IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge Philip A. Brimmer

Civil Action No. 10-cv-00868-PAB-CBS

MARIA GALLARDO and
D.R.G., a minor child by and through
her natural mother and next best friend, MARIA GALLARDO,

Plaintiffs,

v.

UNITED STATES OF AMERICA,

Defendant.

ORDER

The Court presided over a trial to the court in this Federal Tort Claims Act case, involving alleged medical malpractice in the birth of a child, from April 9 to April 24, 2012. The evidence and arguments of counsel raise three principal issues – whether the physician who delivered plaintiff D.R.G. violated the standard of care; if so, did such violation of the standard of care cause D.R.G.'s cerebral palsy; and, if that is the cause, what damages are D.R.G. and plaintiff Maria Gallardo entitled to receive. Pursuant to Federal Rule of Civil Procedure 52(a)(1), the Court makes the following findings of fact and conclusions of law.

I. FINDINGS OF FACT

A. Overview and Definitions

1. On February 11, 2007, plaintiff Maria Gallardo, age 32, was admitted to Memorial Hospital in Colorado Springs, Colorado, complaining of reduced fetal

movement. She was 40 weeks and three days pregnant with D.R.G.

2. Ms. Gallardo was placed on an electronic fetal monitor ("EFM") at approximately 3:00 p.m. that afternoon, which provided the medical staff with a continuous read out, or "strip," indicating the fetal heart rate as well as the strength and frequency of uterine contractions. Ms. Gallardo's attending physician and nurses monitored the EFM strip until D.R.G. was born at 2:22 a.m. on February 12, 2007.

3. Dr. Michael L. Hall, an obstetrician with nearly thirty years of experience, testified on behalf of the plaintiffs regarding the standard of care. As part of his testimony, he provided definitions for the various events one can see on an EFM strip. The experts in this case did not dispute these definitions. The most important aspects of an EFM strip, as described largely, though not exclusively, through the testimony of Dr. Hall, are the following:

a. A normal baseline fetal heart rate should be somewhere between 110 and 160 beats per minute and is assessed by looking at the heart rate over a ten-minute period. If the baseline heart rate exceeds that range, it is described as tachycardia. If it falls below that range, it is called bradycardia. Tachycardia and bradycardia can be signs of hypoxia, or lack of oxygen, and resulting build-up of excess acid in the baby, known as acidosis.

b. From the baseline, an obstetrician can identify accelerations and decelerations in heart rate, which are temporary changes in heart rate that do not constitute a new baseline.

c. Accelerations are defined as increases in fetal heart rate of at least fifteen beats per minute lasting at least fifteen seconds. An acceleration is a

reassuring sign regarding the health of the fetus.

d. A deceleration is a decrease in the fetal heart rate. There are different types of decelerations. A late deceleration begins after the start of a contraction, reaches its nadir after the contraction peaks, and resolves, or returns to baseline, after the contraction has completed. Late decelerations are a sign of hypoxia in the baby if variability is also decreased.[1] Early decelerations more closely mirror contractions and indicate some head compression during contractions. Variable decelerations are of short duration and are a sign of possible cord compression, causing ischemia, or a reduction of blood flow to the baby.[2] A prolonged deceleration is a deceleration lasting between two and ten minutes and is also a sign of possible hypoxia.[3] If it lasts for ten minutes, there has been a change in baseline.

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[1] *See* Ex. B-45, The American College of Obstetricians and Gynecologists, *Neonatal Encephalopathy and Cerebral Palsy: Defining the Pathogenesis and Pathophysiology*, at 26 (Jan. 2003) ("ACOG Green Book") ("Uterine contractions produce intermittent diminution in blood flow to the intervillous space where oxygen exchange occurs. If this intermittent interruption of flow exceeds a critical level, the fetal heart rate responds specifically with a pattern of late deceleration. Late deceleration begins as a vagal reflex; when fetal oxygenation is sufficiently impaired to produce fetal metabolic acidosis from anaerobic glycolysis, direct myocardial depression occurs. When the late deceleration is of the reflex type, the fetal heart rate tracing characteristically has good variability and fetal reactivity, but as the fetus develops metabolic acidosis, the fetal heart rate loses its variability.") (endnotes omitted).

[2] *See* Ex. B-45, ACOG Green Book, at 26 ("When the umbilical cord is compressed, a fetal heart rate pattern of variable deceleration develops.") (endnote omitted).

[3] *See* Ex. B-45, ACOG Green Book, at 26 ("If uteroplacental oxygen transfer is acutely and substantially impaired, the resulting fetal heart rate pattern is a prolonged deceleration.").

e. Variability, or the fluctuations in heart rate, is also an important aspect of interpreting EFM strips. Variability is the most sensitive indicator of whether a baby is suffering from hypoxia. The various ranges of variability are: absent, minimal, moderate, and marked. Minimal variability means fluctuation of less than five beats per minute. Moderate variability is six to twenty-five beats per minute. Marked variability means greater than twenty-five beats per minute.

f. In regard to uterine activity, obstetricians look for hyperstimulation and hypertonus. Hyperstimulation refers to contractions occurring at a more rapid pace than desired, which in 2007 was defined as more than five in a ten-minute period. It is often caused by the use of Pitocin, a synthetic form of oxytocin, used to induce or strengthen contractions. One potential intervention to reduce hyperstimulation is to administer Terbutaline, a medication that can slow the rate of contractions. Hypertonus refers to the uterine tone, or pressure, and is measured in millimeters of mercury. Normal resting tone of over twenty-five millimeters of mercury is abnormal. Hyperstimulation and hypertonus can both put additional stress on the baby, resulting in hypoxia because the baby needs time between contractions as well as sufficient relaxation of the uterine pressure to recover from the stress of a contraction.

B. Expert Witnesses

4. Four experts, Dr. Hall, Dr. Jeffrey McCutcheon, Dr. Michael Ross, and Dr. Robert Gore, referred to herein collectively as “the experts,” offered their opinions

regarding the standard of care in this case.[4]

5. Dr. McCutcheon was the obstetrician attending to Ms. Gallardo that day and who performed the delivery of D.R.G. Dr. McCutcheon, who has approximately seventeen years of clinical practice experience as an obstetrician, testified regarding the care he provided in this case, including his interpretation of the EFM strip.

