In the United States Court of Federal Claims

No. 95-34V
(Filed: July 28, 2004)

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IRENE BAKER GRUBER, by and through her Parents and Natural Guardians, MICHAEL GRUBER and LANA BAKER,

Petitioners,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

* *

National Vaccine Injury Compensation Program; Significant Aggravation; *Whitecotton*; Preexisting Condition.

Timothy B. Saylor, Allen Schulman & Assoc. Co., LPA, Canton, Ohio, for petitioners.

Mark C. Raby, Senior Trial Counsel, U.S. Department of Justice, Civil Division, Torts Branch, for respondent. With him on the briefs were *Vincent J. Matanoski*, Assistant Director, *Mark W. Rogers*, Acting Deputy Director, *Timothy P. Garren*, Director, and *Peter D. Keisler*, Assistant Attorney General.

OPINION

BRUGGINK, *Judge*.

Petitioners, Michael Gruber and Lana Baker, filed a petition for compensation under the National Vaccine Injury Compensation Program on

January 13, 1995.[1/] Petitioners alleged that their daughter, Irene Baker Gruber, suffered a significant aggravation of an underlying neurological disorder as the result of a diphtheria-pertussis-tetanus ("DPT") vaccination she received on January 16, 1992. On April 12, 1995, respondent filed a report recommending that the Chief Special Master dismiss the case based on lack of evidence to support a finding that Irene's condition is vaccine-related. An evidentiary hearing was held on December 11, 1997. On December 22, 1998, the Chief Special Master ruled that the petitioners were entitled to compensation under the Vaccine Act. *Gruber v. Sec. of Dep't of Health & Human Serv.*, No. 95-34V, slip op. (Fed. Cl. Dec. 22, 1998) (Decision on Entitlement). The Chief Special Master issued a Decision on Damages on January 20, 2004. Pending is respondent's February 19, 2004 motion for review of the Chief Special Master's decision on entitlement. Oral argument was held on May 3, 2004.

The essential facts, as found by the Chief Special Master, are not in dispute. The following background facts are drawn from his decision on entitlement. Irene was born on July 23, 1991, in Columbus, Ohio. At her first few appointments she was noted by her pediatrician, Dr. Roach, as a healthy baby. She received her first set of immunizations on September 18, 1991, and her second set on November 20, 1991. Irene's father testified that in late November or early December 1991, he and his wife noticed that Irene was suffering from occasional episodes of eye fluttering, which did not occur on a daily basis but were more common after Irene had just woken from a nap. By January 1992, these episodes had become more common, but did not yet raise her parents' concern for Irene's health. On January 16, 1992, Irene was brought to Dr. Roach. He observed several of Irene's eye-fluttering episodes at that time, but did not consider them unusual. Irene then received her third DPT shot that afternoon. Although it was not then diagnosed, both parties' experts agree that, with hindsight, Irene was showing symptoms of Severe Myoclonic Epilepsy ("SME") before her third vaccination. SME is a rare disorder of unknown origin with a consistently catastrophic prognosis.

The Grubers did not notice anything unusual about Irene's behavior the evening following her third vaccination. However, the next morning, Irene's body began to jerk during a diaper change. The Grubers brought Irene to Dr.

[1/] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, as amended, 42 U.S.C. § 300aa-1 *et seq*. (1991 & Supp. 1998) ("Vaccine Act").

Roach's office that morning. Irene was examined by Dr. Royhans, who suspected Irene's behavior to be caused by a seizure, and scheduled an EEG for Irene for February 4. Dr. Royhans impression, as recorded in his records, was that Irene had experienced a "seizure – time related to DPT." *Gruber*, slip op. at 3. A notation instructed that no more vaccinations were to be given to Irene. A Vaccine Adverse Events Reporting System form was completed on January 17, 1992, reporting these events.

Irene's parents recorded that she had other seizures on January 29, February 2, February 13, and March 14, 1992. Mr. Gruber testified that the seizures occurring after the January 16 vaccination increased in frequency and intensity.

> [W]here I referred to as the November through January 16th time period where I would say things were subtle and barely noticeable, after January 16th, it basically came right at you and hit you squarely between the eyes. There was no question as far as that she was, you know . . . having a problem.

Id. at 4.

