No. 95-295V
(Filed February 3, 1998)

* *	*	National Childhood Vaccine
AMANDA K. RIGGS, as parent and legal	*	Compensation Act, 42 U.S.C.
representative of the estate of GABRIEL	*	§§ 300aa-1 to 300aa-34 (1994);
LUCAS, deceased,	*	effect of new regulations on
	*	statutory Vaccine Injury Table
Petitioner,	*	and interpretive aids, regulatory
	*	guidance on identifying signs of
v.	*	encephalopathy, continuous
	*	sleep as indicator of significantly
SECRETARY OF THE DEPARTMENT	*	decreased level of consciousness.
OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	
* *	*	

David Daulton, Norfolk, Virginia, for petitioner.

Vincent Matanoski, Washington, D.C., with whom was *Assistant Attorney General Frank W. Hunger*, for respondent.

OPINION

MEROW, *Judge*.

Petitioner Amanda Riggs seeks review of the August 5, 1997 decision denying her claim under the National Childhood Vaccine Compensation Act of 1986, 42 U.S.C. §§ 300aa-1 to 300aa-34 (1994) ("Vaccine Act" or "Act"), for the death of her two-month old son, Gabriel Lucas. *Riggs v. Secretary of the Dep't of Health & Human Servs.*, No. 95-0295V, 1997 WL 523900 (Fed. Cl. Spec. Mstr.). Petitioner alleged that Gabriel suffered an encephalopathy (*i.e.*, a significant impairment of brain function) as a result of a diphtheria-pertussis-tetanus ("DPT") vaccination administered on April 16, 1993. Proof of an encephalopathy within 72 hours of a DPT vaccination raises a presumption that the occurrence was caused by the vaccine and, if that presumption is left unrebutted, gives rise to an entitlement to compensation under the Act for resulting injury or death. In this case, petitioner alleged that an encephalopathy was evidenced by, among other things, the fact that Gabriel slept almost continuously for approximately 60 out of the 72 hours between the administration of the DPT vaccine and his death on April 19, 1993.

Relying upon new Department of Health and Human Services ("HHS") vaccine regulations, 42 C.F.R. § 100.3 (1995), the special master determined that this evidence, alone or in combination with other factors, failed to establish an encephalopathy under the Vaccine Act. The special master found that these new regulations "severely limit the signs that can be considered encephalopathic," 1997 WL 523900, * 3, and more particularly that under those regulations "[s]leepiness is specifically disqualified," *id*. at * 4, as such a sign. On review here, petitioner alleges that the special master misapplied the new regulations, and that this misapplication led to the denial of her claim.

As explained more fully below, while HHS considered eliminating the statutory presumption relating to encephalopathy during the above-referenced rulemaking, it ultimately maintained that presumption in favor of clarifying the clinical signs and symptoms which demonstrate an encephalopathy. Those regulatory changes neither eliminate the statutory presumption, nor carry the proscriptive legal import ascribed to them by the special master below. Most importantly, the regulations do not provide that sleep, alone or in combination with other factors, is insufficient to demonstrate an encephalopathy under the Vaccine Act as matter of law.

Rather, the regulations provide that an encephalopathy is indicated by "a significantly decreased level of consciousness lasting for at least 24 hours" during the 72 hours following a DPT vaccination. 42 C.F.R. § 100.3(b)(2)(i)(A). Sixty hours of almost continuous sleeping during the 72 hours following a DPT vaccination meets this regulatory standard and, taken together with the other clinical signs consistent with an encephalopathy that were present in this case, is sufficient to establish an encephalopathy under the Act. Since respondent did not demonstrate that Gabriel's death was, more likely than not, caused by factors unrelated to the vaccine, petitioner is entitled to compensation. The decision below is therefore reversed and remanded for an award of compensation to petitioner. 42 U.S.C. § 300aa-12(e)(2)(C).

