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UNITED STATES COURT OF APPEALS

TENTH CIRCUIT

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

Plaintiffs - Appellants,

v.

UNITED STATES OF AMERICA,

Defendant - Appellee.

No. 12-1325

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLORADO (D.C. No. 1:10-cv-00868-PAB-CBS)

Michael Goodman, PC, Englewood, Colorado, (William G. Fischer, PC, Colorado Springs, Colorado, with him on the briefs), for Plaintiffs-Appellants.

Laurie K. Dean, Special Assistant United States Attorney, (John F. Walsh, United States Attorney, with her on the brief), Denver, Colorado, for Plaintiff-Appellee.

Before **BRISCOE**, Chief Judge, **HOLLOWAY**^{*} and **HOLMES**, Circuit Judges.

^{*} The late Honorable William J. Holloway, Jr., United States Senior Circuit Judge, participated as a panel member when this case was heard, but passed away before final disposition. "The practice of this court permits the remaining two panel judges, if in agreement, to act as a quorum in resolving the appeal." <u>United</u> (continued...)

BRISCOE, Chief Judge.

Plaintiffs Maria Gallardo and her minor child, DRG, who was born with cerebral palsy, filed this action against the United States of America pursuant to the Federal Tort Claims Act. Plaintiffs claimed that the performance of Ms. Gallardo's attending obstetrician, Dr. Jeffery McCutcheon, fell below the applicable standard of care during the labor and delivery of DRG. After conducting a bench trial, the district court found in favor of the United States. Plaintiffs now appeal. Exercising jurisdiction pursuant to 28 U.S.C. § 1291, we affirm the judgment of the district court.

Ι

Factual background

On the afternoon of February 11, 2007, Ms. Gallardo went to Memorial Hospital in Colorado Springs, Colorado, complaining of reduced fetal movement. At approximately 3:10 p.m., a triage nurse placed an electronic fetal monitor (EFM) on Ms. Gallardo. The EFM strip (i.e., the paper printout produced by the EFM) showed some reactivity, but also showed a deceleration in the fetal heart

^{*(...}continued)

<u>States v. Wiles</u>, 106 F.3d 1516, 1516 n.* (10th Cir. 1997); <u>see also</u> 28 U.S.C. § 46(d) (noting circuit court may adopt procedure permitting disposition of an appeal where remaining quorum of panel agrees on the disposition). The remaining panel members have acted as a quorum with respect to this opinion.

rate. Based upon these circumstances, and the fact that Ms. Gallardo was experiencing some early contractions, Ms. Gallardo's attending physician, Dr. McCutcheon, admitted her to the hospital. Dr. McCutcheon, a board-certified obstetrician and gynecologist, was employed as the clinical director of the Women's Care Center at Peak Vista Community Health Center, a federallyoperated facility that provided a variety of health services to underprivileged patients in the Colorado Springs area.

At approximately 5:00 p.m., Dr. McCutcheon ordered the nursing staff to administer Pitocin to Ms. Gallardo via an intravenous line (IV). Pitocin, a synthetic form of oxytocin, is used to induce or strengthen contractions. At approximately 5:30 p.m., Dr. McCutcheon ordered the amount of Pitocin to be increased slightly. Shortly before 6:00 p.m., the EFM strip showed a late deceleration. A late deceleration begins after the start of a contraction, reaches its nadir after the contraction peaks, and returns to baseline after the contraction has completed. Late decelerations are a sign of fetal hypoxia (lack of oxygen) if heart rate variability is also decreased. Because of the late deceleration, Dr. McCutcheon ordered the Pitocin to be turned off. To address any possible fetal hypoxia, the staff also changed Ms. Gallardo's position and administered oxygen and an IV bolus to Ms. Gallardo. By 6:30 p.m., the EFM strip appeared normal again. Consequently, Dr. McCutcheon ordered the Pitocin to be turned back on.

At approximately 7:40 p.m., the EFM strip began to exhibit

hyperstimulation, which is more than five contractions in a ten minute period of time. At approximately 8:00 p.m., Dr. McCutcheon ruptured Ms. Gallardo's membranes, placed a fetal scalp electrode on the baby's head to measure its heart rate and inserted a pressure catheter inside Ms. Gallardo's uterus in order to measure the contractions. Shortly thereafter, the staff began to see mild variable decelerations in the baby's heart rate. Variable decelerations are of short duration and are a sign of possible umbilical cord compression. Dr. McCutcheon responded by ordering an amniofusion, which involves injecting fluid up near the baby in the amniotic cavity in an attempt to alleviate cord compression. The amniofusion continued for the remainder of the labor and delivery.

At approximately 8:20 p.m., the nursing staff stopped the Pitocin because the EFM strip was exhibiting tachysystole. Tachysystole, also known as hyperstimulation, means an excessive number of contractions, generally defined as six or more contractions in a ten minute period. The baby responded positively to the Pitocin being turned off. However, tachysystole was consistently present throughout the remainder of the labor and delivery.

