

THE STATE OF SOUTH CAROLINA
In the Court of Appeals

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APPEAL FROM SPARTANBURG COUNTY APR 11 2015
Court of Common Pleas

SC Court of Appeals

J. Mark Hayes, II, Circuit Court Judge

Case No. 2013-CP-42-2404
Appellate Case No. 2015-001828

Lisa McKaughan, Individually
and as Personal Representative
of the Estate of William Farr,

.....

Appellant

v.

Upstate Lung and Critical Care
Specialists, P.C. and Sau-Yin
Wan, M.D.

.....

Respondents.

FINAL REPLY BRIEF OF APPELLANT

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REPLY ARGUMENT

I. Dr. Milby's causation testimony was based on a valid, reliable pathology methodology.

Respondents devote a substantial portion of their brief to proposing an application of a reliability analysis they argue supports the circuit court's ruling that excluded Dr. Milby's causation testimony. Resps.' Br. at 10-16 (citing State v. Council, 335 S.C. 1, 515 S.E.2d 508 (1999)). However, this proposal actually demonstrates the circuit court's error of law because, like the circuit court, Respondents' application of the Council factors does not analyze what Rule 702, SCRE's reliability standard actually tests. Rule 702's reliability requirement, as stated in the Council factors, tests an expert's methodology, not his conclusions. State v. Cain, 413 S.C. 508, 776 S.E.2d 374 (Ct. App. 2015) (finding court's expert reliability analysis "focuses on [the] argument that . . . methodology was not reliable"). Cain's "focus" on methodology rather than conclusions is consistent with federal courts' interpretation of FRE 702. In Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579, 594 (1993), the U.S. Supreme Court held that Rule 702's "focus, of course, must be **solely on principles and methodology, not on the conclusions they generate.**" (emphasis added). See also Westberry v. Gislaved Gummi AB, 178 F.3d 257, 261 (4th Cir. 1999) (quoting Daubert).

Post-Daubert federal opinions have specifically limited their reliability analysis to methodology rather than an expert's conclusions. TFWS, Inc. v. Schaefer, 325 F.3d 234, 240 (4th Cir. 2003) ("a court evaluates the methodology or reasoning that the proffered scientific or technical expert uses to reach his conclusion; the court does not evaluate the conclusion itself"); Wise v. C.R. Bard, Inc., Civil Action No. 2:12-cv-01378, 2015 WL 521202 at *21 (S.D. W. Va. Feb. 7, 2015) ("the court is not to decide whether an opinion

is scientifically correct; it is to evaluate the method a proffered expert uses in reaching that opinion”); Ruark v. BMW of N. Am., LLC, Civil Action No. ELH-09-2738, 2014 WL 351640 (D. Md. Jan. 30, 2014) (finding reliability question was “whether [expert] reliably collected his data with a proper methodology, not whether the conclusions he drew from the data are correct”).¹ Other state courts have recognized Rule 702 reliability focuses on methodology. State v. Porter, 698 A.2d 739, 753 (Conn. 1997) (“As long as the expert’s methodology is well founded, the nature of the expert’s conclusion is generally irrelevant, even if it is controversial or unique”).

The reliability analysis must be limited to methodology because courts, despite their extensive legal acumen, are ill equipped to evaluate the accuracy of intricate scientific conclusions in complex medical fields like anatomic pathology. Daubert, 509 U.S. at 601 (Rehnquist, C.J. concurring in part, dissenting in part) (arguing FRE 702 does not grant courts “authority to become amateur scientists”). Thus, in resolving Respondents’ reliability challenge to Appellant’s causation evidence, the circuit court’s limited role was to examine the methodology by which Dr. Milby determined Mr. Farr’s second cancer was metastatic as opposed to an independently originating tumor.

