

OFFICE OF SPECIAL MASTERS
No. 93-333V
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YVETTE HARRIS and JOHN PHIPPS, as Legal	*	
Representatives and Natural Guardians of their	*	
Minor Daughter, EBONY PHIPPS,	*	
	*	
Petitioners,	*	NOT TO BE PUBLISHED
	*	
v.	*	
	*	
SECRETARY OF HEALTH AND	*	
HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	
***** *	*	

RULING ON ACAUSATION@ ISSUE

HASTINGS, *Special Master.*

This is an action seeking an award under the National Vaccine Injury Compensation Program (see 42 U.S.C. ' 300aa-10 *et seq.*¹), on behalf of petitioners= daughter, Ebony Phipps. For the reasons stated below, I conclude that petitioners have shown it Amore probable than not@ that Ebony=s transverse myelitis was vaccine-caused.

I

BACKGROUND FACTS

Ebony Phipps, daughter of the petitioners, was born on December 12, 1989. On March 13, 1991, Ebony received a number of inoculations, including a combined AMMR@(measles, mumps, rubella) immunization. On March 25, 1991, Ebony was taken to a hospital emergency room, where it was noted that she had been experiencing diarrhea, fever, and irritability for two days. (

See M.R. 80.²) She was discharged, but two days later reappeared at the emergency room with continuing fever and diarrhea, plus vomiting, weakness and a lack of feeling in her legs. (M.R. 81-83.) Ebony was admitted to the hospital, where she was diagnosed to be suffering from a serious neurological condition known as transverse myelitis.

Unfortunately, Ebony still suffers from the grave ill effects of her transverse myelitis. She has permanent spinal cord injuries that may well keep her from ever becoming ambulatory, and she will likely also continue to suffer permanently from other related problems.

II

THE ISSUE IN THIS CASE

Under the National Vaccine Injury Compensation Program (hereinafter the Program), compensation awards are made to individuals who have suffered injuries after receiving certain vaccines. There are two separate means of establishing entitlement to compensation. First, if an injury listed on the Vaccine Injury Table found at 42 U.S.C. § 300aa-14(a) occurred within a time period after vaccination, also specified in the Table, then the injury may be *presumed* to qualify for compensation. Second, compensation may also be awarded for injuries not listed on the Table, but entitlement in such cases is dependent upon proof by a preponderance of evidence that the vaccine *actually caused* the injury. § 300aa-11(c)(1)(C)(ii).

This case falls into the latter category of attempted proof. The MMR vaccination is one covered by the statute, but transverse myelitis is not an injury listed in the Vaccine Injury Table. Therefore, the burden on the petitioners³ to prove by a preponderance of evidence that the MMR vaccination actually caused Ebony's transverse myelitis.

III

THE APPLICABLE LEGAL STANDARD

To begin with, I note that in analyzing a contention of actual causation in a Program case, the presumptions available under the Vaccine Injury Table are, of course, inoperative. It is clear that the burden is on a petitioner to show that, in fact, the vaccination in question more likely than not caused the injury. *Hines v. Secretary of HHS*, 940 F. 2d 1518, 1525 (Fed. Cir. 1991); *Carter v. Secretary of HHS*, 21 Cl. Ct. 651, 654 (1990); *Strother v. Secretary of HHS*, 21 Cl. Ct. 365, 369-70 (1990), *aff'd*, 973 F. 2d 326 (Fed. Cir. 1991); *Shaw v. Secretary of HHS*, 18 Cl. Ct. 646, 650-51 (1989). Thus, the petitioner must supply proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect. *Strother*, 21 Cl. Ct. at 370; *accord*, *Hines*, 940 F. 2d at 1525; *Carter*, 21 Cl. Ct. at 654; *Hasler v. United States*, 718 F.2d 202, 205-06 (6th Cir. 1993); *Novak v. United States*, 865 F.2d 718, 724 (6th Cir. 1989).

It is stressed in many of these cases that a temporal relationship between the vaccination and the

onset of an injury or condition is, by itself, not sufficient to carry the burden of demonstrating causation. *See, e.g., Strother*, 21 Cl. Ct. at 370; *Shaw*, 18 Cl. Ct. at 650-51; *Carter*, 21 Cl. Ct. at 654. That is, while a close temporal association may be an important *part* of a causation conclusion, there must exist sufficient medical evidence of a causal relationship between the vaccine and the type of injury in question to justify a conclusion that the temporal association in the particular person indicates a causal relationship.

IV

DISCUSSION

A. Summary of parties=positions

To carry their burden of demonstrating actual causation in this case, petitioners have relied chiefly upon the opinions of Dr. Robert F. Cullen, Jr., and Dr. Robert S. Rust, Jr., two physicians with superb qualifications in the field of pediatric neurology. Respondent has countered testimony of two excellently qualified physicians, pediatric neurologist Dr. John T. Sladky and Dr. John L. Sever, a physician with an extensive background in pediatrics, immunology, infectious diseases, and other medical specialties. All four physicians filed written reports, and also testified at evidentiary hearings held on March 21,⁴ 1994, and December 10, 1997. I will set forth below summaries of the positions of the two sides in this case.

