

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 97-30858

BARRY PICK, (Deceased); MRS. BARRY
(LAURA) PICK, Individually, and as substitute
plaintiff in place and stead of Barry Pick, deceased,

Plaintiffs-Appellants,

versus

AMERICAN MEDICAL SYSTEMS, INC.,

Defendant-Appellee.

Appeal from the United States District Court
for the Eastern District of Louisiana
(94-CV-1729-C1)

October 1, 1999

Before REAVLEY, HIGGINBOTHAM and DENNIS, Circuit Judges.

PER CURIAM:*

Appealing the summary judgment against her, appellant Laura Pick contends that the district court's decision to exclude the testimony of Edward Hyman, M.D. and

Quentin Deming, M.D. was an abuse of discretion. We affirm the judgment for

*Pursuant to 5TH CIR. R. 47.5, the Court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5TH CIR. R. 47.5.4.

American Medical Systems, Inc. (“AMS”).

“[A] court of appeals is to apply an abuse-of-discretion standard when it review[s] a trial court’s decision to admit or exclude expert testimony. That standard applies as much to the trial court’s decisions about how to determine reliability as to its ultimate conclusion....Thus, whether Daubert’s specific factors are, or are not, reasonable measures of reliability in a particular case is a matter that the law grants the trial judge broad latitude to determine.” Kumho Tire Co., Ltd. v. Carmichael, 119 S.Ct. 1167, 1176 (1999) (interpreting Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S.Ct. 2786 (1993)) (internal quotations and citations omitted).

I. Dr. Hyman’s Testimony

The district court excluded Dr. Hyman’s diagnosis that Mr. Pick suffered from SCD as well as Dr. Hyman’s opinion that an AMS penile prosthesis can cause SCD. We do not reach the issue of whether or not Dr. Hyman’s theory of SCD, as set forth in his published articles, is sufficiently reliable to be entered into evidence. The two real problems with Dr. Hyman’s testimony are (1) the method by which he diagnosed Mr. Pick and (2) his inconsistent testimony as to whether an AMS penile prosthesis is capable of causing SCD.

In order to detect SCD, Dr. Hyman primarily relies on a urinalysis technique that he developed specifically for that purpose. Dr. Hyman acknowledges that his technique differs from the standardized urinalysis method used in laboratories around the world and is similar to technology predating the 1940's. He claims that his methodology is “far

more sensitive” that what is used in “routine laboratories” and can find “stealthy bacteria” that the routine laboratories cannot.

Dr. Hyman’s method for detecting SCD differs from standard urinalysis in the manner in which a urine sample is centrifuged, stained, and analyzed. The method requires a urine sample collected from a patient to be divided into equally weighted portions and placed into two test tubes which are then loaded into a centrifuge. Two equally weighted tubes are required in this process to balance the centrifuge. The sample is then centrifuged at two to three times the normal speed. After the centrifuging the sample, Dr. Hyman pours off the supernate clear liquid from one of the tubes and replaces it with a buffer solution. He then re-disperses the sediment before repeating the process a second time. Dr. Hyman acknowledges that standard medical laboratories often do not centrifuge urine samples at all.

After the sample has been centrifuged, Dr. Hyman creates a slide from the processed tube using a stain which he asserts allows him to see bacteria under a microscope that are not visible by normal testing methods. When asked if using this stain is a standard testing procedure that is ordinarily used by other laboratories, Dr. Hyman replied “I don’t think so.” As to which dye Dr. Hyman’s method uses, the testimony before the district court was unclear whether, or under what circumstances, Dr. Hyman’s method uses a standard dye used in other laboratories. Dr. Hyman alternately testified that he uses a standardized stain, a “counterstain,” or a modified stain that he developed himself.

Once the slide is prepared, Dr. Hyman views the slide under a microscope and analyzes it by estimating the number of various particles he sees using a subjective scale of 0 to 4. With respect to white blood cells, for example, Dr. Hyman would “take a guess” and rank the number of white blood cells in a sample on his scale of 0 to 4, with 1 indicating a normal number of cells. Dr. Hyman acknowledges that standard laboratories do not use his 0 to 4 analysis. Dr. Hyman also uses his scale to quantify the presence of gram-positive cocci and diplococci, which are types of bacteria. Dr. Hyman asserts that a 1 on his scale for both of these particles indicates the presence of SCD. In addition, Dr. Hyman uses his scale to quantify the number of “exploded cocci” present in a slide. Dr. Hyman describes these “explodeds” as rounded dead bacteria. Dr. Hyman claims to have discovered these particles and asserts that they had never previously been described. He believes that the presence of “explodeds” at or above a level of 1 on his scale to be the most accurate method of determining if a patient suffers from SCD.

