ORIGINAL

IN THE UNITED STATES COURT OF FEDERAL CLAIMS OFFICE OF SPECIAL MASTERS

2007

IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER, OR A SIMILAR))) P)		AUG 16 OSM U.S. COUI FEDERAL C
NEURODEVELOPMENTAL DISORDER			
Various Petitioners,)	AUTISM MASTER FILE Special Master Hastings	
v.)	Special Master Hastings	
SECRETARY OF HEALTH AND HUMAN SERVICES,)		
Respondent.)))		

RESPONDENT'S NOTICE OF FILING

Enclosed for filing is respondent's "Proposed schedule for proceedings on the PSC's second theory of causation in the Omnibus Autism Proceeding," dated July 6, 2007.

Respectfully submitted,

PETER D. KEISLER Assistant Attorney General

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DATED: 16 AUGUST 2007



U.S. Department of Justice

Civil Division

Washington, D.C. 20530

July 6, 2007

VIA FACSIMILE AND USPS

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Denise Vowell
Patricia Campbell-Smith
U.S. Court of Federal Claims
Office of Special Masters
1440 New York Ave., N.W., Suite 200
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Fax: (202) 357-6381

Re: <u>Proposed schedule for proceedings on the PSC's second theory of causation in the Omnibus Autism Proceeding</u>

Dear Special Masters:

On June 25, 2007, Thomas Powers, one of the co-chairs of the Petitioners' Steering Committee ("PSC"), filed the PSC's proposal for the schedule of the general causation proceedings concerning their second theory of how vaccines, or a component thereof, can cause autism or a similar neurologic disorder. In this second theory, the PSC posits that thimerosal contained in certain childhood vaccines was a cause of autism, or a similar neurologic disorder, in certain children. This filing was based on informal proposals sent to respondent and the court on May 23, 2007, and June 1, 2007. The PSC's proposal is summarized below:

- 1. By August 31, 2007: Petitioners will submit medical records in 15-20 omnibus claims as possible "test cases," will identify three test cases for hearing, and will submit "general causation expert reports that the PSC expects to rely on in this round of hearings."
- 2. By November 30, 2007: the PSC proposes respondent file expert reports.
- 3. By mid-to-late January 2008: First hearing.

Respondent provides the Special Masters with this counter-proposal in response to the PSC's June 25, 2007 filing.

Respondent expects that the PSC's second theory, that thimerosal contained in certain childhood vaccines was a cause of autism, or similar neurological disorder, in certain children will be as, if not more, complex than the PSC's first theory of causation, which was presented at a trial that lasted twelve days and concluded on June 26, 2007. Respondent considers this issue extremely important, and respondent's proposal is based on a realistic appreciation of the resources that respondent can expend and when such resources will be available. Respondent's proposal recognizes both the parties', and the Special Masters', interest in the rapid resolution of the issues through a fair and comprehensive proceeding, and it takes into account the lessons learned thus far from the proceedings of the first test case of the PSC's first theory of causation.

Respondent believes that both fairness and practicality dictate that respondent's time frame for responding to the PSC's second theory of causation should commence only after the close of the final test case on the PSC's first theory of causation. Respondent has considered that the same level of effort put forth in Cedillo should not be necessary in the subsequent test cases on that theory, and respondent's proposal reflects this consideration. Nevertheless, those cases will be factually distinct from the first, will require review of what may be extensive medical documentation, and likely will require additional expert testimony. Respondent will only first see the medical information in the cases, at most, a few months prior to trial. This compressed schedule will require that most of the litigation personnel familiar with the autism issues work on the preparation and trial of these two test cases.

Respondent learned from the first test case on the PSC's first theory of causation that preparing a response in a case with issues of the magnitude present in the Omnibus Autism Proceeding is an extraordinarily difficult, time-consuming, and labor-intensive process. Respondent devoted all personnel familiar with the autism litigation to preparing the response to one test case, and respondent still struggled to meet the deadline of responding in sixty days. The second theory is certainly as important as the first, and likely as complex. Moreover, three test cases will simultaneously be designated and will require simultaneous attention.