By 11:00 p.m., Ms. Gallardo was dilated four centimeters and at a -2 station (meaning relatively high in the pelvis). At approximately 11:10 p.m., the staff recognized that the EFM strip was exhibiting a prolonged variable deceleration. A prolonged deceleration is a deceleration lasting between two and ten minutes and is a sign of possible fetal hypoxia. Another prolonged

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deceleration occurred shortly after 11:30 p.m. At that time, Ms. Gallardo's cervix was dilated five centimeters and the baby remained at a negative station.

At approximately 12:35 a.m., another prolonged deceleration occurred. A member of the nursing staff allegedly examined Ms. Gallardo¹ and determined that she was completely dilated, but that the baby was still at a negative station. At approximately 12:42 a.m., Ms. Gallardo, pursuant to Dr. McCutcheon's instructions, began pushing. After one push, the EFM strip showed a prolonged deceleration. As a result of the prolonged deceleration, Dr. McCutcheon had Ms. Gallardo stop pushing for a few contractions.

Dr. McCutcheon continued to monitor the strip and interpreted it as showing that the baby's heart rate was recovering and maintaining good variability. In light of that, and because he believed that delivery would occur relatively quickly, Dr. McCutcheon instructed Ms. Gallardo to begin pushing again. At approximately 1:10 a.m., the EFM strip was showing persistent late decelerations, tachycardia (a baseline fetal heart rate exceeding the top normal rate of 160 beats per minute), and diminished variability. Variability is the most sensitive indicator of whether a baby is suffering from hypoxia. Minimal or diminished variability means fluctuation of less than five beats per minute. Minimal or diminished variability is considered abnormal; in contrast, moderate variability, which is six to twenty-five beats per minute, is considered reassuring.

¹ As we shall discuss below, this is a disputed fact.

The nursing staff responded to these concerning indications by giving Ms. Gallardo oxygen and an IV bolus and notifying Dr. McCutcheon. But the nursing staff also instructed Ms. Gallardo to keep pushing.

At approximately 1:30 a.m., the EFM strip continued to show persistent late decelerations. The nursing staff again notified Dr. McCutcheon and, from that point forward, he remained at Ms. Gallardo's bedside.² Dr. McCutcheon instructed Ms. Gallardo to stop pushing. The EFM strip, however, continued to indicate that the baby was experiencing tachycardia. And the internal pressure catheter indicated that the baseline hypertonus, i.e., the uterine tone or pressure, was elevated. In such conditions, the baby does not receive enough rest between contractions and is at risk of developing hypoxia.

Dr. McCutcheon instructed Ms. Gallardo to begin pushing again. The EFM strip indicated another prolonged deceleration, minimal variability, and tachycardia. Per Dr. McCutcheon's instructions, however, Ms. Gallardo continued to push and eventually delivered DRG at 2:22 a.m. DRG's cord gases at birth were severely acidotic with a base deficit of approximately 18.³ DRG was

² According to Dr. McCutcheon, he visited Ms. Gallardo's room twice during the first stage of labor, App. at 419, several times during the pushing phase, <u>id.</u> at 432, and ultimately remained in Gallardo's room from approximately 1:30 a.m. until delivery, <u>id.</u> at 450.

³ According to the evidence in the record, the threshold of metabolic acidosis that is associated with fetal injury is a base deficit of greater than or equal to 12.

initially diagnosed with hypoxic-eschemic encephalopathy. Ultimately, however, DRG was diagnosed with cerebral palsy.

Procedural background

On April 19, 2010, after exhausting the administrative remedies offered by the United States Department of Health and Human Services, Ms. Gallardo and DRG initiated this action by filing suit against the United States pursuant to the Federal Tort Claims Act (FTCA).⁴ The complaint alleged, in pertinent part, that Dr. McCutcheon's performance "fell below the standard of care" in several respects, Complaint at 7, including (a) "not properly interpreting the fetal monitoring strip," id., (b) "continuing to push with evidence of acidosis as evidenced by prolonged decelerations, minimal to absent variability, persistent late decelerations, and tachycardia, in the presence of tachysystole and uterine hypertonus," <u>id.</u> at 8, (c) "not initiating a cesarean section . . . at 0050 on February 12, 2007, if not before," id., and (d) "not properly interpreting the severity of the pattern demonstrated by the [fetal heart rate monitor]," id. Ms. Gallardo and DRG sought judgment against the United States "for the sum and amount of \$60,000,000.00 plus [their] cost [sic] in this action, [and] pre and post judgment interests [sic] in accordance with the law." Id. at 12.

The case was tried to the district court beginning on April 9, 2012, and

⁴ The complaint also asserted claims against the City of Colorado Springs. Those claims are not at issue in this appeal.

concluding on April 24, 2012. On June 28, 2012, the district court issued a written order finding in favor of the United States on plaintiffs' claims under the FTCA. Final judgment was entered in the case on June 29, 2012. Plaintiffs filed a timely notice of appeal.

Π

On appeal, plaintiffs assert seven separate challenges to the district court's order finding in favor of the United States. As outlined in greater detail below, we conclude that all seven of these challenges lack merit. And, for that reason, we affirm the district court's judgment in favor of the United States.

