

ORIGINAL

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

FILED

FEB 26 2007

OSM
U.S. COURT OF
FEDERAL CLAIMS

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.

**PSC REPLY BRIEF REGARDING
GENERAL CAUSATION HEARING**

AUTISM MASTER FILE

Special Master George Hastings

PSC REPLY RE GENERAL CAUSATION PROCEEDINGS

Petitioners generally agree with the approach to conducting a series of “test cases” to resolve issues of general causation in this omnibus proceeding as outlined most recently by the Special masters in the “Autism Update” of January 19, 2007. This submission will address those issues where the PSC objects to specific proposals by the Special Masters, and it will address issues raised by respondent’s January 26, 2007 Response.

A. Scope of Hearings

Respondent erroneously attempts to limit the scope of the general causation inquiry in these proceedings solely to “autism” and “autism spectrum disorders.”¹ As described in General Order No. 1, however, the injuries at issue here include “neurodevelopmental disorders *similar to* autism,”² and are not limited exclusively to cases where, for example, a specific diagnosis of autism is given. To the extent that respondent seeks to limit the scope of these proceedings to only those cases with a formal diagnosis of autism, respondent’s position is contrary to the General Order No. 1, contrary to how petitioners have described their intent throughout this proceeding, and incorrectly suggests that claims without a formal diagnosis of autism are not

¹ Resp. Brief of January 26, 2007, p.2, fn.3

² Autism General Order #1, July 3, 2002, pp. 2, 4, 5 (emphasis added).

proper for adjudication in this proceeding. Petitioners' experts and evidence will describe a range of injuries and symptoms generally caused by exposure to thimerosal-containing vaccines ("TCVs"), the MMR, or a combination of both. Those injuries and symptoms will certainly include autism and autism spectrum disorders ("ASDs"), as well as other similar neurological and neurodevelopmental injuries and symptoms.

Petitioners therefore object to any suggestion that a formal ASD or autism diagnosis be a prerequisite to a claimant's ability to proceed in the Omnibus, and petitioners object to limiting their presentation of evidence to strictly "autism only" injuries.

B. Test Cases and Additional Special Masters

Petitioners agree to select individual claims to bring to hearing as "test cases" as proposed by the Special Masters. It is anticipated that the evidence and testimony in each test case will be filed and submitted simultaneously in both that individual claimant's file and in the Autism Master File. As evidence in the Master File, the evidence and testimony in each test case will be relied upon by the PSC in subsequent test cases, with each test case in sequence generating additional evidence and testimony as appropriate. The evidence and testimony developed through the test cases will represent the PSC's body of evidence in support of general causation relating to each of the three theories of causation that the PSC anticipates presenting in this proceeding, beginning in June 2007.

Although the issue is moot at this point based on recent Orders and Updates³ by the Special Masters, the PSC renews its objection to appointing additional Special Masters to adjudicate general causation issues in this omnibus proceeding. Specifically, the PSC believes that multiple decisions by multiple Special Masters addressing nearly identical issues of law, fact, science and medicine in the test cases will generate significant confusion and delay at the appellate level, further slowing progress towards resolving claims in the omnibus. For all the reasons described in its initial brief on this issue, the PSC objects to adding Special Masters who will each make separate decisions on general causation issues.

C. Multiple Hearings

The PSC supports suggestions by the Special Masters that general causation in these cases be resolved by a series of hearings relating to each of the three theories of causation petitioners have disclosed. As a practical matter there is no one theory of causation that properly addresses the injuries of every single claimant in the omnibus, or even every group of claimants. There are over 4700 claims in the omnibus, with different levels of TCV exposure, different sequences of shots, differences in the onset of symptoms, differences in presentation of symptoms and diagnoses, with some receiving the MMR once, or twice, or not at all. While the claims are similar enough to be properly resolved in a consolidated omnibus proceeding, they are not so identical that the causation issues are amenable to resolution in one hearing or in one test case.

From the beginning it was anticipated that resolving issues of general causation in this proceeding would involve lengthy hearings and the presentation of a huge amount of evidence. Petitioners never believed that one case, with one hearing, could possibly allow for the presentation of all of that evidence. As recently described by the Special Masters,⁴ it was assumed that this process would involve:

“[L]engthy evidentiary hearings involving a substantial amount of evidence concerning the “general causation issue” thereby creating a substantial body of evidence that could thereafter be applied to many individual cases.”