1. Theory of petitioners=experts

Petitioners= experts rely first upon certain evidence in the medical literature relevant to the *general issue* of whether the MMR vaccination--and particularly the rubella component of that vaccination--is capable of causing transverse myelitis.⁵ (Hereinafter, I will often refer to transverse myelitis as TM.) They start with the fact that while there is no fully-accepted scientific consensus concerning the causation of TM, there seems to be a widely-held belief among medical scientists that a few specific types of viruses probably do cause TM. The rubella virus is not among the handful of specific viruses that have been most strongly linked to TM. The rubella virus does, however, fit within the *general category* of viruses, the *enveloped* viruses, that has been most strongly linked to TM.⁶ Moreover, there have been a number of case reports in which individuals developed TM shortly after experiencing the rubella disease, which, of course, is caused by the rubella virus.

In addition, petitioners= experts point to the fact that a great deal of evidence indicates that the rubella virus, in its non-vaccine, *wild* form, can cause serious neurological problems. The evidence in this regard is well summarized in the medical journal article by Waxham and Wolinsky, *Rubella Virus and Its Effects on the Central Nervous System*, filed by petitioners in the record of this case on March 25, 1994. The fact that the rubella virus is accepted as causing *certain* types of neurological problems adds credence, in the view of petitioners= experts, to the theory that the virus can cause *other* types of neurological consequences, such as transverse myelitis.

Turning to the rubella *vaccine*, petitioners= experts note that the vaccine consists of a specially attenuated--i.e., weakened--form of the rubella virus itself, which is introduced into the vaccinee's system. This fact naturally leads to suspicion that any ill effects that can result from the *wild* rubella virus could also possibly be caused by the *attenuated* form of the rubella virus contained in the vaccine. Further, it is known that occasionally the rubella vaccine has caused some ill effects upon recipients. For example, it is well established that the rubella vaccine causes short-term episodes of arthritis in some recipients, and there is some evidence that in a few cases there are long- term arthritic consequences as well. *See, e.g., Ahern et al. v. Secretary of HHS*, No. 90-1435V, 1993 WL 179430 (Fed. Cl. Spec. Mstr. January 11, 1993.) And these cases of arthritis are often associated with minor neurologic symptoms known as paresthesias. @ *Id.* at *7. In addition, as discussed at the first evidentiary hearing in this case, there exists strong evidence that one of the early forms of the rubella vaccine caused some distinct neurological problems, the so-called "catcher's crouch syndrome" cases. (*See, e.g.,* 1-Tr. 45-47.⁷)

Petitioners=experts also note that it is generally accepted that certain *other* types of *vaccines*--specifically, the rabies and smallpox vaccines--have in fact, caused *transverse myelitis*. This adds legitimacy to their view that additional *vaccines*, such as the rubella vaccine, can cause TM.

Finally, petitioners=experts noted that there are also several case reports in the medical literature of *transverse myelitis* itself occurring shortly after *rubella vaccination*.

In light of all this evidence summarized above, petitioners=two experts believe that when an individual develops TM after a rubella vaccination, it is reasonable to conclude that the vaccination was *more* probably than not@ the cause of the TM *if* all three of the following criteria are satisfied: (1) the onset of the TM must have occurred between one and four weeks after vaccination (which is the period during which the effects of a rubella virus would normally be seen after a human is exposed to the virus); (2) the TM was monophasic⁸ in course; and (3) no better explanation for the TM exists. Petitioners= experts argued that Ebony's history here meets all of these criteria. In this regard, they noted especially that extensive testing performed on Ebony specifically ruled out a great many potential non-vaccine causes for her TM.

In addition to the theory stated above, petitioner=s experts also point to the results of certain testing performed upon Ebony in the hospital shortly after the onset of her TM, which indicated an elevated level of antibody to rubella in her spinal fluid. They argued that these test results provide additional, specific support for the view that Ebony=s TM was caused by her rubella vaccination.

Based upon the general theory set forth above plus the test results, petitioners= experts have asserted, there exists sufficient evidence upon which to conclude that it is *more* probable than not@that Ebony=s transverse myelitis was caused by her rubella vaccine.

2. View of respondent=s experts

Respondent=s two experts, on the other hand, argued that the available evidence is not strong

enough to justify the conclusion that it is probable that Ebony's TM was caused by her MMR vaccination. They explained that the causation of TM in general is not well understood, and that in a great many such cases no cause is ever identified.

As to the theory that *viruses in general* are a common cause of TM, respondent's experts expressed caution, arguing that while this proposition has often been suggested, there does not exist strong proof for it. While they acknowledge that in a large number of TM cases it is reported that the victim had suffered a viral infection in the previous weeks, they point out that this could be wholly by chance, since most individuals suffer from several viral infections per year.

As to the evidence linking the *rubella virus* to neurological problems, respondent's experts, particularly Dr. Sladky, noted that there is considerable reason for being cautious before jumping to the conclusion that the rubella *vaccine* can cause any problem that can be caused by the rubella virus in its *wild* form. The vaccine, Dr. Sladky pointed out, is specifically prepared with the goal of producing an antibody response to the rubella virus *without* producing the ill effects of the rubella disease--this is the purpose of the *attenuation* of the virus in production of the vaccine.⁹ Dr. Sladky also argued that there exists little evidence that the rubella vaccine has ever caused the more serious neurologic consequences that the rubella disease sometimes does, such as rubella encephalopathy. He pointed out that the clearest association of the rubella vaccine to neurological problems--the *catcher's crouch syndrome* cases--occurred with an early version of the rubella vaccine, and has not been observed after vaccination with the newer, safer version of the rubella vaccine that Ebony received. Therefore, Dr. Sladky argued, there exists only scant evidence for accepting, and important reasons for questioning, the general proposition that *anything that the wild rubella virus can cause, the rubella vaccination can cause as well.*

As to the specific issue of whether the rubella virus can cause *transverse myelitis*, Dr. Sladky noted that the medical literature evidence is particularly slim. He analyzed the case reports linking the *wild* rubella virus to TM, concluding that in the medical articles cited by Dr. Rust there were only four well-documented cases of TM after rubella infection. And as to the articles cited by Dr. Rust involving the rubella *vaccine*, Dr. Sladky argued that some of the reported cases involved neurologic problems other than TM, so that only three cases involved actual TM after rubella vaccination.¹⁰ And he argued that in one of those cases the TM came *too soon* after vaccination to likely have been vaccine-caused, while in another case there existed another possible cause for the TM besides the vaccination.