An EEG was performed on February 4, recording Irene's brain activity while awake and sleeping. It was reported as abnormal. Two follow-up EEGs also reported abnormal brain activity. Not long after the third EEG, on March 6, 1992, Irene was admitted to Children's Hospital in Columbus, Ohio, following a twenty-minute seizure that resolved spontaneously in the emergency room. During her hospitalization, another EEG was performed which recorded a large number of clinical episodes of generalized myoclonic seizures. She was discharged on March 8.

On March 22, 1992, Irene experienced her first episode of status epilepticus. Children's Hospital records note that "generalized clonic seizures lasted 50 minutes before valium and dilantin stopped her seizures." *Id*. at 5. She required intubation following valium-induced apnea. Another EEG, conducted on March 25, was again abnormal, showing "moderate to severe generalized slowing of the cerebral activity." *Id*. at 5. By this time, Irene had also developed an acute sensitivity to light. According to Mr. Gruber, sometimes just going outside would be enough to trigger Irene to have a seizure. Her parents had to place cardboard in the windows of their home and car to prevent triggering a seizure.

Over the next few months, Irene's seizure activity continued in the form of multiple myoclonic seizures and generalized tonic-clonic seizures. On August 5, 1992, Dr. Roach's notes indicate Irene's parents noticed her experiencing a "different" type of seizure. She was described as having three to four minutes of continuous eye blinking followed by five minutes of eye deviation to the right, limpness, then 15 minutes of intermittent deviation. Afterward, Irene vomited and became pale.

Despite these seizures, on July 1, 1992 Irene was reported to be "growing normally, along the 75th percentile for height and weight and 50th percentile for head circumference." *Id*. at 5. On August 27, 1992 she was noted to have cognitive, social, and behavioral skills at an age-appropriate level. Her neurodevelopmental functioning was also thought to be age-appropriate. Her general fine/gross motor skills, however, were equivalent to those of a ten-month-old. Pediatrician notes dated September 21, 1992 report that Irene could pull to a stand and could cruise along furniture. By this time she also could say words like "Ma Ma" and "Da Da." An evaluation of October 22, 1992 reports that Irene sat alone at five to six months old and started to say words at 11 months.

Dr. Blaise Bourgeois, who conducted Irene's October 22 evaluation, made specific observations concerning her seizures. He noted that she was experiencing three different seizure types. (1) "generalized myoclonic seizures . . . [that] occur almost every few minutes"; (2) "generalized, predominantly clonic seizures, occasionally with a tonic phase . . . usually last[ing] less than one minute, but on occasions, have persisted for up to an hour"; and (3) "focal seizures." *Id*. Irene's seizures continued for the next few years, requiring medication and further hospitalization.

On March 11, 1996, Irene was admitted to Columbus Children's Hospital for a generalized tonic clonic seizure which progressed to status epilepticus. Irene developed liver failure and was transferred to Children's Hospital Medical Center in Cincinnati, Ohio, in preparation for Irene to receive a liver transplant. Irene's liver enzymes normalized, however, and the transplant was deemed unnecessary. Irene remained hospitalized for three months, and according to Mr. Gruber, all developmental gains Irene made were now lost, and she became severely mentally retarded. Irene is currently in a wheelchair, unable to stand or walk. She has no upper body control and is unable to speak. She cannot control her bowel functions and is totally dependent on her parents.

At the December 11, 1997 evidentiary hearing, the Chief Special Master heard testimony from Dr. Tracy Glauser, who testified on behalf of petitioners, and Dr. Mary Anne Guggenheim, who testified for respondent. Dr. Glauser specializes in child neurology and was one of Irene's treating physicians after July of 1993. Dr. Glauser testified that Irene suffers from SME. SME is very rare. According to Dr. Glauser, in 1992 only 172 cases were reported, and the numbers have remained consistently small. Dr. Glauser stated that the prognosis for SME as consistently "catastrophic." SME patients are often normal initially but virtually all end up being severely retarded. The condition generally begins with the development of one type of seizure, with other types of seizures developing later. Typically, the seizures suffered by SME patients are resistant to any kind of treatment during the first few years and lead to numerous hospitalizations.

Dr. Glauser testified that the seizures suffered by Irene on November 20 and December 4, predating her third vaccination, were myoclonic seizures. The January 17th seizures, in contrast, while still myoclonic, were "much worse" in nature, because of the increase in frequency and severity. Dr. Glauser relied on videotape footage of Irene taken after her January 16 vaccination, which he believes shows Irene suffering from almost continual, brief seizures. According to Dr. Glauser, Irene suffered a "partial onset seizure" on January 17th and thereafter her condition became substantially worse from that time to the point that she could no longer function due to the almost continuous seizures.

