

Petitioners, Rolf and Angela Hazlehurst (the Hazlehursts), as parents of William Yates Hazlehurst (Yates), filed an amended petition on June 13, 2007, pursuant to the National Vaccine Injury Compensation Program² (the Act or the Program), 42 U.S.C. § 300aa-10 et seq. In the amended petition, petitioners alleged that Yates developed regressive autism as a result of the thimerosal containing vaccinations that he received during his first year of life and as a result of the measles, mumps, and rubella (MMR) vaccination that Yates received on February 8, 2001. Amended Petition (Am. Pet.) ¶¶ 5, 8.

Petitioners also consented to the public disclosure of their claim as the second of three test cases exploring the first theory of causation presented in the Omnibus Autism Proceeding (OAP). See Status Report dated July 26, 2007. The OAP is the procedural mechanism adopted, following discussions between petitioners' counsel, respondent's counsel and the Chief Special Master, to address through coordinated proceedings the numerous petitions before the Office of Special Masters seeking compensation for the alleged injury of vaccine-related autism spectrum disorders. The first theory of causation to be considered in the OAP is whether the combination of thimerosal containing vaccines and the MMR vaccine can cause autism.

Petitioners in this case have designated the general causation evidence adduced in the two other test cases on the first theory of causation (namely, the Cedillo case and the Snyder case)³ for consideration, in deciding Yates' claim. But, by filing the motion to strike certain evidence from Dr. Stephen A. Bustin, petitioners seek to exclude particular evidence from consideration. See generally Petitioners' Motion to Strike Certain Evidence from Dr. Stephen A. Bustin (Petrs.' Strike Mot.). Respondent opposes petitioners' motion to strike. See generally Respondent's Opposition to Petitioners' Motion to Strike Certain Evidence from Dr. Stephen A. Bustin (R's Opp.).

I. Pertinent Background to the Filed Motion

In support of the asserted claim that receipt of the MMR vaccine contributed to the

² Hereinafter, for ease of reference, all "section" references to the Vaccine Injury Compensation Act will be to the pertinent subsection of 42 U.S.C. § 300aa (2006 ed.).

³ The first designated test case was Cedillo v. Secretary of Health and Human Services, case no. 98-916V. The third designated test case was Snyder v. Secretary of Health and Human Services, case no. 01-162V.

development of autism, petitioners in the Cedillo case filed expert reports that pointed to “a ‘positive’ biopsy sample sent to the Unigenetics laboratory in Dublin, Ireland as evidence of measles virus persistence in [the gastrointestinal tissue of] Michelle Cedillo.” R’s Opp. at 2 (citing Cedillo Ex. 59 at 8, 9 (expert report of Arthur Krigsman, M.D.), Cedillo Ex. 57 at 7, 8 (expert report of Vera Byers, M.D.), Cedillo Ex. 61 at 5, 15-16 (expert report of Marcel Kinsbourne, M.D.)). These reports filed by petitioners’ experts “also referenced research performed by the Unigenetics laboratory for a paper published by Uhlmann, et al. (2002).”⁴ R’s Opp. at 2.

Respondent filed the expert reports of Robert S. Fujinami, Ph.D., Michael D. Gershon, M.D., Diane Griffin, M.D. Ph.D., and Brian J. Ward, M.D. M. Sc., to “discuss the suspect finding of measles virus persistence in Michelle Cedillo, as well as the public criticisms of the methodology used for the Uhlmann paper (in essence, the methods employed by Unigenetics).” R’s Opp. at 2. Respondent also filed, in the Cedillo case, a motion in limine to strike the testimony of petitioners’ expert gastroenterologist Dr. Krigsman “on Daubert grounds.”⁵ R’s Opp. at 3 n.3. Respondent specifically challenged the reliability of the “Unigenetics-derived laboratory results.” Id. Respondent attached to the motion to strike an affidavit prepared by Dr. Stephen A. Bustin, a molecular biologist in the United Kingdom. Id.

