

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

(Filed: April 16, 2008)



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

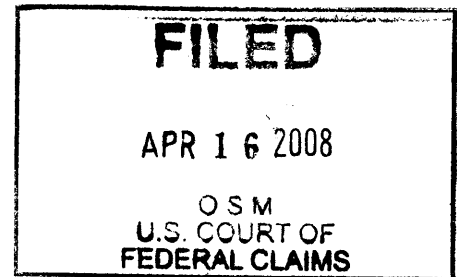
VARIOUS PETITIONERS, *

v. *

SECRETARY OF HEALTH AND *
HUMAN SERVICES, *

Respondent. *

AUTISM MASTER FILE¹



ORDER CONCERNING CASE PROCESSING

1. Background

At the request of the Petitioners' Steering Committee ("PSC"), the undersigned agreed to hold separate hearings on three different theories of vaccine causation of autism spectrum disorders ("ASD") advanced by the PSC in the Omnibus Autism Proceeding ("OAP"). These hearings were designed to present general causation evidence, as well as specific causation evidence, in the context of individual cases. For further discussion of the events leading to the adoption of the "three theory" approach proposed by the PSC, see Autism Updates dated January 19, 2007, and May 14, 2007.

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. From the home page, click on the "Vaccine Info" page, then on the "Autism Proceeding" page.

The first theory, that a combination of the measles vaccine and thimerosal containing vaccines ("TCVs") worked in concert to cause ASD ("Theory 1") was scheduled to be presented in June, 2007. Delays in designating the three test cases led to a series of presentations of general and specific causation evidence at hearings in June, October, and November, 2007, with the majority of the general causation evidence presented in the June hearing. The decisions in each of the first three test cases on the combined measles-TCVs theory are still pending, with the most recent post-hearing evidence filed on April 10, 2008. Whether additional evidence obtained from the U.K. autism litigation will be presented in these Theory 1 test cases remains an open question.

Hearings on the second theory, that TCVs alone cause ASD ("Theory 2"), are scheduled to begin on May 12, 2008. Three test cases were designated as of December, 2007. Hearings on the third theory, that the measles vaccine alone causes ASD ("Theory 3"), are currently scheduled to begin on September 15, 2008, after designation of the three test cases no later than May 5, 2008.

2. Issues Regarding the Theory 2 Hearings

However, on April 3, 2008, the Office of Special Masters was notified that petitioners in one of the three test cases designated for hearing on Theory 2 now wished to withdraw their claim from the OAP and proceed to an individual hearing on a different theory of causation. The reasons for this withdrawal were discussed in an unscheduled status conference on April 4, 2008.² During this status conference the PSC was advised to select a new test case for Theory 2 from the 4900 pending OAP cases, by May 1, 2008. Recognizing the difficulties inherent in getting a case ready for the May 12, 2008 hearing, the undersigned suggested that evidence specific to the third case could be presented at a subsequent proceeding during the week of July 21, 2008, when the testimony of one general causation witness who was unable to attend the May hearing had already been scheduled for presentation.

In an April 14, 2008, letter addressed to the undersigned special masters and to Chief Special Master Golkiewicz, the PSC proposed that the May 12, 2008, hearing concerning Theory 2 proceed with only two test cases. A copy of that letter is attached as Appendix I to this order.

The PSC's letter was the primary topic of discussion at the previously scheduled OAP status conference on April 14, 2008. The proposal to proceed with only two test cases for Theory 2 was rejected by the undersigned for all the reasons set forth in our orders to the PSC prior to the June, 2007, hearing. We briefly reiterate them here.

We again emphasize the importance of having three special masters evaluating the general causation evidence and applying that evidence in their own individual test cases. Three opinions applying the evidence to the facts of specific cases will provide more guidance for the resolution of the remaining cases and will provide three separate evaluations of the evidence and law for appellate

² On April 10, 2008, petitioners filed a formal motion to withdraw their son's case from the OAP, and that motion was granted on April 15, 2008.

review. Additionally, three opinions will reduce the concern that the fate of so many petitioners and their families might rest on the opinion of only one special master.