Standard of review

When a party appeals from a bench trial, we review the district court's factual findings for clear error and its legal conclusions de novo. <u>Roberts v.</u> <u>Printup</u>, 595 F.3d 1181, 1186 (10th Cir. 2010). We review "mixed questions of law and fact . . . 'under the clearly erroneous or de novo standard, depending on whether the mixed question involves primarily a factual inquiry or the consideration of legal principles.'" <u>Id.</u> (quoting <u>Estate of Holl v. Comm'r</u>, 54 F.3d 648, 650 (10th Cir. 1995)).

Substantive law applicable to plaintiffs' medical malpractice claims

In order to establish governmental liability under the FTCA, a plaintiff must establish that the injury at issue was "caused by the negligent or wrongful act or omission of any employee of the Government . . . 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." <u>Harvey v. United States</u>, 685 F.3d 939, 947 (10th Cir. 2012) (internal quotation marks omitted). Thus, in this case, "the FTCA mandates application of" Colorado state law "to resolve questions of substantive liability." <u>Id.</u> (internal quotation marks and brackets omitted).

Colorado law treats "medical malpractice action[s] [a]s a particular type of negligence action." <u>Day v. Johnson</u>, 255 P.3d 1064, 1068 (Colo. 2011). "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." <u>Id.</u> at 1068-69.

"A physician's duty arises out of a[n] [express or implied] contractual relationship when a physician undertakes to treat or otherwise provide medical care to another." <u>Id.</u> at 1069. "[I]n the absence of a special contract," Colorado "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." <u>Id.</u> "Further, if a physician possesses

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ordinary skills and exercises ordinary care in applying it, he is not responsible for a mistake of judgment." <u>Id.</u> Further, a physician "possessing ordinary skill and exercising ordinary care in applying it . . . does not guarantee a successful outcome." <u>Id.</u> "Thus, a medical malpractice claim requires more than proving a poor outcome; a breach of the applicable standard of care is required." <u>Id.</u>

"To establish a breach of the duty of care in a medical malpractice action, the plaintiff must show that the defendant failed to conform to the standard of care ordinarily possessed and exercised by members of the same school of medicine practiced by the defendant." <u>Id.</u> "That standard of care is measured by whether a reasonably careful physician of the same school of medicine as the defendant would have acted in the same manner as did the defendant in treating and caring for the patient." <u>Id.</u> "Thus, the standard of care for medical malpractice is an objective one." <u>Id.</u>

"Unless the subject matter of a medical malpractice action lies within the ambit of common knowledge or experience of ordinary persons, the plaintiff must establish the controlling standard of care, as well as the defendant's failure to adhere to that standard, by expert opinion testimony." <u>Melville v. Southward</u>, 791 P.2d 383, 387 (Colo. 1990). "The reason for the requirement of expert opinion testimony in most medical malpractice cases is obvious: matters relating to medical diagnosis and treatment ordinarily involve a level of technical knowledge and skill beyond the realm of lay knowledge and experience." <u>Id.</u> "Without expert opinion testimony in such cases, the trier of fact would be left with no standard at all against which to evaluate the defendant's conduct." <u>Id.</u>

The expert testimony in this case

At trial, plaintiffs relied on testimony from two expert witnesses: Dr. Michael Hall and Dr. Michael Ross. The government countered that evidence with two witnesses of its own: Dr. McCutcheon and expert witness Dr. Robert Gore. All four of these witnesses were board-certified obstetricians and gynecologists. Three of the four (Drs. Hall, McCutcheon and Gore) were in private practice in the State of Colorado. The fourth (Dr. Ross) had worked primarily as an academician (and teaching clinician) in the State of California.

Both Dr. Hall and Dr. Ross agreed that McCutcheon failed to properly interpret the EFM strip and erred by not performing a cesarean section. The precise details of their opinions differed, however. In Dr. Hall's opinion, Dr. McCutcheon could, and probably should, have performed a cesarean section at approximately 11:00 p.m. or shortly thereafter because, according to Hall's interpretation of the EFM strip, the baby was experiencing ischemic episodes during which it was not receiving enough oxygen. App. at 74-75, 93. Dr. Hall also opined that Dr. McCutcheon allowed Ms. Gallardo to engage in too much pushing, particularly in the time period after 12:50 a.m., and that a cesarean section should certainly have been performed at that time because, according to the EFM strip, the baby was exhibiting bradycardia (low heart rate). <u>Id.</u> at 85, 9394, 161, 213. Dr. Hall explained that, at that point, the risk to the baby from not performing a cesarean section was much greater than the risk to Ms. Gallardo from performing a cesarean section. <u>Id.</u> at 248-49. Lastly, Dr. Hall was of the belief that, because the excessive contractions did not cease after the Pitocin was stopped, there must have been an abruption in the placenta i.e., a serious condition in which the placenta partially or completely separates from the lining of the uterus. <u>Id.</u> at 78-79, 180. And that condition, he opined, necessitated a cesarean section.

