

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Alicia Dittrich-Bigley and
Justin Dittrich-Bigley,
Individually and as next
Friends of CDB, a minor,

Plaintiffs,

v.

**MEMORANDUM OPINION
AND ORDER**
Civil No. 11-1762 (MJD/FLN)

Gen-Probe, Inc., Individually
and d/b/a Gen-Probe Sales &
Service, Inc.,

Defendants.

Mark R. Mueller, Hunter Thomas Hillin and Breanne M. Vandermeer,
Mueller Law Offices, Counsel for Plaintiffs.

Michael D. Hutchens, Elizabeth Snyder Poeschl and Jon R. Russell,
Meagher & Geer, P.L.L.P., Counsel for Defendants.

Before the Court is Gen-Probe's motion to exclude the expert opinions of
Dr. Robert Lerer, Dr. Mark Schleiss, Dr. Sonny Bal and Casey Dye.

I. Background

Plaintiffs Alicia Dittrich-Bigley and Justin Dittrich-Bigley, Individually and

as Next Friends of CDB, a minor, brought this action against Defendants Gen-Probe, Inc. and d/b/a Gen-Probe Sales & Service, Inc. (“Gen-Probe”) alleging a number of claims, including strict liability, negligence and gross negligence.

Gen-Probe, a Delaware corporation, designed, manufactured and distributed the ACCUPROBE Group B Streptococcus Culture ID Test (“GBS Test”). (Second Amended Complaint ¶ 5.) Plaintiffs allege that Group B Streptococcus (“GBS”) is a major infectious cause of illness and death in newborns in the United States and early-onset¹ GBS infections are caused by the transmission of GBS from the mother to the newborn either during delivery or in utero just prior to delivery. (Id.)

In August 2002, the U.S. Centers for Disease Control and Prevention (“CDC”) recommended that pregnant women should be screened for GBS at 35 to 37 weeks gestation. (Id. ¶ 6.) The GBS Test manufactured by Gen-Probe is a rapid DNA test that utilizes the techniques of nucleic acid hybridization for the identification of GBS from culture. (Id. ¶ 7.) The GBS Test contains a probe reagent to identify GBS in a patient specimen, and Gen-Probe uses a TECAN brand automatic pipetting machine to fill each GBS Test vial with 0.1 mL of probe

¹Early onset GBS infections are those that occur within the first week of life.

reagent. (Id.) Following the production of each batch of GBS Tests, the tubing is filled with water. Prior to manufacturing each new batch of GBS Tests, the water in the tubing must be flushed out, or primed, to prevent the test vials from filling with water instead of the probe reagent or a combination of water and reagent.

(Id.)

Plaintiffs allege that on or around September 2008, a servicing technician for Gen-Probe installed new tubing on the TECAN machine. The 81 mL volume tubing was replaced with 101 mL tubing. As a result, the newly installed tubing held an additional 20 mL of water than the previously installed tubing. (Id. ¶ 9.)

The difference in tubing size was not taken into account, however, by the operators of the TECAN machine, and the priming program was not changed to reflect the difference. As a result, until the additional 20 mL was emptied from the tubing, a certain number of vials produced in each batch would be filled with water instead of the probe reagent. (Id. ¶ 10.)

On October 15, 2008, TECAN machine operators reported a problem to supervisors. In response, a molecular biologist at Gen-Probe, Michele Thomas, changed the priming program to a troubleshooting program, but the troubleshooting program only emptied 0.8 mL of water from the tubing during

priming. Thereafter, Thomas approved the machine for use. (Id. ¶ 11.)

On October 16, 2008, the TECAN operators allegedly failed to follow standard operating procedure and skipped required steps in beginning production of the GBS Test using the TECAN machine. As a result, the TECAN machine continued to run the troubleshooting program instead of the correct program, which resulted in only 0.8 mL of water emptied instead of 81 mL. (Id. ¶ 12.)

Problems with the TECAN machine were reported in November 2008. A message was left with Thomas to troubleshoot the machine. (Id. ¶ 14.) A few days later, Thomas investigated the reported problem and it was at this time that she realized the TECAN machine was running with the incorrect priming program and the correct program was restored. (Id. ¶ 15.) This issue was not investigated further. (Id. ¶ 17.) Plaintiffs allege that had it done so, Gen-Probe would have realized that the GBS Tests produced between October 15, 2008 and November 17, 2008, used an inappropriate program that emptied the incorrect amount of water during priming. Gen-Probe should have known that there was a number of kits that would not contain the improper amount of reagent, and that it was reasonably foreseeable that those users and consumers of such

defective kits would receive a false negative result for GBS colonization and would not receive appropriate prophylaxis. (Id.)

On December 3, 2008, Plaintiff Alicia Dittrich-Bigley was screened for GBS using a GBS Test manufactured after September 2008 as part of routine pre-natal care. (Id. ¶ 18-19.) The test result was negative. (Id. ¶ 19.) On December 18, 2008, she gave birth to her son, CDB via vaginal delivery. (Id. ¶ 20.) Plaintiffs allege the history and physical notes from the hospital indicate that, according to prenatal labs, Alicia was GBS negative. (Id.)

On December 23, 2008, Gen-Probe was notified by one of its customers that probe reagent vials contained in GBS Test kits were empty and contained no reagent. (Id. ¶ 21.) Gen-Probe investigated this report and concluded that at least twelve batches had been affected and may contain the incorrect amount of probe reagent or no probe reagent. (Id. ¶ 22.) It was later determined that an additional 18 - for a total of 30 - batches of GBS Tests were affected by the inadequate priming of the TECAN machine. (Id.)