⁴ V. Uhlmann, et al., Potential viral pathologic mechanism for new variant inflammatory disease, Mol. Pathol. 55:84-90 (2002).

⁵ In its decision Daubert v. Merrell Dow Pharmaceuticals, Inc., the United States Supreme Court stated that:

The subject of an expert’s testimony must be “scientific...knowledge.” The adjective “scientific” implies a grounding in the methods and procedures of science. Similarly, the word “knowledge” connotes more than subjective belief or unsupported speculation. The term “applies to any body of known facts or to any body of ideas inferred from such facts or accepted as truths on good grounds.” Of course, it would be unreasonable to conclude that the subject of scientific testimony must be “known” to a certainty; arguably, there are no certainties in science. But, in order to qualify as “scientific knowledge,” an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation- *i.e.*, “good grounds,” based on what is known. In short, the requirement that an expert’s testimony pertain to “scientific knowledge” establishes a standard of evidentiary reliability.

509 U.S. 579, 589-590 (1993) (internal citations omitted).

On the same date of the filing of respondent's motion in limine, petitioners in Cedillo filed an expert report from Karin D. Hepner, Ph.D, a microbiologist. Cedillo Ex. 63 (Dr. Hepner's expert report); Cedillo Ex. 64 (Dr. Hepner's curriculum vitae); R's Opp. at 3. In her report, Dr. Hepner "specifically addressed the reliability of the Unigenetics laboratory results." R's Opp. at 3; Cedillo Ex. 63. Petitioners also filed an expert report on May 28, 2007, from Ronald C. Kennedy, Ph.D, also a microbiologist. R's Opp. at 3; Cedillo Ex. 111 at 2 (Dr. Kennedy's curriculum vitae). In turn, respondent filed, on May 31, 2007, an expert report from Dr. Bustin "specifically critiquing Dr. Hepner's report." R's Opp. at 3.

The reliability of the Unigenetics laboratory results had been challenged earlier in litigation in the United Kingdom on the issue of whether the MMR vaccine contributed to the development of autism in vaccinated children. The theory of vaccine causation advanced by the claimants in that litigation against three manufacturers of the MMR vaccine is not dissimilar to the theory advanced in the OAP by petitioners.

In accordance with the procedures established for third parties to obtain information pertaining to litigation in the United Kingdom, respondent in the Cedillo case filed an application with the court in the United Kingdom requesting the release of certain expert reports that had been prepared in connection with the MMR/autism litigation and were filed under seal there. After considering respondent's application, the judge who had heard the case in the United Kingdom "formally granted respondent access to Dr. Bustin's expert reports [which had been] filed in the . . . [autism] litigation [in the United Kingdom involving the MMR vaccine]." R's Opp. at 3. Respondent filed into the Cedillo case on June 7, 2007, one of two reports that were prepared by Dr. Bustin and were obtained from the court in the United Kingdom. Id.

During a status conference held on June 8, 2007, after the filing of Dr. Bustin's second report, the parties in the Cedillo case made arguments regarding the admissibility of Dr. Bustin's reports. Petitioners specifically objected to the consideration of any expert reports from the United Kingdom litigation if all of the expert reports from that litigation were not available for consideration. See Cedillo Transcript of June 8, 2007 Status Conference at 40.

By Evidentiary Ruling dated June 8, 2007, issued in the Cedillo case, the special master assigned to that case deferred until after the imminent Cedillo hearing his decision concerning whether he would rely on the two submitted reports by Dr. Bustin, specifically Cedillo Ex. WW and Cedillo Ex. XX, as evidence. Cedillo Evidentiary Ruling, June 8, 2007, at 2-3. The special master determined that he would permit Dr. Bustin to testify during the scheduled hearing, and that he would permit both parties to question Dr. Bustin

regarding the content of his reports. See Cedillo Evidentiary Ruling, June 8, 2007, at 2-3. The special master also ruled that he would afford the petitioners in Cedillo a period of time following the hearing to present rebuttal evidence. Id.

