STATE OF FLORIDA DIVISION OF ADMINISTRATIVE HEARINGS

| MARIO BALANDRA and ROSEMARY |) | | | |
|-----------------------------|---|--------|-----|----------|
| BALANDRA, as parents and |) | | | |
| natural guardians of SOPHIA |) | | | |
| BALANDRA, a minor, |) | | | |
| |) | | | |
| Petitioners, |) | | | |
| |) | | | |
| vs. |) | Case N | No. | 01-4889N |
| |) | | | |
| FLORIDA BIRTH-RELATED |) | | | |
| NEUROLOGICAL INJURY |) | | | |
| COMPENSATION ASSOCIATION, |) | | | |
| |) | | | |
| Respondent. |) | | | |
| |) | | | |

FINAL ORDER

Pursuant to notice, the Division of Administrative Hearings, by Administrative Law Judge William J. Kendrick, held a final hearing in the above-styled case on August 26, 2002, by video teleconference, with sites in Tallahassee and Fort Myers, Florida.

APPEARANCES

| For Petitioner: | Mario Balandra and Rosemary Balandra, <u>pro se</u> 3929 Groveland Avenue Sarasota, Florida 34231 |
|-----------------|---|
| For Respondent: | Lynn Walker Wright, Esquire Wright, Railey & Harding, P.A. 2716 Rew Circle, Suite 102 Ocoee, Florida 34761 |

STATEMENT OF THE ISSUE

At issue in this proceeding is whether Sophia Balandra, a minor, qualifies for coverage under the Florida Birth-Related Neurological Injury Compensation Plan.

PRELIMINARY STATEMENT

On December 24, 2001, Mario Balandra and Rosemary Balandra, as parents and natural guardians of Sophia Balandra (Sophia), a minor, filed a petition (claim) with the Division of Administrative Hearings (DOAH) for compensation under the Florida Birth-Related Neurological Injury Compensation Plan (Plan).

DOAH served the Florida Birth-Related Neurological Injury Compensation Association (NICA) with a copy of the claim on December 24, 2001. NICA reviewed the claim, and on April 1, 2002, gave notice that it had "determined that such claim is not a 'birth-related neurological injury' within the meaning of Section 766.302(2), Florida Statutes," and requested that "an order [be entered] setting a hearing in this cause on the issue of . . . compensability." Such a hearing was duly-noticed for, and held on, August 26, 2002.

At hearing, the parties stipulated to the factual matters set forth in paragraphs 1, 2, and 4 of the Findings of Fact. Rosemary Balandra testified on behalf of Petitioners, and Petitioners' Exhibits 1A and 1B (the medical records, two volumes, filed with DOAH on December 24, 2001), as well as

Petitioners' Exhibit 2 (a report of neurological evaluation by Michael Duchowny, M.D., dated March 19, 2002), were received into evidence. Respondent called no witnesses; however, Respondent's Exhibit 1 (the deposition of Donald Willis, M.D., filed with DOAH on July 31, 2002) was received into evidence.

The transcript of hearing was filed on September 9, 2002, and the parties were accorded 10 days from that date to file proposed final orders. Respondent elected to file such a proposal, and it has been duly-considered.

FINDINGS OF FACT

Preliminary findings

1. Petitioners, Mario Balandra and Rosemary Balandra, are the parents and natural guardians of Sophia Balandra. Sophia was born a live infant on January 2, 1997, at Sarasota Memorial Hospital, a hospital located in Sarasota, Florida, and her birth weight exceeded 2,500 grams.

2. The physician providing obstetrical services at Sophia's birth was Michael S. Finazzo, M.D., who, at all times material hereto, was a "participating physician" in the Florida Birth-Related Neurological Injury Compensation Plan, as defined by Section 766.302(7), Florida Statutes.

Coverage under the Plan

3. Pertinent to this case, coverage is afforded by the Plan for infants who suffer a "birth-related neurological injury,"

defined as an "injury to the brain . . . caused by oxygen deprivation . . . occurring in the course of labor, delivery, or resuscitation in the immediate post-delivery period in a hospital, which renders the infant permanently and substantially mentally and physically impaired." Sections 766.302(2) and 766.309(1)(a), Florida Statutes.

4. Here, it is undisputed, and the parties have so stipulated, that Sophia suffered an injury to the brain, caused by oxygen deprivation, which rendered her permanently and substantially mentally and physically impaired. Consequently, with regard to the issue of compensability, the only issue that remains for resolution is whether the proof supports the conclusion that, more likely than not, Sophia's brain injury occurred in the course of labor, delivery, or resuscitation in the immediate post-delivery period, as required for coverage under the Plan.