On December 28, 2008, CDB was seen at the New River Medical Clinic with a low grade fever and decreased left arm movement. (Ex. B².) Radiology

²Unless otherwise noted, referenced exhibits are defense exhibits.

was negative for any left arm injury, but he was diagnosed with Erb's Palsy of the left arm. (Id.) The next day, CDB was seen at the Buffalo Clinic with the same symptoms. He was diagnosed with a left shoulder brachial plexus injury. (Ex. C.)

On December 30, 2008, CDB was admitted to the hospital because of a persistent low-grade fever and decreased left arm movement. (Ex. D.) He underwent a septic work-up wherein blood and cerebrospinal fluid ("CSF") was drawn. (Ex. E.) CDB's test results showed elevated C-reactive protein and white blood cell count. (Id.) The blood and CSF cultures did not identify GBS, or any other infectious agent, so CDB was treated with antibiotic against a broad spectrum of potential pathogens. (Id.) He was ultimately diagnosed with osteomyelitis, which is an acute bone infection that can be caused by GBS, Staphylococcus Aureus, Group A Streptococcus, Enteric Gram-Negative Bacilli or other organisms. (Ex. F; Ex. T (Expert Report of Dr. Don Goldman); Ex. U (Goldmann Dep. at 23-25).) Plaintiffs allege that CDB continues to suffer from the effects of this infection.

Also on December 30, 2008, Gen-Probe issued a voluntary recall notice to its customers and distributors of the GBS Test after it was determined that certain

assay tubes did not contain the probe reagent. (Am. Comp. ¶ 23.) The recall notice provided that physicians should be notified of the possibility that the affected batches could result in a false negative. (Id.) Alicia's physician was notified that the GBS Test performed on Alicia was done with one of the affected batches subject to the recall. (Id.)

CDB has been treating with Dr. Ann Van Heest, an orthopedic specialist, for his left arm issues. (Ex. H.) Dr. Van Heest's treatment has focused on non-surgical therapies to improve range of motion, strength and active functional use. (Id.) Dr. Van Heest believes that at the present time, it is premature to fully delineate what long term problems CDB will have over the next 14 years. (Id.) She believes there is a less than 50% chance that CDB will require arm lengthening surgery. (Ex. I; Ex. J (Van Heest Dep. at 28-29, 34).)

In the summer of 2010, CDB was seen by Dr. Matthew Griebie for suspected asthma. (Ex. L.) During a bronchoscopy, Dr. Griebie noted that CDB was unable to fully open his jaw. (Id.) CDB was then seen by Dr. James Swift, an oral surgeon, for his jaw issues. (Ex. M.) Dr. Swift diagnosed CDB with temporomandibular joint ankylosis and abnormal bone formation. (Id.) There are a number of causes of jaw ankylosis, including trauma, congenital anomalies,

developmental growth changes, infections, systemic joint conditions and heterotopic bone formation with trauma being the most common cause. (Ex. O (Opinion Letter of Dr. James R. Friction, DDS, MS).) Dr. Swift did not see any evidence of a bone infection when he examined CDB. (Ex. N (Swift Dep. at 14).) Dr. Swift does not have an opinion on what caused CDB's jaw ankylosis, but agreed that trauma is the most common cause. (Id. at 15-16.) CDB underwent a right TMJ arthroplasty with ankylosis release in April 2011. (Ex. R.) Dr. Swift stated that future surgical intervention for CDB is impossible to predict at this time. (Ex. N. (Swift Dep. at 29-31); Ex. S (Opinion Letter of Dr. James Swift).)

II. Standard under Rule 702

Rule 702 of the Federal Rules of Evidence provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

The role of the trial court is to serve as "gatekeepers to 'insure that the proffered expert testimony is both relevant and reliable.'" Wagner v. Hesston Corp., 450 F.3d 756, 758 (8th Cir. 2006) (quoting Anderson v. Raymond Corp., 340

F.3d 520, 523 (8th Cir. 2003)). In Daubert v. Merrell Dow Pharmaceuticals, Inc., the Supreme Court provided some general observations for the lower courts to consider in making determinations as to whether the scientific knowledge is relevant and reliable, such as whether it has been tested, subjected to peer review and publication, what is the known or potential rate of error, and whether it is generally accepted.” 509 U.S. 579, 593-95 (1993).

In Kumho Tire Company, Ltd. v. Carmichael, the Court extended the Daubert reasoning to non-scientist experts stating:

We conclude that Daubert’s general principles apply to the expert matters described in Rule 702. The Rule, in respect to all such matters, ‘establishes a standard of evidentiary reliability.’ It ‘requires a valid . . . connection to the pertinent inquiry as a precondition to admissibility.’ And where such testimony’s factual basis, data, principles, methods, or their application are called sufficiently into question, . . . the trial judge must determine whether the testimony has ‘a reliable basis in the knowledge and experience of the [the relevant] discipline.’

526 U.S. 137, 149 (1999) (quoting Daubert, 509 U.S. at 590-92) (citation omitted).

When addressing the reliability factor, the Court has held that “nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap

between the data and the opinion proffered.” Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997). Moreover,

[T]he factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination. Only if the expert’s opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded.

Bonner v. ISP Tech, Inc., 259 F. 3d 924, 929-30 (8th Cir. 2001) (citing Hose v. Chicago NW. Transp. Co., 70 F. 3d 968, 974 (8th Cir. 1996)).

