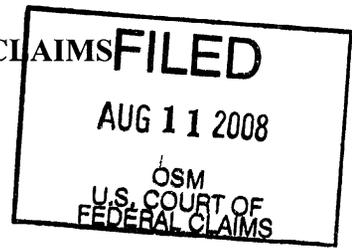


ORIGINAL
IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS



_____)
 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 OPPOSITION TO PETITIONERS’ REQUEST FOR RECONSIDERATION

On July 28, 2008, the PSC filed a Motion for Reconsideration: Toxicology Rebuttal Testimony and Evidence (“Motion for Reconsideration”), requesting relief from the Court’s orders limiting rebuttal evidence. Respondent respectfully opposes the PSC’s motion on the grounds that the evidence the PSC seeks to introduce is not truly “rebuttal,” and because the PSC’s motion raises the specter of endless litigation. At some point, the record in this case must be closed so a decision can be entered. Indeed, the Court has already ordered that the record on general causation evidence is closed. Respondent urges the Court to stand by that Order.

I. Relevant Procedural Background

The Court held an evidentiary hearing in the above-captioned case from May 12-30, 2008. During that proceeding, petitioners and respondent presented extensive evidence regarding

the PSC's second theory of general causation – that thimerosal-containing vaccines alone cause autism spectrum disorders (“Theory II”) – as well as case-specific evidence concerning William Mead and Jordan King.

Prior to the hearing, the Court ordered the parties to file written reports from the medical experts upon whom they intended to rely. On August 28, 2007, the PSC filed their first two expert reports on general causation, from Sander Greenland, Ph.D., and Richard Deth, Ph.D. On September 4, 2007, petitioners filed the report of H. Vasken Aposhian, Ph.D. On October 12, 2007, subsequent to the filing of these reports, the Court issued an Order detailing the schedule for the filing of any rebuttal reports from the PSC's experts:

At recent status conferences, Mr. Powers has noted that the PSC might file expert reports in “rebuttal” to the respondent's expert reports. Accordingly, we hereby specify that any such rebuttal expert report must be filed within 30 days of the filing date of the respondent's particular expert report to be rebutted.

Order, October 12, 2007, at 2. The Order also stated that “[a]s discussed . . . we expect that with the filing of the PSC's expert reports on November 19, 2007 [from Elizabeth Mumper, M.D.], the PSC's experts will have *fully explained* the PSC's second causation theory. . . .” Id. (emphasis in original).

On February 25, 2008, respondent filed fourteen expert reports on general causation, including those of Thomas Clarkson, M.D., Ph.D.; Laszlo Magos, M.D., D.C.P., F.R.C.Path.; and Jeffrey Brent, M.D., Ph.D. The PSC elected not to file any rebuttal reports to any of respondent's expert reports. However, on April 4, 2008, one month before the trial was scheduled to commence, the PSC added a neurologist, Marcel Kinsbourne, M.D., to their list of

expert witnesses. On April 21, 2008, three weeks before the start of trial, the PSC filed Dr. Kinsbourne's report, which introduced a new theory of causation.

Before the trial started, respondent notified the Court and the PSC that two of respondent's expert witnesses, Dr. Clarkson and Dr. Magos, were unable to testify in May 2008. Specifically, during a telephonic status conference, held on March 20, 2008, respondent informed the Court that Dr. Clarkson was unavailable to testify in May, but could testify in July. The Court and the PSC agreed that Dr. Clarkson could testify in July, as documented in the Court's Order of April 16, 2008:

[D]uring the week of July 21, 2008 . . . the testimony of one general causation witness who [is] unable to attend the May hearing [has] already been scheduled for presentation.

Order, April 16, 2008, at 2. On April 25, 2008, respondent informed the Court and the PSC that Dr. Magos was also unable to testify in May, but that he could testify during the week of July 21, 2008. The PSC had no objection.