6. As noted above, Dr. Hall is an obstetrician who testified on behalf of the plaintiffs regarding the standard of care.

7. Dr. Michael Ross also testified as an obstetrical expert on behalf of the plaintiffs, offering his own interpretation of the EFM strip. Dr. Ross is a highly experienced obstetrician and gynecologist who also specializes in maternal fetal medicine, which focuses on high risk pregnancy. He has clinical and research experience in obstetrics and maternal fetal medicine.

8. Defendants called Dr. Robert Gore, an obstetrician with approximately thirty years of clinical experience, to offer his opinions regarding the care provided in this case.

C. Chronology of Events During Labor

9. Shortly after Ms. Gallardo was placed on the EFM at about 3:00 p.m., Dr.

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[4]In regard to the standard of care, plaintiffs also called Patricia Fedorka, R.N., Ph.D., to testify regarding the care provided by the nurses during the labor and delivery in this case. Plaintiffs contend that Dr. Fedorka's testimony regarding the nurses' failure to recognize and appropriately respond to what she interpreted to be signs that the baby was in trouble is relevant because Dr. McCutcheon, as the "captain of the ship," is ultimately responsible. Defendant sought to exclude the testimony, arguing that the hospital that employed the nurses was no longer a defendant in this case, that the Federal Tort Claims Act does not permit the government to be held vicariously liable, and that the "captain of the ship" doctrine does not apply in any event. The Court addresses these arguments in its Conclusions of Law.

McCutcheon identified a deceleration in fetal heart rate. Some contractions were already occurring. Dr. McCutcheon decided to admit Ms. Gallardo to the hospital to augment labor. Dr. McCutcheon opted to use Pitocin to do so, a decision with which no expert has taken issue.

10. The various experts in this case generally agree that there were no indications on the early EFM strip that D.R.G. was in distress. However, Dr. McCutcheon and Dr. Gore explained why the strip was not sufficiently reassuring to justify sending Ms. Gallardo home.

11. A deceleration took place at approximately 6:00 p.m. that evening.

a. In response, Dr. McCutcheon and the nurses took certain interventions, including turning the Pitocin off, administering oxygen to Ms. Gallardo, having her change position, and giving her an infusion of fluids intravenously, known as an IV bolus.

b. In Dr. Hall's estimation, the baby's response to these interventions was excellent.

12. Dr. McCutcheon had Pitocin turned back on at approximately 6:30 p.m.

13. Through 7:25 p.m., Dr. Michael Ross, one of plaintiffs' obstetrical experts, interpreted the EFM strip as looking good. Dr. Hall interpreted the strip as remaining reassuring through 8:00 p.m.

14. Shortly after 8:00 p.m., Dr. McCutcheon added an internal uterine monitor, which is a pressure catheter that provides more accurate information than the external monitor regarding contractions and the level of uterine tone. The monitor revealed hyperstimulation and hypertonus.

a. At this point in the labor, Dr. Ross interpreted the pressure reading, or tonus, to be on the high end of the normal range.

b. Dr. Hall identified some mild variable decelerations at this point, possibly indicating some umbilical cord compression during contractions. Dr. Hall testified that Dr. McCutcheon ordered an amnioinfusion, which involves injecting fluid up near the baby in the amniotic cavity to attempt to prevent continued compression of the umbilical cord during contractions. That intervention, in Dr. Hall's opinion, was an appropriate response to the mild variable decelerations.

15. Despite the amnioinfusion, the EFM strip continued to show some minor variable decelerations as well as hyperstimulation and hypertonus.

a. Therefore, Dr. McCutcheon again turned the Pitocin off. Due to the fact that Pitocin is rapidly metabolized, turning off the Pitocin can quickly resolve hyperstimulation and hypertonus.

b. Dr. Hall noted that, after the Pitocin was turned off, the contractions did initially space out a little bit. Dr. Hall testified that the heart rate pattern was still good, which he viewed as a sign that the baby was healthy and responding appropriately at that point.

c. Dr. Ross indicated that, as of 8:51 p.m., the baby continued to do fine, demonstrating the ability to tolerate the uterine contractions.

16. The recurring mild variable decelerations continued after 8:51 p.m., but the baby appeared to be tolerating them well through at least 10:50 p.m., according to Dr. Ross.

17. At approximately 11:00 p.m., Ms. Gallardo's cervix was four centimeters dilated and 75% effaced, which refers to the thinning and shortening of the cervix. A "complete" cervix, ready for delivery, is dilated ten centimeters and is 100% effaced. The baby was still at a negative station, meaning still relatively high in the pelvis.

18. A prolonged deceleration commenced at approximately 11:00 p.m.

a. Dr. McCutcheon examined Ms. Gallardo after the prolonged deceleration.

b. Dr. Hall testified that it was appropriate for Dr. McCutcheon to examine Ms. Gallardo after the prolonged deceleration. Dr. Hall, however, would have done a caesarean section ("C-section") at this point because he believed that the prolonged deceleration was a sign that the baby was worsening. Dr. Hall nevertheless acknowledged that, after the prolonged deceleration, variability was still good.[5] When presented with a prolonged deceleration under these circumstances, Dr. Hall testified that a doctor may make a judgment call to let labor proceed for another 10 to 15 minutes, but not more than 20 minutes, before conducting a C-section in the absence of any improvement.

19. Dr. Hall described the EFM strip at 11:10 p.m. as "bizarre" and difficult to assess. Dr. Ross, however, testified that, as of 11:15 p.m., he would not have taken any additional interventions.

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[5]The reassuring signs identified by Dr. McCutcheon included variability (which he described as the most important indicator of the baby's acid/base status) and the presence of accelerations. Dr. Hall agreed that variability in the heart rate is the most sensitive indicator of fetal hypoxia. Dr. Hall testified that, if variability remains good, the significance of late decelerations is reduced.