III. Gen-Probe’s Motion to Exclude Expert Testimony

A. Testimony as to Reliability of GBS Test

Plaintiffs have designated a number of experts to provide expert medical opinions. Two of those experts, Dr. Robert Lerer and Dr. Mark Schleiss, have indicated on their expert disclosures that they would opine that had Ms. Dittrich-Bigley been tested with a reliable GBS Test, Ms. Dittrich-Bigley most likely would have tested positive for GBS. Gen-Probe argues that to the extent any of Plaintiffs’ expert opinions are based on the assumption that Ms. Dittrich-Bigley received a defective GBS Test kit, such opinion must be excluded.

Following its investigation of the allegedly defective GBS Tests, Gen-Probe determined only a small number of probe reagent tubes in the lots manufactured

in the period September to October 2008 were likely affected. (Ex. DD (Final Investigation Report at GP001848).) To determine the number of GBS Tests affected, Gen-Probe ran a mock fill experiment under the same manufacturing conditions as the affected batches. (Ex. DD (Final Investigation Report at GP001853); Ex. EE (Rockwell Dep. at 33-34).) The results of this experiment demonstrated that by vial 33 of each batch, 25% of the specified amount of probe reagent had been added to the vial. (Id.) Gen-Probe further notes that a probe reagent vial with only 25% of the specified amount of probe reagent is sufficient to detect GBS. (Ex. DD (Final Investigation Report at GP001856); Ex. EE (Rockwell Dep. at 34).)

The GBS Test kit administered to Ms. Dittrich-Bigley was within one of the affected batches - batch 553599. (Ex. DD (Final Investigation Report at GP001878).) Batch 553599 contained 18,615 probe reagent tubes. (Id.) Referring back to its experiment, if only 33 vials contained less than 25% reagent, Gen-Probe asserts there is only a .0018 probability that a tube being selected at random from batch 553599 contained less than 25% of the specified reagent. Gen-Probe further asserts that Dr. John Adams, who has a Ph.D. in statistics, analyzed the data and opined that only 16-25 of the tubes would have had less than 25% of

the reagent, resulting in only a .086 to .134% chance of receiving the tube with less than 25% reagent. (Ex. FF (Report of John Adams); Ex. GG (Adams Dep. at 20-21).)

Based on the above, Gen-Probe argues there is no evidentiary support for Drs. Lerer's and Schleiss's testimony that Ms. Dittrich-Bigley received a defective GBS Test kit, therefore they cannot reasonably conclude that it is more likely than not that Ms. Dittrich-Bigley received a defective kit.

Plaintiffs respond that aside from the obvious bias in conducting an internal mock fill experiment that could not be reproduced, and that health care providers were told to discard the affected GBS Test kits which prevented a count of the actual number of defective kits, the predictability that a certain number of GBS Test kits were defective is not the relevant inquiry. Instead, the inquiry is whether a given GBS Test kit was defective, and the proof is in the circumstances. According to the CDC, the chances are very high - 95 to 98% - that a nondefective kit will correctly determine the GBS status of the expectant mother. Plaintiffs thus argue it is reasonable to conclude that Ms. Dittrich-Bigley was GBS positive given the likelihood that CDB's osteomyelitis was acquired at birth due to an early onset GBS infection and the likelihood that GBS was the

causative agent due to its prevalence and the manner in which the disease process revealed itself.

To the extent that Plaintiffs' experts seek to provide an expert opinion that Ms. Dittrich-Bigley received a defective GBS Test kit, the Court agrees that such an opinion is not based on reliable evidence. While Plaintiffs challenge Gen-Probe's evidence that the probability that the subject GBS Test kit was defective is .086% to .18%, Plaintiffs concede that a nondefective GBS Test has a two to five percent chance of providing a false negative result. (Plaintiffs Mem. in Opp. at 15 (noting that the predictive value of a negative GBS test is 95-98 percent).) The record thus demonstrates that the probability of receiving a false negative result is slightly larger than the probability that Ms. Dittrich-Bigley received a defective GBS Test kit due to manufacturing errors. In addition, Dr. Lerer testified at his deposition that he did not intend to offer an opinion as to the adequacy of the GBS Test administered to Ms. Dittrich-Bigley. (Ex. JJ (Lerer Dep. at 25, 41).) Similarly, with regard to Dr. Adams' report, Dr. Schleiss testified that he would have to defer to an expert on how to interpret that kind of information to determine the implications of the aberrant batch of GBS Test kits at issue in this case. (Ex. NN (Schleiss Dep. at 27-28).) Accordingly, to the extent that Gen-Probe

moves to exclude any expert testimony that it is more likely than not that Ms. Dittrich-Bigley received a defective GBS Test, the motion will be granted.

The Court further finds that Dr. Lerer is not qualified to render the opinion that if a reliable test had been performed, Ms. Dittrich-Bigley would have tested positive. He admitted at his deposition that he does not have any expertise as to the reliability of GBS testing, and that he would not be providing an opinion as to the product at issue because he is not an obstetrician and does not perform such testing. (Ex. JJ, Lerer Dep. at 25.) In fact, in response to the question of whether a proper test could result in a false negative, Dr. Lerer testified “I’m not an expert in obstetrics. I think it’s a great question, but I’m not the person to answer it as an expert witness.” (Id. at 65.) He further admitted that he was unaware of the procedures required to obtain a reliable GBS test. (Id.) Dr. Lerer did clarify, however, that while he does not do the tests “if somebody asked me, Doctor, assume that there was something the matter with the test or the way the test was done, then could that result in a negative screen, then the answer is, of course, yes.” (Id. at 63.)