Dr. Ross opined that the baby appeared to be healthy and doing fine up to approximately 12:35 a.m. Id. at 275. More specifically, Dr. Ross opined that it was not until the second stage of labor, i.e., the pushing phase, that the EFM strip began to indicate the development of severe acidosis on the part of the baby. Id. at 276. Dr. Ross agreed with Dr. Hall that it was unreasonable for Dr. McCutcheon to have Ms. Gallardo push with almost every contraction because it left the baby with little or no time to recover and, consequently, the baby rapidly accumulated acidosis. Id. at 281, 309. That acidosis, Dr. Ross opined, began building at approximately 12:30 a.m. (with the first push) and ultimately reached an injurious level, i.e., likely resulted in brain injury and ultimately cerebral palsy, at approximately 1:40 a.m. Id. at 307, 330. Thus, Dr. Ross testified, a cesarean section, or some other measure, should have been performed prior to that time. Id. at 307, 322. In sum, Dr. Ross opined that Dr. McCutcheon did not appropriately manage the baby, based upon the EFM strip, and thus breached the standard of care. <u>Id.</u> at 284.

Drs. McCutcheon and Gore, on the other hand, both testified that Dr. McCutcheon's actions fell within the standard of care. Dr. McCutcheon testified that when he admitted Ms. Gallardo to the hospital, there was nothing he was aware of that would have indicated a high-risk pregnancy. Id. at 415. In fact, Dr. McCutcheon testified, he believed she was at a decreased risk of having delayed labor or needing a cesarean section because she had previously delivered two babies vaginally and had what is referred to as a "clinically proven pelvis." Id. at 417. Dr. McCutcheon admitted, however, that the first stage of Ms. Gallardo's labor did not "go textbook smooth" and in fact "was a stressful situation." Id. at 432. Dr. McCutcheon also admitted that throughout Ms. Gallardo's labor "[i]t was an idea we might have to do" a cesarean section. Id. at 435. According to Dr. McCutcheon, he most seriously considered performing a cesarean section when Ms. Gallardo was at 4 centimeters (approximately 11:00 p.m.), and later on during the latter phases of the second stage of labor (approximately 2:00 a.m.). Id. at 436, 463. However, Dr. McCutcheon testified, in his opinion the EFM strip never reached a Category III because at all times he observed what he believed to be at least some minimal variability. Id. at 466. Dr. McCutcheon also testified that, based upon Ms. Gallardo's previous delivery history and his assessment of the baby as being "clinically small," he believed that Ms. Gallardo would rapidly

deliver once she started pushing. <u>Id.</u> at 449. Lastly, Dr. McCutcheon testified that he chose not to perform a cesarean section during the latter phases of the second stage of labor (after Ms. Gallardo had been pushing for a long period of time) because it would have taken a certain amount of time to move Ms. Gallardo from her delivery room to an operating room and to prepare the operating room for delivery, and because there is an increased risk of injury (to both the baby and the mother) when doing a cesarean section on a woman who is completely dilated. <u>Id.</u> at 467.

Dr. Gore testified that, in his opinion, Dr. McCutcheon "acted in a reasonable and careful manner as a similar physician in similar circumstances," and was not "substandard in his care and treatment for Ms. Gallardo." <u>Id.</u> at 541. Dr. Gore proceeded to explain that, in his opinion, "electronic fetal monitoring has a [sic] extremely high false positive rate, an extremely low positive predictive value for certainly predicting cerebral palsy yet alone hypoxic-ischemic encephalopathy yet alone the severity of acidosis." <u>Id.</u> at 545. Dr. Gore agreed with Dr. McCutcheon that Ms. Gallardo was "relatively low risk" because of her two prior vaginal deliveries, and that it was reasonable for Dr. McCutcheon to induce Ms. Gallardo and plan for a vaginal delivery after induction. <u>Id.</u> at 551-52. Dr. Gore testified that there would have been risks associated with performing a cesarean section, with those risks being slightly increased at the end of the second stage of labor (when the baby was at a plus station). <u>Id.</u> at 556-57.

Dr. Gore also explained that, in his opinion, managing the second stage of labor is one of the hardest jobs for an obstetrician because it requires constant evaluation of the risk to the baby versus the risk to the mother. Id. at 557. In managing these risks, Dr. Gore testified, obstetricians "are constantly evaluating the [fetal monitor] tracing and the mother's previous clinical history, her previous delivery history, her body [weight]," and other factors. Id. Dr. Gore testified that all babies experience stress during labor and delivery, including a decrease in blood flow from the uterine contractions, and that the vast majority of babies tolerate that stress. Id. at 560. In particular, Dr. Gore testified that a tremendous number of babies with metabolic acidosis (developed during the delivery process) have no resulting disease or condition. Id. at 584. Dr. Gore also testified that he had never, in the course of delivering approximately 3,000 babies, performed a cesarean section just because of tachysystole (i.e., too many frequent contractions). Id. at 551. In sum, Dr. Gore opined that, in light of all the information Dr. McCutcheon had available to him during the labor and delivery of DRG, his prospective management and care was within the standard of care. Id. at 562.