20. Another prolonged deceleration occurred shortly after 11:30 p.m. At this point, the cervix was five centimeters dilated, 90% effaced, and the baby remained at a negative station.

a. Dr. McCutcheon testified about reassuring aspects of the strip preceding this deceleration, explaining how at 11:31 p.m. that evening there was a baseline of 120 beats per minute, with multiple accelerations and good variability. Although there were mild early decelerations with two contractions, he deemed the EFM strip at this point to be very reassuring. Dr. McCutcheon believed the heart rate showed good variability before and after the 11:30 p.m. prolonged deceleration. After the deceleration, however, it became more difficult to read the tracing; therefore, an external monitor was placed back on Ms. Gallardo along with the internal monitors. Both monitors remained in place for the remainder of the labor.

b. Dr. Hall testified that this prolonged deceleration was a sign of increasing hypoxia, from which it is difficult to recover at some point. He also identified elevated resting uterine tone.

21. At around midnight, Dr. McCutcheon saw good variability and a baseline of 140, with one mild early deceleration, five contractions in 10 minutes, and a good maternal pulse. Dr. McCutcheon thought this was a reassuring strip.

a. At approximately midnight, Dr. Hall identified continued hyperstimulation and hypertonus with reduced variability following the nonreassuring readings in the preceding time period. Dr. Hall believed something should have been done to address the hyperstimulation and

hypertonus.

b. Unlike Dr. Hall, Dr. Ross did not find the reduced variability in this time period to be a worrisome sign. Rather, he identified what he believed to be signs of quiet and active sleep states at around 12:20 a.m.

22. Through approximately 12:30 a.m., Dr. McCutcheon testified that the strip showed a baseline of 140, with an acceleration around 12:25 a.m. According to Dr. McCutcheon, this was followed by a period where he identified decelerations with contractions but also continued variability, though some of the variability was marked. Dr. McCutcheon also identified an acceleration after a contraction, which reassured him.

23. At approximately 12:35 a.m, there was a prolonged deceleration. Dr. McCutcheon examined Ms. Gallardo and discovered that her cervix had completely effaced, which he testified is often associated with such a heart rate response. Dr. McCutcheon monitored the heart rate and saw that it started to climb back up and showed good variability.

24. At 12:40 a.m., the cervix was fully dilated and 100% effaced, but the baby was still at a negative station. Dr. McCutcheon decided to have Ms. Gallardo start pushing. He expected, upon doing so, that delivery would happen relatively quickly as Ms. Gallardo had previously given birth naturally to two children, had a "roomy" pelvis, and there were no indications that the baby was especially big.

a. As discussed above, by this time, Dr. Hall believed that the baby was already struggling.

b. At the commencement of pushing, Dr. Ross interpreted the strip as

indicating that the baby was likely fine and demonstrating an ability to tolerate labor.

25. The first push occurred at 12:42 a.m. on February 12, 2007 and was followed by a prolonged deceleration. All the experts agreed that such a deceleration is concerning.

26. As a result of the prolonged deceleration, Dr. McCutcheon had Ms. Gallardo stop pushing for a few contractions. Dr. McCutcheon monitored the EFM strip and interpreted it as showing the heart rate was recovering and maintaining good variability.

a. He therefore had Ms. Gallardo start pushing again because he believed, based on her clinical presentation, that delivery would occur relatively soon.

b. Dr. Hall and Dr. Ross testified that the prolonged deceleration after the first push was followed by a period of too much pushing, too close together. As noted above, hyperstimulation refers to contractions occurring at more rapid pace than desired, which in 2007 was defined as more than five in a ten-minute period. Dr. Hall and Dr. Ross both believed that Maria Gallardo was experiencing hyperstimulation during the pushing phase with non-reassuring EFM patterns.

27. Dr. McCutcheon testified that, during the pushing phase, he identified deeper late decelerations, tachycardia, and some variability. Furthermore, he recognized both hyperstimulation and hypertonus. Dr. McCutcheon did not view the contractions as interrupting the heart rate from reaching a baseline. Rather, Dr. McCutcheon identified points he believed the heart rate reached plateaus, such as in

the minutes just after 1:00 a.m., which marked the baseline heart rate at approximately 160 beats per minute.

a. By 12:55 a.m., Dr. Hall identified what he considered to be an undulating ominous strip with periods of reduced variability. He testified that this indicates, as do the recurring late decelerations during the pushing phase, that the baby was becoming acidotic.[6]

b. At 12:55 a.m., Dr. Ross identified another deceleration with a late return. Dr. Ross described the EFM strip here as of significant concern, but did not describe it as undulating. Rather, he believed that the heart rate was not returning to any baseline that could be identified, being interrupted by contractions which prevented the heart rate from reaching its baseline. Consequently, Dr. Ross stated that, based on his interpretation of the meaning of "baseline variability," a term defined by the American College of Obstetricians and Gynecologists ("ACOG") in a set of guidelines published after the events of this case,[7] variability could not be determined. Dr. Ross testified that, in the face of such non-reassuring signs in the minutes preceding 1:00 a.m., Dr. McCutcheon should have recognized that the baby was becoming hypoxic and that continued pushing would further restrict blood flow. While most babies and placentas can tolerate such restriction during the pushing phase, Dr. Ross said

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[6] *See* Ex. B-41, Bruce K. Young, M.D., "Intrapartum fetal heart rate assessment," UpToDate, at 10 (last updated Jan. 10, 2012) ("If variability is decreased in the setting of repetitive decelerations and absent accelerations, we suggest delivery.").

[7] *See* ACOG Practice Bulletin No. 106, "Intrapartum Fetal Heart Rate Monitoring: Nomenclature, Interpretation, and General Management Principles," Ex. B-38, at 2.

that the EFM strip was indicating that this baby and placenta could not. Dr. Ross believed that Dr. McCutcheon at least should have had Ms. Gallardo stop pushing to see how the baby's heart rate would respond. The failure of the heart rate to return to baseline continued past 1:00 a.m.

c. All of the experts agree that late decelerations and tachycardia reflect potential hypoxia. Dr. Gore, however, testified that, while these signs are not normal, they do happen and that, for instance, in regard to hyperstimulation, babies are normally able to recover quickly between contractions. Dr. Gore agreed that no baseline could be determined during the pushing phase, but stated that the fetal heart rate maintained at least minimal variability throughout.