Finally, as to Ebony's specific case, respondent's experts made two points. First, they noted that in the several days prior to the onset of her TM symptoms, Ebony had experienced symptoms of fever, diarrhea, and vomiting, which had been diagnosed to result from *viral gastroenteritis*. (M.R. 80.) They suggest that these symptoms were caused by some unidentified virus, which virus also could have caused the TM.

Second, respondent's experts strongly contested the interpretation by petitioners' experts of the testing of Ebony's spinal fluid. They argued, for reasons to be discussed in detail below, that the

test results do not add any significant weight to the argument that Ebony's TM was vaccine-caused.¹¹

B. Analysis

The factual question at issue here is a very close one. All four of the experts who appeared before me have superb credentials relevant to the issue at hand, and I believe that all four testified candidly. The issue is clearly one upon which reasonable minds can disagree. However, after full consideration of all the evidence of record, I conclude that it is at least slightly more probable than not that Ebony's TM was caused by the MMR vaccination that she received on March 13, 1991.

I base this conclusion on a *combination* of the two major points upon which petitioners' experts relied. That is, I would not necessarily adopt as an absolute rule the *general theory* advanced by petitioners' experts--that is, the theory that it is reasonable to attribute to the rubella vaccine *any* monophasic case of TM that follows one to four weeks after rubella vaccination, if no other cause is identified. I simply do not either accept or reject that general theory, because there is no need to do either in this case. In this case, rather, the evidence not only meets that theory's general criteria, but there is one *additional* important piece of evidence--the fact that the testing of Ebony's blood and cerebrospinal fluid yielded an elevated Rubella antibody index. The fact that *both* circumstances occurred in this case--*i.e.*, the criteria were met *plus* the Rubella antibody index--was elevated--allows me to reach my conclusion here.

1. General considerations

As to the general theory that the rubella vaccine *can* cause TM, I certainly acknowledge, as did petitioners' own experts, that this proposition is *not* scientifically well-established. The number of cases linking the *wild* rubella virus to TM are few, and the number linking the rubella *vaccine* to TM are fewer. It is certainly *possible* that the temporal connection between the rubella vaccine and TM in the few reported cases, and in this case, is purely coincidental. The legal standard that I am to apply in this case, however, means that petitioner need *not* establish a causal connection that meets the very high standards for scientific acceptance as proven. *See, e.g., Ferebee v. Chevron Chemical*, 736 F. 2d 1529, 1535-36 (D.C. Cir. 1984). Rather, the test is whether it is *more probable than not* that Ebony's particular case of TM was caused by her vaccination. In this case, I found the overall proof sufficient to meet that standard.

As discussed above at pp. 3-4, petitioners' experts in this case described (1) evidence linking viruses in general causally to TM; (2) evidence placing the *rubella* virus within the general category of viruses (*i.e.*, the enveloped viruses) that are most strongly linked to TM; (3) evidence linking the *wild* rubella virus causally to a number of neurologic problems; (4) evidence linking the rubella *vaccine* to serious complications, including neurological ones; and (5) evidence linking other types of *vaccines*, including the smallpox and rabies vaccinations, causally to *transverse myelitis*. In addition, a small number of case reports described cases in which TM closely followed either infection by the wild rubella virus or the rubella vaccine itself. Based upon all this evidence, the petitioners' experts in this case found it reasonable to conclude it

probable--though not established-- that if a person experienced monophasic TM one to four weeks after a rubella vaccination, with no other cause identified, such TM was vaccine-caused. I found persuasive the testimony of petitioners' experts that this conclusion is at least a plausible, defensible one to draw from the available evidence.

To be sure, respondents' experts certainly were on target in stressing that the number of case reports describing TM after either the rubella disease or rubella vaccination is quite small upon which to base any conclusion regarding causation. These numbers make it seem likely that both the wild rubella virus and the rubella vaccine are a cause, at most, of only a very small percentage of the cases of TM. But all the testifying experts agreed that because TM itself is a fairly rare complication,¹² and because the rubella vaccine could be the cause, at most, of a very small percentage of TM cases, an epidemiological study large enough to scientifically prove that the rubella vaccine occasionally causes TM will very likely never even be attempted. Thus, there can never be absolute certainty on this point, and I must reach conclusions based upon the best evidence available.

In this case, there are a number of reasons why I am persuaded to accept the analysis of the petitioners' experts that the available evidence, although limited, justifies a conclusion that Ebony's TM was probably vaccine-caused. First, the two experts that testified on petitioners' behalf both have outstanding credentials. Dr. Rust, among other positions, currently is an associate professor of neurology at Harvard Medical School, and previously was chief of child neurology at the University of Wisconsin School of Medicine. Dr. Cullen, among other credentials, serves as chief of pediatric neurology at Miami Children's Hospital, thereby supervising, in his understanding, the largest department of pediatric neurology in the country. (1-Tr. 7-8.) And I concluded that these experts were giving me their honest opinions on this difficult and complicated issue.