Dr. Glauser testified that because there are so few SME cases, it is difficult to say with specificity what course or progression is characteristic. While the seizures do generally increase in frequency and severity, Dr. Glauser did not know within what time frame the deterioration occurs or whether the deterioration is quick, slow, or steady. However, Dr. Glauser noted that "I still think that the intensity and the frequency of the seizures that we saw in the video is more than I would have expected [for SME], having read the literature about it," and he attributes the markedly increased severity of Irene's condition to the January 16 vaccination. *Id*. at. 7. Based on a medical article suggesting a temporal relationship between vaccination and afebrile seizures, Dr. Glauser believed a DPT vaccination could aggravate SME. *See* Charlotte Dravet et al., *Severe Myoclonic Epilepsy in Infants*, *in* EPILEPTIC SYNDROMES IN INFANCY, CHILDHOOD AND ADOLESCENCE, 75, 77 (2d ed. 1992).

Dr. Guggenheim testified for respondent. She also specializes in child neurology. It was her position that Irene's condition was not significantly aggravated by her third DPT vaccination, but rather that her course reflects a progression consistent with SME. Based on the videotapes, Dr. Guggenheim believes that the first symptoms of Irene's condition appeared in November, almost two months before her third DPT vaccination. By early January, but before her third DPT vaccination, Dr. Guggenheim noted that Irene had developed "funny mouth movements" and "a little bit of body jerk" in addition to her eye fluttering. Furthermore, in Dr. Guggenheim's opinion, the duration of Irene's seizures had already begun to increase by the middle of January from a half second to a couple of seconds. According to Dr. Guggenheim, the seizure Irene suffered soon after her third vaccination was simply the first episode of a second type of seizure, and because it is consistent with the nature of SME to have three to five different types of seizures, that episode cannot be considered a significant deterioration of Irene's condition. Irene's SME was simply becoming more obvious, and had not become aggravated.

The Chief Special Master accepted the experts' factual conclusion that Irene's myclonic seizures, which appeared in 1991, represented the onset of SME, a condition that could not have been diagnosed prior to Irene's third DPT vaccination. The Chief Special Master also accepted the experts' conclusion that the prognosis for SME is very bad and that the clinical outcome is always poor. The Chief Special Master also found that there was no dispute that Irene's current poor condition was caused by her SME. Dr. Glauser, indeed, had testified that Irene's medical course did not deviate from the expected course of SME. The Chief Special Master made this one of his findings. It is Dr. Glauser's position, however, that Irene suffered an "abnormal reaction" to her January 16, 1992 DPT vaccination that resulted in a distinct and significant worsening of her seizures. The Chief Special Master agreed, concluding as a matter of law that Irene's condition was significantly aggravated by her January 16, 1992 vaccine.

DISCUSSION

This case presents the question of whether, having found that the vaccine did not affect Irene's preexisting condition as a matter of medical fact,

the Chief Special Master erred in concluding that Irene's condition was nevertheless significantly aggravated by the vaccine as a matter of law.[2/]

Under the Vaccine Act, if a petitioner proves by a preponderance of the evidence that she suffered the onset or significant aggravation of an injury, disability, illness, or condition contained in the Vaccine Injury Table, 42 U.S.C. § 300aa-14(a) ("Table"), and the first symptom or manifestation of onset or significant aggravation occurred during the Table period after vaccination, petitioner is entitled to a presumption that the vaccination caused the onset or significant aggravation. *Id*. § 300aa-13(a). Once a petitioner gains such a presumption she may seek compensation not only for that injury or aggravation, but also for any acute complication or sequela of the illness, disability, injury, or condition to the extent it is shown that they result from the aggravation. *Id*. at § 300aa-14(a)(I)(E).