FACTS

A hearing was held in this matter on July 8, 1997, in Norfolk, Virginia. Petitioner, Amanda Riggs, petitioner's parents, Nina and Bret Lucas, and petitioner's roommate, Linda Pitcock, testified. Also testifying for petitioner were Dr. Larry White, a pediatric neurologist, and Dr. Mark Geier. Dr. Russell D. Snyder, a neurologist, and Dr. Virginia M. Anderson, a pathologist, testified on behalf of respondent. While respondent argued that the testimony for petitioner should be discounted because it was not documented in contemporaneous medical records, the special master found that petitioner and her witnesses were both credible and forthright, and therefore accepted their factual description of Gabriel's clinical course as accurate and truthful.

According to that description, prior to his vaccination, Gabriel was a happy, healthy baby with a voracious appetite. Although Gabriel had suffered from a cold for approximately two weeks before his vaccination, he was described as "healthy as a horse" by his pediatrician directly prior to receiving his DPT shot. See Hr'g Tr. at 16. Petitioner testified that Gabriel had, in fact, maintained his normal sleeping and eating patterns during that two-week time period. *Id.* Those normal patterns included feeding approximately every three hours; overnight, Gabriel would regularly awaken for these feedings on his own accord. Hr'g Tr. at 14.

Following his vaccination on Friday, April 16, 1993, Gabriel fell asleep, slept through his feeding, fed less than usual when awakened for it, and went back to sleep, sleeping through the night for 12 hours. He awoke Saturday morning only when roused by petitioner, but spent the day almost continuously asleep. Gabriel slept through his feedings, a trip to the local mall, a trip to the supermarket and a visit to friends Saturday evening. He again slept through the night for approximately 12 hours. He awoke for a feeding on Sunday when roused by petitioner, and again ate less than usual, slept through a trip to McDonald's, and again slept through the night. Gabriel awoke on his own accord Monday morning, fed, and fell back asleep. Shortly thereafter, petitioner discovered that Gabriel was not breathing and took

him to the hospital, where he was pronounced dead. Approximately 72 hours had elapsed between Gabriel's vaccination and his death on Monday, April 19, 1993. Gabriel had spent roughly 60 of those hours asleep.

Testimony delivered at the July 8, 1997 hearing reflected that during the brief time Gabriel was awake during that 72 hour period, he fed less than usual, was irritable, cried inconsolably and sometimes appeared disengaged. Gabriel did, however, smile at his care givers on at least two occasions, and made eye contact with petitioner at least once. Hr'g Tr. at 95. Although petitioner and her witnesses remarked that they were concerned that Gabriel was sleeping too much, petitioner testified that it was against her natural inclination to wake him up from sleep. Hr'g Tr. at 30. Experts for both sides testified that Gabriel's condition warranted medical attention. Hr'g Tr. at 73, 228, 239.

Petitioner's experts testified that Gabriel's death was, more likely than not, caused by an encephalopathy. In their view, Gabriel's extended period of sleep indicated an acute abnormality or impairment of brain function, and that this together with his irritability, inconsolable crying, disinterest in food, and periodic disengagement when awake, were sufficient to demonstrate an encephalopathy. Hr'g Tr. at 71-73, 148-49, 151. Respondent's experts disagreed, and testified that the cause of death was sudden infant death syndrome ("SIDS"). Experts for petitioner described SIDS as the otherwise unexplainable death of a healthy infant. Hr'g Tr. at 79.

ANALYSIS

This court has jurisdiction to review the decision below pursuant to 42 U.S.C. § 300aa-12(e)(2), and will not disturb that decision unless it was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. 42 U.S.C. § 300aa-12(e)(2)(B). Petitioner's challenges to the application of the vaccine regulations to her claim raise questions of law, and as such are subject to *de novo* review by this court. *Munn v. Secretary of the Dep't of Health & Human Servs.*, 970 F.2d 863 (Fed. Cir. 1992).

I. Statutory Background

Congress enacted the National Vaccine Program in 1986 to provide for the "optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines." 42 U.S.C. § 300aa-1. To help effect this goal, Congress created a forum outside of the tort system for vaccine-related injury and death claims, requiring that such claims first be heard by special masters of this court. 42 U.S.C. § 300aa-10(a), 11. Congress also provided that the adjudication of those claims be governed by relaxed causation standards relative to tort, and prescribed that compensation for successful petitioners be subject to a statutory limit. 42 U.S.C. § 300aa-15.