Based on Dr. Lerer’s admissions during his deposition, the Court finds that Dr. Lerer’s opinion that Ms. Dittrich-Bigley would have tested positive for GBS

had a reliable test been used has no reliable foundation and should thus be excluded. However, the Court finds that Dr. Lerer's opinion that generally, an unreliable GBS test or a GBS test performed incorrectly, could result in a false negative is properly supported and is thus admissible.

Similarly, Dr. Schleiss admitted that there are "a lot of issues with false negatives and false positives" with respect to GBS testing, but believed the tests had a "pretty high sensitivity and specificity." (Ex. NN (Schleiss Dep. at 32).) Dr. Schleiss was not able to address the probabilities the Ms. Dittrich-Bigley was given a reliable GBS test. (*Id.* at 29.) Accordingly, to the extent that Dr. Schleiss opined that if a reliable test had been performed, Ms. Dittrich-Bigley would have tested positive, such opinion is not based on a reliable foundation. Dr. Schleiss may, however, testify as to his general knowledge as to the accuracy of GBS tests.

B. Dr. Robert Lerer

Dr. Lerer has been retained by Plaintiffs as a medical expert. Based on his experience, education and training, and his review of CDB's medical records, Dr. Lerer has provided the following opinions:

- 1) CDB's osteomyelitis was more likely than not caused by Type III serotype streptococcus;
- 2) Type III serotype strep is detectable by routine GBS screening;

- 3) CDB had GBS on or prior to one week of age, based on the symptoms, persistent fever, and the natural course of this particular strain of strep;
- 4) CDB most likely contracted strep during the labor and delivery process;
- 5) If a reliable test for GBS had been performed, Ms. Dittrich-Bigley would have most likely tested positive;
- 6) If a positive test result had been obtained, Ms. Dittrich-Bigley would have received prophylactic antibiotics during labor; and
- 7) If prophylactic antibiotics had been administered, it is more likely than not that CDB would not have contracted osteomyelitis.

(Ex. II (Lerer Declaration at 2-3).)

1. Qualifications

Dr. Lerer is a pediatrician licensed and practicing medicine in Ohio. He obtained his degree from Johns Hopkins Medical School and completed his residency at Yale University & Yale-New Haven Hospital. He is board certified in pediatrics and received a specialized fellowship in neonatology. (Id. (Lerer Curriculum Vitae).)

Gen-Probe asserts that Dr. Lerer is not qualified to render the opinion that GBS caused CDB's osteomyelitis, as there is no evidence he possesses the specialized expertise in the etiology of osteomyelitis. Gen-Probe further argues that Dr. Lerer is not qualified to render an opinion about the efficacy of prophylactic antibiotics in preventing GBS infection in newborns or whether

antibiotics were administered because he is not an obstetrician or an infectious disease expert.

Gaps in an expert's qualifications generally go to the weight of the opinion, not to admissibility. See Robinson v. GEICO Gen. Ins. Co., 447 F.3d 1096, 1100 (8th Cir. 2006) (finding that "[m]ost courts have held that a physician with general knowledge may testify regarding medical issues that a specialist might treat in a clinical setting.") The Court finds that Dr. Lerer is qualified to provide opinions as to causation and to the efficacy of prophylactic antibiotics.

2. Causation

Generally, causation is divided into two components: general and specific. General causation is whether *X can* cause *Y*. Specific causation is whether *X did* cause *Y*. In a personal injury case, an opinion of specific causation may be made upon a differential diagnosis. In re Baycol Products Litig., No 02-1124, 2008 WL 8797733, at *7 (D. Minn. Aug. 25, 2008). While conducting a differential diagnosis is one way to satisfy the requirements of Rule 702 and Daubert, the admissibility of expert medical testimony nonetheless must be done on a case-by-case basis. Id. A differential diagnosis requires that all potential causes be considered, and then rule out the least plausible cause of injury until the most likely remains.

Glastetter v. Novartis Pharm. Corp., 252 F.3d 986, 989-90 (8th Cir. 2001).

Dr. Lerer has offered opinions as to specific causation in this case: that CDB's osteomyelitis and jaw ankylosis were caused by an early-onset GBS infection, and that he most likely contracted the infection during labor and delivery. (Ex. II (Lerer Declaration).) Gen-Probe argues that these opinions are not based on a reliable foundation or derived from reliable methodology.

Gen-Probe asserts that none of CDB's treating physicians made such a diagnosis, and CDB's symptoms were not those typical of a GBS infection. In fact, Dr. Lerer conceded that osteomyelitis from a GBS infection is very rare. (Ex. JJ (Lerer Dep. at 25-26).) Gen-Probe further asserts that Dr. Lerer did not perform a differential diagnosis to rule out other potential causes. In this case, Gen-Probe argues that a differential diagnosis is essential as there are a number of potential causes of osteomyelitis besides GBS, including: Staphylococcus Aureus, Group A Streptococcus, Enteric Gram-negative bacilli and a number of other organisms. (Ex. T (Expert Report Dr. Don Goldmann).) Gen-Probe asserts that Staphylococcus Aureus has been reported to be the most common cause of osteomyelitis in children. (Ex. X (Feign RD, et al., Textbook of Pediatric Infectious Diseases 713, 722 and Fig. 62-1 (5th Ed. 2005).)

Gen-Probe also argues that to the extent that Dr. Lerer bases his opinions on statistics, he does not provide any references to the literature upon which he relies, and at his deposition, he admitted that he did not do any literature research in connection with his expert opinion. (Ex. JJ (Lerer Dep. at 26).) If Dr. Lerer is relying on statistics generated from epidemiological studies, such reliance is improper as such studies are exclusively concerned with general causation - not specific causation. (Ex. KK (Reference Manual on Scientific Evidence, 608, 609, FEDERAL JUDICIAL CENTER 2011 (3d ed.).) In addition, Dr. Lerer admitted during his deposition that use of statistical probabilities is unreliable and an invalid methodology in establishing specific causation. (Ex. JJ (Lerer Dep. at 73-74).)