The district court's decision

After considering all of this evidence, the district court "conclude[d] 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." Order at 25 (Dist. Ct. Docket No. 192). In reaching this conclusion, the district court relied heavily on guidelines and materials issued by the American College of Obstetricians and Gynecologists (ACOG) at or before the time of DRG's birth.⁵ To begin with, the district court noted that ACOG Bulletin No. 70 (ACOG No. 70) stated "that persistently non-reassuring EFM strips, such as this one, provide only a limited amount of clinical guidance to an obstetrician," id. at 26, and "informs obstetricians to take certain non-operative interventions in the face of a persistently non-reassuring strip," id. at 27. The district court also noted that "ACOG No. 70 implies that" rapid dilation and descent of the baby "might provide a more concrete explanation for . . . decelerations than the weak statistical connection between certain non-reassuring patterns and neurological injury." Id. Lastly, the district court noted that "ACOG No. 70 specifically cautions against concluding that EFM interpretation is predictive and reliable," id. at 28, and that "the ACOG Green Book informed obstetricians in 2003 that the 'incidence of cerebral palsy has remained essentially unchanged despite the common use of intrapartum fetal heart rate monitoring in both high- and low-risk patients," id. at 28-29.

⁵ There was general agreement among the expert witnesses in this case that the ACOG recommendations and technical bulletins are a valid source of data for a practicing obstetrician/gynecologist.

Although the district court acknowledged the differing opinions offered by Dr. Hall and Dr. Ross, it did not give those opinions controlling weight in determining the standard of care applicable to Dr. McCutcheon's conduct. For example, the district court acknowledged Dr. Hall's testimony "that 'minimal' variability is an indicator of fetal hypoxia and resulting acidosis," id. at 26, but noted that the ACOG publications were much more equivocal on this issue, and further noted that "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," id. (quoting Ex. B-41, Bruce K. Young, M.D., "Intrapartum fetal heart rate assessment," UpToDate, at 4 (last updated Jan. 10, 2012)). Likewise, although the district court noted that Dr. Ross "indicated that no baseline heart rate could be determined during the pushing phase" of labor in this case, it noted that Dr. Ross's "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." Id. at 29. And, the district court noted, although "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, ... 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." <u>Id.</u> Ultimately, the district court concluded that "[t]he standard of care in the face of persistently non-reassuring EFM strips in February 2007 could include [the]

wide range of approaches" advocated by the various experts in this case. <u>Id.</u> at 30.

Finally, the district court noted that "Dr. McCutcheon identified at least minimal variability through the labor, an interpretation that the Court [could not] conclude was unreasonable." <u>Id.</u> at 26. Similarly, the district court "conclude[d] 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." <u>Id.</u> at 29.

Plaintiffs' challenges to the district court's decision

1) Did the district court apply the wrong standard of care?

Plaintiffs first complain that the district court "ignored the standard of care established by" their expert witness, Dr. Ross. Aplt. Br. at 20. Indeed, plaintiffs assert, the district court "disregarded" that standard of care "based upon an erroneous interpretation of the meaning of standard of care in Colorado." <u>Id.</u> at 20-21. In support, plaintiffs note that the district court, in its findings of fact and conclusions of law, stated that while "Dr. Ross recounted advice he had been given about the need to slow labor down in the face of non-reassuring [EFM] strips of this sort, . . . 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." Order at 29. "This holding," plaintiffs argue, indicates that the district court "erroneously imposed a burden on Dr. Ross to provide extrinsic evidence to support his opinion as to the standard of care." Aplt. Br. at 21. But, they argue, "[n]o Colorado case requires that an expert reference external sources to show that his or her opinions are the correct standard of care." <u>Id.</u> The district court also, plaintiffs argue, "applied the wrong standard of care when it required Dr. Ross to establish the standard of care was 'generally accepted.'" <u>Id.</u> at 22. Indeed, plaintiffs argue, "[t]he Colorado Supreme Court has specifically rejected this requirement because the standard of care cannot be determined simply by counting how many physicians follow a particular practice." <u>Id.</u> (citing <u>State Bd.</u> <u>of Med. Exam'rs v. McCroskey</u>, 880 P.2d 1188, 1194 (Colo. 1994)).

<u>McCroskey</u>, the case cited by plaintiffs, involved an appeal from a disciplinary proceeding filed by the State Board of Medical Examiners against a physician. The administrative law judge who initially heard the case found that the defendant physician "did not violate the standard of care by applying the 'respectable minority' test," under which "a deviation from a higher standard of care practiced by the majority is excusable when it is shown that a respectable minority of physicians approved of the course of action selected." 880 P.2d at 1194. The Colorado Supreme Court, however, expressly overruled the respectable minority test. Citing its decision in <u>United Blood Serv. v. Quintana</u>, 827 P.2d 509 (Colo. 1992), the Colorado Supreme Court explained "that the standards of medical practice cannot be determined simply by counting how many physicians follow a particular practice." 880 P.2d at 1194. "In other words," the Colorado Supreme Court explained, "ascertaining the objectively reasonable standard of care is more than just a factual finding of what all, most, or even a 'respectable minority' of physicians do, although the actual practice in a community is certainly the starting point in any analysis." <u>Id.</u> at 1194-95. That is because "[t]he customary or prevailing practice may not be adequate or objectively reasonable in light of all the facts and circumstances." <u>Id.</u> at 1195.