Under the Act, a petitioner's burden of demonstrating that a vaccine caused injury or death is relaxed by providing that certain injuries or conditions will be presumed to have been caused by the vaccine. Accordingly, petitioners may establish entitlement to compensation by showing that the injured or deceased suffered one of the injuries or conditions listed in the Act's Vaccine Injury Table ("Table"), 42 U.S.C. § 300aa-14(a), and that the first manifestation of that injury occurred within the time-frame provided in the Table. The Table is followed by a section containing qualifications and aids to interpretation ("interpretive aids"), which describe the signs tending to indicate that a Table injury or condition has occurred. 42 U.S.C. § 300aa-14(b). If the petitioner demonstrates a Table injury or condition, that injury or condition is presumed to have been caused by the vaccine. 42 U.S.C. § 300aa-11(c)(1)(C)(i).[(1)] Compensation will be due in such a case unless the respondent can demonstrate by a preponderance of the evidence that the injury or condition was not caused by the vaccine.

Congress placed encephalopathy on the Table, and provided that an encephalopathy occurring within 72

hours of a DPT vaccination would be presumed to have been caused by the vaccine. 42 U.S.C. § 300aa-14(a). Accordingly, a petitioner able to demonstrate an encephalopathy within that time frame is entitled to compensation under the Act unless the respondent can show by a preponderance of evidence that the encephalopathy was caused by factors unrelated to the vaccine. 42 U.S.C. § 300aa-11(c)(1)(C)(i) (petitions for compensation for Table injury); 42 U.S.C. § 300aa-13(a) (preponderance of evidence standard).[(2)]

Congress also provided that the determination of whether an encephalopathy had been shown should be guided by the following interpretive aid:

The term "encephalopathy" means any significant acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent impairment. Signs and symptoms such as high pitched and unusual screaming, persistent unconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram.

42 U.S.C. § 300aa-14(b)(3)(A).

Upon enacting the Vaccine Act, Congress recognized that new medical evidence could later reveal that injuries or conditions not on the list should be presumed caused by a given vaccination, and conversely that such evidence could reveal that injuries and conditions on the list should not enjoy that presumption. See H.R. Rep. No. 99-908, at 18 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6359. Reflecting this recognition, Congress directed HHS to study the relationship between vaccines and injuries, disease and other medical conditions, and gave HHS the power to promulgate regulations to add or delete injuries and conditions on the Table based upon such study. 42 U.S.C. § 300aa-14(c)(1), (3). Congress also provided that such changes would then be applied to claims filed after their effective date.[(3)] 42 U.S.C. § 300aa-14(c)(4). To aid HHS in this process of revision, Congress created the National Vaccine Advisory Committee ("NVAC") and the Advisory Commission on Childhood Vaccines ("ACCV").

II. HHS Vaccine Regulations

With a view toward modifying the Table, HHS commissioned the Institute of Medicine ("IOM") to study the relationship between vaccines and certain injuries and medical conditions. Based upon the IOM report, HHS issued a proposed rule to modify the Vaccine Injury Table on August 14, 1992. National Vaccine Injury Compensation Program; Revision of the Vaccine Injury Table, 57 Fed. Reg. 36,878 (August 14, 1992). With respect to encephalopathy, the preamble to the rule reflects that HHS focused on IOM report findings that evidence supported the link between DPT and acute encephalopathy, but did not support such a link generally between DPT and chronic encephalopathy. Based upon the IOM findings, NVAC recommended that encephalopathy be removed from the Table entirely, while ACCV recommended that encephalopathy be retained on the Table with modifications to the interpretive aids to reflect this distinction.[(4)]

In the final rule, HHS adopted the ACCV recommendation, maintaining encephalopathy on the Table, and modifying the interpretive aids to provide that chronic encephalopathy would only be entitled to the

statutory presumption where the injured individual had experienced an acute encephalopathy within the 72 hour time frame, and the chronic condition persisted for 6 months thereafter.[(5)] See 60 Fed. Reg. at 7,678.