Second, the records made by Ebony's actual treating physicians during the initial stages of her ailment indicate that these physicians, who were unaffected by any bias inherent in opinions supplied by expert witnesses for litigation purposes, also suspected that the rubella vaccination was the cause of Ebony's TM. For example, Dr. Bernard Maria, a pediatric neurologist who evaluated Ebony, stated in a letter dated May 15, 1991, his "impression" that it "is possible that this is related to post-immunization process, sometimes seen following Rubella vaccination." (M.R. 315.) A physician named Dr. Gilmore, on April 1, 1991, also wrote a note indicating a suspicion that the rubella immunization was the cause. (M.R. 411.) Further, two more medical notations--it is unclear who the physician or physicians were, but these notes were apparently made by someone other than Dr. Maria or Dr. Gilmore--again mention the possibility that the rubella vaccine caused the TM. The first, made on April 2, 1991, states the "impression" that the TM was "possibly post-immunization/post infectious following Rubella vaccine." (M.R. 413.) The second, part of a hospital discharge summary dated April 11, 1991, states that the "major suspicion is post-Rubella immunization." (M.R. 430-31.) Finally, notes made by Dr. Cullen when he first consulted on Ebony's case, in October of 1991, state that "Dr. Allen Lenoir of Infectious Diseases felt that the most likely situation would be that of an MMR reaction." (M.R. 453.) Moreover, the fact that an expensive "organism-specific antibody index" test was done *only* with respect to rubella, and not with respect to any other potentially causative agent, is

further indication that Ebony's treating physicians suspected the rubella vaccine to be the cause of her TM.

Third, I note that the record of this case contains additional expert opinions, not yet mentioned in this opinion, that are relevant here and supportive of my conclusion. That is, I note that when I first became aware that this case involved an allegation that a case of TM was caused by the rubella component of an MMR inoculation, I introduced into the record of this case statements of two medical experts who had testified before me in a prior Program proceeding concerning the *general* issue of the possible causal relationship between the rubella vaccine and neurological problems. Those experts expressed the view, ultimately also adopted by the petitioners' two experts in this case, that if an individual experienced the onset of a monophasic case of TM between one and four weeks after a rubella immunization, and no other cause for the TM was found, it would be reasonable to conclude that the TM was *probably* vaccine-caused. (See the letter of Dr. Jerry S. Wolinsky and the transcript of testimony of Dr. Donald Gilden contained in the documents that I filed in this case on December 15, 1993.) Both Dr. Wolinsky and Dr. Gilden are pediatric neurologists with outstanding backgrounds, and when they testified before me in 1992 I was also favorably impressed that both were candid witnesses.¹³ Dr. Wolinsky was praised by Dr. Gilden as *the most knowledgeable * * * expert in this country* concerning the neurologic complications of rubella virus, and by respondent's expert Dr. Sladky in this case as *brilliant*. (1-Tr. 29.) Moreover, it is noteworthy that Dr. Gilden in the earlier case was testifying as an expert recruited by the *respondent*.

Accordingly, the fact that the general theory of petitioners' experts in this case was endorsed by these two additional pediatric neurologists, Drs. Wolinsky and Gilden, also adds to the credibility of petitioners' case.

2. Antibody index results

Another issue worthy of some discussion is the importance of the rubella antibody index test performed on Ebony, the results of which were reported on April 2, 1991. (M.R. 305.) I will attempt to explain the controversy surrounding this point in language as simplified as possible.

As explained by the experts, the *general* purpose of an organism-specific antibody index test is to help determine what caused an injury. More specifically, the test attempts to determine whether synthesis of antibodies against a specific organism is occurring *within the central nervous system*. If such synthesis is in fact occurring, that could be an indication that such organism was the cause of the individual's injury. A problem, however, is that it is not sufficient to simply test the person's fluid that runs through the central nervous system, the cerebrospinal fluid (CSF), and measure the level of organism-specific antibody therein. That is because a simple elevated level of antibody in the CSF might be simply due to a phenomenon described as *leakage* across the *blood-brain barrier* (BBB). That is, if a healthy person has good immunity to a particular organism, such as the rubella virus, he will have an elevated level of antibody to that organism in his blood (*serum*), but not in his CSF. There exists a barrier between the blood and the CSF, which in a healthy person keeps such *serum antibody* in the blood and out of the CSF. But with some types of neurological injury, such as TM, that *A*

blood-brain barrier is breached, allowing blood antibody to leak into the CSF. If that barrier is breached, thus, a simple test of the level of antibody in the CSF will *not* indicate whether synthesis of antibody is occurring *in the central nervous system*, because the antibody found in the CSF might simply be a result of leakage from the blood.

The Organism-specific antibody index, or OSAI, then, was developed as a way of telling whether any excess antibody to a particular organism found in the CSF is truly a result of synthesis in the central nervous system--also known as intra-blood-brain barrier (AIBBB) synthesis--rather than leakage from the blood.

In Ebony's case, antibody to rubella indeed was found in the CSF at a distinctly elevated rate. But the CSF testing also made it clear that in fact her blood-brain barrier had been breached (a result of her TM), so that the elevated rubella antibody in the CSF *could* have been merely a product of leakage across the breach. Therefore, the organism-specific rubella antibody index was necessary in order to determine whether to accord any significance to the elevated rubella antibody level in the CSF.