The district court in this case ruled consistently with, rather than contrary to, McCroskey and Quintana. As we have outlined, the district court was presented, by way of expert witness testimony and references to various publications, with several differing opinions regarding how EFM strips should be interpreted and how much of a link there is between EFM values and cerebral palsy. More specifically, the evidence presented to the district court was conflicting regarding whether there is a link between cerebral palsy and high levels of acidosis that occur in some babies during labor and delivery. Dr. Ross represented the extreme end of this spectrum in terms of his opinions regarding the predictive value of the EFM values in this case and DRG's cerebral palsy. He opined that DRG was probably a "healthy baby that [didn't] ha[ve] any neurological compromise" at the outset of Ms. Gallardo's labor, App. at 271, and that DRG's neurological injury, which led to her cerebral palsy, occurred during the second stage of delivery, between approximately 1:30 and 1:40 a.m. on the

morning of her birth, once her "base deficit" (a term that relates to accumulated acidosis) reached a level of 12, <u>id.</u> at 305-07. Based upon these opinions, Dr. Ross in turn opined that Dr. McCutcheon breached the standard of care by failing to properly manage Ms. Gallardo's labor. <u>Id.</u> at 344.

The district court, however, chose not to accept Dr. Ross's testimony as defining the controlling standard of care because it was inconsistent not only with the opinions expressed by Drs. McCutcheon and Gore, but more importantly because it was inconsistent with the positions taken by ACOG in its publications and guidelines. In other words, the district court effectively determined that ACOG's positions, particularly its position that EFM strips have questionable predictive value when it comes to cerebral palsy, were adequate or objectively reasonable. And, by doing so, the district court did not necessarily impose any unwarranted burden on Dr. Ross. Rather, it simply chose to reject Dr. Ross's opinions on this point and, in the end, determined "the generally accepted standard of medical practice . . . by evaluati[ng] . . . the expert testimony in light of the controlling legal principles." <u>McCroskey</u>, 880 P.2d at 1195.

2) Did the district court erroneously disregard Dr. Hall's opinions?

Plaintiffs next argue that the district court erroneously disregarded the opinions of their other expert witness, Dr. Hall. In support, plaintiffs assert that the district court "found Dr. Hall had opined that his personal practice would have been to perform a c-section at 11:00 pm," and in turn "erroneously use[d] this

personal practice as a statement of the standard of care." Aplt. Br. at 23. In fact, plaintiffs argue, "Dr. Hall opined that the standard of care required Dr. McCutcheon to change his management and intervene, including potentially performing a c-section, based upon the baby's 10-minute deceleration in response to the first push at 12:42 a.m." <u>Id.</u> "These opinions," plaintiffs argue, "are similar to and consistent with Dr. Ross's." <u>Id.</u>

We reject plaintiffs' arguments. Although plaintiffs' expert witnesses, Drs. Hall and Ross, agreed that Dr. McCutcheon should have taken some preventive action, most notably performing a cesarean section, based upon the baby's tenminute deceleration in response to the first push at 12:42 a.m., they otherwise disagreed in a number of important respects. Indeed, the district court highlighted those differences in its opinion:

[A]lthough 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. As of 11:10 p.m, Dr. Hall believed the EFM strip was "bizarre." 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.

Dr. Hall testified that a prolonged deceleration after 11:30 p.m. that evening was a sign of increasing hypoxia. 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 around 12:20 a.m. as a sign that the baby was going through quiet and active sleep stages which was not a sign of fetal distress.

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. 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.

Order at 24-25 (internal citations omitted). Notably, plaintiffs do not challenge any of these findings as clearly erroneous, and, in any event, a review of the record on appeal indicates that the findings are well supported by the trial testimony.

Moreover, it is clear that the district court took into account the varying nature of the expert opinion testimony in this case, including all of Dr. Hall's testimony, in arriving at its conclusion that "[t]he standard of care in the face of persistently non-reassuring EFM strips in February 2007 could include a wide range of approaches." Order at 30. And, in turn, the district court evaluated Dr. McCutcheon's care in relation to this wide-ranging standard of care.

3) Did the district court apply a subjective standard of care?

Plaintiffs argue that the district court "erroneously established a standard requiring [them] to show that Dr. McCutcheon's personal interpretation of the [EFM strip] and his response in relation to his personal interpretation was unreasonable." Aplt. Br. at 25. In support, plaintiffs point to the following sentence in the district court's Order: "Consequently, plaintiffs have not shown that Dr. McCutcheon's decisions, based upon *his* interpretation of the EFM strip and clinical assessment of Ms. Gallardo as various points in the labor, constitute failures to diligently provide reasonable care or to exercise *his best judgment* in light of *his* interpretation of the EFM strip and the entire clinical presentation."

This argument is nonsensical. As the above-outlined principles of Colorado law make clear, it is precisely the decisions made by the defendant physician that are at issue in a malpractice case and that, necessarily, are compared to the appropriate standard of care. Thus, the district court did not err in examining Dr. McCutcheon's conduct in this case, including his interpretation of the EFM strip and his responses to those interpretations.