Dr. Lerer also identified CDB's jaw injury, which was not symptomatic for 1.5 years after delivery, as being linked to the early-onset GBS infection. Gen-Probe argues that there is no admissible medical evidence that the jaw ankylosis was caused by GBS or osteomyelitis. In addition, Dr. Lerer did not disclose this opinion in his expert report, therefore he should be precluded from offering such opinion pursuant to Rule 26(a)(2) and 37 of the Federal Rules of Civil Procedure.

Nonetheless, Gen-Probe argues such opinion is inadmissible. Dr. Lerer

testified that he believed his opinion was supported by medical literature, but did not reference such literature. He further stated that CDB's jaw ankylosis was caused by GBS, as a post infectious phenomenon, and that he was only repeating the opinions of CDB's treaters. (Ex. JJ (Lerer Dep. at 78).) Gen-Probe asserts that none of CDB's treaters holds such an opinion. Dr. Lerer further admitted that he had never treated a patient with jaw ankylosis caused by infection and he could not explain how CDB's jaw problem arose 1.5 years after birth, stating that you need to ask a dentist or orthopedist about that. (Id.)

Plaintiffs respond that Dr. Lerer intends to provide a general causation opinion based on medical literature and a specific causation opinion by reference to the literature in the context of the clinical facts of this case. Plaintiffs further assert that Dr. Lerer's opinions are well supported by medical literature. (Plaintiffs' Exs. W, U, Y, Z, AA, BB, CC, DD, EE, FF and GG.) Dr. Lerer also relies on statistics in providing a backdrop for his evaluation of this case, but he does not rely on statistics with regard to his opinion as to specific causation. Instead, he relies on the medical facts in this case in the context of what is known about the disease process.

Plaintiffs further assert that Dr. Lerer's opinion that CDB suffered from

early-onset GBS infection as the result of GBS transmission during delivery is not based solely on a hospital scan. Dr. Lerer also relies on the opinions of CDB's treating physicians that the abnormalities represented bone destruction due to GBS osteomyelitis. Just as Dr. Lerer did, the treating physicians were relying on the entire constellation of clinical facts rather than simply a bone scan.

Plaintiffs also argue that Dr. Lerer's opinion regarding the cause of the jaw ankylosis is sound and based on scientific principles and methodology. There is clear evidence of an osteomyelitis at birth that would be consistent with jaw ankylosis, and there is no evidence to support any of the other causes suggested by Gen-Probe. Other causes are effectively ruled out when there is no scientific basis to believe those medical facts exist.

Based on the record before it, the Court finds that there is a reliable foundation for Dr. Lerer's general causation opinions to be presented to a jury. With respect to the specific causation opinion that CDB's osteomyelitis was caused by an early-onset GBS infection, and that he most likely contracted the infection during labor and delivery - the Court finds such expert testimony sufficiently reliable under Rule 702. Gen-Probe is free to challenge the factual basis of such opinion at trial.

With respect to the specific causation opinion that CDB's jaw ankylosis was caused by an early-onset GBS infection, the Court finds that such opinion is not reliable. At his deposition, he testified that he was simply repeating the opinions of CDB's treating physicians that the jaw ankylosis was caused by an infection. (Ex. JJ (Lerer Dep. at 77).) However, there is no evidence in the record supporting this statement. In fact, Dr. Swift, CDB's treating oral surgeon, testified that he had no opinion as to what it was that caused CDB's ankylosis. (Ex. N (Swift Dep. at 15).) Accordingly, the Court will preclude Dr. Lerer from offering an opinion that the CDB's jaw ankylosis was caused by a GBS infection.

3. Antibiotic

Dr. Lerer also opines that if Ms. Dittrich-Bigley would have tested positive for GBS, she would have been given antibiotics, and that an antibiotic would have prevented an infection. Gen-Probe moves to exclude these opinions as Dr. Lerer is not an obstetrician, and is not qualified to provide an opinion on the standards of care or the protocols used concerning the circumstances under which an obstetrician would administer antibiotics. In addition, he is not an infectious disease expert and does not provide any foundation or methodology for his opinion that antibiotics would have prevented an infection. Dr. Lerer

admitted that he was not aware of the percentage of GBS-positive women who gave birth to a GBS-infected child after being given prophylactic antibiotics. (Ex. JJ (Lerer Dep. at 65).) Moreover, the CDC has reported that although intravenous administration of penicillin and ampicillin has been proven effective, alternative antibiotics and alternative administration have not. Dr. Lerer does not provide any opinion as to which antibiotic, or how, it would have been administered.

Plaintiffs respond that the CDC has reported that with antibiotic prophylaxis, the efficacy of preventing early-onset GBS infection in infants is as high as one hundred percent. (Plaintiffs' Ex. V (Morbidity and Mortality Weekly Report at 4).) There is thus support for Dr. Lerer's opinion that generally, antibiotic prophylaxis is an effective means to prevent early-onset GBS infection in infants.

Based on the above, the Court finds Dr. Lerer's opinions as to the efficacy of antibiotic prophylaxis in general are properly supported and are therefore reliable. Because it is Dr. Lerer's opinion that antibiotics are 100% effective in preventing early-onset GBS infections, it thus follows that Dr. Lerer's opinion that had Ms. Dittrich-Bigley been given antibiotics prior to CDB's birth, the antibiotics would have prevented infection in CDB is properly supported. Gen-

Probe is free to challenge Dr. Lerer on cross-examination as to the factual bases for these opinions.