28. At 1:45 a.m., Dr. McCutcheon had Ms. Gallardo stop pushing because he was seeing deeper late decelerations and the baby had not been delivered as rapidly as he expected. The baby responded with a tachycardic heart rate between 180 and 190 beats per minute. Dr. McCutcheon stated that he believed the heart rate was slowly descending, which he interpreted as a sign that the baby was recovering from the normal stresses associated with the effort of pushing and the resulting maternal fever. During this period when no pushing took place, Dr. McCutcheon identified minimal to moderate variability with no decelerations during contractions. Dr. McCutcheon testified that babies can tolerate 180 beats per minute but he did not consider giving Terbutaline because it can cause the heart rate to go up.

a. Dr. Hall interpreted the lack of decelerations and tachycardia differently than Dr. McCutcheon. He believed the baby was not responding anymore and was in a "pre-death" pattern.

b. Dr. Ross testified that the tachycardia reflected fetal stress.

29. Dr. McCutcheon identified a late deceleration with a contraction at 1:59 a.m., while Ms. Gallardo was still resting. In response, Dr. McCutcheon examined Ms. Gallardo, found that the baby had rapidly descended, which he said can cause such late decelerations.[8] Dr. Gore stated that such rapid descent was a good sign and that it was reasonable to thereafter expect a rapid delivery.

30. In light of the rapid descent, Dr. McCutcheon decided to have Ms. Gallardo start pushing again at approximately 2:01 a.m. He testified that, in the end stages of labor, babies are under significant stress and become somewhat hypoxic, which can result in strips looking like the one in this case. Dr. McCutcheon could not tell how hypoxic the baby had become, but indicated that babies usually recover. In light of this strip, therefore, Dr. McCutcheon knew he did not have much additional time to have Ms. Gallardo continue with the plan of care for a vaginal delivery.

a. Dr. Gore shared Dr. McCutcheon's position that EFM strips like the one at this point in the labor can be seen due to the normal stress babies are under in the late stage of labor. Dr. Gore did, however, agree that an increasingly hypoxic baby is the worst case scenario.

b. Dr. Ross identified a dramatic prolonged deceleration when pushing was recommenced shortly after 2:00 a.m.

c. Dr. Hall described the remainder of the EFM strip to the point of

[8] *See* Ex. B-41, Young, at 9 (stating that the "[m]anagement of nonreassuring FHR patterns" includes determining the "likely cause of the abnormality, if possible," including "rapid descent of fetal head").

delivery as ominous.

31. D.R.G. was delivered at 2:22 a.m. Blood was drawn from the umbilical cord for testing, among other things, the acid/base status of D.R.G. These cord blood gases indicated that D.R.G. was severely acidotic at the time of delivery. Later brain scans revealed swelling and damage throughout many regions of the brain, which experts testified indicated a hypoxic-ischemic[9] brain injury. D.R.G. was eventually diagnosed with severe cerebral palsy.[10]

32. Throughout the labor, Dr. McCutcheon considered the possibility of a C-section. As labor progressed, Dr. McCutcheon testified that the risks associated with a C-section correspondingly increased. Dr. Gore testified that the risk of maternal death in a C-section is, overall, approximately 40 per 100,000 women, but that he believed the risk increases in unplanned C-sections. Dr. McCutcheon and Dr. Gore stated that C-sections also pose risks to internal organs, though they did not quantify this risk. Dr. McCutcheon said that there are also greater risks with heavier and shorter patients, like Maria Gallardo. In regard to whether a C-section at 2:00 a.m. would have made sense, Dr. McCutcheon said he probably could have done a C-section in 10-20 minutes, but he stated it is hard to predict how long it would actually take.

33. In summary, the experts each interpreted the EFM differently and disagreed regarding certain actions that should have been taken at various points in the labor.

a. Dr. McCutcheon discussed the non-reassuring signs on the EFM strip,

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[9]Ischemia refers to restriction in blood flow.

[10]Cerebral palsy is not formally diagnosed until a child is two or three years old.

but explained either how the interventions employed were effective or offered alternative explanations for the EFM signs. Dr. McCutcheon noted that labor was progressing and that Ms. Gallardo's clinical presentation led him to believe that delivery would happen relatively quickly. Moreover, Dr. McCutcheon identified reassuring signs he saw throughout that supported his conclusion that it was preferable to continue with the plan for a vaginal delivery.

b. Dr. Hall interpreted the EFM strip in this case to indicate that the baby was beginning to struggle as early as 11:00 p.m. that evening and that, as a result, Dr. Hall would have considered an operative delivery at that time. Dr. Hall would not have permitted the labor to continue for longer than another twenty minutes after 11:00 p.m. without signs of improvement on the EFM strip, which he never saw.

c. Dr. Ross opined that the baby began to struggle when Dr. McCutcheon had Ms. Gallardo start pushing at approximately 12:42 a.m. in conjunction with contractions she was experiencing. Dr. Ross believes that Dr. McCutcheon should not have permitted Ms. Gallardo to push with nearly every contraction for over an hour.[11] Dr. Ross believes Dr. McCutcheon should have had her stop pushing earlier to see how the baby responded and, if the baby did not show signs of recovery, he should have considered an operative delivery to prevent increased hypoxia during the pushing phase.

d. Dr. Gore identified at least minimal variability through the labor in this

[11]Dr. McCutcheon testified that, upon review of the uterine monitor strip, Maria Gallardo pushed with 19 of 22 contractions between 12:56 a.m. and 1:30 a.m.

case. Dr. Gore believed that, weighing the risks of a C-section against the low predictive value of EFM, Dr. McCutcheon's care in this case was reasonable.

