ORIGINAL

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

FILED IN RE: CLAIMS FOR VACCINE APR 2 7 2007 INJURIES RESULTING IN AUTISM SPECTRUM DISORDER, OR A SIMILAR) OSM NEURODEVELOPMENTAL DISORDER.) U.S. COURT OF FEDERAL CLAIMS Various Petitioners, **AUTISM MASTER FILE** Special Master Hastings v. Special Master Vowell SECRETARY OF HEALTH AND Special Master Campbell-Smith HUMAN SERVICES, Respondent.

RESPONSE TO "PSC UPDATE RE TEST CASE DESIGNATIONS" AND MOTION FOR APPROPRIATE RELIEF

The response of the Petitioners Steering Committee (PSC) to the Court's Order to identify the two remaining "test cases" compels respondent to renew his objections to the construct of an "omnibus" approach to these cases, and respectfully to move that the Court return to the traditional and statutorily-required procedure for resolving all claims under the Vaccine Act. After five years of "omnibus" proceedings, this Court set a deadline of March 30, 2007, extended to April 6, 2007, for the PSC to identify the last two of the three "test cases" so the "omnibus" trial for these cases could finally commence. The PSC declined to meet the deadline, claiming it so lacked basic information about the cases comprising the omnibus, it was unable to choose two test cases from among the over 4,700 currently pending. Moreover, the PSC recently advocated a "series of hearings" concerning causation on the basis that "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." PSC Reply Re General Causation Proceedings (February 26, 2007) at

3. These developments cast serious doubt over the utility of further "omnibus" processing.

Respondent's concern throughout these proceedings has been the profound lack of information regarding the vast majority of the pending "omnibus" cases. Without basic information regarding the claims that have been filed, it has even been impossible to determine that they present issues in common sufficient to justify "omnibus autism" proceedings. The PSC's current inability to identify cases sufficiently similar to Cedillo v. HHS, (Fed. Cl. No. 98-916V), to merit joint trial confirms respondent's concerns. The Court ordered the PSC to find two cases with facts similar enough to those in Cedillo to present the same basic theory of causation. Similarity of issues is the most fundamental basis for aggregating cases and trying them together, which is what the Court has been trying to do with the autism cases since 2002. The PSC responded to the Court's Order – not by complying with it, nor by even speculating as to when the PSC might comply – but by representing that the PSC is working "diligently" to find such cases. Though the PSC shifts blame from itself to the Court for this state of affairs, the essence of its response is that, for the present, the PSC does not know of any case presenting the same causation issues as are implicated in Cedillo.

The Court based the original "Autism General Order" on proffers by petitioners' counsel that literally thousands of cases would be filed presenting the same basic scientific question.

Autism General Order #1 (July 3, 2002) at 2. Respondent had no opportunity to object to the evidence upon which that Order was based because none was ever offered. And this profound lack of information was converted into a rule of the proceedings by the Court's Order, thereby relieving petitioners of their fundamental responsibility under the Vaccine Act to produce basic

documentation regarding their claims with their petitions. <u>Id.</u> at 6; <u>see generally</u> Discussion of Issue of "Short-Form" Petitions (July 8, 2002). The basic premise for Autism General Order #1 was that there were so many claims, presenting the same basic scientific question, that requiring production of medical records and documents in all these cases would overburden the Court and hinder the efficient processing of claims. <u>Id.</u> at 2. The problem with that assumption, of course, is that without some minimal showing of what these cases were about, the Court and respondent had no real way of knowing if the assumption were true. Five years later, we still do not know.

The lack of any factual information about the "autism omnibus" cases before this Court has resulted in a situation where, after five years of omnibus processing of thousands of cases, the Court has not been provided with sufficient information to permit the Court to select cases for trial. Instead, the PSC, which is not even a "party" recognized under the Vaccine Act, has been ordered to select those cases. And now, when the PSC states on the deadline for selecting these cases that it cannot, the Court lacks the information to do so itself. Even the basic premise for establishing an "omnibus" approach to these cases – that there would be thousands presenting the same basic scientific questions – remains nothing more than the unsupported representation of counsel. Now the PSC reveals that even it is without information to know whether these cases should be processed in omnibus fashion. When pinned down to name three cases that could be litigated on the same scientific issue, the PSC informs that it cannot do so five years into the litigation.

This confirms that departing from the Vaccine Act and instituting omnibus proceedings for cases lacking any documentation was not a viable course. At this juncture, these proceedings have devolved into what could have been done in the first place – one trial in a single case. Given the PSC's approach, there is no reason to believe the result will have any affect whatsoever on any other case. All of this prompts respondent to renew his recommendation that the Court begin a process of: (1) requiring petitioners to document their petitions as required by Section 11 of the Act; (2) reviewing the basic nature of the claims; (3) prioritizing the claims in some reasonable fashion; (4) dismissing those with jurisdictional defects; (5) allowing the parties to evaluate cases for merit; (6) setting deadlines for production of expert witness evidence; and (7) conducting trials when appropriate. These steps will allow a vibrant, effective, *and informed* process to begin to resolve these claims.

¹ It also raises the question about what basis the PSC had for asserting that there are a "significant number" of cases pending that involve the "claim that a *combination of thimerosal exposure and the MMR vaccine caused injury.*" Petitioners' Proposed Conduct of General Causation Proceeding (January 9, 2007) at 1 (emphasis in original). The Court relied on this assertion to revamp the omnibus proceedings to proceed on a "test case" basis, cancelling the scheduled hearing on all general causation issues and relieving the PSC of its obligation to present its written general causation evidence in February, 2007.

² The PSC claims vast factual differences exist among the cases, asserting "[t]here are over 4700 claims in the omnibus, with different levels of TCV [thimerosal containing vaccine] exposure, different sequences of shots, differences in the onset of symptoms, differences in the presentation of symptoms and diagnoses, with some receiving MMR once, or twice, or not at all." PSC Reply Re General Causation Proceedings at 3. When pressed by respondent to designate those cases involving the same causation theory as in <u>Cedillo</u>, the PSC refused, stating that it is "insupportable" to force them to designate like cases before trial of a test case. <u>Id.</u> at 5. As a result, there is no reasonable expectation that the outcome of the <u>Cedillo</u> case will resolve anything but that case alone. The PSC appears to that it is free to abandon the causation theory advanced in <u>Cedillo</u>, or to retry the same theory multiple times, without any impact on other "omnibus" cases.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this 27th day of April, 2007, a copy of **RESPONSE TO "PSC UPDATE RE TEST CASE DESIGNATIONS" AND MOTION FOR APPROPRIATE RELIEF** was served by Federal Express upon:

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and

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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."

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