Mrs. Balandra's antepartum course and Sophia's birth

5. Mrs. Balandra's antepartum course was without significant complication until January 2, 1997, when, with the fetus at approximately 38 weeks gestation (estimated date of delivery January 17, 1997), she presented to her obstetrician's office complaining of decreased fetal movement.¹ At the time, auscultation revealed a low fetal heart rate (in the 90-beat per minute range), and it was thought that Mrs. Balandra may have "a

fetus with a heart block or . . [that] deceleration was occurring." Given the circumstances, Mrs. Balandra was referred to Sarasota Memorial Hospital for further monitoring and assessment.

6. Mrs. Balandra was admitted to Sarasota Memorial Hospital at or about 4:56 p.m., January 2, 1997. At the time, external fetal monitoring revealed a fetal heart tone of 140-144 beatsper-minute, with minimum variability. Biophysical profile, completed at or about 5:24 p.m., was nonreassuring, at 4/8, with 2 points deducted for lack of fetal movement and 2 points deducted for lack of fetal tone.

7. At 5:40 p.m., fetal heart tone was noted as 150-160 beats per minute (a mild fetal tachycardia). Shortly thereafter, Dr. Finazzo was apprised of Mrs. Balandra's status, and he ordered that she be prepared for cesarean section. At the time, Mrs. Balandra was not in labor, and she would not thereafter be in labor at anytime prior to Sophia's delivery. Dr. Finazzo's assessment and plan were, as follows:

> ON REVIEW THE ASSESSMENT WAS THAT THE PATIENT HAD AN INTRAUTERINE PREGNANCY AT 38 WEEKS GESTATION WITH A PREVIOUS CESAREAN SECTION AND THE PATIENT DESIRED A REPEAT CESAREAN SECTION. SHE HAS EXPRESSED DESIRE IN THE PAST TO HAVE A BILATERAL TUBAL LIGATION BUT GIVEN THE FACT THAT THERE IS POTENTIAL FETAL HARM, THE PATIENT HAS OPTED TO GIVE ME THE AUTHORITY TO DECIDE WHETHER OR NOT TO PROCEED WITH TUBAL LIGATION OR NOT AS SHE CLAIMS THAT IF I THOUGHT THE BABY WOULD NOT SUBSEQUENTLY

DO WELL, DO NOT DO THE TUBAL LIGATION. THIS WAS DISCUSSED WITH THE PATIENT, BOTH PREOPERATIVELY AND INTRAOPERATIVELY. SHE HAD BEEN EXPLAINED THE ONE IN THREE HUNDRED FAILURE RATE OF THIS OPERATION, ITS IRREVERSIBLE NATURE AND THAT REVERSIBLE METHODS OF BIRTH CONTROL ARE AVAILABLE. SHE ACCEPTED ALL OF THIS AND LEFT THIS AUTHORITY UP TO ME BASED UPON HOW THE FETUS IS TO DO.

PLAN:

WILL PROCEED WITH CESAREAN SECTION AND POSSIBLE BILATERAL TUBAL LIGATION UNDER SPINAL ANESTHESIA. WILL GO AS SOON AS POSSIBLE WHEN ANESTHESIA HAS PREPARED AND WILL CONTINUE CLOSE MONITORING IN IMMEDIATE PREOPERATIVE PERIOD. IN ADDITION, THE PATIENT HAD A CULTURE THAT WAS POSITIVE FOR GROUP B STREPTOCOCCUS ONE WEEK AGO AND SHE WILL BE GIVEN PROPHYLACTIC ANTIBIOTIC AMPICILLIN OR UNASYN BEFORE THIS PROCEDURE.

8. At 5:45 p.m., fetal heart tone was noted to decrease to 70 beats per minute for 20 seconds, then increase to 90-110 beats per minute for 70 seconds, and then increase to 90-120 beats per minute for 30 seconds, followed by a return to baseline. Thereafter, at 5:55 p.m., fetal heart tone was noted at 155-160 beats per minute, with minimum to average variability, and Mrs. Balandra's abdomen was prepared for surgery.

9. At 6:05 p.m., when Dr. Finazzo arrived at labor and delivery, fetal heart tone was noted as 158-164 beats per minute, with no further decelerations. Thereafter, at 6:10 p.m., Mrs. Balandra was transported, via bed, to the operating room.