C. Dr. Mark Schleiss

Dr. Schleiss is a pediatric infectious disease specialist and has been retained by Plaintiffs as a medical expert. Based on his review of CDB's medical records, medical literature and based on his experience, education and training, Dr. Schleiss has provided the following opinions:

- 1) CDB's osteomyelitis was caused by GBS;
- 2) CDB's Erb's palsy presentation was secondary to osteomyelitis;
- 3) Type III strep is detectable through routine GBS screening;
- 4) Staph would be a plausible, but less likely, explanation;
- 5) CDB most likely contracted GBS during the labor and delivery process;
- 6) If a reliable screening test for GBS had been performed, Ms. Dittrich-Bigley would most likely have tested positive;
- 7) The negative predictive value of GBS cultures at less than or equal to 5 weeks before delivery is 95-98% and would have been higher for Ms. Dittrich-Bigley;
- 8) If a positive test result had been obtained, such result would have allowed for timely treatment which would have prevented infection in CDB; and
- 9) Had prophylactic antibiotics had been administered, CDB would have been spared from infection and all of the attendant sequelae.

(Ex. MM (Schleiss Expert Disclosure).)

1. Causation

Gen-Probe asserts that CDB's medical providers have never confirmed a GBS infection in CDB. Moreover, the CDC has concluded that GBS infection is characterized by sepsis, pneumonia or meningitis and infants with early-onset GBS infections generally present with respiratory distress, apnea or other signs of sepsis within 24-48 hours, and CDB did not experience any of these conditions. Yet, Dr. Schleiss opines that CDB was infected with GBS. He testified that it is a medical probabilities situation. (Ex. NN (Schleiss Dep at 23).) To support his conclusion, he relies on three case studies. Gen-Probe argues that these studies do not support his opinions.

One article, *An etiologic shift in infantile osteomyelitis, The emergence of the group B streptococcus*, (hereinafter referred to as the "Edwards's Study") is a case series reporting on 21 infants who suffered from osteomyelitis between 1966-77. (Ex. OO.) The infectious agents were GBS (8), *Staphylococcus aureus* (6), gram-negative bacilli (4) and other agents accounted for the remainder. (*Id.* at 579.) Gen-Probe asserts this article does not support Dr. Schleiss' opinion that GBS is the most likely cause of osteomyelitis, as the majority of the infections described in this article were caused by an agent other than GBS. The article also involved

subjects that presented with single bone involvement where CDB presented with multiple bone involvement. (Id. at 581.) The authors also noted no functional deficits, whereas CDB is alleged to have suffered such deficits. (Id. at 582.)

The next article, *Skeletal infection by group B beta-haemolytic streptococci in neonates*, reports on one case of GBS osteomyelitis. (Ex. P P.) GBS was confirmed in that case - not in this case. Next, the report relates to late-onset GBS, here early onset is alleged. The report also involved single bone involvement, and the infant gained full use of the arm within five days. The authors noted that obstetric trauma appeared to predispose to infection. In this case, there is no evidence of obstetric trauma.

The final article is *Streptococcal Skeletal Infections, Observations in Four Infants*. (Ex. QQ.) GBS was confirmed in all four cases. The authors also noted that “traditional diagnostic methods [] are necessary for a bacteriologic diagnosis and optimal therapy.” (Id. at 467.) The authors noted that GBS confirmation is necessary for a bacteriologic diagnosis because GBS osteomyelitis in the cases resemble that observed in other forms of osteomyelitis. (Id.)

Gen-Probe further notes that Dr. Schleiss did not perform a differential diagnosis to rule out other causes even though other causes were discussed in the

literature upon which he relies. Dr. Schleiss agreed that it was possible that Ms. Dittrich-Bigley could have contracted GBS between the screening and delivery. (Ex. NN (Schleiss Dep. at 28-29).) He believes that CDB was infected during labor and delivery because that is the statistically most plausible explanation. (Id. at 28.)

Finally, Gen-Probe argues that Dr. Schleiss's causation opinions are based on speculation. At his deposition, he testified that the only unequivocal confirmation is to grow the organism by culture, and without that, it is just an educated guess. (Id. at 31-32.)

Although there are bases upon which to distinguish the above articles from the specific facts of this case, the Court nonetheless finds that the articles lend support for the general causation opinion that infant osteomyelitis may be caused by an early-onset GBS infection. Dr. Schleiss reviewed CDB's medical records and the relevant medical literature, and based on that review and his experience, he has rendered opinions as to the cause of CDB's injuries. Gen-Probe has not demonstrated that these opinions are so fundamentally unsupported so as not to offer any assistance to the trier of fact. Accordingly, Gen-Probe's motion to exclude Dr. Schleiss's opinions as to causation of CDB's osteomyelitis will be

denied.

2. Jaw Ankylosis Opinion

Gen-Probe argues that at his deposition, Dr. Schleiss indicated that he would provide the opinion that CDB's jaw issues resulted from the previously diagnosed osteomyelitis. (Ex. NN (Schleiss Dep. at 35).) Specifically, he testified that CDB's jaw was seeded during his acute hematogenous osteomyelitis. (Id.) He further testified that this opinion was based on a patient that he had treated years earlier, who had been diagnosed with osteomyelitis in the hip, and who later experienced complications in the jaw from the osteomyelitis. (Id.)