Three days later, by Order dated June 11, 2007, the undersigned and the two other special masters involved in the OAP deferred deciding, for purposes of the OAP and for the reasons outlined in the June 8, 2007 ruling issued in Cedillo, whether we would rely on Dr. Bustin's two reports, Cedillo Ex. WW and Cedillo Ex. XX, as evidence in the OAP. Order, June 11, 2007, at 1. By that same order, we decided that the parties would be permitted to question Dr. Bustin and other expert witnesses concerning the contents of Dr. Bustin's reports during the scheduled proceedings beginning on June 11, 2007. Id. Additionally, the undersigned and the two other special masters advised that we would "favorably consider joining in a request for release of relevant reports" if the OAP's Petitioners' Steering Committee⁶ filed a formal application in the United Kingdom court for the release of additional expert reports from the proceeding conducted there. Id.

After the Cedillo hearing, petitioners in the Cedillo case effectively renewed their motion to strike Dr. Bustin's expert report and testimony.

II. Reliance by Both Parties in This Case on the General Causation Evidence Presented during the Cedillo Hearing

The Hazlehursts in this case have agreed to have their claim heard as the second test case to proceed under the first theory of general causation advanced in the OAP by the PSC. As the parents of Michelle Cedillo urged in the Cedillo case (the first test case), the parents of Yates Hazlehurst similarly attributed the development of their child's autism to "the MMR vaccination that Yates . . . received, or a combination of the MMR vaccination and the [t]himerosal[-]containing vaccinations that he received during the first twelve months" of his life. Amended Petition ¶ 5.

In support of the Hazlehursts' claim, petitioners filed the expert report of Jean-Ronel Corbier, M.D., a neurologist. Hazlehurst Ex. 26 (Dr. Corbier's expert report). Dr. Corbier relied in his report on the 2002 Uhlmann article, among others, for "support [of] the hypothesized 'association between the presence of measles virus and gut pathology in children with developmental disorders.'" R's Opp. at 4 (citing Hazlehurst Ex. 26 at 13-14 (Dr. Corbier's expert report)). Dr. Corbier also testified about this hypothesis and referred to the 2002 Uhlmann article during the Hazlehurst hearing. See Hazlehurst Tr. at

⁶ The Petitioners' Steering Committee (PSC) is a designated group of petitioners' counsel representing the interests of petitioners in the OAP.

265-280. The 2002 Uhlmann article reports a finding of measles virus persisting in the gastrointestinal tissue of autistic children based on certain test results obtained from the Unigenetics laboratory.

The parties in Hazlehurst intended to rely heavily during the Hazlehurst hearing on the general causation evidence presented in Cedillo, and the parties authorized the undersigned to consider the general causation evidence presented in Cedillo in this case. See Orders dated September 18, 2007, March 18, 2008, and August 12, 2008. However, similar to petitioners in the Cedillo case, petitioners here have moved to strike certain evidence from consideration, specifically, two of Dr. Bustin's reports and portions of his hearing testimony that challenge the reliability of the test results obtained from the Unigenetics laboratory. The Hazlehursts filed their Motion to Strike Certain Evidence from Dr. Stephen A. Bustin on September 4, 2007.

III. Scope of Petitioners' Motion to Strike

In the Cedillo case, Dr. Bustin offered three expert reports (Cedillo Ex. UU, Cedillo Ex. WW, and Cedillo Ex. XX), trial testimony (Cedillo Transcript at 1933-2069), and a power point presentation during his testimony (Cedillo Respondent's Trial Exhibit 13). Petrs.' Strike Mot. at 2. Dr. Bustin described in his first report, see Cedillo Ex. UU, and addressed further in his testimony during the Cedillo hearing, the use of the laboratory technique of polymerase chain reaction (PCR) for the purpose of identifying and quantifying nucleic acid sequences—whether deoxyribonucleic acid (DNA) or ribonucleic acid (RNA)—in biological material. See also Cedillo Ex. XX at 9 (Dr. Bustin's second report) (describing a method of performing PCR). As part of his opinion, Dr. Bustin included a critique of the 2002 Uhlmann article, which was submitted as Cedillo Ex. 59M by petitioners. See generally Cedillo Ex. XX at 48-53.