10. According to the records, Mrs. Balandra was in the operating room at 6:15 p.m., anesthesia started at 6:15 p.m., surgery started at 6:42 p.m., and Sophia was delivered at 6:50 p.m. Pertinent to this case, Dr. Finazzo's operative notes describe Sophia's delivery, as follows:

> . . . A LOW-TRANSVERSE INCISION WAS MADE INTO THE UTERUS. THIS WAS EXTENDED BILATERALLY IN ELLIPTICAL FASHION USING THE TWO INDEX FINGERS. A MODERATE AMOUNT OF MECONIUM FLUID WAS NOTED. A HAND WAS THEN PLACED INTO THE UTERINE CAVITY AND THE FETAL HEAD WAS FLEXED, ELEVATED AND BROUGHT OUT THROUGH THE UTERINE INCISION. THE NARES AND OROPHARYNX WERE SUCTIONED USING THE DELEE TO RETRIEVE ANY POTENTIAL MECONIUM, AND THE REST OF THE BABY'S BODY WAS DELIVERED ATRAUMATICALLY. AFTER IT WAS DELIVERED, THE CORD WAS CLAMPED TIMES TWO AND CUT, AND THE BABY WAS HANDED TO THE WAITING NEONATOLOGIST.

> THE CORD WAS CLAMPED CLOSE TO THE FETAL UMBILICUS AS THERE WAS A SEGMENT OF CORD THAT APPEARED TO BE ABNORMAL, A THROMBOSIS OR ANEURYSM OR BLEEDING INTO THE CORD AT THIS SITE. AT THIS TIME, THIS EXTRA SEGMENT OF CORD WAS ISOLATED, CLAMPED AND SENT TO THE PATHOLOGIST. THE REST OF THE CORD WAS USED TO COLLECT CORD BLOOD AND COLLECT CORD ABG.

> > * * *

AFTER A SINGLE FIGURE-OF-EIGHT OF 0 MONOCRYL WAS USED TO OBTAIN COMPLETE HEMOSTASIS, A DECISION WAS MADE NOT TO PROCEED WITH BILATERAL TUBAL LIGATION. THIS WAS DONE IN CONSULTATION WITH THE PATIENT AS BEFORE SURGERY, THE PATIENT HAD TOLD ME SHE ONLY WANTED TUBAL LIGATION DONE IF I COULD BE SURE THAT THE NEWBORN WAS DOING WELL AND WOULD NOT HAVE ANY LONG-TERM PROBLEMS OR POTENTIAL FOR NEONATAL DEATH. THE APGARS AT THAT TIME WERE 5 [AT ONE MINUTE] AND 6 AT FIVE MINUTES. THEREFORE, A DECISION WAS MADE NOT TO PROCEED WITH TUBAL LIGATION. THE PATIENT AGREED WITH THIS AT THE TIME OF SURGERY

11. Sophia's course after she was handed to the waiting neonatologist, John S. Gallagher, M.D., and until 7:10 p.m., when she was transferred to the neonatal intensive care unit (NICU) for further observation and therapy, was detailed in

Dr. Gallagher's History and Physical, as follows:

APGARS WERE 5, 6 AND 8 AT ONE, FIVE AND TEN MINUTES RESPECTIVELY.[²] AT DELIVERY, THERE WAS SOME MODERATE MECONIUM NOTED AND THE BABY WAS WELL DELEE SUCTIONED AFTER DELIVERY OF THE HEAD BY DR. FINAZZO

THE BABY MADE A FEW GASPING EFFORTS AT THAT POINT BUT WAS FLOPPY AND SO THE CORDS WERE VISUALIZED AND I PASSED A SUCTION CATHETER PAST THE CORD. [I] OBTAIN[ED] A SMALL AMOUNT OF WATERY MECONIUM FLUID WHICH QUICKLY CLEARED. [AT 6:51 P.M., THE BABY WAS GIVEN BLOWBY OXYGEN.] I THEN STIMULATED THE BABY AND HAD GOOD HEART RATE BUT VIRTUALLY NO RESPIRATORY EFFORT. FOR THAT REASON, SHE WAS INTUBATED WITH A 3.5 ENDOTRACHEAL TUBE. Α MECONIUM ASPIRATOR WAS USED AND NO MECONIUM WAS OBTAINED AT THAT POINT. [AT 2 1/2 MINUTES(6:52.5 P.M.)] WE AGAIN EXTUBATED THE BABY, SUCTIONING AS WE WITHDREW THE TUBE. WΕ THEN CONTINUED DRYING AND STIMULATING THE BABY BUT AGAIN SAW POOR RESPIRATORY EFFORT AND COLOR AND [AT 6:53 P.M., AND CONTINUING UNTIL 6:54 P.M.] GAVE BAG AND MASK VENTILATION WHICH KEPT THE HEART RATE ABOVE 100 BUT FAILED TO REINSTITUTE RESPIRATIONS. AT THIS POINT, IT SEEMED THAT THE BABY HAD SOME SECONDARY APNEA AND SO [AT 6:54 P.M.] WE AGAIN INTUBATED HER, THIS TIME WITH A 3.0 ENDOTRACHEAL TUBE AND RESUMED SUCTIONING AND BAGGING. SOME MECONIUM WAS OBTAINED WITH DEEP SUCTIONING THROUGH THE TUBE AT THIS POINT, AND IT DID CLEAR. WE USED A SMALL