If petitioner is entitled to the presumption, her claim may nevertheless still fail if respondent makes an affirmative showing by a preponderance of the evidence that the illness, disability, injury, or condition described in the petition is due to factors unrelated to the administration of the vaccine. *Id*. § 300aa-13(a)(1)(B). However, a "factor unrelated" does not include "any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause,

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[2/] Petitioners' claim was initially characterized as one of initial onset, but as petitioners' counsel explained at oral argument, as videotape evidence became available both experts came to agree that Irene was experiencing seizure activity prior to her third DPT vaccination, and petitioners' claim was recharacterized as one of significant aggravation. *See* Tr. at 68-69.

factor, injury, illness, or condition . . . ." *Id*. § 300aa-13(a)(2)(A).[3/] It is undisputed in this case that SME is an idiopathic condition.[4/]

The Vaccine Act provides that the term "significant aggravation" means "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." *Id*. § 33(4). Noting that the term "significant aggravation" had been the subject of numerous cases, the Chief Special Master looked to the Federal Circuit's most recent explanation in *Whitecotton v. Secretary of HHS*, 81 F.3d 1099 (Fed. Cir. 1996) ("*Whitecotton III* "), for guidance. *Whitecotton III* sets out the following test for application in a case of significant aggravation:

> (1) assess the person's condition prior to administration of the vaccine, (2) assess the person's current condition, and (3) determine if the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination within the meaning of the statute. If the special master concludes that the person has suffered a significant aggravation, the special master must then . . . (4) determine whether the first symptom or manifestation of the significant aggravation occurred within the time period prescribed by the Table.

[3/] Other prerequisites to compensation include: (1) that the injured party suffered the residual effects of a vaccine-related injury for more than six months after the administration of the vaccine, 42 U.S.C. § 11(c)(1)(D)(I); (2) that petitioner incurred in excess of $1,000 in unreimbursable vaccine-related expenses, *id*. § 11(c)(1)(D)(I)(i); (3) that the vaccine was administered in the United States, *id*. § 11(c)(1)(B)(i)(I); (4) that petitioner did not previously collect a judgment or settlement in a prior civil action for damages for the vaccine-related injury, *id*. § 11(c)(1)(E); and (5) that the action be brought by the injured person's legal representative. *Id*. § 11(b)(1)(A).

[4/] Respondent merely concedes that under the current state of the law SME constitutes an idiopathic condition which cannot qualify as a "factor unrelated." Respondent wishes to preserve its right on appeal to argue the interpretation of section 300aa-13. *See Koston v. Sec'y of Dep't of Health & Human Serv*., 974 F.2d 157, 161 (Fed. Cir. 1992) (concluding that "Rhett's Syndrome" cannot qualify as a factor unrelated because it is "an illness of unknown origin").

Whitecotton III, 81 F.3d at 1107.

The Chief Special Master's Analysis

Relying on this test, the Chief Special Master noted first that there was no dispute that prior to her vaccination, Irene suffered myoclonic seizures. "Residual seizure disorder" is listed as a Table injury. The Chief Special Master then observed that Irene's current condition was "very poor." In applying the third step of the *Whitecotton III* test, the Chief Special Master concluded that he was simply to compare Irene's pre- and post-vaccination conditions. The Chief Special Master determined that Irene's current condition was indeed "strikingly worse" than her pre-vaccination condition. The Chief Special Master decided, therefore, that Irene's current condition constituted a significant aggravation of her preexisting seizure condition without taking into consideration any evidence concerning the nature of Irene's SME.

The last step the Chief Special Master took was to determine whether the first symptom or manifestation of the significant aggravation occurred within the Table time period—within 72 hours of Irene's final DPT vaccination. Because there was no dispute that on the morning of January 17, 1992 Irene suffered the first episode of a new type of seizure, the Chief Special Master concluded that the fourth element of the test was also met, and that petitioners had therefore made a prima facie showing under the Vaccine Act and were entitled to a presumption of causation.

In so holding, the Chief Special Master rejected respondent's argument that for a disease like SME, "the special master must carefully consider whether a new development is a sign of onset of a 'significant aggravation' of the condition, or, rather, simply one more manifestation of the inexorable downward course of the condition." *Gruber*, slip op. at 12-13. Respondent's approach would have required the Chief Special Master to consider reliable scientific evidence regarding the nature and expected course of the underlying disease in applying the fourth element of the *Whitecotton III* test. The Chief Special Master conceded the medical logic of defendant's argument but rejected it:

> Intuitively, it does seem reasonable that, in determining whether a significant aggravation has occurred, one would have to consider whether the preexisting condition may not have been

> aggravated by DPT, but, rather, progressed in a predictable manner. . . . However, *Whitecotton* relieves petitioners of the burden, essentially, of demonstrating that the preexisting condition was aggravated and requires a far simpler showing.