Gen-Probe argues Dr. Schleiss' opinion that CDB's jaw ankylosis was caused by osteomyelitis lacks a reliable foundation and is derived from unreliable methodology. The opinion is not based on references to any literature or studies that support such opinion. Instead, it is based solely on the case history of a prior patient he treated in 2003. (Id. at 35-36.) That case is distinguishable from this case, however, because the GBS infection was confirmed through cultures. (Id.) In addition, without seeing the patient or reviewing medical records, Dr. Schleiss merely surmised that the jaw issues in that child were the result of GBS infection. Gen-Probe asserts that even if

confirmed, it is merely one case report which is not a reliable basis for causation.

Additionally, Gen-Probe argues that Dr. Schleiss's opinion as to causation of CDB's jaw ankylosis is not reliable because he did not conduct a differential diagnosis to rule in osteomyelitis and rule out other causes.

The Court finds that Dr. Schleiss's experience as a pediatric infectious disease specialist, together with his experiences treating another patient with osteomyelitis and jaw ankylosis, the clinical facts of this case, and the absence of other factors that would point to another etiology, provides sufficiently reliable support for his conclusions as to the cause of CDB's jaw ankylosis. As with Dr. Lerer, Gen-Probe is free to challenge the factual basis of this opinion on cross-examination.

3. Antibiotic

Dr. Schleiss also opines that if Ms. Dittrich-Bigley would have tested positive for GBS, she would have been given antibiotics. Gen-Probe argues that Dr. Schleiss is not qualified to render such an opinion, as he has no experience in the area of obstetrics. As such, he cannot provide such an opinion on the standards of care, or the protocols concerning the circumstances under which an obstetrician would administer antibiotics. Dr. Schleiss also does not provide any

foundation or methodology for this opinion.

The Court finds that there is sufficient support in the medical literature to support the opinion that generally, antibiotic prophylaxis is an effective means to prevent early-onset GBS infection in infants. Accordingly, the Court finds Dr. Schleiss's opinions as to the efficacy of antibiotic prophylaxis in general is properly supported and is therefore reliable. It thus follows that his opinion that had Ms. Dittrich-Bigley been given antibiotics prior to CDB's birth, the antibiotics would have prevented infection in CDB is properly supported. Gen-Probe is free to challenge Dr. Schleiss on cross-examination as to the factual bases for this opinion.

D. Dr. Sonny Bal

Dr. Bal is an Associate Professor in the Department of Orthopaedic Surgery at the University of Missouri Health Care in Columbia, Missouri. He attended Cornell University Medical College, the University of California Hospitals and Clinics in General Surgery and the University of Missouri School of Medicine in Kansas City in the Orthopaedic Surgery Department. Dr. Bal reviewed CDB's medical records and has provided the opinion that to a reasonable degree of medical certainty, CDB will more likely than not require an arm lengthening

procedure as he grows and that he will require replacement of his entire left shoulder joint. (Ex. RR.)

1. Qualifications

Gen-Probe argues that Dr. Bal does not have the specialized expertise to render the opinion as to CDB's future care, as he has never treated a child with GBS caused osteomyelitis. Further, he has never performed pediatric surgeries, and he has never performed an arm-lengthening surgery on a patient of any age. His speciality is hip and knee replacements.

As noted previously, gaps in an expert's qualifications go to the weight of the opinion, not to admissibility. Dr. Bal is a board certified orthopedic surgeon, and as such, he is qualified to provide opinions as to orthopedic surgeries.

2. Reliability

Gen-Probe further argues that Dr. Bal's opinions are not based on a reliable foundation or derived from a reliable methodology. With regard to the opinion that CDB will require an arm lengthening procedure, Dr. Bal admitted that such opinion was not based on any research, just on his experience and simple reason. (Ex. S S (Bal Dep. at 15-16).) Dr. Bal further admitted that he did not know whether CDB even had an arm length discrepancy, and admitted that some of his

opinions may be speculative. (Id. at 20, 25, 26.) Gen-Probe further points out that Dr. Bal's opinion is contrary to the opinion of CDB's treating physician, Dr. Van Heest, that it is more likely than not that CDB will not need an arm lengthening procedure. (See Ex. I at 3.)

With regard to the opinion that CDB will need shoulder surgery, Gen-Probe argues that Dr. Bal has also failed to sufficiently explain the foundation of this opinion, and the methodology used to reach such opinion, other than stating it is based on his review of the medical records and his experience. Under Daubert, Gen-Probe argues that expert witnesses must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for an opinion and how that experience is reliably applied.

There is no dispute that CDB suffered from osteomyelitis, and that CDB has suffered a growth plate abnormality in his left shoulder. At his deposition, Dr. Bal sufficiently explained the basis for his opinion that CDB will require arm lengthening surgery in the future. He testified because of the growth plate injury "the arm or the humerus, that particular one, is not going to grow from that growth plate. The only place it can grow is the elbow." (Ex. S S (Bal Dep. at 15).) He further explained that where there is a growth plate injury from infection,

there will be a limb length discrepancy. (Id.) He also pointed out that CDB's treating physician has also indicated that the extent of the discrepancy is unknown, and will not be known until CDB stops growing. (Id. at 24-25.)

With regard to the opinion that CDB will require shoulder replacement surgery, Dr. Bal explained that such surgery will be required because CDB has already suffered damage to the ball and socket of his left shoulder. (Id. at 30.) In addition, CDB's treating orthopedic physician also believes CDB will require shoulder replacement surgery. (Id. at 38.)