As set forth in the motion to strike filed in this case, petitioners do not object to the undersigned's consideration of Dr. Bustin's initial report, Cedillo Ex. UU, or to the undersigned's consideration of "the first 29 pages of [Dr. Bustin's] testimony (of 136 pages) [which] provide information on PCR testing and a critique of the Uhlmann article which describes the identification of measles in the gut tissue of children with autism." Petrs.' Strike Mot. at 2. Petitioners do object, however, to the undersigned's consideration of the other reports submitted by Dr. Bustin, the balance of his hearing testimony, and most of his power point presentation. See id.

Petitioners assert that Cedillo Ex. WW and Cedillo Ex. XX are reports that "Dr. Bustin prepared for Merck and Company, Aventis Pharmaceuticals, and GlaxoSmithKline to assist in their defense against claims made against them in litigation in the United

Kingdom.” *Petrs.’ Strike Mot.* at 2. Moreover, petitioners assert that “[m]ost of Dr. Bustin’s testimony at the Cedillo hearing and all but 4 (of 25) slides in Dr. Bustin’s Power-Point[sic] presentation were also based on Dr. Bustin’s work for Mer[c]k, Aventis, and GSK.” *Id.* (citations omitted). Noting that the “claimants in the U.K. litigation relied on PCR testing from Unigenetics laboratory for both claimant specific evidence and in support of the general proposition that some children with regressive autism might have persistent measles infections,” petitioners contend that Dr. Bustin “was hired by Merck, Aventis and GSK to discredit the PCR results from Unigenetics laboratory.” *Id.* at 2-3. Accordingly, petitioners move to strike those portions of Dr. Bustin’s reports, testimony, and slides “that are based on the review of Unigenetics laboratory’s procedures and PCR results” that Dr. Bustin performed for the defendants in the U.K. litigation. *Id.* at 3.

IV. Analysis

A. Applicable Legal Standard

Vaccine Rule 8(c) provides guidance to a special master concerning the receipt of evidence related to a vaccine claim. In pertinent part, Vaccine Rule 8(c) instructs that a special master must “consider all relevant and reliable evidence, governed by principles of fundamental fairness to both parties.” Rules of the Court of Federal Claims (RCFC), App. B, Vaccine Rule 8(c).

B. The Parties’ Arguments

Petitioners argue that the “principles of fundamental fairness” contemplated by Vaccine Rule 8(c) should guide the undersigned’s decision regarding the admissibility of the challenged portions of Dr. Bustin’s reports, testimony, and trial presentation. *Petrs.’ Strike Mot.* at 3. Petitioners assert that admission of the challenged portions of Dr. Bustin’s report, testimony, and trial presentation would be unfair to petitioners because petitioners do not have access either to Unigenetics laboratory, to its computers and equipment, or to its lab notebooks and backup data. *Id.* at 5-6. Petitioners further assert that because the lab no longer exists and because Dr. Bustin has not provided the materials that he reviewed during his two-day investigative visit to the lab, petitioners are not able to examine the materials that informed Dr. Bustin’s opinion. *Id.* at 6.

Moreover, petitioners contend, because the lab does not exist anymore and no backup materials from the lab have been made available to either petitioners or the undersigned, petitioners are unable to retain an expert to review the material that informed Dr. Bustin’s opinion, and the undersigned lacks an “objective way. . . to determine whether the results shown at the hearing in Cedillo reflected a pattern that casts

doubt on the validity of Unigenetics' results or are exceptional cases of poor technique or poor record keeping." Id. Petitioners assert that they do not have the resources "to pursue additional documents or witnesses in the United Kingdom" to measure the reliability of the conclusions drawn by Dr. Bustin from his review of the lab facility and lab notebooks. Id. at 6-7. Additionally, petitioners complain that the submission of Dr. Bustin's two reports, respectively on June 7, 2007 and June 8, 2007, was untimely. Id.