The trial commenced on May 12, 2008. Petitioners presented toxicology testimony from Dr. Aposhian, and respondent presented responsive testimony on toxicology from Dr. Brent. It was always respondent's understanding that petitioners would present their rebuttal evidence during the May proceedings. In fact, the three week schedule for trial in May was engineered for such rebuttal. Yet, during the May hearing, counsel for petitioners first asserted that they desired to wait until July to present the entirety of their rebuttal evidence. See Transcript of Proceedings ("Tr."), May 16, 2008, at 1680. This prompted a spirited discussion of the issue on the record, during which the Court asked counsel for respondent to clarify his position regarding possible

rebuttal testimony in July 2008:

SPECIAL MASTER HASTINGS: So you are asking us to limit any rebuttal that come[s] in after Magos and Clarkson to only rebuttal of their testimony?

MR. MATANOSKI: That's correct.

SPECIAL MASTER HASTINGS: You're asking that the Petitioners, if they have any rebuttal to the rest of the government's case, that they bring that in at the end of the third week of this trial?

MR. MATANOSKI: That's correct, sir.

Id. at 1687. Counsel for respondent continued to note the potential effect of the PSC's proposal regarding the possibility of rebuttal testimony in July:

MR. MATANOSKI: Your Honor, again, this is a change in the procedure, and it actually may have affected, because [of] this late change in the procedure, whether we would even call [Drs. Clarkson and Magos] or not. We want to be at an end of this proceeding.

Id. at 1688-89.

On May 19, 2008, discussions regarding petitioners' newly proposed schedule for rebuttal testimony resumed, with the Special Masters expressing their own surprise at the PSC's proposal:

SPECIAL MASTER VOWELL: I think the reason that all three Special Masters were quite surprised when [petitioners] proposed presenting rebuttal at the proceeding in July is that we had scheduled Dr. Magos and Dr. Clarkson to testify on Thursday and Friday, which then meant obviously we were going to go into the following week that we had not set aside.

Tr., May 19, 2008, at 2043-44. That evening, counsel for both parties convened with the Special

Masters, off the record, and held further discussions regarding petitioners' proposed schedule for rebuttal testimony. The following day, on May 20, 2008, the Court announced its ruling:

SPECIAL MASTER VOWELL: Friday [July 25, 2008] will be reserved to the Petitioners to provide rebuttal to Drs. Clarkson and Magos, but we will strictly enforce that it has to be rebutting what Drs. Clarkson and Magos testified to, not the gamut of what we've heard or what we will hear in the next week and half.

Tr., May 20, 2008, at 2151. The Court asked petitioners' counsel to confirm whether this ruling comported with the Special Masters' recitation of their decision the prior evening, to which petitioners' counsel replied that the oral ruling was an "accurate recitation." Id. at 2151-52.

Presciently, respondent then raised a further concern regarding potential rebuttal from petitioners:

MR. MATANOSKI: I just wanted to, for the record, as far as in another proceeding earlier in this omnibus trial, we had rebuttal close at the end of that proceeding and then there were some written submissions [from petitioners] thereafter. I just wanted to make sure that that's not the process that we're adopting here today, but rather, in this process the rebuttal is going to end at the end of this trial.

Id. at 2152. The Special Master responded by stating that this was her "fervent hope." Id.

Following the May trial, the Court conducted a telephonic status conference with the parties, on June 12, 2008, at which time counsel for respondent indicated that respondent was satisfied with the evidentiary record as it now stood, and respondent no longer intended to call Drs. Clarkson and Magos to testify in July. Order, June 17, 2008, at 1. The PSC responded by indicating that they would still seek to call Dr. Aposhian in rebuttal to the *reports* of Drs. Clarkson and Magos. Id. While noting that "petitioners had ample opportunity to produce rebuttal reports by their own experts prior to the May, 2008, hearing," the Court nevertheless issued an Order, on June 17, 2008, granting the PSC's request for rebuttal at the July 2008,

