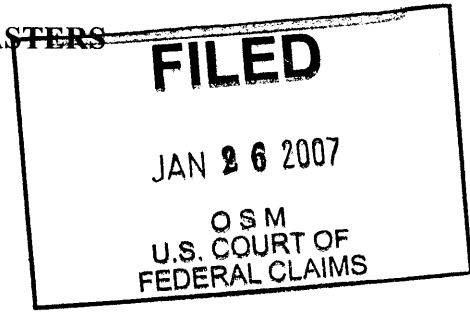


# ORIGINAL

## IN THE UNITED STATES COURT OF FEDERAL CLAIMS

### OFFICE OF SPECIAL MASTERS



\_\_\_\_\_)  
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  
Special Master Hastings

**RESPONDENT'S RESPONSE TO PETITIONERS' PROPOSED CONDUCT OF  
GENERAL CAUSATION HEARING AND SUBSEQUENT EFFECT OF RULING**

On January 9, 2007, the Petitioners' Steering Committee (PSC) submitted a memorandum presenting positions on "various outstanding" issues pertaining to the Omnibus Autism Proceeding (OAP). In that pleading, the PSC proposes a new format and schedule for trying the general causation issue before the Court.<sup>1</sup> Respondent agrees with the proposed format, utilizing a test case or cases with facts representative of those in most of the pending OAP cases to try the general causation issue, but objects to the proposed piecemeal trial of causation issues in a series of, as yet, unscheduled future hearings.<sup>2</sup>

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<sup>1</sup> The Court has defined the "general causation issue" as "the issue of whether thimerosal-containing vaccines and/or MMR vaccine can cause autism and/or similar disorders. . ." See, e.g., Autism Update -- November 27, 2006. Throughout this brief, respondent uses the term "general causation issue" consistent with the Court's definition.

<sup>2</sup> Respondent will not respond to several aspects of the PSC's proposal. The Chief Special Master's Notice Regarding Reassignment, appointing two more special masters to the OAP, (continued...)

The PSC proposes that the hearing on the general causation issue begin with a “test case” in June, 2007. Petitioners’ Proposed Conduct of General Causation Hearing and Subsequent Effect of Ruling (PSC Proposal) at 1. This test case, according to the PSC, will be “representative” of “a significant number” of cases alleging that “*a combination of thimerosal exposure and the MMR vaccine caused injury.*”<sup>3</sup> *Id.* (italics in original).

From the outset, respondent has advocated examination of the general causation issue in the context of a test case.<sup>4</sup> Indeed, respondent has consistently maintained that a special master’s

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<sup>2</sup>(...continued)

moots responding to the PSC argument against additional special masters hearing the causation evidence. Further, a major portion of the PSC proposal is argument concerning the legal standard applicable to deciding actual causation cases. As discussed at the status conference on January 12, 2007, respondent will not address the actual causation standard in this response.

<sup>3</sup> The Omnibus Autism Proceeding, as the name implies, concerns autism and autistic spectrum disorders. As respondent observed in Respondent’s Response to Petitioners’ Second Motion to Compel, the PSC appears to be unilaterally broadening the scope of the proceeding. This concern is heightened by the PSC’s January 9, 2007, describing the inquiry before the Court as “whether thimerosal, or the MMR vaccine, or a combination of the two, can cause **neurological injuries**,” or in the particular context of their proposal for the June, 2007, trial, whether the combination of the thimerosal-containing vaccines and MMR can cause “*injury.*” PSC Proposal at 1 (emphasis supplied; italics in original).

As recently as November 27, 2006, the Court framed the Omnibus Autism Proceeding inquiry as “whether thimerosal-containing vaccines and/or MMR vaccines can cause autism and/or similar disorders.” Autism Update -- November 27, 2006 at 3. Respondent is relying on the Court’s determination of the issue to be tried and preparing accordingly, focusing on thimerosal-containing vaccines and MMR vaccine, alone or in combination, can “autism and/or similar disorders” i.e., disorders similar to autism.

<sup>4</sup> Though Autism General Order #1 provides that during informal meetings concerning how to handle autism cases, “respondent’s representatives did not oppose petitioners’ general plan . . . that the conduct a general inquiry into the causation question, then apply the conclusions reached in that inquiry to the individual cases,” that portrayal understated respondent’s divergent views on many aspects of the process outlined in that Order. Autism General Order #1 at 3 (July 3, 2002). The Court’s recent Autism Update more accurately describes respondent’s position on  
(continued...)

authority under the Vaccine Act emanates from a petition filed under section 300aa-11 under the Act, and that the OAP proceedings, to the extent they are general, abstract proceedings not grounded in a particular petition, bring into question the special master's authority to render a decision or even conduct proceedings under the Vaccine Act. So respondent agrees with the proposition that a test case be used for trying the general causation issue.