AMOUNT OF SALINE TO HELP ENSURE THAT THE PROXIMAL AIRWAY WAS CLEAR AS WELL AND THIS DID CLEAR READILY. BREATH SOUNDS WERE EQUAL AND GENERALLY CLEAR WITH GOOD CHEST MOVEMENT WITH THE BAGGING ON LOW PRESSURE, WHICH WAS ALWAYS KEPT IN THE TEENS TO LOW 20'S, SUFFICIENT TO KEEP THE HEART RATE UP AND IMPROVE THE COLOR. THE ENDOTRACHEAL TUBE WAS KEPT AT ABOUT 8 CM. AND AGAIN AS NOTED, BREATH SOUNDS WERE EQUAL.

WE CONTINUED THE BAGGING AND PULMONARY SUCTIONING AND LAVAGE FOR THE NEXT SEVERAL MINUTES AND THE BABY'S RESPIRATORY EFFORTS GRADUALLY BECAME MORE CONSISTENT. BY AROUND THE SEVEN MINUTE MARK [6:57 P.M.], THE BABY WAS MAKING FAIRLY CONSISTENT RESPIRATORY EFFORTS. BY AROUND 15 MINUTES OR SO [7:05 P.M.], WE HAD EXTUBATED AGAIN [AND CEASED BAGGING], AS THE LUNGS SOUNDED CLEAR AND THERE WAS NO FURTHER MECONIUM.

* * *

THE BABY WAS BROUGHT TO THE SPECIAL CARE NURSERY FOR FURTHER OBSERVATION AND THERAPY INCLUDING ANTIBIOTICS GIVEN THE GROUP-B STREP HISTORY.

PHYSICAL EXAMINATION:

GENERAL DESCRIPTION: THE BABY IS AN APPROXIMATELY TERM FEMALE WITH IMPROVED RESPIRATORY EFFORT AND GOOD PERFUSION BUT SATURATION DIPPING IN THE LOW 80'S ON ROOM AIR, AND SO BABY WAS PLACED INTO HOOD OXYGEN WITH IMPROVEMENT IN SATURATION TO THE UPPER 90'S.

HEAD, EYES, EARS, NOSE AND THROAT: FONTANELLE IS SOFT.

CHEST: SYMMETRICAL WITH EQUAL AND RATHER CLEAR BREATH SOUNDS WITH FAIR GOOD EXCHANGE.

CARDIOVASCULAR: THERE IS NO MURMUR. THE PULSES AND PERFUSION ARE GOOD.

ABDOMEN: SOFT. THE BABY'S TONE IMPROVED, ALTHOUGH REFLEX IRRITABILITY STILL SOMEWHAT DIMINISHED.

WE WILL OBTAIN A CBC AND BLOOD CULTURE AND START ANTIBIOTICS AS NOTED. ALSO WILL OBTAIN A CHEST RADIOGRAPH TO MONITOR FOR ANY ASPIRATION EFFECT. CHEM-STRIP IS ALSO PENDING.

* * *

ADMISSION IMPRESSIONS:

1) TERM FEMALE.

 STATUS POST PERINATAL STRESS, PERHAPS RELATED TO GESTATIONAL DIABETES AND UMBILICAL CORD HEMATOMA WITH LOW BIOPHYSICAL PROFILE AND CORD PH.
APPARENT MECONIUM, AT LEAST IN THE PROXIMAL AIRWAYS, RULE OUT ASPIRATION.
RULE OUT SEPSIS.

12. At or about 7:50 p.m., following her admission to the

special care nursery, Sophia's oxygen saturation levels began to fall and she was re-intubated. Dr. Gallagher's progress note regarding the event read, as follows:

> THE BABY, DESPITE HAVING RELATIVELY CLEAR LUNGS STARTED DROPPING HER OXYGEN SATURATION AND HAD LOW BLOOD PRESSURES AND IS STARTED NOW ON DOPAMINE AND HAD NEGATIVE TRANSILLUMINATION OF THE CHEST WITH STAT CHEST X-RAY. WE HAVE RE-INTUBATED THE BABY AND THERE ARE SOME COURSE BREATH SOUNDS BUT WE HAVE NOT OBTAINED ANY MORE MECONIUM, AS YET. OBVIOUSLY, THE BABY IS AT SOME RISK FOR ASPIRATION PNEUMONITIS AND PERHAPS, PULMONARY HYPERTENSION AND WILL TRY TO MAINTAIN THE OXYGEN SATURATIONS AS BEST WE CAN AND SEE WHAT MIGHT BE CONTRIBUTING LOW BLOOD PRESSURE AT THIS POINT. WE HAVE ALREADY STARTED DOPAMINE AND WILL GIVE VOLUME BOLUS AS NEEDED AS WELL.