D. ACOG Guidelines

34. ACOG issued clinical guidelines for the use of EFM in December 2005. *See* ACOG Practice Bulletin No. 70, "Intrapartum Fetal Heart Rate Monitoring" ("ACOG No. 70"), Ex. B-37. ACOG No. 70 discussed the widely varying interpretation of EFM strips and their limited predictive value. For example, ACOG No. 70 notes that different obstetricians interpret the same EFM tracing differently. *See* ACOG No. 70 at 4 ("There is a wide variation in the way obstetricians interpret and respond to EFM tracings. When four obstetricians . . . examined 50 cardiotocograms, they agreed in only 22% of the cases. Two months later, during the second review of the same 50 tracings, the clinicians interpreted 21% of the tracings differently than they did during the first evaluation.") (endnotes omitted).[12] ACOG No. 70 described EFM strips in terms of them being "reassuring," "nonreassuring," and "ominous." It also described them as "normal, equivocal, or ominous." ACOG No. 70 at 4. ACOG No. 70 advises obstetricians that, "in most cases, normal FHR variability provides reassurance about fetal status." Ex. B-37 at 5.[13]

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[12]ACOG 70 also concluded that "[r]einterpretation of the FHR tracing, especially knowing the neonatal outcome, is not reliable." Ex. B-37 at 7.

[13]Some witnesses also referred to an ACOG Practice Bulletin issued after the events in this case, which categorized EFM strips as normal (Category I), indeterminate (Category II), and abnormal (Category III). *See* Ex. B-38, ACOG Practice Bulletin No. 106, "Intrapartum Fetal Heart Rate Monitoring: Nomenclature, Interpretation, and General Management Principles," July 2009 ("ACOG No. 106"). A Category II strip apparently aligns roughly with what was formerly described as a "nonreassuring" or "equivocal" strip. Category II strips "are not predictive of abnormal fetal acid-base

35. Dr. Hall testified that a non-reassuring strip is predictive of hypoxic ischemic injury. ACOG No. 70 has a different view, noting that there is greater interpretive agreement among obstetricians "if the tracing is reassuring." Ex. B-37 at 4. Moreover, ACOG No. 70 states that "[t]here is an unrealistic expectation that a nonreasuring FHR tracing is predictive of cerebral palsy." *Id.* at 3 ("The false-positive rate is extremely high, at greater than 99%.").[14]

36. Dr. Hall testified that, in his view, reassuring strips have moderate variability and accelerations along with small variable decelerations and early decelerations. If there is moderate variability without accelerations, the strip would still be "more reassuring than not." Docket No. 182 at 27, l.17. Dr. Hall stated that the term "non-reassuring" refers to "everything else," such as diminished variability, late decelerations, moderate to severe variable decelerations, and prolonged decelerations. If the EFM strip lacks variability and has an unstable baseline, it is ominous or preterminal, according to Dr. Hall. Dr. Hall testified that an obstetrician should not let an EFM strip stay in a non-reassuring state indefinitely.

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status, yet presently there is not adequate evidence to classify these as Category I or Category III." Ex. B-38 at 2.

[14] *Cf.* Ex. B-45, ACOG Green Book, at 27-28 ("The correlation of intrapartum fetal heart rate patterns with outcome is problematic. Even if intrapartum fetal heart rate patterns were predictive of all bad outcome [sic] from hypoxia, there would be no value unless the patterns gave sufficient warning to allow the clinician to intervene and take appropriate action to prevent the bad outcome. If, however, abnormal patterns did give warning in sufficient time to prevent a bad outcome, there would be no correlation with outcome. Fetuses who are severely asphyxiated during the intrapartum period will have abnormal fetal heart rate patterns. However, most patients with nonreassuring fetal heart rate patterns give birth to neonates with normal Apgar scores. Abnormal electronic fetal heart patterns are poor predictors of subsequent development of cerebral palsy.") (endnotes omitted).

37. According to ACOG No. 70, when faced with a "persistently nonreassuring FHR tracing," an obstetrician should evaluate potential causes. Ex. B-37 at 6. "Initial evaluation and treatment may include:

- Discontinuation of any labor stimulating agent
- Cervical examination to assess for umbilical cord prolapse or rapid cervical dilation or descent of the fetal head.
- Changing maternal position to left or right lateral recumbent position, reducing compression of the vena cava and improving uteroplacental blood flow
- Monitoring maternal blood pressure level for evidence of hypotension, especially in those with regional anesthesia (if present, treatment with ephedrine or phenylephrine may be warranted)
- Assessment of patient for uterine hyperstimulation by evaluating uterine contraction frequency and duration"

Ex. B-37 at 6. ACOG No. 70 also notes that "[m]aternal oxygen commonly is used in cases of a persistently nonreassuring pattern." Ex. B-37 at 6.

38. "Often, the nonreassuring FHR patterns persist and do not respond to change in position or oxygenation." Ex. B-37 at 6. When such is the case, using a medication such as Terbutaline "to abolish uterine contractions and perhaps avoid umbilical cord compression" "has been suggested." Ex. B-37 at 6. However, ACOG No. 70 states that, "although [anti-contraction medication] appears to reduce the number of FHR abnormalities, there is insufficient evidence to recommend it." Ex. B-37 at 6.

39. ACOG No. 70 states that, "[w]hen the FHR abnormality is recurrent variable decelerations, amnioinfusion to relieve umbilical cord compression should be considered." Ex. B-37 at 7.

II. CONCLUSIONS OF LAW

A. Federal Tort Claims Act

On account of being employed by a federally funded clinic, Dr. McCutcheon is deemed to be an employee of the Public Health Service. *See* 42 U.S.C. § 233(g). As such, the physician is covered under the Federal Tort Claims Act ("FTCA"), 28 U.S.C. § 1346(b) and §§ 2671-80, pursuant to which the Court exercises jurisdiction over this case. The FTCA provides that the United States may be held liable for "the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred." 28 U.S.C. § 1346(b)(1).