The "test case," however, should be representative of the greatest number of claims currently pending in the OAP. Instead, the PSC has proposed that the trial in June focus solely on one theory they intend to advance: that thimerosal-containing vaccines working in combination with MMR vaccine causes autism or autistic spectrum disorders. This particular theory – that the two vaccines working in combination cause autism – has never been the primary focus of the PSC's causation case. With respect to the rest of their general causation case, they state "[i]t is expected that additional hearings will follow this [June] hearing, hearings addressing questions of causation involving thimerosal exposure only (without MMR involvement), and MMR exposure only (without thimerosal involvement)."<sup>5</sup> PSC Proposal at 2.

While the PSC states that its proposal concerns "outstanding" issues – that is, issues to be

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<sup>4</sup>(...continued)

the particular question of the format for trying the general causation issue. Autism Update -- January 19, 2007 at 6.

<sup>5</sup> Moreover, the specific case chosen by the PSC appears unsuitable even for the narrow theory in question. Michelle Cedillo had a rash and a fever approximately one week after her MMR vaccination. Cedillo v. HHS, Fed. Cl. No. 98-916V, Exhibit 8 at 1. At that time, she "stopped talking." Cedillo, Marcel Kinsbourne, M.D. report dated April 23, 2001, at 1. Approximately two weeks after vaccination she had a fever of 105.7 degrees Fahrenheit. Cedillo, Exhibit 8 at 1. These events were so striking and arose so soon after vaccination that the petition in Cedillo alleges a "Table" encephalopathy. High fever, sudden loss of developmental skills, and abrupt behavioral change have not been the usual factual predicate in OAP claims for which respondent has information, raising concern that this case will be representative of few of the cases.

resolved – the scope of general causation inquiry to commence in June, 2007, could not be considered one of them. PSC Proposal at 1. The Court has always planned on one trial to hear all theories of causation. From the inception of the OAP, “an evidentiary hearing” on the “general causation issues” was planned. Never was there proposed by either party, let alone approved by the Court, a piecemeal approach. Autism General Order #1 at 3 (July 3, 2002) . There was never any doubt that the general causation trial would encompass all causation theories. The Order defining the OAP included a “Master Scheduling Order” that provided only one trial on causation issues. Autism General Order #1, Appendix E. In keeping, “Autism Updates” issued by the Court prior to this PSC proposal described the trial on causation as “the hearing on the general causation issue” (Autism Update -- September 24, 2003 at 4) or “an evidentiary hearing concerning the general causation issue.” See, e.g., Autism Update -- August 30, 2004 at 3; Autism Update -- April 28, 2005 at 3. Thus, for four and a half years the OAP has been geared to resolution of the general causation issue in one trial, not a series of hearings on theories. The PSC proposal is a radical departure from the process that was in place, and that, if adopted, will necessarily result in a substantial delay in the resolution of the general causation issue.

The PSC proposal, which advances no timetable for future hearings, amounts to an open-ended motion for enlargement of time to reveal their causation evidence and indefinite delay in presenting the main thrust of their causation case. It is becoming clear that what will be revealed through expert reports in February and tried in June is just a limited aspect of the PSC case. In keeping, of the seventeen experts the PSC has designated to address the general causation issue, only one will testify in June. Joining that expert are three new experts, again suggesting that this

is not the primary causation theory the PSC has been pursuing for the last four and a half years. Prior to proposing the June, 2007, trial date, the PSC had considered requesting separate trials on two theories -- that thimerosal-containing vaccines cause autism and that MMR vaccine causes autism -- without ever raising the combined effect theory they now propose:

Another important item is that the Committee has determined that it will *not* seek separate hearings concerning (1) the issue of whether thimerosal-containing vaccines can cause autism, and (2) the issue of whether MMR vaccines can cause autism. The Committee views these as closely related topics, and, at the 2007 hearing, the Committee will present its evidence on *both* topics.

Autism Update -- September 7, 2006 (*italics in original*). Unless and until the PSC makes a credible showing that the test case will indeed resolve a substantial proportion of the OAP cases, the request to delay presentation of all available evidence should be denied.

