargement requested by the PSC. We hereby extend the PSC's deadline by two weeks, to November 19, 2007. The respondent's deadline for expert reports, then, will be February 25, 2008, thereby allowing 98 days for respondent to respond. Our revised schedule will then allow 77 days between the filing of respondent's expert reports and the beginning of trial on May 12, 2008.

We note that further details concerning the schedules adopted for the PSC's second and third theories will be published in the next "Autism Update," to be issued in the next few days.

Patricia Campbell-Smith

Special Master

Denise Vowel

Special Master

George L. Hastings, Jr.

Special Master