Id. at 13. The Chief Special Master's conclusion was based on his understanding of the current state of the law as articulated by *Whitecotton III*: "[W]hen the court is considering whether there has been a vaccine-related Table significant aggravation of a preexisting condition, the court may *not* take into any facet of the nature of the disease process of the underlying condition. Only consideration of the *symptoms* suffered before and after vaccination is permitted." *Id*. at 13-14.

The Chief Special Master noted that the government normally still has the opportunity to rebut a petitioner's prima facie showing if it can show, by a preponderance of the evidence, that a "factor unrelated" to the administration of the vaccination, including the preexisting condition, was the cause of the vaccine's post-vaccination significant aggravation. That defense was not available to the respondent here, however, because Irene's condition, SME, was idiopathic and therefore not a "factor unrelated."

Respondent also argued before the Chief Special Master that petitioners had not shown that Irene suffered the "residual effects or complications" of a Table significant aggravation for more than six months after vaccination as required by section 11(c)(1)(D)(I), and that petitioners failed to demonstrate that Irene's current condition is a sequela or acute complication of a vaccine injury under the Table at section 14. The Chief Special Master rejected these arguments, finding them both attempts to relitigate the causation argument already raised and rejected in the context of the four-part *Whitecotton III* test:

> The inquiry by which a Table significant aggravation determination is made essentially invalidates respondent's concerns because the analysis *includes* a consideration of Irene's current condition. The finding that Irene suffered a significant aggravation does not mean that Irene's injury is limited to an event that occurred just within the Table time period following vaccination. It is only the *first manifestation or onset* of the Table injury that had to have occurred withing Table time. . . . If the onset is found to have occurred within Table time, then it follows ineluctably that the current condition is related to or

> resulted from the event that occurred within the Table time frame.

Gruber, slip op. at 20. Furthermore,

> Sequelae, by definition, arise from the vaccine injury and comprise, or are part of, the current condition. Given these findings, it would be fictitious to consider that the significant aggravation and sequela inquiries are distinguishable and separable; the *Whitecotton* test has in effect merged the inquiries. Thus, petitioners automatically fulfill the sequela requirement by successfully demonstrating a Table significant aggravation of Irene's condition. In addition, because over six years have passed since the onset of Irene's injury, petitioners fulfill the six-month statutory requirement as well.

Id. The net result of the Chief Special Master's reading of *Whitecotton III*, therefore, leads, as he concedes, to the counter-intuitive result that a significant aggravation claim can be made out even where expert witnesses agree that a petitioner's post-vaccination condition is entirely consistent with her condition prior to vaccination.

Respondent's Argument

Respondent argues that, having found that there is no dispute that Irene's current condition was caused by her SME, the Chief Special Master erred in concluding as a matter of law that her condition was significantly aggravated by the vaccine. Respondent acknowledges the applicability of the four-part *Whitecotton III* test, but believes it was misapplied here. In respondent's view, the third step of the *Whitecotton III* test—whether the person's current condition constitutes a "significant aggravation" of the condition prior to vaccination—must be read in harmony with the statutory definition of "significant aggravation." The statutory definition of "significant aggravation" means "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. § 300aa-33(4). Respondent emphasizes the words "which results in" and argues that this definition necessarily adds an element of causation to a petitioner's prima facie showing. At oral argument, respondent explained that it is the government's position

that it should be able to introduce evidence of a preexisting condition during the determination of whether there was an aggravation.

Applying Whitecotton III

Whitecotton III represents the latest in a series of efforts by this court, the Federal Circuit, and the Supreme Court to articulate a method for applying the statutory standards for recovery for "significant aggravation" of a Table injury. *Whitecotton III* specifically rejected the test set out by this court in *Misasi v. Secretary of the Department of Health & Human Services*, 23 Cl. Ct. 322 (1991). The *Misasi* test required the special master to apply the four following steps in assessing whether there had been a significant aggravation of a pre-existing condition: (1) assess the individual's condition prior to administration of the vaccine, *i.e.*, evaluate the nature and extent of the individual's pre-existing condition, (2) assess the individual's current condition after the administration of the vaccine, (3) predict the individual's condition had the vaccine not been administered, and (4) compare the individual's current condition with the predicted condition had the vaccine not been administered. *Id*. at 324. Furthermore, a determination that a change in condition constituted a "significant aggravation" had to be based on a thorough review and analysis of the injured person's condition before and after the vaccination in question, including consideration of what changes could reasonably have been expected in the course of the condition in the absence of any aggravation. *Id*. at n.1. The court in *Misasi* placed the burden on petitioner to affirmatively establish that the injured person's pre-vaccination condition was not the explanation for his or her current injured or aggravated condition. In *Misasi*, the petitioner's claim was rejected based on respondent's expert testimony that petitioner's condition was the expected result of her pre-vaccine condition and not the vaccine itself. *Id*. at 325.