Respondent argues that pursuant to Vaccine Rule 8(c), the undersigned must "consider all relevant and reliable evidence." R's Opp. at 9. Respondent contends that "throughout his reports and testimony, Dr. Bustin carefully discussed the methods he used to examine the Unigenetics data." Id. Moreover, respondent asserts, Dr. Bustin's reports and testimony "speak[] directly to the reliability of petitioners' evidence regarding measles proliferation in the gut . . . and . . . are . . . vital to assessing the reliability of petitioners' theory of causation." Id.

Respondent points out that "both parties filed material" after the "Court-imposed deadline of May 25, 2007 for all evidence in Cedillo." R's Opp. at 10. Although "unable to file the UK litigation reports of Dr. Bustin until several days prior to the start of the Cedillo hearing," respondent contends that "[t]he topic of Dr. Bustin's reports . . . was not new or surprising to either party." Id. Respondent asserts that the filing of Dr. Bustin's affidavit prior to the court-imposed deadline and the earlier identification of Dr. Bustin as one of respondent's witnesses at the upcoming Cedillo hearing constituted notice to petitioners that respondent intended to rely on Dr. Bustin's expertise. See id. That Dr. Bustin had access to information about Unigenetics "as part of his work in the UK Litigation, and that he would provide additional evidence and testimony if permitted to do so by the UK Court" was stated explicitly in his filed affidavit. Id. (citing Cedillo, Affidavit of Stephen A. Bustin, May 22, 2007 ¶ 22). Moreover, respondent contends, "the PSC had been on notice for several months that the validity of the Unigenetics laboratory result for Michelle Cedillo would be challenged, as would the results reflected in the Uhlmann paper relied upon by the PSC's experts." R's Opp. at 10.

Respondent argues that petitioners' complaint that Dr. Bustin's reports and testimony are unreliable and consideration of his reports and testimony is unfair to petitioners "because they are unable to rebut them . . . ignores the fact that several of the PSC's own experts had direct knowledge of the same problems identified by Dr. Bustin." Id. at 11 (emphasis added). Respondent states that among petitioners experts, "Drs. Kennedy, Kinsbourne and Byers were all experts in the UK litigation, appearing on behalf of the party seeking to vindicate the Unigenetics results." Id. at 12. Additionally, Dr. Kennedy "had both knowledge of PCR and access to information on the Unigenetics laboratory." Id.

C. Deferral of Ruling on Motion to Strike in This Case

As indicated in the Order dated June 11, 2007, the undersigned joined the two other special masters involved in the OAP, in the deferral of a decision, for purposes of the OAP and for the reasons outlined in the June 8, 2007 Evidentiary Ruling (issued in the Cedillo case), on whether we would rely on Dr. Bustin's two reports, Cedillo Ex. WW and Cedillo Ex. XX, as evidence in the OAP. Order, June 11, 2007, at 1 (filed in Cedillo). Additionally, by Order dated October 1, 2007 issued in this case, the undersigned declined to issue a ruling on petitioners' motion to strike prior to the hearing in this case and "urged counsel to prepare for trial as though Dr. Bustin's testimony would be admitted." See Order, October 1, 2007, at 2.

D. Petitioners' Efforts to Obtain the Release of Additional Reports Prepared In Connection with the Litigation in the United Kingdom

The undersigned and the special masters hearing the two other test cases on the first theory of general causation have afforded petitioners an opportunity to make application to the court in the United Kingdom to obtain the release of additional expert reports prepared in connection with the MMR/autism litigation. Petitioners in the Cedillo case were advised in June 2007, at the commencement of the hearing in the Cedillo case, the first of the test case hearings, that the special masters would support their effort to obtain the release of additional documents from the court in the United Kingdom. Petitioners in the Snyder case and as represented by the Petitioners' Steering Committee were advised again at the conclusion of the hearing in the Snyder case, the third of the test case hearings, that the special masters would support efforts by petitioners to obtain the release of additional documents from the court in the United Kingdom. See Snyder Tr. at 923-924. Petitioners were urged to make affirmative efforts to seek the release of any additional documents that petitioners desired the special masters to consider.