With approximately 4900 cases in the OAP, many of which were filed on behalf of children who received TCVs, we are confident that the PSC will be able to find an additional case to serve as a replacement test case for the TCV theory of causation. If the PSC is unable to do so, the undersigned will select a case from our dockets to serve as the third case. We recognize that this process may possibly delay the issuance of one or more of the decisions in the Theory 2 test cases. That disadvantage is far outweighed by the advantages inherent in obtaining three evaluations of the general causation evidence to guide resolution of the remaining cases and to frame issues for appellate review.

Accordingly, the PSC is ordered to designate an additional test case prior to the commencement of the Theory 2 general causation hearing on May 12, 2008. If the PSC fails to do so, we will begin the process of selecting a third case ourselves.³ Once a case is selected, the special master assigned to that case will apply the general causation evidence from the May, 2008, Theory 2 hearing, and any additional evidence that the parties may present, to the facts of the selected case.

3. Issues Regarding the Theory 3 Hearings

The PSC's April 14, 2008, letter also indicated that the third theory of causation would largely rely upon the general causation evidence already presented in the three Theory 1 test cases, *Cedillo*, *Hazlehurst*, and *Snyder*, and proposed the presentation of specific causation evidence in only one case for Theory 3. The PSC specifically identified its proposed solitary test case for Theory 3 during the April 14 status conference, and counsel for those petitioners were included in that status conference. The PSC represented that no new general causation evidence was anticipated, and counsel for the petitioners indicated that testimony from two treating physicians and the petitioners themselves would comprise their evidence on the solitary Theory 3 test case.

Based on the evidence presented in the Theory 1 cases and the PSC's April 14 letter, it appears that an additional round of test cases on Theory 3 may be unnecessary.⁴ Although the PSC

³ Just prior to the June, 2007, general causation hearing on Theory 1, the undersigned announced our intention to select cases in the OAP for the causation hearing if the PSC was unable to do so. We noted that the PSC had been on notice since December, 2006, that three test cases would be required. The designation of the *Hazlehurst* and *Snyder* cases just prior to the start of the June, 2007, hearing obviated the need for us to select two additional cases for hearing.

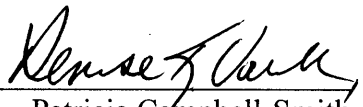

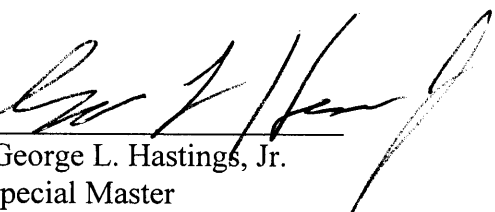
⁴ Since the inception of the OAP it has been clear that any petitioner desiring a hearing could request one. It follows that if the petitioners in the case identified as the sole Theory 3 test case wish their case to proceed to a hearing on their individual claim on behalf of their son (utilizing the general causation evidence already developed in Theory 1), the assigned special master will

originally represented that three different theories would be presented, it now appears that Theory 3 is simply Theory 1, minus any suggestion of a TCV-weakened or disregulated immune system. Thus, the evidence produced in the Theory 1 cases may allow us to address and answer the question of whether the measles vaccine can cause ASD, independent of any involvement of TCVs on the children in question. Therefore, it appears to us that there may simply be no need for a Theory 3 “general causation proceeding”--*i.e.*, a full-scale proceeding involving both general causation and three individual cases decided by three different special masters. It may be reasonable, instead, as the PSC now apparently proposes, to allow the petitioners in the newly identified case to rely on the general causation evidence from the Theory 1 cases, adding in the testimony of the treating physicians, before a single special master.

Counsel for both the PSC and respondent are hereby invited to file any additional arguments on the issue of whether we should now diverge from our original plan for a full-scale three-case Theory 3 proceeding, and instead proceed as the PSC now proposes with the identified case. Any written argument should be filed before our next OAP status conference, scheduled for May 2, 2008. We will then discuss this issue further during that status conference.