The proposal by the OSM to conduct a series of hearings, in a number of test cases, spread out over time, is a reasonable approach to the presentation of what does promise to be a complex and substantial body of evidence relating to the several issues of general causation that must be decided in order to ultimately resolve individual claims.

D. Timing of Hearings

The OSM proposed recently that hearings on the theories that either TCVs or the MMR, acting independently of each other, caused the injuries at issue in the omnibus be held in June-

³ See, e.g., “Autism Update,” January 19, 2007.

⁴ “Autism Update, January 19, 2007, p. 6.

September 2008, with a schedule for submitting expert reports and filing other pleadings or evidence to be established working backwards from those dates.⁵ The PSC certainly supports an opportunity to present evidence on those theories of causation as soon as possible, but holding those hearings depends on the PSC obtaining the evidence needed to present those cases. In part, for example, the PSC has awaited the long and slow process of document production from the respondent, a process imposed on the parties by federal statutes and rules controlling the ability of government agencies to share material originally submitted by nonparty manufacturers. That process was only completed within the past few weeks.

The ability of the PSC to present a case based on relevant evidence, more significantly, has been delayed by the ongoing refusal of the respondent's client agencies to provide access to critical data in the Vaccine Safety Datalink ("VSD") that could describe, in a population, whether there is an association between TCVs and adverse health outcomes such as those at issue in this proceeding. Petitioners have developed an extensive record on this issue, both in filings with the Court, in expert submissions to the Special Master, and in evidentiary hearings before the Special Master. Petitioners have currently pending a motion to compel access to the VSD in order to obtain relevant, necessary evidence for the Special Masters to consider in resolving the issue of whether TCVs in general, can cause neurodevelopmental injuries.

For purposes of brevity, the PSC will not restate those arguments here, but the PSC incorporates by reference Petitioners' Motion to Compel Government Discovery (March 4, 2004); Petitioners' Reply in Support of Motion to Compel Government Discovery (June 6, 2004); Petitioners' Supplemental Reply in Support of Motion to Compel Government Discovery (June 28, 2004); the evidence, testimony, exhibits and argument presented in support of the Motion to Compel Government Discovery (September 29, 2004); Petitioners' Amended Motion to Compel Government Discovery (April 8, 2005); and Petitioners' Second Motion to Compel

⁵ The PSC previously agreed to schedule the first test case, involving the combined causative effect of TCVs and the MMR, on June 11, 2007. The PSC further agrees to select two additional test cases relating to this theory of causation, with hearings on those additional cases to be conducted between June-September 2007.

Government Discovery (December 8, 2006).

While the PSC would prefer to conduct hearings on test cases relating to TCV causation between June-September 2008, the PSC cannot commit to those dates at this point with the VSD access issues unresolved and a Motion to Compel pending. For all of the reasons described in the PSC's earlier filings, access to the VSD pursuant to the current Motion to Compel is necessary to the Special Masters' consideration of the general causation issues relating to "TCV-only" claims, and it would be premature to conduct hearings on test cases involving that theory until the essential evidence is available.

E. Pre-Hearing "Designation" of Individual Cases

Respondent urges that the OSM require the PSC to designate before trial "those cases whose outcome will hinge on" the outcome of the first test case hearings in June-September 2007.⁶ The PSC strongly opposes such a proposal for several reasons. First, there is no support in the statute for requiring any individual claimant, in advance of a hearing on his or her case, to agree that the outcome of some other case be binding upon them. While the general causation hearings are designed to provide guidance for resolving individual claims similar to the test cases, neither the statute nor "General Order No. 1" suggest individual claims in the omnibus be decided *before* the evidence is heard. Forcing individual claimants to be bound by the outcome of another case, before the other case is heard, effectively forces a decision on the merits of the individual case without the benefit of evidence, and is insupportable.

In addition, the Omnibus Proceeding anticipates that general causation hearings would *first* develop a body of evidence that individual claimants would rely upon "*thereafter*"⁷ in resolving their claims; that is, individual claimants would rely on the evidence adduced during general causation hearings to identify the after an extensive record regarding general causation is developed, not the other way around. The sequence of events is simple and logical: presenting evidence first, and then allowing individual claimants to then decide how best to resolve their

⁶ Resp. Brief, at p. 9.

⁷ "Autism Update," January 19, 2007, p. 6.

cases based on the evidence. Respondent's position is completely backward and illogical.