hearing. Id. This rebuttal, however, was “limited to [] the matters presented in the reports of Drs. Magos and Clarkson.” Id. Recognizing that the PSC would most likely not limit rebuttal to the matters presented in the reports of Dr. Clarkson and Dr. Magos, during a subsequent telephonic status conference, held on June 27, 2008, counsel for respondent informed the Court that respondent was withdrawing the expert reports of Drs. Clarkson and Magos from the record. Order, July 3, 2008, at 2. The PSC responded that they would now seek to recall Dr. Aposhian to rebut evidence presented by respondent during the *May 2008 hearing*, rather than to rebut the reports of Drs. Clarkson and Magos. Id.

A July 3, 2008, Order documents the Court’s response to the PSC’s continued attempts to call Dr. Aposhian as a rebuttal witness, stating that “such rebuttal would be inconsistent with our June 17 Order.” The Court further stated:

[W]e clearly ruled during the May hearing [that] the July extension of the general causation hearing was *expressly to be limited* to the testimony of Drs. Magos and Clarkson, and any rebuttal by petitioners to that testimony.

Id. (emphasis in original). The Order also stated that respondent’s withdrawal of the expert reports of Drs. Clarkson and Magos had eliminated the need for *any* rebuttal from the PSC’s experts, and that the Special Masters “now consider[ed] the Theory 2 *general causation* evidence to be closed.” Id. (emphasis in original). Nevertheless, on July 28, 2008, the PSC filed a Motion for Reconsideration seeking, in part, leave to file a rebuttal report prepared by Dr. Aposhian allegedly in response to the testimony given by Dr. Brent during the May 2008 trial. This motion comes more than four months after the PSC’s deadline for the filing of reports in rebuttal to those filed by respondent, including those of Drs. Brent, Clarkson, and Magos. The motion also comes

more than two months after the PSC confirmed, on the record, that any rebuttal they intended to present following the May hearing would be limited to rebutting the *testimony* of Drs. Clarkson and Magos.

The reconsideration currently being sought by the PSC asks the Court for leave to file a rebuttal report from Dr. Aposhian. Id. However, without having entertained a response from respondent, and without having received a ruling in their favor from the Court, the PSC has taken the liberty of prematurely filing into evidence the very report at issue. Attached to the July 28, 2008, Motion for Reconsideration is a report prepared by Dr. Aposhian, which is offered by the PSC as “rebuttal” to the May 2008, testimony of Dr. Brent. Id. On August 4, 2008, the PSC took the additional liberty of filing into evidence an additional thirty-one pieces of medical literature, despite the Court’s July 3, 2008, ruling that the Theory II general causation evidentiary record is now closed. Order, July 3, 2008, at 2. Consistent with the more than two hundred articles the PSC filed less than one week before the start of trial, the newly-filed articles were not cited by any of the PSC’s experts, were not used during the examination of either parties’ expert witnesses, and contain no explanation whatsoever as to how they relate to the PSC’s case. Moreover, with the exception of one article, every piece of literature filed by the PSC on August 4, 2008, was published and available to them well in advance of the May 2008 trial.

II. Argument

A. The document attached to the PSC’s motion is not a “rebuttal” report.

The PSC asserts in their Motion for Reconsideration that the attached report from Dr. Aposhian is a “rebuttal” to Dr. Brent’s testimony from the May trial. This is an incorrect

characterization of the document. The vast majority of Dr. Aposhian's purported "rebuttal" report addresses items outside the scope of Dr. Brent's expert report and his testimony on direct examination. Other portions are simply an effort to recapitulate Dr. Aposhian's original report that the PSC filed in September 2007, or his testimony (which was markedly different from his report). For instance, respondent agrees that Dr. Brent discussed the Burbacher paper, as did Dr. Aposhian during his testimony. However, while Dr. Brent was asked about several topics in Dr. Aposhian's "rebuttal" report by petitioners' counsel during cross-examination, this line of questioning – solely at the behest of petitioners' counsel – does not justify additional "rebuttal" testimony by the PSC's expert at a later date.