Before setting forth a schedule, respondent has some concerns about one aspect of the PSC's proposal which does not relate to scheduling. The PSC's proposal states that the PSC will submit "general causation expert reports" at the same time they complete the filing of medical records in 15-20 cases and identify three test cases. It is respondent's understanding that the trial on the second theory of causation will be conducted similarly to that of the first theory of causation; that is, the experts' testimony will be based largely on the specific facts of the test case(s). It is unclear from the PSC's proposal whether they share this understanding.

Because the general causation theories are so important, possibly having a dramatic effect on important issues of public health in the United States, the schedule set forth by the Special Masters for the PSC's second theory of causation must enable respondent to dedicate sufficient resources to the PSC's second and third theories of causation. Such dedication of resources would not be possible if respondent's time frame to respond to the second theory commences before the completion of the test cases on the first theory proposed by the PSC.

For the reasons stated above, respondent's proposal is as follows:

- 1. As proposed by the PSC, petitioners immediately begin submitting medical records in 15-20 omnibus claims as potential test cases and complete the submission of medical records in those claims by the end of August 2007.
- 2. As proposed by the PSC, petitioners designate three test cases and file expert reports by August 31, 2007. Respondent proposes that the Special Masters require that those expert reports address both the second causation theory in general and the theory as applied to the specific facts of the test cases.
- 3. If the PSC files no more than 10 expert reports, respondent proposes filing responsive expert reports 90 days from the close of the last test case on the first theory. If the number of expert reports filed by the PSC exceeds 10, respondent proposes the filing of responsive expert reports 120 days after the close of the last test case on the first theory. Respondent considers this proposal a tentative proposal, as the complexity of the theory (or theories) proposed by petitioners' experts on the thimerosal toxicity theory will naturally have an effect on the amount of time it will take to find experts and for those experts to prepare responses. As such, respondent cannot definitively assess the time it will need to respond to the PSC's next theory in advance of reviewing the theory or theories expressed in the PSC's expert reports. Nevertheless, for purposes of this proposal, respondent uses the number of experts submitting reports as a rough gauge of the complexity of the theory and believes that respondent will likely be able to work within this schedule.
- 4. Finally, respondent proposes that the trial on the second theory commence 75 days from the submission of our expert reports. Based on the experience of the <u>Cedillo</u> case, including the numerous issues that were raised and the many complications that developed so close to the start of the trial, the court should allow a sufficient amount of time, which respondent suggests is 75 days, between the submission of the final expert reports and the hearing.

This proposed schedule is premised on the PSC's proposal to designate three test cases with complete medical records and file all expert reports supporting their second causation theory by August 31, 2007. Although it is likely that the two remaining test cases on the first theory of causation will not be tried until after August 31, 2007, respondent will be able to devote some resources to preparing respondent's case on the second theory prior to completion of those two trials. Respondent's proposed deadline for filing respondent's expert reports is based on the assumption that work on identifying issues, locating appropriate experts, copying files, and other case preparation tasks will be undertaken between August 31, 2007, and the completion of trials in the test cases on the PSC's first theory of causation.

I would be pleased to discuss this proposal should the Special Masters-desire.

Sincerely,

Vincent J. Matanosk Assistant Director

U.S. Department of Justice

Civil Division, Torts Branch

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cc: Tom Powers

CERTIFICATE OF SERVICE

I certify that on this 16th day of August, 2007, a copy of **RESPONDENT'S NOTICE OF**FILING was served by first-class mail, postage prepaid, upon:

Michael L. Williams, Esq. Williams Love, et al. 9755 SW Barnes Road Suite 450 Portland, OR 97225-6681

and

John H. Kim, Esq. The Kim Law Firm 4309 Yoakum Blvd, Suite 2000 Houston, TX 77006

In addition, respondent hereby provides his written consent, pursuant to Section 12(d)(4) of the Vaccine Act, to disclose this pleading on the Court of Federal Claims's website/"Docket of Omnibus Autism Proceeding."

Couplor