The single-page document summarizing the results of the testing on Ebony states a value of 1.2 for the rubella antibody index, while also indicating that the normal value for that index would be less than 1.0. (M.R. 305.) A crucial question in this case is what, if any, significance should be given to the fact that the 1.2 value for Ebony's index exceeds the normal value. The evidence on this point is contradictory, and the interpretations of the experts are in sharp dispute.

First, the same document that contains the results of Ebony's test provides, at the bottom of the page, an explanation of the results, including the notation that index results between 1.0 or 2.0 are considered indeterminate and should be further evaluated * * *. (M.R. 305.¹⁴) However, petitioners have also obtained another document distributed by the same laboratory that performed the testing on Ebony--*i.e.*, Speciality Laboratories, Inc.--dated July 1991. This document describes the clinical utility of Speciality Laboratories' OSAI testing, and indicates that an OSAI greater than 1 (*i.e.*, more organism-specific immunoglobulin in CSF than in serum) is incontrovertible evidence that BBB synthesis of organism-specific IgG is occurring and strongly suggests a CNS infection by the specific organism being evaluated. (See documents filed by petitioners on March 25, 1994, last page--hereafter the July 1991 sheet.) In other words, under the explanation given on the sheet that contained Ebony's test results, an index value of 1.2 would be indeterminate; but under the interpretation in the July 1991 sheet, that same value would incontrovertibly indicate rubella antibody production in Ebony's central nervous system, and also strongly suggest that the rubella virus had infected Ebony's central nervous system.

The confusion engendered by these two contradictory interpretations caused me to keep the record in this case open after the first evidentiary hearing in this case. I instructed the parties to make every effort to obtain an explanation for the discrepancy. A letter from Specialty Laboratories and accompanying documentation was obtained (*see* respondent's Ex. J, filed on July 28, 1994) and one of respondent's experts also obtained an oral explanation from that laboratory's manager (*see* 3-Tr. 119-124). To be sure, the explanations obtained are still far from

crystal clear. But from the record before me, it appears that Specialty Laboratories¹⁵ has repeatedly adjusted its own evaluation as to how to best interpret the numerical results from a rubella OSAI.¹⁶ Apparently, the July 1991 sheet, although dated after the date of Ebony's testing in April 1991, represented the laboratory's *initial* estimate as to where to best place the numerical dividing point between (1) a result that is *unquestionably* indicative of IBBB-synthesis of rubella-specific antibody, and (2) a result that is above normal, and *possibly* indicates the occurrence of such synthesis, but calls for further testing to confirm the finding. This initial estimate, stating that any value above 1.0 would constitute an *incontrovertible* indication of IBBB synthesis, resulted from the laboratory's analysis of related testing done by other laboratories. Then, after gaining its own experience in performing such testing, Specialty Laboratories apparently adjusted its interpretation of the tests to a more cautious stance, reaching the interpretation set forth at M.R. 305, that values between 1.0 and 2.0 would be indeterminate and only values above 2.0 would be considered clearly positive. Still later, the laboratory issued yet another interpretation, finding all values above 1.5 to be clearly positive. (*See* Resp. Ex. J, third page, dated April 1993.) But, by May 24, 1994, when Specialty Laboratories issued the letter contained at Ex. J (first page), the laboratory apparently had retreated to the interpretation contained at M.R. 305--*i.e.*, that values between 1 and 2 were indeterminate, and only values above 2 were considered positive.

In light of these changing judgments by Specialty Laboratories itself as to how best to interpret a rubella antibody index result, what is the appropriate interpretation of the result of the test on Ebony in this case? The question is certainly a difficult one. One very important factor, of course, is that the laboratory in question seems to have adhered to the position that the numerical value obtained on Ebony's rubella antibody index, 1.2, should be considered *indeterminate*, calling for another test. (Ex. J, first page.) Thus, there is obviously considerable appeal in the argument of respondent's experts in this case that one should assign no significance whatsoever to the result of Ebony's rubella antibody index.

Petitioner's experts, particularly Dr. Rust, however, have made a strong argument that in the overall context of this case, Ebony's rubella antibody index result should be assigned some significance. They do not argue that the result is *incontrovertible* evidence of IBBB-synthesis of rubella antibody, as would be the case if we applied the standard set forth in the July 1991 sheet. They accept the figure as *indeterminate*, in the sense of failing to afford *definite* proof of IBBB synthesis. They agree that the ideal proof would have been another test on Ebony to compute another rubella antibody index, which might have given a definitive result one way or the other.

However, petitioner's experts argue, it *is* still significant that Ebony's test result of 1.2 was notably *above the normal value*, which was less than 1.0. This was definitely *not* a *negative* result--a negative result, less than 1.0, would *not* have prompted the recommendation of another test. Instead, this was a result that *was* elevated enough above the normal value that Specialty Laboratories interpreted it as calling for another test. Petitioner's experts argue, therefore, that this *somewhat* elevated value, though not *definitive* evidence, is still *significant* evidence that Ebony was experiencing IBBB synthesis of rubella antibody, which in turn could indicate that the rubella vaccine was the cause of her TM.

Considering all of the evidence of record on this difficult point, I find the arguments of petitioners' experts to be somewhat more persuasive than those of respondents' experts. Of course, it is unfortunate that a second, follow-up rubella antibody index was not calculated, but in fact no such testing was done, so I must evaluate the evidence that is available. And the crucial fact here is that Ebony's rubella antibody index result was *not* in the normal range, but was somewhat elevated. It was not elevated enough to *definitively* demonstrate IBBB synthesis of rubella-specific antibody, but provides *some* indication that such synthesis was occurring.