To the extent plaintiffs are attempting to argue that the district court accepted Dr. McCutcheon's personal interpretation of the EFM strip as the "correct" interpretation, the district court clearly did not do so. Rather, it found that the EFM strips in this case were "persistently non-reassuring," but could be interpreted and responded to in differing ways by a reasonable physician. Order at 30.

4) Did the district court erroneously find that Dr. McCutcheon examined Ms. Gallardo at 12:35 a.m.?

Plaintiffs next assert that the district court erroneously found that Dr. McCutcheon examined Ms. Gallardo at 12:35 a.m., in response to decelerations, when in fact the evidence presented at trial established that a nurse performed the examination of Ms. Gallardo. This factual error is significant, plaintiffs assert, because the district court relied on ACOG No. 70 to outline the standard of care in this situation, and ACOG No. 70 "recommends evaluation and intervention with non-reassuring EFM strips to protect the health of the mother and the baby." Aplt. Br. at 27. "In order to find . . . that Dr. McCutcheon met th[e] standard [of care outlined in ACOG No. 70]," plaintiffs argue, "the [district] court err[ed] in creating an examination that did not occur." <u>Id.</u> at 28.

Our review of the trial record persuades us that the district court clearly erred in finding that Dr. McCutcheon personally performed the 12:35 a.m. examination of Ms. Gallardo. Although the record firmly established that Ms. Gallardo was physically examined at 12:35 a.m., the record, as best we can tell, indicates that the examination was performed by a nurse rather than Dr. McCutcheon. And, notably, the United States does not argue otherwise in its appellate response brief.

But we agree with the United States that this error was harmless and did not affect plaintiffs' substantial rights. See Fed. R. Civ. P. 61. Dr. McCutcheon testified that during the labor portion of Ms. Gallardo's labor and delivery, he was "on the labor/delivery deck, which is the nursing station associated with the rooms around labor and delivery," and Ms. Gallardo's "room was directly adjacent to one of the nursing stations." App. at 422. Dr. McCutcheon further testified that he and the nursing staff communicated frequently throughout Ms. Gallardo's first stage of labor, id. at 432, and that he gave Ms. Gallardo his full attention from Ms. Gallardo's first push to the end of her delivery, id. at 450. Dr. McCutcheon also testified that he had confidence in the nursing staff's assessment of the extent of a patient's dilation. In sum, a reasonable inference from all of Dr. McCutcheon's testimony was that he relied upon the nursing staff's physical examinations of Ms. Gallardo, including the examination performed at 12:35 a.m. Consequently, we conclude that the district court did not err in determining that Dr. McCutcheon satisfied the standards outlined in ACOG No. 70. In other words, we agree with the government that "[w]hether Dr. McCutcheon personally performed the exam [at 12:35 a.m.], or had his concerns addressed by a nurse's exam, is not material to the district court's finding that Dr. McCutcheon appropriately responded to a concerning deceleration." Aplee. Br. at 39.

5) Did the district court fail to address plaintiffs' experts' most significant criticisms of Dr. McCutcheon?

Plaintiffs complain that the district "court's opinion lacks specific findings of fact for the period during which Dr. Hall and Dr. Ross were most critical of Dr. McCutcheon," i.e., "the period from the initiation of pushing at approximately 12:42 until approximately 1:45." Aplt. Br. at 28. And plaintiffs assert, citing the testimony of their expert witnesses, that "DRG's condition during this time—as evidenced by the EFM—[wa]s rife with signs that she [wa]s being deprived of sufficient oxygen due to excessive contractions, excessive pushing, and excessive uterine pressure." Id.

It is apparent, however, that the district court's Order contains specific findings of fact covering the time period from 12:42 a.m. through 1:45 a.m. <u>See</u> Order at 11-13. For example, the district court found that "[t]he first push occurred at 12:42 a.m. . . . and was followed by a prolonged deceleration" that "[a]ll the experts agreed . . . [wa]s concerning." <u>Id.</u> at 11. And, for each critical time segment during this period, the district court expressly noted the criticisms leveled at Dr. McCutcheon by plaintiffs' expert witnesses. <u>Id.</u> at 11-13. Thus, there is no merit to plaintiffs' argument.

Relatedly, plaintiffs argue that the district court "clearly erred by accepting Dr. McCutcheon's *assumption* of a baseline heart rate" during the period "from the initiation of pushing at 12:42 a.m. through 1:30 a.m." <u>Id.</u> at 30 (italics in

original). And the district court in turn erred, plaintiffs argue, "by reviewing Dr. McCutcheon's care based on the assumed baseline" and "erroneously conclud[ing] that the care was reasonable." <u>Id.</u>

In concluding that Dr. McCutcheon did not breach the standard of care, the district court did not necessarily agree with Dr. McCutcheon's interpretation of the EFM strip, particularly Dr. McCutcheon's conclusion that the strip indicated a baseline heart rate of "approximately 160ish," App. at 517, during the time period between 12:42 a.m. and 1:30 a.m.⁶ Rather, the district court merely concluded, consistent with statements in ACOG No. 70, that obstetrician interpretations of EFM strips can vary widely and that EFM strips have limited predictive value, particularly with respect to any connection between labor/delivery events and cerebral palsy. Although plaintiffs disagree with this conclusion, it is adequately supported by the trial record and therefore not clearly erroneous.