In the meantime, the petitioners’ counsel should file the petitioners’ case-specific expert reports in the identified case no later than May 5, 2008. However, the currently-scheduled deadline of May 5, 2008, for designating and filing expert reports in three Theory 3 test cases, is hereby suspended, pending the outcome of the upcoming discussions concerning the PSC’s proposal.

The PSC shall identify a third Theory 2 test case by Monday, May 12, 2008. A schedule for filing any additional medical records and expert reports will be established after designation of the case.

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| Patricia Campbell-Smith Special Master | Denise Vowell Special Master | George L. Hastings, Jr. Special Master |
| | <i>Special Master</i> | |

accommodate their desires. Those petitioners have not been identified by name in this Order, as it is our intent to post this order on the OAP website.

LAW OFFICES OF
WILLIAMS LOVE O'LEARY & POWERS, P.C.SUITE 450
9755 SW BARNES ROAD
PORTLAND, OREGON 97225-6681TELEPHONE 503/295-2924
FAX NUMBER 503/295-3720
TOLL FREE 800/842-1595
WWW.WDOLAW.COMMICHAEL L. WILLIAMS
mwilliams@wdolaw.comLINDA C. LOVE
llove@wdolaw.comLESLIE W. O'LEARY
loleary@wdolaw.comTHOMAS B. POWERS
tpowers@wdolaw.com

April 14, 2008

VIA FACSIMILE, EMAIL AND USPS

Special Master George Hastings
Special Master Patricia Campbell-Smith
Special Master Denise Vowell
U.S. Court of Federal Claims
1440 New York Avenue, NW, Suite 200
Washington, D.C. 20005

Chief Special Master Gary Golkiewicz
U.S. Court of Federal Claims
717 Madison Place, NW, Room 103
Washington, DC 20005

Re: Omnibus Autism Proceedings

Dear Special Masters,

We are writing on behalf of the Petitioners' Steering Committee to address the issue of how the general causation proceedings are conducted, to explain the PSC's position regarding the designation and trial of "test cases" under the "thimerosal-only" and "MMR-only" theories of causation between May and September 2008, and to propose a modest revision of that process. The PSC will be prepared to discuss these issues during the telephonic status conference currently scheduled for Monday April 14 at 3:00 pm EDT.

As you know, the recent withdrawal of Alexander Krakow's claim as a test case for the "thimerosal-only" hearings in May 2008 leaves the Special Masters with two individual cases (*King* and *Mead*) designated as test cases for the May hearings. In the telephonic status conference held on Friday April 4, 2008, the Special Masters asked the PSC to identify and designate a third or "substitute" test case given the withdrawal of the Krakow claim. The PSC was directed to make that designation no later than May 12, 2008, the commencement of the "thimerosal-only" hearings. The Special Masters indicated that a schedule for hearing that third test case would follow after the designation of the case and the filing of medical records.

It is the PSC's position, however, that a third test case would work only to slow the resolution of the key question: do thimerosal containing vaccines belong on the differential diagnosis list of potential causal factors in autism, along with other environmental agents like terbutaline and thalidomide? A third test case is unnecessary to the development of any additional evidence regarding general causation pertaining to the "thimerosal-only" theory. The goals of the OAP (as described in the Chief Special Master's *General Order #1* of July 3, 2002) will be satisfied in

regards to the presentation of general causation evidence by hearing the two test cases currently set for hearing beginning May 12, 2008. A third test case, as will be explained below, will not add any evidence beyond what will be presented in the *King* and *Mead* test cases relating to the issues of general causation that the OAP is designed to address. The PSC therefore proposes that the “thimerosal-only” general causation hearings consist of evidence adduced in the *King* and *Mead* cases without need for a third test case.