In this regard, I note that respondents' experts at the hearing of December 10, 1997, seemed to argue that the apparent slight elevation shown in Ebony's rubella antibody index could simply be the result of the fact that her blood-brain barrier had been breached as a consequence of her TM. However, as Dr. Rust stressed, the rubella antibody index is an *index*, specifically *designed* to account for the fact that a blood-brain barrier breach has occurred. The fact that this *index* value was elevated, thus, is more significant than the mere fact that Ebony's rubella antibody CSF level was elevated. The latter elevation *could* simply be a result of the blood-brain barrier breach. The *index* value, on the other hand, is by definition *designed* to reflect only increased antibody presence that *cannot* be attributed to the blood-brain barrier breach.

Of course, because Ebony's rubella antibody index was only in the indeterminate range under the most appropriate interpretation of that index, it certainly could not be concluded with confidence, on the basis of that result *alone*, that IBBB synthesis of rubella specific antibody was occurring in Ebony.¹⁷ Moreover, as Dr. Sladky explained, even if such synthesis were definitely occurring, that would not *necessarily* indicate that the rubella virus had caused Ebony's TM. However, Ebony's rubella antibody index result must be evaluated in the *overall context* of her case. That is, as explained above, there exists considerable evidence for the *general* theory that if a monophasic case of TM is exhibited one to four weeks after a rubella vaccination, and no other cause is identified, then it is reasonable to attribute the TM causally to the vaccination. And Ebony's case meets those criteria. In that context, the fact that Ebony's rubella antibody index was elevated from the normal range, while insufficient *by itself* to support a conclusion that the vaccination caused Ebony's TM, does offer significant *support* for such a conclusion, since it affords *some* evidence that IBBB synthesis was occurring in Ebony.

3. Suggestion of alternative cause

As noted above, respondents' experts also pointed to another possible cause for Ebony's TM. They noted that beginning about March 23, 1991, several days prior to the onset of the weakness in Ebony's legs, Ebony experienced several days of diarrhea,¹⁸ fever, increased irritability, and vomiting. (M.R. 80-81.) She was diagnosed on March 25 to be suffering from *Aviral gastroenteritis*. (M.R. 80.) Respondents' experts have suggested that the virus that caused these symptoms, likely a virus within the *Enterovirus* family, might also have caused Ebony's TM.

Petitioners' experts, however, responded to this suggestion in several ways. First, they opined that in light of the clear TM symptoms that Ebony experienced about March 27, the diagnosis of *Aviral gastroenteritis* made on March 25 could well have been erroneous. They stated that the symptoms of fever, irritability, and vomiting have sometimes been reported as occurring with

TM, and might result from the TM itself. They suggested that the reported *Adiarrhea* might not have been actual diarrhea, but instead fecal incontinence caused by the initial stages of the TM itself.

In addition, Dr. Rust pointed out that even if the diagnosis of viral gastroenteritis was correct, nevertheless the chances were slim that the virus that caused such gastroenteritis also caused the TM. He explained that viruses of the type suggested by respondent to have caused the gastroenteritis, the enteroviruses, have *not* been causally linked to TM in the way that the *enveloped* viruses, such as the rubella virus, have been.

I found the testimony of petitioners' experts to be more persuasive on this issue, based chiefly upon the testimony of Dr. Rust described in the preceding paragraph. Respondent's experts did not persuasively rebut that testimony. Thus, even assuming that Ebony did suffer from viral gastroenteritis, I am not persuaded that there is much likelihood that the virus that caused her gastroenteritis also caused the TM.

4. Possibility of causation by measles or mumps components of MMR vaccination

Another point worth a brief discussion is the possibility that Ebony's TM was the result of the *measles* or *mumps* components of her MMR vaccination. As noted by petitioners' experts, there have been some reported cases in which TM has been observed with onset shortly after infection with the *wild* viruses of both measles and mumps. Also, the record of this case contains a discussion of several case reports of TM after measles *vaccination*.¹⁹ Further, both the mumps and measles viruses are among the *enveloped* viruses, the type of virus most commonly thought to be causally linked to TM. (See 3-Tr. 209; see also fourth page of Dr. Rust's opinion filed on June 16, 1997.)

In this case, both Dr. Rust and Dr. Cullen focused their opinions chiefly upon the *rubella* component of the MMR vaccination, apparently chiefly because of Ebony's elevated rubella antibody index, discussed above at pp. 9-12 of this Ruling. However, the question in this case really is whether it is *more probable than not* that *any* component of Ebony's MMR inoculation caused her TM. In other words, to determine whether the *more probable than not* standard has been achieved, it is appropriate to *add together* the likelihoods that each component of the vaccine was the cause. And Drs. Cullen and Rust have testified that while they find the rubella component to be the most likely culprit in this case, there is at least some chance that either the measles or mumps vaccines caused Ebony's TM. (See 3-Tr. 90-91, 201-05.)

In the final analysis, I find it *more probable than not* that the *rubella* component of the MMR vaccination caused Ebony's TM. However, I add that the possibility that the measles or mumps components *could* have been the cause adds some slight additional weight to my conclusion that it is probable that the *MMR vaccination*, viewed as a whole, caused the TM.

