

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

ROLF and ANGELA HAZLEHURST,
Parents of WILLIAM YATES
HAZLEHURST, a minor,

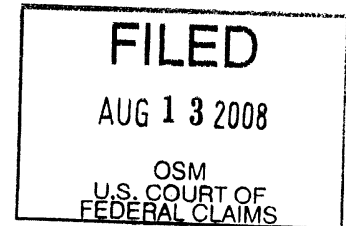
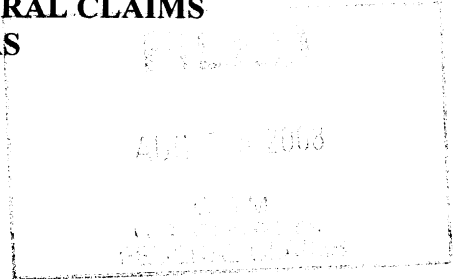
Petitioners,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

No. 03-654V
Special Master Campbell-Smith



**RESPONSE TO PSC NOTICE RE: UK LITIGATION MATERIALS AND THE FIRST
THEORY OF GENERAL CAUSATION**

On July 30, 2008, the Petitioners' Steering Committee ("PSC") filed a notice formally abandoning their efforts to obtain sealed documents generated during the MMR litigation in the United Kingdom ("UK Notice").¹ Certain statements made by the PSC in that notice require clarification from respondent.

The PSC initially notes that it "first sought to obtain expert reports filed in the UK litigation by the pharmaceutical company defendants in 2004." UK Notice at 1. The PSC then stated that the pharmaceutical companies refused informal requests for the reports, and then alleged that the special masters and respondent denied similar requests. *Id.* The PSC's efforts at that time were an inappropriate attempt to use Vaccine Act's discovery procedures to obtain

¹ The PSC's notice was filed into the Omnibus file and in the Snyder case. For the sake of clarity, respondent is filing the response into the Omnibus as well as in all three Theory I test cases.

documents not directly available to the Court. As the PSC is well aware (and even acknowledges in its most recent pleading), the UK expert reports were sealed by a court in the United Kingdom. Thus, the pharmaceutical defendants were not at liberty to disclose the reports to this Court, the PSC, or to respondent absent a specific grant of permission from the presiding Court in the United Kingdom. The PSC did not seek such permission before the Theory I trials commenced.

This permission from the presiding Court in the United Kingdom, however, is precisely what respondent set out to obtain following the filing of the PSC's Theory I expert reports in February 2007, which relied heavily upon testing results from the Unigenetics Laboratory in Dublin, Ireland. Based upon this reliance, in addition to information from respondent's experts and other public sources, respondent believed that evidence existed from the UK litigation that examined the reliability of the Unigenetics laboratory data. Respondent viewed this as critical evidence not otherwise available to the Court. As respondent has explained in previous filings, the process of formally petitioning the UK Court for access to the expert reports was somewhat complex, and thus it was not until June 7, 2007, that permission was granted by a judge in the United Kingdom to release several of those expert reports. Respondent filed the reports upon receipt.

It bears repeating that respondent is not the burdened party in these proceedings. Thus, it was not respondent's "duty" to obtain all information from the UK proceedings, nor is there any error in respondent requesting (and obtaining) the material from the UK litigation that respondent viewed to be the most relevant to its defense of these cases. The PSC objected to the filing of the expert reports respondent obtained, and as a remedy the Court afforded the PSC a very generous period of time— *over one year*— to seek additional evidence or provide rebuttal testimony from

their experts. The PSC filed supplemental expert reports from Dr. Kennedy and Dr. Hepner, and, at the direction of the Court following the Snyder proceedings, announced their intention to seek material from the UK litigation. To further support the PSC's efforts, all three special masters signed a letter of support which urged the presiding judge in the UK litigation to grant the PSC's request. That the PSC was unsuccessful in this effort does not tarnish the relevance and importance of this evidence produced by respondent relating to the Unigenetics laboratory data.

Interestingly, one of the major reasons the PSC abandoned their effort was because all but one of the authors of the expert reports they sought in the UK litigation would not consent to their release for use in the Omnibus Autism Proceedings. One expert who declined the PSC's request was Dr. John O'Leary, the former Director of the Unigenetics laboratory. Since the filing of the reports in the UK litigation, Dr. O'Leary has publicly stated that he does not think there is a link between the MMR vaccination and autism. See Cedillo, Respondent's Exhibit AAA. By contrast, the experts respondent contacted all readily agreed to release their reports for the proceedings before this Court.

Respondent relies primarily upon the expert reports filed by Dr. Stephen Bustin and Dr. Bertus Rima. Respondent filed affidavits concerning the Unigenetics laboratory from both experts several months before the Theory I hearing— which were independent of the reports prepared for the UK litigation— and both experts were subject to cross-examination by counsel for petitioners in these proceedings. Dr. Bustin and Dr. Rima limited their testimony to evidence that was clearly documented in their expert reports from the UK litigation, and also to their independent evaluations of the merits of the Theory I cases. As discussed in the PSC's UK

Notice, Dr. Bustin's expert report included a discussion of one of the laboratory notebook entries. A copy of the relevant pages from the laboratory notebook were included in Dr. Bustin's report and filed in these proceedings. Although Dr. Bustin and Dr. Rima stated that they were aware of additional abnormalities and issues with the Unigenetics laboratory data, they specifically limited their testimony to what was contained in their reports, and thus to what was available to both parties and the Court in this litigation.

Finally, the PSC fails to note that several of their own experts prepared reports for the UK litigation, and thus were intimately familiar with the investigation of the Unigenetics laboratory data. Dr. Kennedy testified at length about his experience with the Unigenetics laboratory during the Cedillo and Snyder trials, including details of a meeting he attended with one of the Unigenetics laboratory directors. Although the PSC had the option of pursuing material from the UK litigation to support its case, and was given ample time by this Court to do so, the PSC has made the decision to abandon this effort.

Ultimately, respondent determined that information critical to respondent's defense of these cases had been developed during the course of the UK litigation. Respondent undertook an effort to obtain that information, and was granted access to reports respondent believed to be of critical importance to the Court's evaluation of these cases. Although that access was not granted until just before the Theory I trial, the Court gave the PSC an extremely generous period of time to present rebuttal to the information presented in the reports. There is no prejudice to petitioners in considering any of the evidence respondent filed in these proceedings.

Respectfully submitted,

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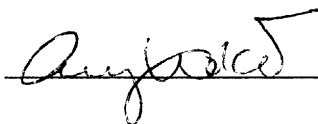
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DATED: August 13, 2008

CERTIFICATE OF SERVICE

I hereby certify that on this 13th day of August, 2008, a true and correct copy of the foregoing **RESPONSE TO PSC NOTICE RE: UK LITIGATION MATERIALS AND THE FIRST THEORY OF GENERAL CAUSATION** was served by first-class mail, postage prepaid, upon:

Curtis R. Webb, Esq.
Webb, Webb & Guerry
155 Second Avenue North
P.O. Box 1768
Twin Falls, ID 83303-1768



A handwritten signature in cursive script, appearing to read "Curtis R. Webb", is written over a horizontal line.