13. On January 3, 1997, the first postnatal day, Sophia remained in serious condition. Dr. Gallagher's progress note regarding her presentation that day read, as follows:

THE PATIENT HAS CONTINUED TO HAVE SEVERE METABOLIC ACIDOSIS OVERNIGHT. [S]HE HAS THUS FAR HAD NO URINE OUTPUT. WE HAVE KEPT THE FLUID SOMEWHAT RESTRICTED IN TERMS OF THE INTRAVENOUS BECAUSE OF THE INITIAL FETAL STRESS AND THE NEED FOR RESUSCITATIVE MEASURES, BUT, OF COURSE, WE HAVE GIVEN SOME BOLUSES OVERNIGHT OF BICARB AND HAVE GIVEN A SALINE BOLUS EARLIER.

THE PULSE PRESSURES AND MEAN BLOOD PRESSURES HAVE BEEN GOOD OVERNIGHT ON ABOUT EIGHT MICROGRAMS OF DOPAMINE. THE PERFUSION IS IMPROVED FROM EARLIER THIS MORNING, BUT IT IS STILL AROUND THREE TO FOUR SECONDS.

* * *

THE INITIAL CBC HAD SHOWN MARKED ELEVATION OF THE WHITE COUNT AROUND 50,000 WITH REPEAT PENDING TODAY. I HAVE BEEN TOLD THAT OVERNIGHT MOTHER HAD DEVELOPED FEVER AS WELL.

* * *

THE BABY IS SOMEWHAT MORE ACTIVE AND ALERT THIS MORNING DESPITE THE ONGOING ACIDOSIS, AND THE PUPILS APPEAR TO BE SOMEWHAT DILATED AND DO REACT. FONTANELLE IS SOFT, AND THE BABY MOVES ALL EXTREMITIES WHEN STIMULATED.

THIS MOST LIKELY REPRESENTS OVERWHELMING SEPSIS, AND THE OVERALL PROGNOSIS IS UNCERTAIN AT THIS POINT

14. Sophia remained hospitalized until January 30, 1997,

when she was discharged to her parent's care. Apart from matters

previously discussed, Sophia's history was described in

Dr. Gallagher's discharge summary, as follows:

THERE WAS QUESTION OF SEIZURE ACTIVITY OBSERVED AND BABY WAS STARTED ON PHENOBARBITAL BY THE FIRST POSTNATAL DAY. THERE WAS IMPROVING METABOLIC ACIDOSIS BY DAY TWO BUT STILL SOME LABILE OXYGENATION.

BY DAY THREE, THE BABY WAS WEANING SOMEWHAT ON HIGH FREQUENCY VENTILATOR, HAD BILATERAL AIR BRONCHOGRAMS THOUGHT TO BE CONSISTENT WITH EITHER PNEUMONITIS OR RESPIRATORY DISTRESS SYNDROME.

THE BABY ALSO DEVELOPED SOME THROMBOCYTOPENIA DURING THIS TIME AND ELEVATION OF THE WHITE COUNT BUT THE CLINICAL COURSE WAS CONSISTENT WITH SOME SORT OF AN INFECTIOUS PROCESS, PERHAPS A VIRAL PNEUMONITIS, ALTHOUGH THERE WAS NO CONFIRMATION OF THAT AT DISCHARGE.

OVER THE NEXT SEVERAL DAYS, THE BABY CONTINUED ON HIGH FREQUENCY VENTILATION UP TO 100 PERCENT OXYGEN WITH PRESUMED PULMONARY HYPERTENSION DURING THIS TIME AS WELL. AIR FLUID INTAKE WAS SUGGESTED AS POSSIBLE TO IMPROVE THE OUTPUT AND SHE REQUIRED SOME ONGOING SEDATION AS WELL.

THE EEG WAS DEFERRED INITIALLY BECAUSE OF THE HIGH FREQUENCY VENTILATOR.

THE BABY WAS TREATED PRESUMPTIVELY WITH ACYCLOVIR COURSE AS WELL ALTHOUGH THERE WAS NO GROWTH OF HFC ON THE CULTURES.