a. Identifying Acute Encephalopathy

By contrast with this focus upon whether evidence supported finding that DPT presumptively caused chronic neurological disorders, HHS characterized the regulatory treatment concerning the identification of acute encephalopathy as a clarification of existing statutory language, not a sea change. Responding to the ACCV's objection that the addition of language to the proposed rule that an acute encephalopathy be sufficiently severe as to require hospitalization, the HHS characterized the changes to encephalopathy this way:

The requirement contained within the revised Aids to Interpretation is meant to include only those events which are so serious that they require medical intervention (whether or not such intervention was actually sought), and are, therefore, properly referred to as encephalopathies. The requirement is simply meant to exclude those conditions which are not serious enough to warrant medical attention. These types of minor symptoms (e.g., excessive crying, sleepiness) were specifically excluded from the definition of encephalopathy contained within the statute, but have been alleged by some petitioners to be signs and symptoms of an encephalopathy. The revised Qualifications and Aids to Interpretation simply seek to make clear the intent of Congress.

National Vaccine Injury Compensation Program; Revision of the Vaccine Injury Table, 60 Fed. Reg. 7,678, 7,681 (Feb. 8, 1995) (preamble to final rule).

Accordingly, HHS provided that an acute encephalopathy is one which is "sufficiently severe so as to require hospitalization," 42 C.F.R. § 100.3(b)(2)(i),[(6)] as indicated "by a significantly decreased level of consciousness lasting for at least 24 hours," 42 C.F.R. § 100.3(b)(2)(i)(A), during the 72 hour post-vaccination time period. In an effort to clarify what it meant by "significantly decreased level of consciousness," HHS considered requiring that only a showing of stupor or coma would be sufficient, 57 Fed. Reg. at 36,883, but deleted this language from the final rule, explaining that:

[T]he Department agrees that the term "stupor" is imprecise and somewhat restrictive, and has therefore decided to specify the clinical signs reflective of an acute encephalopathy and delete the terms "stupor and coma." Acknowledging the difficulty of defining "encephalopathy," the Department has focused on clinical criteria that clearly distinguishes infants and children with brain dysfunction from those with transient "lethargy." The diminished alertness and motor activity, which characterize the lethargic infant or child, are frequently observed as the physiological response to fever, infection or other acute illness. The severity and duration of the behavioral changes differentiate mere lethargy from the more serious impairment of consciousness that is the hallmark of encephalopathy (i.e., obtundation, stupor, coma).

60 Fed. Reg. at 7,687. The HHS explanation thus recognizes a continuum of levels of consciousness, and reflects the view that those clinical signs falling on the more serious end of that continuum may demonstrate a compensable encephalopathy under the Act.[(7)] While on the one extreme an actual loss of consciousness, that is, coma, is not required to meet the standard, on the other extreme lethargy would not be enough to meet the standard.

Instead of requiring a showing of stupor or coma in order to demonstrate a significantly decreased level of consciousness, HHS provided that a petitioner could make this showing by demonstrating the existence of clinical signs falling into one of three categories:

A "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater ... (1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli); (2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or (3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

42 C.F.R. § 100.3(b)(2)(i)(D). Construing this provision, the special master found that Gabriel's clinical signs, in particular his extensive sleeping, were insufficient to demonstrate a significantly decreased level of consciousness.

i. Excessive Sleep as a Sign of Significantly Decreased Level of Consciousness

It is undisputed that Gabriel slept almost continuously for 60 hours out of the 72 hours in between his vaccination and death, that he rarely awoke on his own accord during this time period, and that this was contrary to his usual practice. Petitioner's expert testified that such an extended period of sleeping amounted to a significantly decreased level of consciousness, and thereby indicated an acute abnormality or impairment of brain function. Hr'g Tr. at 71-73, 148-49, 151. While finding that this view "merit[ed] consideration," 1997 WL 523900, * 4, the special master felt constrained by the new regulation to reject it on the ground that "Gabriel was arousable; the evidence does not suggest he was unconscious, only asleep. Sleepiness is specifically disqualified by subparagraph (E) of the amended regulations." *Id.* at * 3.