AMS’s experts are consistent in their criticism of Dr. Hyman’s methodology. The main points of this criticism are as follows: (1) other than Dr. Hyman and Dr. Deming, no other doctor, hospital, or medical laboratory recognizes his procedures as scientifically valid; (2) Dr. Hyman never conducted blinded control studies to validate the accuracy of his method; (3) his procedures do not protect against contamination of the urine samples, i.e. in Mr. Pick’s case the sample was taken by Mr. Pick himself, at home, with no documented supervision; (4) centrifuging the urine isolates and highlights contaminating organisms; (5) Dr. Hyman’s 0 through 4 scale is subjective and unable to be validated by

independent researchers; and (6) Dr. Hyman's claim that his theory is affirmed by positive results from treatment has not been documented and, in any event, does not take the placebo effect or the effect of other, concurrent, treatment into account.

Appellant alternately argues that even if Dr. Hyman's method does not meet the Daubert standard of reliability, Dr. Hyman's diagnosis of SCD is sufficiently reliable because Dr. Hyman reached this opinion through "differential diagnosis." This circuit has not written on the question of whether an expert opinion based on differential diagnosis can meet the Daubert standard, and this case does not require it. Assuming that the process of differential diagnosis can provide sufficient scientific reliability, Dr. Hyman did not base his opinion regarding the cause of Mr. Pick's illness on differential diagnosis. Differential diagnosis is a process of elimination by which medical practitioners determine the most likely cause of a set of signs or symptoms from a set of possible causes. Dr. Hyman, however, did not review Mr. Pick's medical records before diagnosing him with SCD. If Dr. Hyman had examined Mr. Pick's medical records, he would have discovered that Mr. Pick complained of the same symptoms prior to the implantation of the AMS device. Dr. Hyman's failure to rule out other possible causes of Mr. Pick's symptoms therefore forecloses the argument that Dr. Hyman's opinion is reliable because it is a product of differential diagnosis.

Appellant also argues that the fact that Mr. Pick "improved" under Dr. Hyman's unique antibiotic treatment for SCD independently indicates the reliability of Dr. Hyman's diagnosis. There is conflicting evidence, however, regarding whether Mr. Pick

symptom's actually did improve under the care of Dr. Hyman. In addition, Dr. Hyman made no attempt to separate out the possible beneficial effects of the concurrent regimen of non-antibiotic drugs and artificial feeding Mr. Pick received while in the hospital for Dr. Hyman's antibiotic treatment. The district court could consider this evidence insufficient to demonstrate the reliability of Dr. Hyman's diagnosis.

Given the unique nature of Dr. Hyman's method, AMS' experts consistent criticism of his method, Dr. Hyman's inability to objectively demonstrate his method's accuracy, and Dr. Hyman's failure to review Mr. Pick's medical history prior to diagnosing him with SCD, we find that the district court did not abuse its discretion in excluding Dr. Hyman's opinion that Mr. Pick suffered from SCD.

The district court also acted within its discretion to exclude Dr. Hyman's opinion that an AMS penile prosthesis is capable of causing SCD. When asked in his January 27, 1996 deposition if he had ever conducted any research with regard to the cause of SCD, Dr. Hyman testified that he had not done any research except for "reviewing the literature." In addition, Dr. Hyman had not published any articles regarding the cause of SCD. Dr. Hyman testified, "No, I haven't published anything on the chain of events which result in it. No, I have not. I can speculate, and that's all I can do." As the appellants point out, Dr. Hyman's testimony in his February 21, 1996 deposition does indicate that he believes that an AMS penile prosthesis is both capable of causing SCD and did in fact cause SCD in Mr. Pick. Dr. Hyman's testimony in his January 27, 1996 deposition, however, was sufficient for the district court to find that Dr. Hyman's opinion that an AMS penile prosthesis can cause SCD does not meet the standard for scientific

reliability under Daubert.

II. Dr. Deming's Testimony

Likewise, the district court did not abuse its discretion in excluding Dr. Deming's opinion that Mr. Pick suffered from SCD. Dr. Deming did not review Mr. Pick's medical records and never physically examined Mr. Pick. Dr. Deming based his opinion on a photograph of a slide of edema fluid taken from Mr. Pick's leg as well as multiple photographs of slides of Mr. Pick's urine. The samples were collected by Dr. Hyman and the slides were prepared using Dr. Hyman's method of detecting SCD. As discussed, however, the district court, in its discretion, determined that Dr. Hyman's method was scientifically unreliable under Daubert. The district court therefore acted within its discretion to exclude Dr. Deming's opinion as based on an unreliable source.

III. The Summary Judgment

Without Dr. Hyman's and Dr. Deming's testimony, there is no genuine issue of material fact with regard to whether Mr. Pick actually suffered from SCD or whether an AMS penile prosthesis is capable of causing the disease. The summary judgment against the appellants on the grounds of specific and general causation is therefore upheld.

AFFIRMED.