Yet, the circuit court never referenced or analyzed Dr. Milby’s methodology underlying his causation testimony. Similarly, Respondents’ brief focuses on their

¹ See also Deutsch v. Novartis Pharm. Corp., 768 F. Supp. 2d 420 (E.D.N.Y. 2011) (citing Amorgianos v. Nat’l R.R. Passenger Corp., 303 F.3d 256, 266 (2d Cir. 2002) (“the court ‘must focus on the principles and methodology employed by the expert, without regard to the conclusions the expert has reached or the district court’s belief as to the correctness of those conclusions’”)); Kenneth J. Chesebro, Taking Daubert’s Focus Seriously: The Methodology/Conclusion Distinction, 15 CARDOZO L. REV. 1747, 1748 (1994) (“It is completely inappropriate for either the proponent of scientific testimony or her opponent to advance Rule 702 admissibility arguments that depend on the ultimate conclusion reached by the expert”).

disagreement with Dr. Milby's conclusion while glossing over the methodology leading to that conclusion. A proper analysis of Dr. Milby's testimony focusing on his methodology demonstrates that the Rule 702's reliability requirement was satisfied and Dr. Milby's testimony should not have been excluded. Dr. Milby, an anatomic and clinical pathologist, outlined his methods at trial during direct examination. Dr. Milby first stated his conclusion that Mr. Farr's 2010 tumor metastasized to his other lung in the form of the 2012 tumor. (R. p. 498, lines 7-8). Immediately, Dr. Milby then explained the bases for that opinion and the methodology by which he reached his conclusion. (R. p. 498, lines 9-22).

As Dr. Milby testified, a pathologist's clinical duties include examining body tissues and making diagnoses or causal connections based on distinctive characteristics of tissue and its cells. (R. p. 494, lines 13-22).² Dr. Milby conducted a pathologic review of tissue from both of Mr. Farr's tumors. "Slides" of the tumors were prepared for microscopic examination by taking samples of tumor tissue removed during Mr. Farr's surgeries, subjecting them to standard procedures for fixation/processing, and adding alcohols or reagents to enable precise cuts. (R. p. 499, lines 21-25). Once a portion of the processed tissue is cut, the resulting sliver of tumor cells is called a "section," which is then affixed to a glass slide and stained in a way that illuminates the cells' organelles when viewed microscopically. (R. p. 500, lines 1-6). Dr. Milby examined the 2010 tumor and 2012 tumor at 40 and 400 times magnification. (R. p. 534, lines 5-10; 538, lines 6-9).

² A medical dictionary defines "pathology" as "the medical science, and specialty practice, concerned with all aspects of disease, but with specific reference to the essential nature, causes and development of abnormal conditions, as well as the structural and functional changes that result from the disease processes." *Massie v. State*, 709 A.2d 1316, 1320 n. 1 (Md. 1997) (quoting *Steadman's Med. Dictionary* (5th ed. 1982)).

This methodology meets Rule 702's reliability requirement which, at its core, seeks only "to make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999); see also Rule 703, SCRE (permitting an expert to base his opinion on facts or data "of a type reasonably relied upon by experts in the particular field"). Dr. Milby applied the same methodology to Mr. Farr's tumors when serving as an expert witness that he applies in his clinical practice where he examines 1-2 lung cancers per week. (R. p. 497, lines 17-21). The treating pathologists used a similar methodology when examining each of Mr. Farr's two tumors individually. See R. pp. 501-02. In fact, a microscopic side-by-side comparison of two tumors is the best available means to determine if a second tumor was a metastasis of the first. (R. p. 500, lines 14-18).

Plus, Dr. Milby did more than just describe his methodology, he also demonstrated the process during his testimony. He took photographs of what his lab's microscopes displayed for each tumor and presented them for the jury's observation. (R. p. 531, lines 4-7). During his direct exam, he explained each slide, placed photos of each tumor's cells side-by-side for the jury to observe, and pointed out the distinct characteristics demonstrating the tumors were the same cancer. (R. p. 531-39). This is a recognized, accepted, and reliable pathologic methodology. See Adams v. Lab. Corp. of Am., 760 F.3d 1322, 1329 (11th Cir. 2014) (finding pathology expert's methodology reliable when she reviewed slides, photographed them, referred to them in her testimony, and marked the photos to indicate abnormalities).