6) Did the district court fail to properly recognize the importance of EFM strips?

Plaintiffs argue that the district court "erroneously concluded that the standard of care requiring assessment and intervention is somehow obviated because EFM is not perfect." Aplt. Br. at 33. In support, plaintiffs argue that

⁶ A baseline heart rate is the mean fetal heart rate rounded to increments of five beats per minute during a ten-minute segment. A normal baseline heart rate is considered by ACOG to be between 110 and 160 beats per minute. A baseline heart rate exceeding 160 beats per minute is considered by ACOG to represent tachycardia.

"everyone but the court agreed that EFM provides information about the oxygen status of the baby" and "that the late decelerations in this case indicated hypoxia." <u>Id.</u> at 34. Plaintiffs further argue that the district court "selectively quote[d] and as a result misread[] ACOG No. 70," when, "[i]n fact, ACOG No. 70 supports use of EFM, and all of the doctors in this case use EFM to evaluate the oxygen status of the baby." <u>Id.</u> And, plaintiffs argue, "[w]hile EFM may not always predict when an injury will occur, it guides the standard of care because it notifies the physician that there is increased risk of injury." <u>Id.</u> at 35. In sum, plaintiffs argue, "[t]he standard of care is to use and pay attention to EFM, [sic] because it informs the physician if the baby is at risk of injury, not because it will predict whether a specific individual will suffer from cerebral palsy." <u>Id.</u> at 36.

There are at least two flaws in plaintiffs' arguments. To begin with, the district court concluded that the standard of care incorporated the use of EFM during labor and delivery. Where the district court departed from the plaintiffs' position, however, was in concluding that EFM strips have questionable predictive value with respect to the relationship between acidosis and resulting neurological injury to the baby, and its related conclusion that "[t]he standard of care in the face of persistently non-reassuring EFM strips in February 2007 could include . . . a wide range of approaches." Order at 30. Second, and relatedly, plaintiffs failed to present sufficient evidence linking DRG's cerebral palsy to the acidosis she experienced as a result of the labor and delivery. Indeed, the only

tangible evidence on this point was the testimony of Dr. Ross. The district court concluded, and we conclude reasonably so based upon the evidence presented to it, that Dr. Ross's opinions were outweighed by other evidence, including, in particular, ACOG's position that the rate of cerebral palsy has remained approximately the same over the last 30 years, despite the use of fetal heart rate monitoring.

7) Did the district court allow testimony concerning subsequent medical nomenclature?

In their final argument, plaintiffs assert that the district court erred by allowing the government to cross-examine plaintiffs' expert witness, Dr. Hall, "about a category system enacted in 2009 [i.e., ACOG's Category I through III nomenclature], approximately two and a half years after DRG's birth."⁷ Aplt. Br. at 37. By allowing testimony on this category system, plaintiffs argue, the district court "enhanced [their] burden of proof by requiring that they show Dr. McCutcheon breached the standard of care not only as of the date of DRG's delivery, but also when the care was analyzed under a system put in place subsequent to the delivery." <u>Id.</u> at 37-38. "We review a trial court's decision to admit evidence for abuse of discretion." <u>Ryan Dev. Co. v. Indiana Lumbermens Mut. Ins. Co.</u>, 711 F.3d 1165, 1170 (10th Cir. 2013)).

⁷ In 2007, ACOG categorized EFM strips as "reassuring," "non-reassuring," and "ominous." In 2009, ACOG revised these categories as "Category I," "Category II," and "Category III."

Our review of the record in this case persuades us that the district court did not abuse its discretion in allowing the government to cross-examine Dr. Hall regarding ACOG's category system. To begin with, the government correctly notes that plaintiffs' counsel did not timely object to the admission of ACOG No. 106, which outlined ACOG's 2009 categorization system. In any event, even assuming that plaintiffs' objection was timely preserved, our review of the record indicates that the government did not introduce ACOG No. 106 in an attempt to use it to establish the controlling standard of care in this case. Rather, the government simply used it as one tool for cross-examining Dr. Hall in order to clarify how obstetricians talk about and classify EFM strips.

Finally, even assuming that the district court should not have admitted the evidence, it is clear that the error was harmless. <u>See generally Storagecraft Tech.</u> <u>Corp. v. Kirby</u>, 744 F.3d 1183, 1190-91 (10th Cir. 2014) (noting that the erroneous admission of expert testimony is subject to harmless error review). In its written order, the district court focused properly on "[t]he standard of care . . . in February 2007." Order at 30. And in doing so, the district court relied heavily on ACOG No. 70, a publication that was issued prior to Ms. Gallardo's labor and delivery. To be sure, the district court briefly referenced ACOG No. 106, which was published after Ms. Gallardo's labor and delivery, but it did so only to highlight that ACOG No. 106 continued to agree with ACOG No. 70 "that persistently non-reassuring EFM strips, such as [the one in this case], provide only a limited amount of clinical guidance to an obstetrician." Id. at 26.

III

The judgment of the district court is AFFIRMED.