SHE GRADUALLY WEANED FROM FENTANYL DRIP. INITIAL ORGANIC ACID STUDIES WERE ALL ELEVATED, PRESUMABLY SECONDARY TO THE SEVERE METABOLIC ACIDOSIS AND THERE WAS NO ONGOING METABOLIC ACIDOSIS AT THAT POINT.

AROUND DAY 13, THE BABY WAS EXTUBATED AND SUBSEQUENTLY STARTED ON FEEDINGS. EEG AROUND THIS TIME WAS ABNORMAL WITH ATTENUATED BACKGROUND RHYTHM AND EXCESSIVE DISCONTINUITY. WAS THOUGHT TO BE CONSISTENT WITH DIFFUSE CEREBRAL DYSFUNCTION WITH NO SUBCLINICAL SEIZURE ACTIVITY NOTED ON IT.

THE BABY HAD SOME DIFFICULTY ADVANCING ON FEEDINGS, WAS JITTERY AT TIMES WITH WEAK CRY AND SUCK AND HAD MRI PERFORMED SUBSEQUENTLY WHICH SHOWED SIGNS OF MULTICYSTIC ENCEPHALOMACIA.

THE BABY DEVELOPED SOME COLD STASIS RELATED TO THE PROLONGED HYPERALIMENTATION.

THE BABY WAS DISCHARGED TO FOLLOW-UP WITH NEUROLOGIST AT ALL CHILDREN'S AND ALSO DR. PETRUSKY FOR THE FOLLOWING WEEK. ARRANGEMENTS WERE MADE WITH THE EIP PROGRAM AS WELL.

DISCHARGE MEDICATIONS: PHENOBARBITAL 6 MG Q.12.

FINAL DIAGNOSES:

1. TERM FEMALE.

2. STATUS POST PERINATAL STRESS WITH APPARENT HYPOXIC ISCHEMIC ENCEPHALOPATHY AND EVIDENCE OF ENCEPHALOMACIA ON MRI. THERE WAS ALSO INITIAL SEVERE METABOLIC ACIDOSIS AND CLINICAL SEIZURES ASSOCIATED WITH THIS.

3. APPARENT PNEUMONITIS, RESOLVED WITH NEGATIVE CULTURES.

The timing of Sophia's neurologic injury

15. To address the issue of whether Sophia's brain injury occurred "in the course of labor, delivery, or resuscitation in the immediate post-delivery period," as required for coverage under the Plan, Petitioners offered selected medical records relating to Mrs. Balandra's antepartum course, as well as those associated with Sophia's birth and subsequent development. Additionally, Mrs. Balandra testified on her own behalf, and Respondent offered the testimony of Dr. Donald Willis, a physician board-certified in obstetrics and gynecology, as well as maternal-fetal medicine.

16. As for the timing of Sophia's injury, it was Dr. Willis' opinion, based on his review of the medical records, that Sophia's brain injury, and her ensuing neurological impairment, occurred prior to delivery.³ In so concluding, Dr. Willis noted that when Mrs. Balandra presented to her doctor on the day of delivery, she complained of decreased fetal movement, that during auscultation of the fetal heart rate in the doctor's office the fetal heart rate was low (into the 90-beat per minute range), and that when she presented at the hospital, her biophysical profile was abnormal, with a score of four out of eight. Dr. Willis further observed, that following admission, the fetal monitor strip revealed mild fetal tachycardia, with poor heart rate variability, and a spontaneous deceleration to 70 beats per minute. Moreover, Dr. Willis noted that on delivery, Sophia's Appar scores were depressed (at five, six, and eight, at 1, 5, and 10-minutes respectively), and the umbilical cord artery Ph was low, at 6.97 (acidotic). Finally, Dr. Willis noted "an umbilical artery Doppler [was done] which showed absent in -

diastolic flow . . . a sign of placental problems which . . . [are] associated with fetal distress."

In contrast to the proof offered by Respondent 17. regarding the timing of Sophia's injury, Petitioners offered no medical testimony regarding the timing of Sophia's injury. Consequently, given that Dr. Willis' opinion is logical and consistent with the other evidence, it must be resolved that Sophia's injury occurred prior to delivery and that, since Mrs. Balandra was not in labor at the time, Sophia's injury does not qualify for coverage under the Plan. See, e.g., Vero Beach Care Center v. Ricks, 476 So. 2d 262, 264 (Fla. 1st DCA 1985)("[L]ay testimony is legally insufficient to support a finding of causation where the medical condition involved is not readily observable."), and Thomas v. Salvation Army, 562 So. 2d 746, 749 (Fla. 1st DCA 1990)("In evaluating medical evidence, a judge of compensation claims may not reject uncontroverted medical testimony without a reasonable explanation.")