During a comparison of the tumors, Dr. Milby observed multiple similarities providing compelling evidence that the second tumor was a metastasis of the first. Even though there are 3 different types of lung cancer (R. p. 502, lines 15-16), Mr. Farr's tumors were both adenocarcinoma. Even though there are nearly ten different cell subtypes for adenocarcinoma (R. p. 531-32), Mr. Farr's two tumors both contained precisely the same three—acinar, lepidic, and papillary cells. (R. p. 533-37). Finally, at the higher magnification (400x), the nucleus of the first tumor cells were nearly identical in appearance to the nucleus of the second tumor cells. (R. p. 540, lines 7-12). On its own, the nuclei comparison was “compelling” evidence of metastasis. *Id.* Together with the other pathologic findings (i.e. same cancer type and cell subtypes), the aggregate evidence of metastasis was overwhelming.

Accordingly, the evidence produced at trial showed Dr. Milby's conclusion that Mr. Farr's second tumor was a metastasis of his first tumor was the product of a reliable, standard pathologic methodology. The circuit court's finding that Dr. Milby's conclusion had been “established as being unreliable” (R. p. 619, line 9) was not only inaccurate, it was also based on an error of law.³ The circuit court never examined Dr. Milby's methodology as Rule 702 requires. Instead, the circuit court accepted Respondents counsel's interpretation of medical literature and their (unfounded) assertion that the literature disagrees with Dr. Milby's conclusion. The focus was required to be on methodology, and Dr. Milby's methodology was sound.

³ See People v. Unger, 749 N.W.2d 272 (Mich. App. 2008) (finding expert was reliable because he “didn't use bizarre methods, he didn't use strange methods . . . [h]e used standard methods of forensic pathology in coming to a conclusion with which [opponent] disagrees”).

II. Respondents' argument regarding publications and literature relies on unsupported assumptions and ignores evidence presented at trial.

As Dr. Milby testified, his causation testimony was in no way dependent on the physical mechanism by which Mr. Farr's tumor traveled from his right lung to his left because his conclusions were based on a microscopic examination providing compelling pathological evidence that both tumors were the same cancer. (R. p. 511, line 24 – 512, line 5). Nevertheless, Dr. Milby referred to multiple authoritative texts demonstrating that adenocarcinoma (i.e. the lung cancer variety from which Mr. Farr suffered) may metastasize from one lung to the other through the airways. Respondent Dr. Wan was presented with one of the same texts and acknowledged its substance. (R. p. 490, lines 19-22) (Dr. Wan agreeing that text indicates "cancers with lepidic growth can spread through the airways from the one lung to another"). Yet, Respondents now argue there is no literature to support Dr. Milby's testimony. Resps.' Br. at 10. This argument is faulty because it relies on unsupported assumptions and ignores evidence presented to the circuit court.

First, Respondents, like the circuit court, assume that supporting literature is an absolute requirement for an expert's methodology to be reliable under Rule 702. Resp. Br. at 10. That assumption is not consistent with South Carolina law and has been specifically rejected on multiple occasions by the U.S. Supreme Court and Fourth Circuit Court of Appeals. Appellant's Br. at 16-19 (citing Daubert, Kumho, Westberry, Cain and others). Notably, Respondents make no effort to distinguish or refute this extensive line of cases rejecting the per se literature requirement the circuit court applied in this case.

Second, Respondents argue the literature Dr. Milby cited provided no support for his testimony because these texts did not relate to the cancer from which Mr. Farr

suffered. Respondents' argument is inaccurate and builds on an unsupported assumption. Both the textbooks and article Dr. Milby referred to relate to adenocarcinoma of the lung. (R. p. 515, lines 7-17; 528, lines 21-25; 529, line 24 – 530, line 1). Respondents try to downplay the substance of these texts by labeling their discussions as "short, generalized statements." Resps.' Br. at 10. Respondents later argue that these texts are irrelevant because none refer to the cancer cell subtype of Mr. Farr's cancer. Resps.' Br. at 11-12. This argument is also inaccurate. As Dr. Wan acknowledged, one the cited texts referred to aerogenic spread of adenocarcinoma with lepidic growth. (R. p. 490, lines 19-22). Both of Mr. Farr's tumors had lepidic growth as Dr. Milby displayed and described during his testimony. (R. p. 536, lines 7-8) ("you can see the lepidic pattern. It looks the same as in 2010 as it does in 2012").