The delay in trying the general causation issue has not been justified. The PSC has given no good reason to limit proceedings to a single aspect of their claim. Nor has the PSC justified a delay in providing its expert witness reports by February 14, 2007, on the general causation issue. In granting the PSC a previous enlargement of time in filing this evidence, the Court warned that it would not brook delays in the submission of expert reports while awaiting the results of studies:

. . . I will defer the due date for the Committee's expert reports until December 31, 2006. [footnote omitted]

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.

Second Ruling Concerning Issue of Time for Filing Expert Reports at 6 (April 26, 2006)(italics in original.) Now, however, the PSC requests to delay the submission of expert reports until the completion of a study that is currently nothing more than a six page proposal from experts they hired. Even were the Court to authorize this proposed research, that would not provide sufficient reason to postpone filing all the PSC's expert reports on February 14, 2007. The proposed study is epidemiological – it will not provide or define a theory of causation. Rather, it proposes to observe the rate at which certain conditions are observed after exposure to both thimerosal-containing vaccines and MMR.<sup>6</sup> Accordingly, the PSC should be required to adhere to the scheduled February 14, 2007, submission of its expert reports explaining all theories of causation regardless of what action the Court may take on its latest discovery motion and regardless of the scope of the issues tried in June, 2007.<sup>7</sup>

More disturbing still, the PSC's proposal leaves unanswered many questions about what the effect will be of splitting the trial of the "general causation issue" into a series of evidentiary hearings each on a particular causation theory. First, while the PSC claims the trial in June will

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<sup>6</sup> While respondent does not accept that the PSC's proposed study provides any legitimate basis for delaying the presentation of the PSC's entire causation case, assuming that it did, that basis would seemingly apply with equal force to the theory that the PSC proposes to try in June. The PSC has not explained why this epidemiological study is critical to the theory that thimerosal-containing vaccines or MMR vaccine cause autism or autistic spectrum disorders, but is not critical to the theory that both vaccines together cause those conditions.

<sup>7</sup> In April, 2006, the PSC experts were given over eight months to put together their reports. In August, 2006, those experts were given an additional 45 days. The PSC has not stated that its experts need more time to describe their theories of causation. In fact, the PSC proposed the June, 2007, trial date for its entire "case for general causation," stating that such a schedule provided "ample" time to prepare its expert evidence. Petitioners' Proposal Re General Causation Proceedings at 2.

involve “a representative case” for a “significant number” of pending OAP cases, the PSC fails to even estimate what that “significant number” might be. PSC Proposal at 1. Nor do they make any representation concerning which specific cases “claim” this particular theory, and whether the causation issue in those particular cases will be resolved by the trial in June.<sup>8</sup> At this point, it is completely unknown which claimants will “rest” their general causation case in June. Absent assurances in this regard, it is impossible to schedule proceedings or prepare a defense with respect to those cases. This complete lack of information regarding the identity of the cases being “tested” and the intentions of those petitioners raises the spectre that the test case in June, and the two cases in the following three months, may be the only cases resolved.<sup>9</sup> Thus, for the June trial to resolve some significant portion of the pending cases as the PSC implies, the PSC must identify those cases.

The PSC’s proposal is also deficient in its failure to provide a timetable for future trials to resolve the general causation issue. Indefinite delay prejudices respondent. Indeterminate delay in the presentation of the entirety of the PSC’s causation case substantially impedes respondent’s efforts to effectively respond. Over the past year, respondent has expended much time and resources on finding experts to respond to the anticipated testimony of the PSC’s expert witnesses. The PSC requested the June, 2007, trial date for its entire causation case and the

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<sup>8</sup> It is impossible for respondent to prudently marshal his resources if he does not know what is at stake. Obviously, greater resources (more experts, etc.) would be justified if this case will govern the result in a thousand cases versus just one or three. It is not responsible or prudent to launch into a hearing with the PSC’s unsupported assertion that a “significant number” of cases will be affected.

<sup>9</sup> The Cedillo case itself will only be finally resolved by this limited trial proposed because the PSC states that, regardless of the outcome of the June trial, the petitioner in that case will not pursue either of the remaining theories that will be tried at some, as yet, unspecified future date.

Court adopted that proposal. Autism Update-- September 7, 2006. In reliance on that Court-sanctioned schedule, respondent told his experts to set aside significant time from mid-February, 2007, through June, 2007, to respond to the PSC's expert reports and to testify at the trial of the general causation issue beginning in mid-June, 2007. Now, about a month before it was scheduled to reveal its causation evidence, the PSC informs the court and respondent that it wishes to postpone the trial of the principal elements of its case and proceed with only one of its three theories of causation.