The Court finds that Dr. Bal's opinions that CDB may need limb lengthening surgery and shoulder replacement in the future are based on a reliable foundation and are derived from a reliable methodology. The motion to exclude Dr. Bal's opinions will be denied.

E. Casey Dye

Casey Dye was retained by Plaintiffs as an expert in the field of life care planning. Dye prepared a life care plan which sets forth CDB's anticipated future medical treatment and present day costs on August 1, 2012. (Ex. TT (Life Care Plan).) Dye was certified as a life care planner on August 3, 2012, after she prepared CDB's plan. CDB's life care plan is only the fourth or fifth plan she has

completed.

Under Minnesota law, a claim for damages for future medical expenses must be supported by evidence that “(1) demonstrate[s] that future medical treatments will be required and (2) establish[es] the amount of the damages.” Lallas v. Paquette, No. A08-1364, 2009 WL 20115821 at *3 (Minn. Ct. App. Jul. 14, 2009) (citing Myers v. Hearth Techs., Inc., 621 N.W.2d 787, 793 (Minn. Ct. App. 2001), rev. denied, (Minn. 2001)). “Both requirements must be substantiated through competent evidence, which ordinarily is established through expert testimony.” Id. Minnesota courts have, however, affirmed awards for future medical expenses in the absence of expert testimony. Shimek v. Weinig AG, No. 99-2015, 2002 WL 1839239, at *2-3 (D. Minn. Aug. 9, 2002) (citing cases). In addition, a plaintiff need not establish future medical expense damages to an absolute certainty, only that the necessity of such expenses are more likely than not. Id. (citing Dornberg v. St. Paul City Ry., 253 Minn. 291, 295, 91 N.W.2d 178, 185 (1958)).

Gen-Probe argues that unless treatment included in the life care plan is supported by a doctor’s recommendation, it is not scientifically reliable. Here, Dye has relied on the opinions of Dr. Gary Yarkony for the inclusion of a speech

language pathology evaluation, a nutritional evaluation, occupational therapy, individual psychological counseling, physical therapy, speech therapy, landscaping, handyman and home care in CDB's life care plan. (Ex. TT at 19, 25-26, 39.) Dr. Yarkony was originally identified as an expert by Plaintiffs, but he has since been de-designated. (Ex. WW.) Gen-Probe argues that as a result, Plaintiffs cannot demonstrate that Dye's inclusion of the above therapies are supported by admissible evidence, and must therefore be excluded. See Hale v. Gannon, Cause No. 1:11-cv-277, 2012 WL 3866864, at *5 (S.D. Ind. Sept. 5, 2012) (finding that "[i]f the underlying treatments are not proved by independent admissible evidence, then [the] projected cost of treatment is irrelevant.")

Similarly, Dye has included future costs for jaw surgeries, orthodontic alignment prior to surgery, physical therapy evaluations after jaw surgeries and post-operative pain medications. (Ex. TT at 20, 22, 35.) These items rely on the opinions of CDB's treating oral surgeon. (Id.) Dr. Swift has opined, however, that surgical intervention is impossible to predict at the present time. (Ex. S.) Dye also relied on Dr Swift for inclusion of individual psychological counseling and evaluation, physical therapy sessions, dental cleaning, x-rays, CT scans, therabite devices and bite pads. (Ex. TT at 25-29.) Gen-Probe asserts there is no

medical evidence to support dental cleaning, therabite devices and bite pads, therefore those items should be excluded. For the remaining items, Dye relies upon a questionnaire that she sent to Dr. Swift. However, Dr. Swift did not complete the questionnaire - it was completed by a surgical resident that has not been named as an expert in this case. (Ex. N (Swift Dep. at 28).) Even if Dr. Swift had completed the questionnaire, there is no opinion within the responses that CDB will need these items to a reasonable degree of medical certainty. (Ex. XX.)

Dye also included costs related to an arm lengthening procedure. Dye relies on Dr. Bal's opinion for inclusion of these items. As noted above, Gen-Probe moves to exclude this opinion of Dr. Bal. If the Court finds such opinion inadmissible, this aspect of Dye's life care plan must be excluded as well.

Dye has also included the costs related to future shoulder surgeries. (Ex. TT at 22, 26.) Dye forecasts the first surgery will take place in 20-30 years, yet CDB's treating physician, Dr. Van Heest, did not provide a reasonable estimate as to when the first surgery would occur. (Ex. J.) Dr. Bal testified at his deposition that shoulder replacement surgery may be unnecessary as alternative treatments, such as stem cell and autologous cartilage treatments may be available. Therefore, inclusion of even one shoulder surgery is speculative.

Plaintiffs assert that it is common practice and standard methodology for life care planners to rely on the opinions of medical experts in formulating a life care plan. (Ex. VV (Dye Affidavit); Ex. XX (Roger Weed and Debra E. Berens, Life Care Planning and Case Management Handbook, at 749, CRC Press (3d ed.).) Dye's opinions are based on her review of the medical records and they are supported by the opinions of experts and is based upon accepted principles of life care planning.

The Court finds that Gen-Probe's arguments go to the factual basis supporting Dye's opinions. Again, a challenge to the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility. Bonner, 259 F.3d at 929-30. Gen-Probe has not demonstrated that Dye's opinions are so fundamentally unsupported to warrant their exclusion. Id.

IT IS HEREBY ORDERED that Gen-Probe's Motion to Exclude Expert Testimony [Doc. No. 56] is GRANTED in part and DENIED in part as set forth in this Memorandum Opinion and Order.

Date: July 31, 2013

s/ Michael J. Davis

Michael J. Davis

Chief Judge

United States District Court