The *Misasi* approach was rejected in *Whitecotton III*. Yet to fully understand *Whitecotton III*, it is necessary to review the Federal Circuit's opinion in *Whitecotton v. Secretary of the Department of Health & Human Services*, 17 F.3d 374 (Fed. Cir. 1994) ("*Whitecotton I*"), and the Supreme Court's decision remanding *Whitecotton I* to the Federal Circuit. *Whitecotton* involved a petition filed on behalf of Maggie Whitecotton, who was born microcephalic and who later developed encephalopathy after her third DPT vaccination. The special master denied compensation, finding that Maggie was born with a brain disorder that was responsible for her encephalopathy and current disabilities. *See Whitecotton I*, 17 F.3d at 375. Even though Maggie

experienced seizures within three days of her third DPT vaccination, the special master rejected both the petitioner's initial onset and significant aggravation claims, finding that Maggie's microcephaly was evidence that her encephalopathy existing before the vaccination, precluding either claim. "There is nothing to distinguish this case from what would reasonably have been expected considering [petitioner's] microcephaly." App. to Pet. For Cert. at 41a-43a. The Federal Circuit reversed the special master's decision, concluding that the government may not defeat a petitioner's proven Table injury in an initial onset claim with a showing of a pre-existing brain disorder evidenced by microcephaly, an ideopathic factor unrelated to the vaccine. *Id*.

The Supreme Court reversed:

> The Court of Appeals declared that nowhere does the Act "expressly state" that a claimant relying on the table to establish a prima facie case for compensation must show "that the child sustained no injury prior to administration of the vaccine," that is, that the first symptom of the injury occurred after vaccination. This statement simply does not square with the plain language of the statute. In laying out the elements of a prima facie case, the Act provides that a claimant relying on the table (and not alleging significant aggravation) must show that "the first symptom or manifestation of the onset . . . of [her table illness] . . . occurred within the time period after vaccine administration set forth in the Vaccine Injury Table." § 300aa-11(c)(1)(C)(i). If a symptom or manifestation of a table injury has occurred before a claimant's vaccination, a symptom or manifestation after the vaccination cannot be the first, or signal the injury's onset. There cannot be two first symptoms or onsets of the same injury. Thus, a demonstration that the claimant experienced symptoms of an injury during the table period, while necessary, is insufficient to make out a prima facie case. *The claimant must also show that no evidence of the injury appeared before the vaccination.*

Shalala v. Whitecotton, 514 U.S. 268, 273-74 (1995) ("*Whitecotton II*") (emphasis supplied). Therefore, for a petitioner to establish a prima facie case in an initial onset claim, he or she must demonstrate that the first injury actually occurred during the Table period, rather than at some time prior to vaccination. Evidence of an earlier onset was fatal in *Whitecotton II* to

petitioner's prima facie case in an initial onset claim. It is important to note that this inquiry occurs before a prima facie case is made out—*i.e.*, before a "factor unrelated" defense would be triggered.

In reaching its conclusion, the majority made no mention of the petitioner's significant aggravation claim and gave no indication of whether any similar burden rested on the petitioner's shoulders in establishing a prima facie case in a significant aggravation claim. Justice O'Connor, in her concurring opinion, however, made it clear that the same analysis applied in either an initial onset or a significant aggravation claim:

> To establish a table case, the statute requires that a claimant prove by a preponderance of the evidence either (1) that she suffered the first symptom or manifestation of the onset of a table condition within the period specified in the table or (2) that she suffered the first symptom or manifestation of a significant aggravation of a pre-existing condition within the same period. . . . [P]roof that the claimant suffered *a* symptom within the period is necessary but not sufficient to satisfy either burden; the word "first" is significant and requires that the claimant demonstrate that the postvaccination symptom, whether of onset or of significant aggravation, was in fact the very first such manifestation.