Respondent anticipates substantial damage to respondent's case would result from adopting the proposal. Many of respondent's experts may be unable or unwilling to testify at multiple trials. Though uncertainty clouds the PSC's intentions, it appears likely the sequence of theories the PSC will present will involve similar scientific disciplines, such as toxicology, neurology, immunology, and epidemiology. There is simply no way for respondent to predict the timing of the PSC's case sufficient to allocate effectively his experts, and secure commitments from these experts for future participation. Nor is it reasonable to suggest that respondent have all his experts testify in June, 2007, as an expedient, because respondent will not yet have received the majority of the PSC's expert reports by that date. Respondent cannot possibly respond credibly and effectively to evidence that has not been offered. Finally, even assuming that there was no impact on the availability of experts flowing from the indeterminate trial schedule advocated by the PSC, its multiple trial approach would drive up the litigation cost as numerous experts would have to write reports and testify several times. In sum, to proceed with a "test case" that does not "test" the major theories underlying the PSC's causation case is neither efficient, prudent, nor fair.



The Court has given clear indication both through comments at the January 12, 2007, status conference and in its subsequent Autism Update of January 19, 2007, that it is inclined to adopt the PSC's proposal to split up the trial of the PSC's various causation theories. If the Court does so, over respondent's objection, respondent requests that the Court adopt the following measures to ensure that there is appreciable progress in the Omnibus Autism Proceeding:

1. That the Court require the PSC to designate, before trial, those cases whose outcome will hinge on the final decision following trial in June, 2007.
2. That the Court honor the schedule for submission on February 14, 2006, of PSC expert reports describing all theories on the general causation issue and the evidence supporting those theories.
3. That the Court order each subsequent hearing on causation be conducted in the test case format, and establish a prompt schedule for proceedings upon which the parties may rely in scheduling witness participation, and that will not be further delayed except upon a showing of good cause.

Finally, the PSC has proposed a "procedure" to be applied in each "distinct hearing" on each of its "three distinct theories of causation." PSC Proposal at 20. Most of the proposed procedure is standard in any trial under the Vaccine Act, with the exception that the PSC's proposal does not provide for any rebuttal by respondent's experts. Respondent submits that such rebuttal would be appropriate and useful to the Court.

The procedure also provides for the special master in each test case to list "criteria . . . to be applied to individual cases proceeding under that theory of causation." Id. This assumes that

the special master will have determined that such theory is scientifically reliable; that it is based on “scientific knowledge” -- derived by “scientific method” and “supported by appropriate validation -- i.e., ‘good grounds,’ based on what is known.” Daubert v. Merrell Dow, 509 U.S. 579, 590 (1993). In the event a particular causation theory does not meet this threshold requirement, there would be no basis for issuing “criteria” applicable to any cases proceeding under that theory.

### **CONCLUSION**

For the reasons set forth above, while the respondent agrees that a test case format for the trial of the general causation issue is appropriate, the proposal for multiple, and as yet unscheduled, trials of causation theories is neither supported nor wise. If adopted, it will lead to delay in the ultimate resolution of the general causation issue, and no good cause for such delay has been demonstrated. Nevertheless, if the Court does embark on this course, then the PSC should be required to designate cases that will be resolved by the first trial they have proposed and reveal their causation theories through expert reports as previously scheduled. Finally, each subsequent hearing should also proceed under the test case format they have proposed.

Respectfully submitted,

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Date: 26 JANUARY 2007

**CERTIFICATE OF SERVICE**

I certify that on this 26<sup>th</sup> day of January, 2007, a copy of **RESPONDENT'S RESPONSE TO PETITIONERS' PROPOSED CONDUCT OF GENERAL CAUSATION HEARING AND SUBSEQUENT EFFECT OF RULING** was served by Federal Express upon:

Michael L. Williams, Esq.  
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and

Ghada A. Anis, Esq.  
Petitioners' Steering Committee  
105 North Alfred Street  
Alexandria, VA 22314

A copy of **RESPONDENT'S RESPONSE TO PETITIONERS' PROPOSED CONDUCT OF GENERAL CAUSATION HEARING AND SUBSEQUENT EFFECT OF RULING** was also provided, via facsimile, upon:

Ghada A. Anis, Esq.  
Petitioners' Steering Committee  
(202) 318-7518

  
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