After the conduct of the Snyder hearing in November 2007, the Petitioners' Steering Committee (PSC) undertook efforts to obtain the disclosure of additional documents from the sealed file in the United Kingdom. On January 8, 2008, the PSC shared with respondent and the three special masters assigned to hear cases in the OAP (including the undersigned) a draft application to be filed with the court in the United Kingdom. See Autism Update, March 27, 2008, at 2. Subsequently during an unrecorded OAP status conference held on March 20, 2008, representatives of the PSC explained that the PSC was seeking consent from the experts whose reports petitioners desired to obtain but that the PSC was having difficulty in obtaining consent from some of the experts for

the release of the experts' reports.⁷ *Id.* at 3. Representatives of the PSC informed the special masters and respondent during an unrecorded OAP status conference held on June 27, 2008 that counsel acting on behalf of the PSC in the United Kingdom had informed the PSC that, without consent from the experts of interest, there was little likelihood of obtaining the release of the desired reports from the court in the United Kingdom. Accordingly, more than one year after the conduct of the hearing in the Cedillo case, the PSC decided not to file an application with the court in the United Kingdom. See Autism Update July 8, 2008, at 2.

E. Consideration of Dr. Bustin's Reports, Testimony, and Power Point Slides

Although petitioners challenge, in their motion to strike, the admissibility of Dr. Bustin's reports, testimony, and power point slides, admissibility challenges generally are brought pursuant to the applicable evidentiary rules of the court to prevent the introduction of irrelevant or unreliable evidence that might confuse a jury hearing the evidence. See, for example, Rules 402 and 403 of the Federal Rules of Evidence (governing the admissibility of evidence). The Federal Rules of Evidence do not apply in vaccine proceedings which are decided, not by a jury, but by special masters with authority to issue final decisions. RCFC App. B, Vaccine Rule 8(c); see also 42 U.S.C. § 300aa-12. It is the common practice in vaccine proceedings to hear all relevant evidence, to evaluate the reliability of the presented evidence and to accord to the record evidence weight that is proportionate to the relevance and reliability of the evidence. See RCFC App. B, Vaccine Rule 8(c).

1. The relevance of Dr. Bustin's reports, testimony, and power point slides

The primary focus of Dr. Bustin's reports, testimony and slides is on the reliability

⁷ The undersigned is aware of the recent publication of an article (referred to as the 2008 Hornig article) that was not filed into the record of this case. See M. Hornig, et al., Lack of Association between Measles Virus Vaccine and Autism with Enteropathy: A Case-Control Study, PloS ONE, Sep.4, 2008, at <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0003140> (last visited January 30, 2009). Some of the co-authors of this article are the same experts who declined to grant their permission for the release of the reports they prepared in connection with the MMR/autism litigation in the United Kingdom. The undersigned, however, does not rely on this article as evidence in reaching her decision on the merits of petitioners' vaccine-causation claim, issued on even date with the undersigned's ruling on petitioners' motion to strike.

of the test results obtained from the Unigenetics laboratory. The reliability of the obtained results (purporting to demonstrate a finding of measles virus in the gastrointestinal tissue of autistic children) is of particular interest because the effect of the measles component of the MMR vaccine, if any, on the development of autistic spectrum disorder in children is one of the core issues presented in the three test cases evaluating the first theory of causation advanced by the petitioners in the OAP. Because the alleged results of the Unigenetics laboratory informed the opinion of petitioners' expert witness in this case, Jean-Ronel Cobier, M.D., see Ps' Ex. 26, as well as the opinions of petitioners' experts in the Cedillo case, opinions on which the Hazlehursts also rely, the reliability of the laboratory results is a relevant issue. While the reliability of laboratory results is not generally questioned in Program cases, the reliability of the test results obtained by the Unigenetics laboratory is an issue that has been raised in the scientific literature, in the United Kingdom litigation concerning vaccine claims similar to the ones at issue in the test cases on the first theory of general causation in the OAP, and in this particular case (which is one of the three test cases on the first theory of general causation in the OAP). Accordingly, the expert opinion offered by Dr. Bustin concerning the reliability of the alleged results of the Unigenetics laboratory is relevant evidence that Vaccine Rule 8(c) instructs a special master to consider. The weight to be assigned to Dr. Bustin's testimony will be addressed further in the separately issued decision in this case on February 12, 2009.