5. Summary

In short, my conclusion in this case is based upon a combination of factors. First, there is the

large body of evidence, described at length above, supporting to the general theory that a monophasic case of TM arising soon after rubella vaccination, without evidence of other cause, is reasonably attributable to the rubella vaccination. Second, this general theory has been adopted not only by the distinguished experts presented by the petitioners in this case, but also by the two other very distinguished experts, Drs. Wolinsky and Gilden, noted above. Third, some of Ebony's own treating physicians left evidence in the medical records of their own suspicions that the rubella vaccination was the cause of Ebony's TM. Fourth, an extensive search for other potential causes ruled out many causes, and did not identify any other likely cause other than Ebony's inoculation. Fifth, Ebony's somewhat elevated rubella antibody index provides additional reason to consider her MMR inoculation as the cause of her TM.

Based upon the combination of all these factors in this case, I find that it is more probable than not that Ebony's TM was caused by her MMR vaccination.²⁰

I will also note that I view the result of this case as consistent with three reported Program cases concerning TM. The first is *McCummings v. Secretary of HHS*, No. 90-903V, 1992 WL 182190 (Fed. Cl. Spec. Mstr. July 10, 1992); *aff'd*, 27 Fed. Cl. 417 (1992); *aff'd*, 14 F.2d 613 (Fed. Cir. 1993); *cert. denied sub nom., McCummings v. Shalala*, 511 U.S. 1032 (1994). This case involved an allegation that a case of TM was caused by either a *DPT* (diphtheria, pertussis, tetanus) vaccination or an *oral polio* vaccination, and the special master found that the petitioner had failed to prove a causal relationship. There are, however, many differences between *McCummings* and this case. First, a reading of the special master's opinion shows that there was little or no evidence connecting the vaccines there in question to TM, comparable to the evidence cited above linking TM to the rubella virus and rubella vaccine. The *McCummings* petitioner offered the opinion of only one expert, who was apparently not of the stature of the experts whose opinions support petitioners here. Moreover, *McCummings* involved no evidence comparable to the rubella antibody index result in this case.

Two other Program cases, on the other hand, each did involve, like this case, the allegation that a case of TM was caused by an MMR vaccination. See *Lodge v. Secretary of HHS*, No. 92-697V, 1994 WL 34609 (Fed. Cl. Spec. Mstr. Jan. 25, 1994), and *Huston v. Secretary of HHS*, No. 90-1080V, 1997 WL 760319 (Fed. Cl. Nov. 25, 1997). In *Lodge*, the special master found that the vaccinee's TM was probably caused by an MMR vaccination, basing that conclusion in part on analysis similar to my analysis here. In *Huston*, in contrast, a judge of this court upheld the opinion of a special master that no causal connection between the MMR vaccination and the individual's TM had been established.

However, the facts of this case and *Huston* are very different in crucial areas. In *Huston*, there was not the rubella antibody index result that is so important here. Moreover, in *Huston*, the published opinion indicates that the vaccinee in question experienced a complete failure to develop antibodies in response to the vaccination. 1997 WL 760319, at *2. In other words, the vaccinee apparently did not develop even the serum antibodies that a person is supposed to develop in response to the vaccination (in order to confer immunity from the diseases in question), indicating that the vaccination probably failed to have any effect at all--even the intended one--on the vaccinee. Because of that complete lack of antibody response, the theory

of petitioners= experts in that case (involving the allegation of a cell-mediated response to the vaccination) seems to have been wholly different from the theory of petitioners= experts in this case. Therefore, the special master in *Huston* faced a factual record very different from the one in this case.

In sum, I find that my ruling here *is* consistent with *Lodge*, and not inconsistent with either *McCummings* or *Huston*. Those latter two cases, with facts significantly different from those here, do not contradict my conclusion here that it is slightly more probable than not that Ebony= TM was caused by her MMR vaccination.²¹

V

FURTHER PROCEDURE

I now find that petitioners have established all the elements required for a Program award, with the exception of the requirement that petitioners incurred unreimbursable expenses in an amount greater than \$1000. (*See* ' 300aa-11(c)(1)(D)(i).) This latter requirement has not yet been specifically addressed by respondent, as far as I am aware. Therefore, the parties should now make a serious, good-faith attempt to resolve that "\$1000 issue." Petitioners should supply to respondent as soon as possible their documentation concerning that issue. Then, within 17 days of the mailing date of such documentation, if respondent is not ready to concede that the A\$1000 requirement@ has been satisfied, respondent=s counsel shall contact petitioners= counsel by telephone to explain in detail the respondent=s difficulties with the petitioners= claim. Opposing counsel shall then work together reasonably and in good faith²² to attempt to obtain evidence satisfactory on this issue.

If the parties are unable to resolve this "\$1000 issue," petitioners shall then file with the Court their claim on this issue, carefully organizing their supporting documentation into exhibits. (The pages of each exhibit must be numbered!) Respondent's written response will be due 25 days from the service date of this filing. I will then schedule a status conference if necessary.

George L. Hastings, Jr. Special Master

¹The applicable statutory provisions defining the Program are found at 42 U.S.C. ' 300aa-10 *et seq.* (1994 ed.). Hereinafter, for ease of citation, all A'@ references will be to 42 U.S.C. (1994 ed.).

²A volume containing extensive medical records was filed with the petition. AM.R. __@ references will be to the numbered pages of those medical records.

³Petitioners have the burden of demonstrating the facts necessary for entitlement to an award by a preponderance of the evidence.@ ' 300aa-13(a)(1)(A). Under that standard, the existence of a fact must be shown to be more probable than not.@ *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

⁴The hearing was actually held on March 21, 1994, though on the face of the transcript it is erroneously noted that the hearing was held on March 31, 1994.

⁵Transverse myelitis is a neurological condition. It involves inflammation which extends across the width of the spinal cord. See Dorland's Illustrated Medical Dictionary 1086-88 (27th ed. 1988).