As noted above, HHS removed the requirement included in the proposed regulation that stupor or coma be shown on the ground that such a requirement would be too restrictive. Thus, the fact that Gabriel was not unconscious and could be aroused are not dispositive of whether his condition demonstrated a significantly decreased level of consciousness. Further, the subparagraph (E) disavowal of "sleepiness" as a clinical sign of an encephalopathy does not support the dismissal of petitioner's claim. See 42 C.F.R. § 100.3(b)(2)(i)(E).

Subparagraph (E) of the HHS regulations restated language in the original statute which had identified those clinical signs that, while consistent with an encephalopathy, standing alone would not be taken to demonstrate that one had occurred. 42 U.S.C. § 300aa-14(b)(3)(A) ("signs and symptoms such as high pitched and unusual screaming, persistent unconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of an encephalopathy"). In its regulation, HHS restated those clinical signs, added sleepiness to the list, and explained that the purpose of this language was to clarify the original statutory intent, not to make a significant new limitation on the signs that could be considered encephalopathic. 60 Fed. Reg. at 7,681 (new regulatory language intended to exclude "minor symptoms" such as excessive crying and sleepiness that were specifically excluded from the statutory definition of encephalopathy).[(8)]

Neither the regulatory language itself, nor the HHS explanation of it, support the view that sleeping for 60 out of 72 hours after a DPT vaccination is the type of "minor symptom" excluded under the regulation. Gabriel was not just sleepy during this time period. He was actually asleep. Sleeping almost continuously for 60 out of 72 hours, and generally failing to awaken without prompting during that time period, amounts to a "decreased or absent response to environment," that qualifies as a sign of significantly decreased level of consciousness under the regulation.

ii. Other Clinical Signs of Significantly Decreased Level of

Consciousness

The special master also dismissed the argument that Gabriel's uncharacteristic disinterest in food was not demonstration of "inconsistent or absent responses to external stimuli." 1997 WL 523900, *3. A showing of signs falling into this category is an additional way of demonstrating that the injured or deceased exhibited a significantly decreased level of consciousness under the regulatory interpretive aid. 42 C.F.R. § 100.3(b)(2)(i)(D) (setting forth three independent categories of signs that meet the significantly decreased level of consciousness criteria).

While the basis for that determination is somewhat unclear, it appears that the special master may have felt constrained to reject this evidence on the ground that it did not fit neatly into the illustrative example, "does not recognize familiar people or things," 42 C.F.R. § 100.3(b)(2)(i)(D)(3), of that category of significantly decreased level of consciousness. To the extent that this was the rationale underlying the rejection of this evidence, it should be noted that those clauses, given their phrasing as parenthetical remarks in a regulatory provision that is a guide to interpretation, are more properly construed as non-exclusive examples of signs that meet the general criteria. They are not an exhaustive explanation of the behavior which meets that criteria.

b. Rebutting the Presumption of an Encephalopathy

As noted earlier, where a petitioner establishes an encephalopathy by a preponderance of the evidence, she is entitled to compensation under the Act unless respondent demonstrates by a preponderance of the evidence that the encephalopathy was caused by factors unrelated to the vaccine. The statute provides, however, that such factors do not include "any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness or condition . . . ." 42 U.S.C. § 13(a)(2)(A).

Respondent maintains that the cause of Gabriel's death was SIDS. SIDS is the term used to diagnose the unexplainable death of an otherwise healthy infant. As such, the special master explained, a SIDS diagnosis falls within the statutory category of factors that will not rebut the presumption. 1997 WL 523900, * 3. The regulations did not change this rule. See 60 Fed. Reg. at 7,691. Respondent did not allege an alternate cause of the encephalopathy.

CONCLUSION

The new HHS regulations do not severely limit the signs that may be considered indicative of an encephalopathic condition. Nor do they provide that a period of relatively continuous sleep for an extensive time may not be considered such a sign. To the contrary, those regulatory provisions have as their aim clarifying the original statutory interpretive aid for encephalopathy, not effecting a significant substantive change to it. In that vein, the regulations provide that an encephalopathy is demonstrated by a showing of a "significantly decreased level of consciousness" for 24 hours during the first 72 hours following a DPT vaccination.