CONCLUSIONS OF LAW

18. The Division of Administrative Hearings has jurisdiction over the parties to, and the subject matter of, these proceedings. Section 766.301, <u>et seq.</u>, Florida Statutes.

19. The Florida Birth-Related Neurological Injury Compensation Plan was established by the Legislature "for the purpose of providing compensation, irrespective of fault, for

birth-related neurological injury claims" relating to births occurring on or after January 1, 1989. Section 766.303(1), Florida Statutes.

20. The injured "infant, his personal representative, parents, dependents, and next of kin," may seek compensation under the Plan by filing a claim for compensation with the Division of Administrative Hearings. Sections 766.302(3), 766.303(2), 766.305(1), and 766.313, Florida Statutes. The Florida Birth-Related Neurological Injury Compensation Association, which administers the Plan, has "45 days from the date of service of a complete claim . . . in which to file a response to the petition and to submit relevant written information relating to the issue of whether the injury is a birth-related neurological injury." Section 766.305(3), Florida Statutes.

21. If NICA determines that the injury alleged in a claim is a compensable birth-related neurological injury, it may award compensation to the claimant, provided that the award is approved by the administrative law judge to whom the claim has been assigned. Section 766.305(6), Florida Statutes. If, however, NICA disputes the claim, as it has in the instant case, the dispute must be resolved by the assigned administrative law judge in accordance with the provisions of Chapter 120, Florida

Statutes. Sections 766.304, 766.307, 766.309, and 766.31, Florida Statutes.

22. In discharging this responsibility, the administrative law judge must make the following determination based upon the available evidence:

(a) Whether the injury claimed is a birthrelated neurological injury. If the claimant has demonstrated, to the satisfaction of the administrative law judge, that the infant has sustained a brain or spinal cord injury caused by oxygen deprivation or mechanical injury and that the infant was thereby rendered permanently and substantially mentally and physically impaired, a rebuttable presumption shall arise that the injury is a birth-related neurological injury as defined in s. 766.303(2).

(b) Whether obstetrical services were delivered by a participating physician in the course of labor, delivery, or resuscitation in the immediate post-delivery period in a hospital; or by a certified nurse midwife in a teaching hospital supervised by a participating physician in the course of labor, delivery, or resuscitation in the immediate post-delivery period in a hospital.

Section 766.309(1), Florida Statutes. An award may be sustained only if the administrative law judge concludes that the "infant has sustained a birth-related neurological injury and that obstetrical services were delivered by a participating physician at birth." Section 766.31(1), Florida Statutes.

23. Pertinent to this case, "birth-related neurological injury" is defined by Section 766.302(2), Florida Statutes, to mean:

. . . injury to the brain or spinal cord of a live infant weighing at least 2,500 grams at birth caused by oxygen deprivation or mechanical injury occurring in the course of labor, delivery, or resuscitation in the immediate post-delivery period in a hospital, which renders the infant permanently and substantially mentally and physically impaired. This definition shall apply to live births only and shall not include disability or death caused by genetic or congenital abnormality.

24. As the claimants, the burden rested on Petitioners to demonstrate entitlement to compensation. Section 766.309(1)(a), Florida Statutes. <u>See also Balino v. Department of Health and</u> <u>Rehabilitative Services</u>, 348 So. 2d 349, 350 (Fla. 1st DCA 1977), ("[T]he burden of proof, apart from statute, is on the party asserting the affirmative issue before an administrative tribunal").

25. Here, given that Mrs. Balandra was never in labor, and Sophia's brain injury occurred prior to delivery, the proof failed to support the conclusion that, more likely than not, Sophia suffered an injury to the brain caused by oxygen deprivation or mechanical injury occurring in the course of labor, delivery, or resuscitation in the immediate post-delivery period in the hospital that rendered her permanently and

substantially mentally and physically impaired. Consequently, the record developed in this case failed to demonstrate that Sophia suffered a "birth-related neurological injury," within the meaning of Section 766.302(2), Florida Statutes, and the subject claim is not compensable under the Plan. Sections 766.302(2), 766.309(1), and 766.31(1), Florida Statutes. <u>See also Florida</u> <u>Birth-Related Neurological Injury Compensation Association v.</u> <u>Florida Division of Administrative Hearings</u>, 686 So. 2d 1349 (Fla. 1997), and <u>Nagy v. Florida Birth-Related Neurological</u> <u>Injury Compensation Association</u>, 813 So. 2d 155 (Fla. 4th DCA 2002).

26. Where, as here, the administrative law judge determines that ". . . the injury alleged is not a birth-related neurological injury . . . he [is required to] enter an order [to such effect] and . . . cause a copy of such order to be sent immediately to the parties by registered or certified mail." Section 766.309(2), Florida Statutes. Such an order constitutes final agency action subject to appellate court review. Section 766.311(1), Florida Statutes.