⁶Dr. Rust made the point that while the number of TM cases reported after infection by *each* of the different individual "enveloped" viruses is relatively small, the *combined* total of these cases is quite impressive and provides fairly strong support for the notion of a causal relationship between enveloped viruses and TM. See Dr. Rust's report filed on June 16, 1997, fifth page.

⁷I will cite to the transcript of the hearing held on March 21, 1994, as A1-Tr.; to the hearing held on December 9, 1997, as A2-Tr.; and to the hearing held on December 10, 1997, as A3-Tr.

⁸The experts in this case did not explain exactly what is meant by a "monophasic" course of TM, but all seemed to agree that Ebony's TM was monophasic. The term seems to mean simply that the patient experienced only one episode of TM, rather than two or more distinct episodes, which is true in Ebony's case.

⁹Dr. Rust replied to this point, however, that while the rubella vaccine does contain an attenuated form of the rubella virus, nevertheless it is *specifically designed to provoke a response from the vaccinee's immune system*, in order to provide the vaccinee with immunity against the virus in the future. And petitioners' experts agree that the likely way in which the vaccination caused the TM was to provoke an *autoimmune* response in Ebony's system--i.e., Ebony's immune system was stimulated by the vaccine to erroneously attack her own nervous system rather than the invading virus. In other words, Dr. Rust's point was that since the very purpose of the rubella vaccine is to stimulate an *immune system response* similar to that which would be stimulated by the wild rubella virus, it seems logical to assume that the relatively rare *improper immune response*--i.e., autoimmune response--that can be triggered by the wild virus can also be triggered by the vaccine.

¹⁰Note that copies of the relevant articles in this regard were filed in this case by petitioners on March 25, 1994.

¹¹Dr. Sladky also pointed out that a study shows that TM generally occurs more often in older individuals, while vaccinations of all types, including MMR and rubella vaccinations, are received more often by very young children. (See the article filed by respondent as Ex. G on March 14, 1994.) He suggested that this fact casts doubt on the theory that vaccinations ever cause TM. But I found that Dr. Rust replied reasonably and persuasively to this argument. (See 3-Tr. 193-94.)

¹²One study indicated that only 1.34 cases of TM develop each year per million people. See Resp. Ex. G filed on March 14, 1994, p. 967.

¹³An article co-authored by Dr. Wolinsky is among the medical literature filed in this case by petitioners on March 25, 1994.

¹⁴Unfortunately, no further testing of Ebony was in fact done at that time.

¹⁵Respondent's expert Dr. Sever explained that this laboratory is one of only two in the country capable of doing this type of testing (3-Tr. 124), and stated the opinion that it is a very reliable laboratory (3-Tr. 122).

¹⁶Such adjustments are apparently not unusual in the field, according to the testimony of Dr.

Sever. As a laboratory gains more experience with a test of this type, it adjusts its interpretations of the test. (3-Tr. 121-23.)

¹⁷It is noteworthy, however, that the record in the case seems to indicate that the interpretation of "organism-specific antibody index" results is a matter subject to different interpretations, even among those qualified to interpret such results. That is, apparently there was a time that Specialty Laboratories would have accepted Ebony's numerical index score, 1.2, as "incontrovertible evidence" of IBBB synthesis of rubella-specific antibody and as "strongly" suggesting that the rubella virus had infected Ebony's central nervous system. This factor adds slightly to the reason to conclude that Ebony's rubella antibody index should be accorded at least some weight in considering the question of whether her TM was vaccine-caused.

¹⁸At the evidentiary hearing held on December 9, 1997, Ebony's parents did not remember any diarrhea. But I find that the record made on March 25, 1991, is the best evidence on this point, indicating that Ebony's parents at that time *did* report the existence of what the parents thought to be diarrhea.

¹⁹In the materials that I placed into the record on December 15, 1993, see the excerpts from the report of a committee of the Institute of Medicine, entitled *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*, pp. 149-50, wherein four case reports of TM after measles vaccination are described. (This Institute of Medicine report was subsequently published in 1994 under that same title by the National Academy Press.)

²⁰Of course, as pointed out by petitioners' own experts, the conclusion that Ebony's own case of TM was *probably* vaccine-caused should not be interpreted as a conclusion that the MMR inoculation is an excessively dangerous vaccination. To the contrary, as noted above, given the huge number of MMR inoculations that have been administered world-wide and the very small number of cases of TM reported after such inoculations, it is clear that any risk of TM or other neurological injury from such inoculation is an extremely small one, confined to very rare instances. It remains clear that MMR vaccination is a generally safe procedure, and that the risks resulting from *failure to receive* such vaccinations far exceeds any small risk involved in *receiving* them.

²¹One other point must be made. In his written report and at the third evidentiary hearing, Dr. Rust argued that Ebony's TM was a result of "acute disseminated encephalomyelitis," also known as "ADEM," and Dr. Cullen concurred. Dr. Sladky disagreed. It is unnecessary for me to resolve this point, because of my resolution of the "actual causation" issue as discussed above. But I note that if for any reason my ruling on the "actual causation" issue should be set aside, a factfinder would then need to address whether Ebony's case properly is classified as falling within the category of ADEM, and, if so, whether that classification means that she suffered an "encephalopathy" within the very broad definition of that term provided in the statute. See ' 300aa-14(a)(1)(B); ' 300aa- 14(b)(3)(A).

²²I will be extremely displeased if I am ultimately called upon to resolve issues that plainly could and should have been resolved by the parties.