2. The reliability of Dr. Bustin's reports, testimony, and power point slides as evidence

The reliability of Dr. Bustin's testimony may be evaluated, in part, by considering the testimony offered by other witnesses in this litigation either with knowledge of the laboratory testing technique of PCR or with personal knowledge about the laboratory testing methods employed by the Unigenetics laboratory. Both parties have presented witnesses with knowledge about PCR techniques in general or the laboratory practices of Unigenetics in particular that inform the undersigned's consideration of the reliability of Dr. Bustin's testimony, and the undersigned's determination that Dr. Bustin's testimony is more likely than not reliable.

Additionally, having had an opportunity to observe Dr. Bustin during his testimony in the Cedillo hearing, the undersigned found Dr. Bustin to be a credible and very knowledgeable witness, who demonstrated a learned facility with the subject matter of his testimony.

3. The fairness of receiving Dr. Bustin's reports, testimony, and power point slides as evidence

As compelled under Vaccine Rule 8(c), the issue of fairness to both parties must be considered also. The undersigned observes that on the issue of the reliability of the test results obtained by the Unigenetics laboratory, petitioners were not without witnesses to address the subject. Petitioners offered the testimony of Dr. Hepner to address the soundness of the testing methods employed by the Unigenetics laboratory. Additionally, among petitioners' offered expert witnesses on the first theory of general causation in the OAP litigation was Dr. Ronald Kennedy, who not only prepared an expert report on the claimants' behalf in the MMR/autism litigation, but also attended a scientific meeting held at the Unigenetics laboratory during which the laboratory's PCR practices were addressed specifically. Dr. Kennedy testified about that meeting during the Cedillo hearing. For more discussion, see Hazlehurst Decision Section III(C)(4)(h)(ii) and see also Cedillo Tr. at 844-845.

Petitioners were afforded an opportunity to obtain the release of additional documents from the court in the United Kingdom in support of their claims and to rebut the evidence introduced by respondent. After a generous period of time elapsed, petitioners informed the special masters assigned to hear the OAP cases that they were abandoning their efforts to obtain the release of the desired documents from the court in the United Kingdom because the efforts were unlikely to be successful without the requisite consent from the experts whose reports petitioners desired to obtain.

In the view of the undersigned, fairness to the parties has been achieved by affording both parties an opportunity, procedurally, to obtain and to present relevant information for consideration in deciding this case. That petitioners were not successful in their efforts to secure the release of the desired documentation from the court in the United Kingdom does not make the opportunity afforded to petitioners less fair. Nor is fairness achieved by declining to consider highly relevant information to this case simply because the experts from whom petitioners need consent, to obtain the release of the experts' report from the court in the United Kingdom, are unwilling to give their consent.

F. Conclusion

As discussed in this ruling, Dr. Bustin's testimony regarding the reliability of the test results obtained by the Unigenetics laboratory are particularly relevant in this case. The testimony of other witnesses in this case together with Dr. Bustin's own presentation as a witness militates in favor of a finding that his testimony is scientifically reliable. Finally, the opportunity afforded to petitioners to make application to the court in the

United Kingdom for the release of additional documents from the MMR/autism litigation that would rebut Dr. Bustin's testimony satisfies the requirement of procedural fairness that inheres in Vaccine 8(c). Having considered petitioners' request in the light of Vaccine Rule 8(c), the undersigned **DENIES** petitioners' motion to strike.

IT IS SO ORDERED.

s/ Patricia E. Campbell-Smith
Patricia E. Campbell-Smith
Special Master