CONCLUSION

Based on the foregoing Findings of Fact and Conclusions of Law, it is

ORDERED that the petition for compensation filed by Mario Balandra and Rosemary Balandra, as parents and natural guardians of Sophia Balandra, a minor, be and the same is hereby denied with prejudice.

DONE AND ORDERED this 3rd day of October, 2002, in Tallahassee, Leon County, Florida.

> WILLIAM J. KENDRICK Administrative Law Judge Division of Administrative Hearings The DeSoto Building 1230 Apalachee Parkway Tallahassee, Florida 32399-3060 (850) 488-9675 SUNCOM 278-9675 Fax Filing (850) 921-6847 www.doah.state.fl.us

> Filed with the Clerk of the Division of Administrative Hearings this 3rd day of October, 2002.

ENDNOTES

1/ While Mrs. Balandra's antepartum course was without significant complication until January 2, 1997, she did present with a number of risk factors, including advanced maternal age, and a history of previous cesarean section and gestational diabetes (with the birth of her first child). Under such circumstances, Mrs. Balandra underwent antepartum testing (nonstress test, with amniotic fluid assessment) twice weekly from December 17, 1996, through December 31, 1996. All tests were reassuring, with reactive nonstress test and normal amniotic fluid index. Additionally, on December 18, 1996, following an automobile accident, Mrs. Balandra had a biophysical profile done at Sarasota Memorial Hospital, which was likewise reassuring with a maximum score of 8 out of 8 ("8/8") for fetal tone (2 points), fetal breathing (2 points), fetal movement (2 points), and amniotic fluid volume (2 points). 2/ The Apgar scores assigned to Sophia are a numeric expression of the condition of a newborn infant, and reflect the sum points gained on assessment of heart rate, respiratory effort, color, muscle tone, and reflex irritability, with each category being assigned a score ranging from the lowest score of 0 through a maximum score of 2. As noted, at one minute, Sophia's Apgar score totaled 5, with heart rate being graded at 2; respiratory effort, muscle tone, and reflex irritability being graded at 1 each; and color being graded at 0. At five minutes, Sophia's Apgar score totaled 6, with heart rate being graded at 2, and respiratory effort, color, muscle tone, and reflex irritability being graded at 1 each. At ten minutes, Sophia's Apgar score totaled 8, with heart rate, respiratory effort, and reflex irritability being graded at 2 each, and color and muscle tone being graded at 1 each. Such scores are low, and evidence of significant depression at birth.

3/ Here, since Sophia was delivered by cesarean section, it may be stated that delivery began at 6:42 p.m., when the cesarean section began and ended at 6:50 p.m., when Sophia was removed from the uterus. As for resuscitation in the immediate postdelivery period, "The Delivery Resuscitation Sheet" reflects that such period ran from Sophia's delivery at 6:50 p.m., until approximately 7:05 p.m.

COPIES FURNISHED: (By certified mail)

Mario Balandra Rosemary Balandra 3929 Groveland Avenue Sarasota, Florida 34231

Lynn Walker Wright, Esquire Wright, Railey & Harding, P.A. 2716 Rew Circle, Suite 102 Ocoee, Florida 34761

Kenney Shipley, Executive Director Florida Birth-Related Neurological Injury Compensation Association 1435 Piedmont Drive, East, Suite 101 Post Office Box 14567 Tallahassee, Florida 32312 Michael S. Finazzo, M.D. 1921 Waldemere Street, No. 307 Sarasota, Florida 34239

Sarasota Memorial Hospital 1700 South Tamiami Trail Sarasota, Florida 34239

Ms. Charlene Willoughby Agency for Health Care Administration Consumer Services Unit Post Office Box 14000 Tallahassee, Florida 32308

Mark Casteel, General Counsel Department of Insurance The Capitol, Lower Level 26 Tallahassee, Florida 32399-0300

NOTICE OF RIGHT TO JUDICIAL REVIEW

A party who is adversely affected by this final order is entitled to judicial review pursuant to Sections 120.68 and 766.311, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings are commenced by filing one copy of a Notice of Appeal with the Agency Clerk of the Division of Administrative Hearings and a second copy, accompanied by filing fees prescribed by law, with the appropriate District Court of Appeal. <u>See</u> Section 120.68(2), Florida Statutes, and Florida Birth-Related Neurological Injury Compensation Association v. Carreras, 598 So. 2d 299 (Fla. 1st DCA 1992). The Notice of Appeal must be filed within 30 days of rendition of the order to be reviewed.