Id. at 277 (O'Connor, J. concurring). Thus, the first symptom or manifestation of an initial onset or of a significant aggravation must be the first such symptom *in fact*. It would seem that Justice O'Connor believes that a petitioner in either an initial onset or significant aggravation claim thus has the affirmative burden of showing that the first symptom or manifestation of either an initial onset or significant aggravation of a Table injury occurred within the Table period specified before the presumption is triggered. In our view, there is nothing in the majority opinion in *Whitecotton II* that is in tension with her views.

On remand, the Federal Circuit reevaluated Maggie's only remaining claim, namely, significant aggravation, and determined that the special master erred in denying it. In doing so the court rejected the *Misasi* framework for establishing whether a significant aggravation had occurred: "[T]he Misasi test improperly required a petitioner to prove, as part of her prima facie case, that petitioner's significant aggravation was not caused by a pre-existing

injury. We therefore decline to adopt and follow the original *Misasi* test in evaluating whether a petitioner has made out a prima facie case for recovery under the Act." *Whitecotton III*, 81 F.3d at 1106. The Federal Circuit offered in its place the new test described above, the one followed in this case by the Chief Special Master.

While similar to the *Misasi* test in certain respects, the court noted the primary difference:

> Instead of asking whether the person's symptoms would have occurred absent the vaccine, our test hoves close to the statutory mandate, and relieves a petitioner of the burden of proving causation if she can show that the first symptom or manifestation of the significant aggravation of her condition occurred within the table time period provided in the statute.

Id. at 1107. The *Misasi* court erred, in short, in putting the burden on a petitioner to predict the natural course of the petitioner's pre-vaccination condition, as well as her current condition had the vaccination not been administered, and then to affirmatively prove that the her current post-vaccination condition was not caused by her pre-vaccination condition.

In the *Whitecotton III* opinion, the Federal Circuit was unable to determine from the special master's findings whether or not the petitioner suffered the first symptom or manifestation of her subsequent significant aggravation within the Table time period and thus remanded. Significantly, the Federal Circuit noted that in making this and any other relevant determinations:

> [T]he permissible scope of the special master's inquiry is virtually unlimited. Congress desired the special masters to have very wide discretion with respect to the evidence they would consider and the weight to be assigned that evidence. . . . Thus, the special master is free to consider evidence from outside the table time period in determining whether an individual suffered the first symptom or manifestation of a significant aggravation of an injury within the table time period.

Id. at 1108 (citing 42 U.S.C. § 300aa-13(b)).

Reading *Whitecotton III* in light of *Whitecotton II*, we believe respondent has the better argument here. Whether the claim is one of initial onset or significant aggravation, the *first* symptom or manifestation has to occur during the Table time period. To put the question in the context of this case, the focus has to be on whether the seizures Irene experienced within three days of the January 16 vaccination were the first symptoms or manifestations of an aggravation of her seizure disorder, as compared to a repetition of symptoms manifested prior to the vaccination. This is a fact that the petitioner must establish by a preponderance of the evidence. In making this determination, as the Federal Circuit has made clear, the special master may consider evidence from outside the Table time period. In our view, this necessarily includes evidence concerning the preexisting condition. To be clear, petitioners do not have the burden of proving that SME did not cause the symptoms experienced during the Table period. Nevertheless, the Chief Special Master may consider, in deciding whether this fourth step is satisfied, evidence sponsored by defendant tending to prove that whatever occurred during the three day window was not the first symptom or manifestation of a significant aggravation of Irene's seizure disorder.

This approach differs from the *Misasi* test in that *Misasi* required a comparison of the petitioner's current condition with the predicted condition had the vaccine not been administered. We make no such requirement here. At step three in the *Whitecotton III* inquiries, the special master need not make any prediction concerning what the natural course of a petitioner's preexisting condition would have been absent the vaccine. Once a Table injury has been identified, a determination of whether a significant aggravation of that injury has occurred properly involves a simple comparison of the petitioner's post-vaccination condition with her pre-vaccination condition. To be more precise, during the third step of the *Whitecotton III* test, the special master is simply looking for a "change for the worse" in the identified Table injury, accompanied by substantial deterioration of health for more than six months following vaccination.