Similarly, it is the PSC’s position that only one test case is necessary to present the evidence relating to the “MMR only” theory of causation, a hearing currently planned for September 2008. The PSC has identified and will designate an “MMR-only” test case in advance of the April 14, 2008 status conference, and the PSC proposes that this test case alone be the basis for presenting general causation evidence relating to the “MMR-only” theory of causation, without need for two additional cases.

The PSC at all times has been mindful that the OAP was created to resolve issues of general causation in a manner that will provide guidance to the parties and the Special Masters in deciding the merits of individual claims pending in the OAP. The PSC also is aware that individual test cases are designed to facilitate the presentation of evidence, and to allow the issuance of decisions within the statutory and procedural framework of a compensation program that generally requires a record to be developed in an individual claim only. The current PSC proposal satisfies all of these objectives.

In developing general causation evidence and preparing for hearings in the “thimerosal-only” test cases in May 2008, the PSC can represent to the Special Masters and respondent that the general causation evidence will be essentially identical regardless of whether there are one, two or many more test cases heard. That is, adding a third test case will not lead to the introduction of any additional general causation evidence whatsoever. Since the goal of the OAP and the test case process is to present and develop general causation evidence, and since adding test cases beyond *King* and *Mead* will not introduce any such evidence regarding the “thimerosal-only” theory of causation, the PSC sees no need for a third case. Adding a third case without any additional general causation evidence will only create expense and delay, with little in return.

Similarly, the three hearings in 2007 that addressed petitioners’ “combined thimerosal-MMR” exposure theory of causation developed all of the general causation evidence that petitioners would rely on in any test cases related to the “MMR-only” theory in September 2008. Any hearings in September would rely on and incorporate the general causation evidence already presented in *Cedillo*, *Hazlehurst*, and *Snyder*. There is nothing to be gained in furtherance of the OAP’s goal of serving as a mechanism for addressing general causation issues by identifying and trying two more test cases. As is the case with the “thimerosal-only” hearings, adding second and third cases without any additional general causation evidence will only create expense and delay, with little in return. It is for this reason that the PSC is proposes to designate one test case only for hearing on the “MMR-only” theory in September.

Petitioners are well aware that the process for conducting these proceedings has evolved significantly since the OAP was established in July 2002, and it has always been the petitioners’ goal that the process should balance the interest of presenting the best and most comprehensive evidence possible with the interest of completing the proceedings in a timely manner. While this

process has taken longer than contemplated in July 2002, it has in fact generated a significant body of evidence, and a voluminous record has been developed in these proceedings. In particular, the record on general causation will, at the conclusion of the test cases already identified, be extremely comprehensive and sufficient to inform decisions by the Special Masters.

Further test cases will add nothing to that general causation record, and will merely further slow down this already laborious process, at a significant cost in time and resources.

The PSC notes that other omnibus proceedings in the program have been resolved based largely on the record developed in a single case serving as an exemplar for other, similar cases that would rely on the same evidence of causation. The OAP is unique in that evidence regarding three theories of causation will be presented in at least 6 individual test cases, providing ample guidance—based on the anticipated decisions in these test cases—to resolving individual claims in the OAP that would rely on that same body of general causation evidence. As was the case in other omnibus proceedings, the petitioners' counsel are most familiar with the medical records in the cases and are able to assess the applicability of the general causation evidence they have developed to those individual claims in proffering representative test cases.

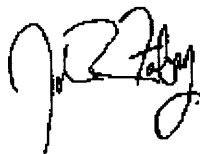
The PSC is prepared to discuss all of this in the April 14 status conference, but felt it important to raise this issue with the Special Masters in advance of that conversation.

Sincerely,

Michael L. Williams, Esq.
Co-Chair of PSC Executive Committee



John Fabry, Esq.
Co-Chair of PSC Executive Committee



cc: Vincent J. Matanoski, Esq., U.S. Department of Justice (via email and USPS)
Lynn Ricciardella, Esq., U.S. Department of Justice (via email and USPS)
Joseph T. Lowe, Staff Attorney, U.S. Court of Federal Claims (via fax, email and USPS)