Because D.R.G. was born in Colorado Springs, Colorado, the Court applies Colorado law in this case. In Colorado, "[a] medical malpractice action is a particular type of negligence action." *Day v. Johnson*, 255 P.3d 1064, 1069 (Colo. 2011) (citing *Greenberg v. Perkins*, 845 P.2d 530, 534 (Colo. 1993). "Like other negligence actions, the plaintiff must show a legal duty of care on the defendant's part, breach of that duty, injury to the plaintiff, and that the defendant's breach caused the plaintiff's injury." *Id.* at 1069-70 (citing *Greenberg*, 845 P.2d at 533).

B. Duty of Care

In Colorado, "the law implies that a physician employed to treat a patient contracts with his patient that: (1) he possesses that reasonable degree of learning and skill which is ordinarily possessed by others of the profession; (2) he will use

reasonable and ordinary care and diligence in the exercise of his skill and the application of his knowledge to accomplish the purpose for which he is employed; and (3) he will use his best judgment in the application of his skill in deciding upon the nature of the injury and the best mode of treatment." *Id.* at 1069 (citation omitted). "And, if he possesses ordinary skill and exercises ordinary care in applying it, he is not responsible for a mistake of judgment." *Bonnet v. Foote*, 107 P. 252, 254 (Colo. 1910) (citations omitted); *see Day*, 255 P.3d at 1070 (citing, *inter alia*, *Bonnet* and *Foose v. Haymond*, 310 P.2d 722, 727 (Colo. 1957) ("To avail himself of the defense of a mistake of judgment, it must appear that the physician used reasonable care in exercising that judgment.").

1. Captain of the Ship Doctrine

Plaintiffs contend that Dr. McCutcheon, as the "captain of the ship," is responsible for any and all negligence that may have occurred during the care of Ms. Gallardo and D.R.G., including any negligence by the nurses. Plaintiffs rely upon *Ochoa v. Vered*, 212 P.3d 963 (Colo. App. 2009), in support of their argument that Dr. McCutcheon can be held responsible for all acts of the nurses who assisted D.R.G.'s delivery. *Ochoa* does not stand for such a sweeping proposition. *Ochoa* stated that the "captain of the ship doctrine, which is grounded in respondeat superior, imposes vicarious liability on a surgeon for the negligence of hospital employees under the surgeon's control and supervision during surgery." 212 P.3d at 966. The cases the *Ochoa* court cites, *Beadles v. Metayka*, 311 P.2d 711, 713-14 (1957), and *Young v. Carpenter*, 694 P.2d 861, 863 (Colo. App. 1984) (involving liability of doctor supervising

a resident during the delivery of a baby), both stand for a more limited proposition.

For example, the *Beadles* court held that the following jury instruction was not improper: "'You are instructed that in the operating room the surgeon is master, and has exclusive control over the acts of the orderly and nurse, and is responsible for the negligence, if any, of the orderly or nurse, during the time the patient is being prepared for the operation in the operating room in accordance with the instructions of the surgeon, and in the presence of the surgeon.'" 311 P.2d at 714. The *Beadles* court proceeded to note that, outside the context of the specific facts of the case (where an anesthetized patient was injured upon being repositioned by an orderly at the direction of the surgeon) this instruction might indeed overstate things somewhat. However, the "personal presence of the physician and the actions of the orderly in response to the directions of the surgeon limits the instruction to this particular case and was not prejudicial." *Id.*

In support of its "captain of the ship" theory of liability, plaintiffs offered the testimony of Dr. Patricia Fedorka on the issue of whether the nurses were negligent in this case. There is no indication, however, that the nurses negligently performed any act that Dr. McCutcheon ordered while he was in the delivery room or out. *See Young*, 694 P.2d at 863 ("A crucial determination in establishing the applicability of the doctrine is the time when the surgeon assumes supervision and direction in the operating room."); *see also O'Connell v. Biomet, Inc.*, 250 P.3d 1278, 1283 (Colo. App. 2010) ("Several Colorado appellate opinions have specifically stated that '[o]nce the operating surgeon assumes control in the operating room, the surgeon is liable for the negligence

of all persons working under the surgeon's supervision.'") (citations omitted).[15] Consequently, the Court concludes that the "captain of the ship" theory is not implicated by Dr. Fedorka's testimony, including her contention that the nurses failed to go up the chain of command, and her testimony is not relevant to standard of care issues.[16] The Court, therefore, focuses on the testimony of Drs. Hall, Ross, McCutcheon, and Gore, along with the relevant exhibits upon which they relied, to determine whether there was a breach of the standard of care in this case.

2. Whether There was a Breach of the Applicable Standard

The Court finds that an obstetrician with a reasonable degree of learning and experience in February of 2007 would have been familiar with ACOG guidelines, including ACOG No. 70, which was issued in December 2005. The ACOG guidelines summarize the state of the research on certain issues at the time of their publication and offer obstetricians guidance on the implication of such research. The experts agreed that the ACOG guidelines were not prescriptions for care in specific circumstances, but rather provided general guidelines for clinical practice.

i. Predictive Value of EFM Strips

ACOG No. 70 informs obstetricians of the widely varying interpretations of EFM

[15]The *Young* case involved holding a doctor liable who was supervising a resident during the delivery of a baby.

[16]Because the Court agrees with defendant that the "captain of the ship" doctrine is not specifically implicated by Dr. Fedorka's testimony, there is no need to address defendant's FTCA waiver and vicarious liability arguments.

strips and their limited predictive value. *See supra* Finding of Fact No. 34.[17] It instructs that, upon reaching a certain interpretation, an obstetrician's confidence in its predictive value should be limited. *See supra* Finding of Fact No. 35.

Obstetricians with extensive learning and experience can reach various conclusions when reading the same EFM strip, as was demonstrated in this case. For instance, although Dr. Ross and Dr. Hall both believed that Dr. McCutcheon should have taken an alternative course, they disagreed regarding both the nature and timing of such alternatives based on their individual interpretations of the EFM strips. Dr. Hall interpreted the prolonged deceleration at 11:00 p.m. as a sign that the baby's condition was worsening and, therefore, would have conducted a C-section at that point or, in the absence of improvement, within 20 minutes. *See supra* Finding of Fact No. 18.b. As of 11:10 p.m., Dr. Hall believed the EFM strip was "bizarre." *See supra* Finding of Fact No. 19. Dr. Ross, however, when describing the strip at 11:15 p.m., testified that he did not believe there was any reason for Dr. McCutcheon to take any additional steps. *See supra* Finding of Fact No. 19.