Moreover, although it is addressed by Dr. Aposhian in his "rebuttal" report, Dr. Brent did not discuss the Pardo, Vahter, or Vargas studies in his report or during his direct testimony. Dr. Brent mentioned neuroinflammation only briefly, simply stating that the levels of mercury in vaccinations are not consistent with the hypothesis offered by the PSC in this case. By contrast, Dr. Aposhian's "rebuttal" devotes a significant amount of time discussing mechanics of neuroinflammation, a topic outside of Dr. Aposhian's area of expertise. As the Court is aware, Dr. Aposhian's original report did not address the PSC's late-generated hypothesis of neuroinflammation put forth by Dr. Kinsbourne three weeks before trial. Requesting leave to file Dr. Aposhian's "rebuttal" report prepared several months after the fact, which incorporates the topic of neuroinflammation, repeats items already included in his original report, and only partially discusses issues actually raised by Dr. Brent, is disingenuous and a clear prejudice to respondent.

Ultimately, if Dr. Aposhian had a response to Dr. Brent's testimony in May, the PSC could have called Dr. Aposhian as a rebuttal witness at the end of the May proceedings, as the Court ordered. They did not. The PSC's offer of "rebuttal" evidence now from Dr. Aposhian is nothing more than an improper attempt to shore up weaknesses in their case. While respondent does not believe the proffered evidence supports, let alone improves, the PSC's case, the motion should be denied.

B. The PSC's continued efforts to misconstrue respondent's decision to withdraw the expert reports of Drs. Clarkson and Magos are improper.

In their Motion for Reconsideration, as well as during closing arguments in the Dwyer case, the PSC has made repeated assertions about the evidence they "would have" elicited from Drs. Magos and Clarkson had they been called to testify for respondent. See Motion for Reconsideration at 4. Although respondent has withdrawn the expert reports of Dr. Magos and Dr. Clarkson from these proceedings, both doctors strongly believe, based on their significant expertise as toxicologists, that there is no link between thimerosal-containing vaccines and autism spectrum disorders. The PSC's misplaced attempts to characterize respondent's decision not to call these experts to testify as an indication that Drs. Magos and Clarkson no longer support the government's position are absolutely incorrect. Both Dr. Magos and Dr. Clarkson continue to endorse fully the opinions offered in their written expert reports, and were prepared to offer oral testimony consistent with those reports.

The PSC's protestations ignore completely the fact that respondent is *not the burdened party* in these cases. It is petitioners' burden to establish, more probably than not, that thimerosal-containing vaccines can cause autism, and that they did so in the three test cases

presented. After an evaluation of the evidence presented in May 2008, respondent concluded that petitioners unequivocally had not met that burden.¹

C. The Court's Orders are clear with respect to rebuttal testimony.

As discussed above, the Court made it abundantly clear to both the PSC and respondent that, with the narrow exception of testimony specifically addressing Dr. Clarkson and Dr. Magos's testimony, all rebuttal evidence must be presented during the May trial. The Court's ruling was explained on-the-record during the May trial. Although the Court's Order of June 17, 2008, fractionally expanded the scope of rebuttal by permitting rebuttal testimony to the reports of Drs. Clarkson and Magos, it reaffirmed in no uncertain terms that no other rebuttal would be countenanced. After respondent withdrew the written reports of Drs. Magos and Clarkson, the Court ruled that, consistent with its previous Orders and discussions with the parties, further rebuttal evidence would be precluded. See Order Concerning Theory 2 General Causation Rebuttal ("July Order"), filed July 3, 2008, at 2. "As we clearly ruled during the May hearing, the July extension of the general causation hearing was *expressly to be limited* to the testimony of Drs. Magos and Clarkson, and any rebuttals by petitioners to that testimony." Id. (emphasis in original).