In this case, petitioners alleges a significant aggravation of Irene's residual seizure disorder. The Chief Special Master correctly noted that there was no dispute that Irene suffered seizures before her January 16 vaccination. It is also clear from the record that Irene's seizure disorder worsened following her January 16 vaccination, and that her health continued to deteriorate. The frequency and intensity of Irene's seizures continued to get worse leading up to her hospitalization on March 11, 1996 when Irene's tonic clonic seizure

progressed to status epilepticus. Irene is currently severally mentally retarded and confined to a wheelchair.

At this stage, the third step of the *Whitecotton III* test, the special master makes no conclusions regarding what caused the aggravation, but simply determines whether *something* made the identified Table injury worse, and that aggravation of the Table injury was accompanied by a general deterioration of health. A petitioner's preexisting condition only has relevance at the fourth step in the *Whitecotton III* test.

The Chief Special Master erred in applying the fourth step of the *Whitecotton III* test by failing to take into account Irene's preexisting condition. The Chief Special Master simply acknowledged that Irene experienced a new type of seizure within the Table time period following Irene's third DPT vaccination. Yet prior to the vaccination, Irene already suffered from SME, the disease which the Chief Special Master determined as a factual matter to be the actual cause of Irene's condition. If a symptom occurring within the Table time period is determined by the Chief Special Master not to be the first symptom or manifestation of an aggravation of a Table injury, but rather a symptom or manifestation of a preexisting condition, petitioners have not made out their case. However, once petitioners have established that an identified Table injury was significantly aggravated, and that the first symptom or manifestation of that aggravation occurred within the Table period, they are afforded the statutory presumption that the aggravation was caused by the vaccine.

Acute Complications and Sequela

We also disagree with the Chief Special Master's conclusion that *Whitecotton III* effectively merged the significant aggravation and sequela inquiries. As explained above, once petitioner has established a significant aggravation of a Table injury she can obtain compensation, not only for that aggravation, but also for any acute complication or sequela resulting from it. 42 U.S.C. § 300aa-14(a)(I)(E). However, to obtain compensation for any sequela, petitioner must establish that the aggravation of the Table injury actually caused them. *Hossack v. Sec'y Dep't of Health & Human Serv.*, 32 Fed. Cl. 769, 776 (1995) ("[A] preponderance of the evidence must show that some logical, direct causal link exists between the presumed Table injury and the alleged sequela."). We do not read *Whitecotton III* as departing from this standard. Here, petitioners allege an aggravation of the residual seizure

disorder Table injury. Thus, to obtain compensation for any sequela they must establish by a preponderance of the evidence that it is causally related to the aggravation of the underlying Table injury—residual seizure disorder.

It appears that the Chief Special Master presumed that every aspect of Irene's current condition is the sequela of the aggravation of her Table residual seizure disorder without making separate fact findings. This approach apparently flowed from an over-broad application of the first three steps in the *Whitecotton III* test. It must be clear that the "condition" which is primarily under consideration in the pre- and post-vaccination inquiries is the allegedly aggravated Table injury. It is true, however, that in making a determination of whether a significant aggravation had occurred the Chief Special Master properly took into consideration not only the worsening of Irene's seizure disorder per se, but also the substantial deterioration of her health which accompanied it.[5/]

A petitioner does not automatically gain compensation for every possible injury or health problem associated with the aggravated Table injury. Rather, under the Vaccine Act, the petitioner must establish that any alleged sequela was actually caused by the significant aggravation of the specific Table injury. If the Chief Special Master determines that Irene suffered the first symptom or manifestation of a significant aggravation of the residual seizure disorder Table injury within the Table time period, petitioners are afforded the presumption that the significant aggravation was caused by the vaccination. A separate examination must then be undertaken as to whether Irene's severe mental retardation, and any other related medical problems, were the actual acute complications or sequela of the significant aggravation of her residual seizure disorder. Petitioners are afforded no presumption as to causation at this step.

[5/] The Vaccine Act's definition of the term "significant aggravation" thus should more properly be understood as "any change for the worse in [*the allegedly aggravated Table injury*] which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." § 33(4).

CONCLUSION

For the reasons set forth above, the Chief Special Master's December 22, 1998 Decision on Entitlement is reversed and remanded for further action consistent with this opinion.

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ERIC G. BRUGGINK,
Judge