Dr. Hall testified that a prolonged deceleration after 11:30 p.m. that evening was a sign of increasing hypoxia. *See supra* Finding of Fact No. 20.b. Dr. Ross, however, did not testify that he had any significant concerns regarding the baby's status at that point in the labor. Dr. Hall was troubled by reduced variability around midnight that evening, but Dr. Ross was not. Dr. Ross described reduced variability at around 12:20 a.m. as a sign that the baby was going through quiet and active sleep stages which was

[17]ACOG 70 also concluded that "[r]einterpretation of the FHR tracing, especially knowing the neonatal outcome, is not reliable." Ex. B-37 at 7.

not a sign of fetal distress. *See supra* Finding of Fact No. 21.b.

Dr. Hall identified both hyperstimulation and hypertonus before the commencement of pushing and believed Dr. McCutcheon should have done something to address these issues. Dr. Ross, however, did not believe that either the hyperstimulation or hypertonus, prior to pushing, required any additional interventions. Furthermore, ACOG No. 70 does not provide specific advice regarding how or whether an obstetrician should address hyperstimulation and hypertonus.

Dr. Hall believed the baby had been having difficulty long before the commencement of pushing at 12:40 a.m. and, therefore, concluded that Dr. McCutcheon should not have proceeded with a planned vaginal delivery. *See supra* Finding of Fact No. 24.a. Dr. Ross did not take issue with Dr. McCutcheon's decision to have Maria Gallardo start pushing (although he criticized Dr. McCutcheon's decision to continue pushing in light of prolonged decelerations), interpreting the strip as indicating that the baby was tolerating labor well prior to commencement of pushing. *See supra* Finding of Fact No. 24.b.; *cf.* Finding of Fact No. 26.b.

ii. Dr. McCutcheon's EFM Interpretation

The Court concludes that Dr. McCutcheon, who interpreted the EFM strip in this case as presenting a "persistently non-reassuring FHR tracing," Ex. B-37, ACOG No. 70 at 6, used reasonable and ordinary care in responding to such tracing and in proceeding with a vaginal delivery. At 11 p.m., Ms. Gallardo's cervix was four centimeters dilated and 75% effaced, with the baby at a negative station. The baby remained at a negative station at 11:30 p.m., by which time the cervix was five

centimeters dilated and 90% effaced. The cervix was fully dilated and effaced by 12:30 a.m., just prior to pushing. As of 1:59 a.m., the baby had rapidly descended. Dr. McCutcheon identified at least minimal variability through the labor, an interpretation that the Court cannot conclude was unreasonable.[18] Dr. Hall testified that "minimal" variability is an indicator of fetal hypoxia and resulting acidosis. However, as recently as January 10, 2012, a clinical information publication distributed to physicians stated that "less than moderate variability does not reliably mean the fetus is acidotic." Ex. B-41, Bruce K. Young, M.D., "Intrapartum fetal heart rate assessment," UpToDate, at 4 (last updated Jan. 10, 2012). With the presence of minimal to moderate variability, ACOG does not categorize this EFM strip in the "ominous" or, as later terminology would describe it, "abnormal" category.[19] What is clear from a review of ACOG No. 70, and even the later published ACOG No. 106, is that persistently non-reassuring EFM strips, such as this one, provide only a limited amount of clinical guidance to an obstetrician. *Cf.* Ex. B-41, Young, at 6 ("Whether there are FHR patterns that may

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[18]Dr. Gore identified at least minimal variability through the labor in this case.

[19]The ACOG Green Book notes that the "National Institute of Child Health and Human Development consensus report stated a normal fetal heart tracing consisting of a normal baseline rate, moderate fetal heart rate variability, presence of accelerations, and absence of decelerations is extremely predictive of a normally oxygenated fetus." Ex. B-45, ACOG Green Book, at 28. "The report also said patterns predictive of current or impending asphyxia placing the fetus at risk for neurologic damage include recurrent late or severe variable decelerations or substantial bradycardia, with *absent* fetal heart rate variability." *Id.* at 28-29 (emphasis added). With that said, "[a]bnormal fetal heart patterns have an extraordinarily high false-positive rate of predicting the development of cerebral palsy." *Id.* at 29; *cf.* Ex. B-41, Young, at 2 ("99.8 percent of nonreassuring FHR tracings are NOT associated with development of cerebral palsy. Furthermore, a fetal neurological disorder may be the cause (rather than the result) of FHR abnormalities.") (citing sources published in 1996 and 2000).

indicate fetal brain damage before labor is controversial. . . . [A] study of 300 neurologically impaired term singletons in whom 54 percent had a probable injury before labor reported one-half had a normal FHR pattern until birth.") (endnote omitted).

Based on the questionable interpretative and predictive reliability of EFM strips, particularly those that are non-reassuring or indeterminate,[20] ACOG No. 70 informs obstetricians to take certain non-operative interventions in the face of a persistently non-reassuring strip. *See* Ex. B-37, ACOG No. 70 at 6. There is no dispute in this case that Dr. McCutcheon responded to the EFM strip consistently with those suggestions. For example, ACOG No. 70 advises obstetricians, in the face of a persistently non-reassuring strip, to conduct a cervical examination to determine if there had been "rapid cervical dilation or descent of the fetal head." *Id.* In response to two particularly concerning decelerations in this case, Dr. McCutcheon did precisely that and discovered, first, rapid dilation and, second, descent of the baby. *See supra* Finding of Fact Nos. 23, 24, 29.[21] ACOG No. 70 implies that these alternative explanations might provide a more concrete explanation for the decelerations than the weak statistical connection between certain non-reassuring patterns and neurological injury. *See* Ex. B-45, ACOG Green Book, at 28 ("The two findings associated with the development of

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[20] *See* Ex. B-37, ACOG No. 70 at 4 (noting that there is "greater agreement if the tracing is reassuring").