¹ The PSC offers argument as to what they contend would be "elucidate[d] from Drs. Clarkson and Magos during cross-examination. See Motion for Reconsideration at 4. They characterize respondent's decision not to present testimony from Drs. Clarkson and Magos as an attempt "to deprive petitioners of the opportunity to develop the facts of these cases through cross-examination." Id. That the PSC needs to "develop the facts of these cases through cross-examination," rather than through their own expert witness reports and testimony, is quite telling, and reflects the weakness of their own evidence.

Now, almost one month after the July Order, and two months after the May trial, the PSC seeks reconsideration of the Court's rulings regarding rebuttal testimony.² This latest maneuver is an overt attempt to prolong the litigation, and a thinly-veiled effort to support a new theory of causation that the PSC put together at the last minute. Indeed, Dr. Kinsbourne admitted during the trial that counsel for petitioners approached him in March 2008, just two months before trial and after the PSC received respondents' expert reports, to offer an opinion regarding neuroinflammation. Tr. at 846. The Court's Orders were clear, and counsel for petitioners understood during the May trial that all rebuttal to testimony presented during the trial must be presented in May. Allowing the PSC to re-open the general causation proceedings at this point would unfairly prejudice respondent, who relied on the process articulated by the Court. It also provides yet another instance in which the PSC has disregarded the Court's rulings and orders during these proceedings.

The PSC's recent filing of scientific literature, after the Court closed the general causation evidentiary record, and without any explanation of the literature's relevance, is further evidence of the PSC's indifference to Court orders in these proceedings. While the Vaccine Program is certainly designed to afford petitioners a full opportunity to present their case, this effort must not be without limits.

² Respondent questions whether the PSC's motion is proper or timely. Pursuant to the Court's rules, the only circumstance permitting a Motion for Reconsideration follows a decision by the special master. See Vaccine Rule 10(c). That rule explicitly requires that such a motion be filed within 21 days of the relevant decision. Id. The PSC filed their motion 41 days after the June Order, and 25 days after the July Order.

The Court has repeatedly stated that it does not want a “trial by ambush.” Respondent assumed that admonition applied to both parties. Yet respondent has been blind-sided on numerous occasions throughout this litigation, most notably by the filing of an expert report from Dr. Kinsbourne just three weeks before the May trial that proffered a completely different theory of causation. Despite this significant prejudice to the government, respondent elected not to request a postponement of the May trial, based on the explicit acknowledgment that the PSC would present their full case at that time, including all evidence on neuroinflammation. Although Dr. Aposhian is not qualified to discuss neuroinflammation, he has certainly attempted to do so in his “rebuttal” report.

The PSC appeals to the “interest of fairness” and asks that they “be permitted to complete the toxicology record in these proceedings by admitting into evidence Dr. Aposhian’s rebuttal report.” Motion for Reconsideration at 4. While it is clear that the PSC seeks to prolong this litigation, and even admitted as much during their closing argument in Dwyer, they have already been given more than *six years* to develop their theory, gather literature, and present evidence in support of their case. That evidence was presented during the trial on general causation evidence in May 2008, and respondent strongly urges the Court to stand by its original orders and keep the evidentiary record closed.

III. Conclusion

The PSC has been afforded a full and fair opportunity to present evidence on Theory II. The new “rebuttal” report for which they now request leave to file would unnecessarily, and

improperly, prolong these proceedings, and unfairly prejudice respondent. Respondent requests that the Court deny the PSC's motion and keep the evidentiary record closed.³

Respectfully submitted,

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Dated: August 11, 2008

³ In the event that the Court grants the PSC's motion over respondent's objection, respondent would seek an appropriate remedy to address the issues raised in Dr. Aposhian's report.

CERTIFICATE OF SERVICE

I hereby certify that on this 11th day of August, 2008, a copy of **RESPONDENT'S OPPOSITION TO PETITIONERS' REQUEST FOR RECONSIDERATION** was served by Federal Express overnight upon:

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and

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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."

A handwritten signature in black ink, appearing to read "Anthony", is written over a horizontal line.