Finally, the pre-trial "designation" of individual claims defeats one of the purposes of the omnibus proceeding, that of conserving resources by not requiring each of the thousands of individual claimants to submit their medical records and completely prepare their cases for hearing until issues of general causation are resolved. In order to make an informed decision about which of the 4800 claims in the omnibus would "hinge on" the final decision of the June 2007 hearing(s), every single one of those claims would need to be completely prepared for hearing in light of the anticipated evidence to be presented during those hearings. A central rationale for the omnibus proceeding is to avoid the huge expense of money and resources involved with of completely preparing many hundreds of individual claims for trial before issues common to those claims can be resolved first.

For all of these reasons, the PSC strongly objects to any suggestion that individual claimants be forced to adopt in advance the outcome of another case before any evidence is presented and before issues of general causation are resolved.

F. Improper Evidentiary Standard

The PSC objects to the backdoor attempt by respondent to apply the incorrect standard of admissibility to scientific and medical evidence in these cases. Respondent indicates that the admissibility standards of *Daubert v. Merrell Dow*, 509 U.S. 579 (1993) be applied as the "criteria" for resolving general causation issues in this proceeding.⁸ The proposal is completely inappropriate for claims in the NVICP and ought to be rejected because *Daubert*: 1) discusses guidelines for deciding purely procedural issues of the admissibility of evidence in the Federal courts and does not provide a substantive standard for resolving a case on the merits; 2) it interprets the Federal Rules of Evidence, rules that do not apply in the NVICP; and 3) it is based on the development of expert evidence and testimony (and rebuttal evidence and testimony) through discovery that is available as a matter of right to the litigants under the Federal Rules of Civil Procedure, which do not apply in the NVICP.

In addition, the idea that a procedural rule of evidence in the Federal courts should be employed as a substantive standard for resolving claims in the NVICP finds no support whatsoever in the Vaccine Act, and is contrary to recent decisions of the Court of Claims and the Federal Circuit describing the evidentiary standards and burdens of proof relevant to resolving causation cases in the NVICP.⁹

For all of these reasons, the notion that *Daubert* should provide the substantive criteria for resolving general causation issues in the omnibus proceeding ought to be explicitly dismissed by the Special Masters. The PSC respectfully requests leave of the Special Masters to provide additional briefing on this issue if, in fact, there is any consideration by the Special Masters that *Daubert* standards would be used in these general causation proceedings.

CONCLUSION

Petitioners agree that issues of general causation be resolved through a series of hearings on selected “test cases,” beginning in June 2007. Petitioners further agree that the evidence developed in the test cases be filed in the Omnibus Master file to be relied upon in resolving individual claims upon the conclusion of the general causation proceeding. The PSC further agrees with General Order No. 1 that these proceedings address the injuries of autism, ASDs, and other similar neurodevelopmental or neurological injuries and symptoms. Petitioners agree that proceeding with general causation hearings on all theories of causation by June-September 2008 is desirable, but the PSC cannot agree to that schedule while the issues raised in the Motion to Compel remain unresolved.

The PSC also rejects any pretrial “designation” of claims that would require individual petitioners to be bound by the decision of any other case before evidence is heard and a record is

⁸ Resp. Brief, at pp. 9-10.

⁹ See, e.g., *Althen v. Sect’y of HHS*, 418 F.3d. 1274 (C.A.Fed. 2005); *Capizzano v. Sect’y of HHS*, 440 F.3d. 1317 (C.A.Fed. 2006).

developed. The PSC also object to apply *Daubert* evidence admissibility standards as criteria in deciding issues of general causation.

DATED this 26th day of February, 2007

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CERTIFICATE OF SERVICE

I hereby certify that on February 26, 2007, I served the foregoing **PSC REPLY BRIEF REGARDING GENERAL CAUSATION HEARING** on the following individual(s):

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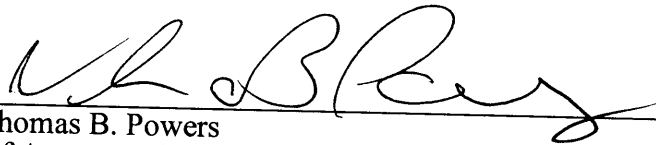
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Petitioners specifically authorize the Court and the Office of Special Masters to post this document, and any attachments or exhibits thereto, on the Court/OSM website, expressly waiving any confidentiality as to the contents of these materials. Petitioners expressly wish to publicly disclose this filing in any other forum designated by the Court or the OSM.

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