[21] The Court notes that Dr. McCutcheon testified that, after the baby's heart rate elevated after pushing ceased around 1:45 a.m., he identified a slow recovery of the heart rate. The heart rate, however, appears to the Court to have stayed generally in the 180 to 190 beats per minute range for the approximately 16 minutes during which Ms. Gallardo was not pushing. Even if one were to assume that this EFM finding was indicative of harm, thus requiring a C-section, neither Dr. Hall nor Dr. Ross believed that intervention at this late stage would have prevented harm to D.R.G.

cerebral palsy were repetitive late decelerations of the fetal heart rate and a decrease in beat-to-beat variability. . . . [T]hese monitor findings had a very high false-positive rate for predicting cerebral palsy.").

Although Dr. Hall believes the EFM strip in this case required early operative intervention, no expert agreed with him on that point. Dr. Hall testified that a fetus cannot be left in Category II non-reassuring status for an indefinite period of time, a conclusion informed by his belief that the EFM strips are reliable predictors of fetal health.[22] In light of the guidance provided by ACOG, however, Dr. McCutcheon cannot be held liable for not adopting Dr. Hall's approach to EFM strips, given that ACOG No. 70 specifically cautions against concluding that EFM interpretation is predictive and reliable.[23] Dr. Gore testified that, faced with the lack of predictive reliability of an EFM strip such as the one in this case, an obstetrician must weigh the potential risks of proceeding with labor against the known risks of a C-section. When assessing the risks associated with a non-reassuring EFM strip, the ACOG Green Book informed obstetricians in 2003 that the "incidence of cerebral palsy has remained essentially

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[22] *Cf.* Ex. B-41, Young, at 10 ("Serial evaluation every 20 to 30 minutes is necessary if the FHR pattern remains nonreassuring. Expeditious delivery is indicated for persistent nonreassuring FHR patterns associated with acidosis or if the presence of acidosis cannot be excluded ([i.e.], category III tracings . . .)).").

[23] *See* Ex. B-41, Young, at 5 ("FHR patterns that are category II are not reassuring and are considered indeterminate. The fetus may not be acidotic; however, continuation of the clinical situation may result in fetal acidosis. Therefore, continued surveillance and evaluation of these patients is indicated. Intervention (provision of supplemental oxygen, change in position, treatment of hypotension, discontinuation of any uterotonic drugs) may be needed if additional assessment suggests a progressively worse situation."); *see also id.* at 7 ("Category II tracings are not predictive of abnormal fetal acid-base status, but require continued surveillance, evaluation, initiation of appropriate corrective measures as indicated, and reevaluation.").

unchanged despite the common use of intrapartum fetal heart rate monitoring in both high- and low-risk patients. This should not be surprising inasmuch as previous beliefs regarding the dominant contribution of intrapartum hypoxia to subsequent neurological abnormalities are unfounded." ACOG Green Book, at 28 (endnotes omitted).[24]

Dr. Ross testified about the effect of pushing and the need to slow labor down in order to permit the baby to rest. As discussed above, *see supra* Finding of Fact No. 27.b., his testimony was based in part on a different interpretation of the EFM strip during the pushing phase. Unlike Dr. Hall and Dr. McCutcheon, Dr. Ross indicated that no baseline heart rate could be determined during the pushing phase. That conclusion was based on a close reading of the definition of "baseline variability," a term defined in ACOG No. 106, which was published two years after D.R.G.'s birth. Moreover, Dr. Ross recounted advice he had been given about the need to slow labor down in the face of non-reassuring strips of this sort. While that may be good practice, he did not provide any basis for the Court to conclude that it is generally accepted and therefore would define the applicable standard of care in this case.

The Court concludes that Dr. McCutcheon identified the EFM strip events discussed in ACOG No. 70, demonstrating his reasonable degree of learning, and responded to them in a fashion that was consistent with the standard of care in his medical specialty. After the fact, different obstetricians interpreted various points in the

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[24] *Cf.* Ex. B-45, ACOG Green Book, at 27 ("Some studies showed increased cesarean delivery rates in patients who had intrapartum electronic fetal monitoring, which led to criticism of fetal heart rate monitoring from a cost-benefit standpoint and controversy over the value of the technique.") (endnotes omitted); Ex. B-41, Young, at 2 ("The major disadvantage of continuous FHR monitoring was that it led to higher operative delivery rates . . . without an associated neonatal benefit.") (endnote omitted).

labor differently and reached different conclusions regarding appropriate plans of care. The standard of care in the face of persistently non-reassuring EFM strips in February 2007 could include such a wide range of approaches. In sum, plaintiffs have not demonstrated by a preponderance of the evidence that a reasonably cautious obstetrician in 2007 would have been required to either slow down labor through administration of Terbutaline or through additional rest of Ms. Gallardo, or perform a C-section before 2:22 a.m. Consequently, plaintiffs have not shown that Dr. McCutcheon's decisions, based upon his interpretation of the EFM strip and clinical assessment of Ms. Gallardo at various points in the labor, constitute failures to diligently provide reasonable care or to exercise his best judgment in light his interpretation of the EFM strip and the entire clinical presentation.

III. CONCLUSION

The brain injuries suffered by D.R.G. are profound and have deprived her of the hallmarks of a normal life. Moreover, her condition has placed many burdens on D.R.G. and her family, especially Mrs. Gallardo, who the testimony showed to be an extraordinarily dedicated and caring mother. Nevertheless, because the Court finds that there was no breach of the standard of care, defendant cannot be held liable for any damages suffered by D.R.G. regardless of when her injuries occurred and how such injuries might have been caused. Therefore, it is

ORDERED that judgment shall enter in favor of defendant and against plaintiffs.

DATED June 28, 2012.

BY THE COURT:

s/Philip A. Brimmer
PHILIP A. BRIMMER
United States District Judge