Here, contrary to his usual practice, Gabriel slept almost continuously for 60 out of those 72 hours, rarely awakening on his own accord during that time. These

established facts meet the "significantly decreased level of consciousness" criterion of the regulations. By demonstrating that factor, and taken together with other clinical signs present here that are compatible with an encephalopathy (*e.g.*, irritability, inconsolable crying), petitioner has sustained her burden under the Act of demonstrating by a preponderance of the evidence that Gabriel suffered an encephalopathy before his death. Since respondent has not demonstrated that this encephalopathy and death were attributable to causes other than the vaccine, petitioner is entitled to compensation.

Accordingly, it is **ORDERED** that the special master's decision is **REVERSED** and **REMANDED**, for

an award of compensation to the petitioner.

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James F. Merow,

Judge

1. The Act also provides that if the petitioner cannot show that the injured or deceased suffered one of the injuries listed in the Table (or did so suffer but outside of the time frame), the petitioner may prove that injury or death was the actually caused by the vaccine. 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I).

2. See *Knudsen v. Secretary of the Dep't of Health & Human Servs.*, 35 F.3d 543, 546 (Fed. Cir. 1994) (explaining and applying statutory presumptions).

3. Petitioner also argues that the regulations may not be applied to a claim which accrued before the regulations took effect because to do so would effect a vested right conferred by the Act. The Vaccine Act does not create such a right. Accordingly, petitioner's argument is without merit. *Black v. Secretary of the Dep't of Health and Human Servs.*, 93 F.3d 781, 787-88 (Fed. Cir. 1996) ("the Vaccine Act does not implicate any 'fundamental right,' for a 'noncontractual claim to receive funds from the public treasury enjoys no constitutionally protected status'"), quoting *Weinberger v. Salfi*, 422 U.S. 749, 772 (1975).

4. While NVAC was charged with considering the scientific issues attending potential changes, ACCV was given the broader mandate to advise HHS concerning new scientific findings and the public policy implications of incorporating those changes into law. See 57 Fed. Reg. at 36,879.

5. Petitioner also alleges that the regulatory modifications to the interpretive aids were beyond the authority of HHS, and are therefore void. In particular, petitioner claims that while the Vaccine Act gives HHS the authority to modify the Vaccine Injury Table, 42 U.S.C. § 300aa-14(c)(1), the statutory grant does not empower HHS to modify the related interpretive aids. This court does not have jurisdiction to consider this challenge. See 42 U.S.C. § 300aa-32 (petitions for review of regulations committed to the courts of appeals of the United States, and must be brought within 60 days of promulgation). It should be noted, in any event, that petitioner's exact challenge was rejected by the First Circuit. *O'Connell v. Shalala*, 79 F.3d 170, 175-77 (1st Cir. 1996).

6. Experts for both petitioner and respondent testified that Gabriel's condition warranted medical attention. Hr'g Tr. 73, 228, 239. In accord with the HHS explanation quoted above, the fact that petitioner did not seek such attention does not detract from this opinion, or defeat her claim.

7. Dorland's Illustrated Medical Dictionary (28th ed. 1988) defines "levels of consciousness," as "clinically differentiable degrees of awareness and alertness such as alert wakefulness, lethargy, clouding of consciousness, stupor and coma." "Stupor" is defined as "a lowered level of consciousness manifested by the subject's responding

to only vigorous stimulation," while "coma" is defined as "a state of unconsciousness from which the patient cannot be aroused, even by powerful stimulation."

8. In response to the ACCV's concern that the introductory language in subparagraph (E) could be construed to mean that sleepiness, irritability, high-pitched and unusual screaming, persistent inconsolable crying and a bulging fontanelle were *incompatible* with encephalopathy, HHS explained that this language was inserted to improve upon the statutory language that had listed certain conditions "compatible with an encephalopathy, but in and of themselves are not conclusive evidence of an encephalopathy," 42 U.S.C. § 300aa-14(b)(3)(A), not to change its meaning. 60 Fed. Reg. at 7,688 (this language reflects that these conditions "do not conclusively establish an encephalopathy, but instead are merely symptoms that are compatible with an encephalopathy").