At its core, Respondents' objection to the literature evidence (and the ultimate basis for the circuit court's exclusion of Dr. Milby's testimony) was that the literature cited did not specifically indicate adenocarcinoma of the lung with three distinct cell subtypes (acinar, lepidic, and papillary) could metastasize by aerogenic means and result in a tumor with the same cell subtypes just in different proportions. That argument is only valid if the proportion of cell subtypes from one tumor to another (i.e. histology) is important to the determination of whether the second tumor was a metastasis of the first. Respondents assume and unilaterally insist that proportion matters. However, the only evidence before the circuit court was that the proportion issue does not matter. Both Dr. Milby and Dr. Singer testified that the differing proportion from the first tumor to the second was irrelevant to determining whether the second tumor was metastatic. (R. pp.

212-13) (“metastases in primaries don’t often have the exact same histology . . . it’s a regular finding”); 500, line 19 – 501, line 2.

In sum, the circuit court erred by relying on a literature requirement Rule 702 does not impose. The circuit court erred further by ignoring the literature Appellant’s experts produced (and that Dr. Wan acknowledged). All of the cited literature related to the type of cancer from which Mr. Farr suffered, and Respondents’ “proportion” argument was at odds with the only evidence in the record.

III. There was no evidence before the circuit court at the time the directed verdict was entered to suggest Mr. Farr’s second tumor arose independently of the first.

Appellant’s expert testimony established a significant causal link between Dr. Wan’s failure to diagnose Mr. Farr’s lung tumor in January 2010 and Mr. Farr’s untimely death from metastatic lung cancer in June 2012. As detailed above, Dr. Milby conducted a pathological examination of both tumors and found they shared distinctive characteristics demonstrating metastasis. This testimony along with Dr. Singer’s oncological testimony established the required causal connection to show Mr. Farr most probably died from cancer, the origin of which was the tumor Dr. Wan failed to identify on the January 2010 x-ray. South Carolina law did not require Appellant to prove anything more to have her medical negligence claim submitted to the jury. See Ellis v. Oliver, 323 S.C. 121, 125, 473 S.E.2d 793, 795 (1996) (discussing “most probably” rule).

However, the circuit court found Appellant was required to not only establish a causal connection but also to explain the mechanism by which the cancer spread. The circuit court made this ruling at Respondents’ urging and, on this same point, Respondents now argue Dr. Milby’s pathological comparison of the actual tumor cells

demonstrating metastasis was insufficient because “there were alternative theories for the origin of the cancer.” Resps.’ Br. at 17. However, at the point when the circuit court directed a verdict in Respondents’ favor, there was no testimony in the record even suggesting the second tumor developed independently of the first.⁴

Respondents’ counsel certainly suggested this defense strategy in his opening statement (R. p. 118) but nothing counsel said was evidence. S.C. Dep’t of Transp. v. Thompson, 357 S.C. 101, 105, 590 S.E.2d 511, 513 (Ct. App. 2003) (citing McManus v. Bank of Greenwood, 171 S.C. 84, 89, 171 S.E. 473, 475 (1933) (“This court has repeatedly held that statements of fact appearing only in arguments of counsel will not be considered”)). When Appellant rested her case, the only evidence on causation was Dr. Singer’s records-based testimony that there was a 95% likelihood that Mr. Farr’s second tumor was a metastasis (R. p. 211, lines 13-21) and Dr. Milby’s microscopic examination demonstrating that the tumors shared numerous characteristics that compelled his conclusion that Mr. Farr’s cancer had metastasized.⁵

Ultimately, the circuit court’s directed verdict was based on its perception that Appellant failed to rebut what the circuit court anticipated Respondents’ evidence would show during their case in chief. That is not the proper standard for directing a verdict. A ruling on a directed verdict motion is based on whether “the evidence as a whole is

⁴ Respondents’ brief suggests their independent origination theory was supported by indications in the medical record that Mr. Farr’s second tumor was “in situ.” Resps.’ Br. at 4. There was no testimony in the record to suggest this term indicated Mr. Farr’s second tumor originated independently. In fact, Dr. Singer testified that “in situ” was irrelevant to the causation question. (R. p. 259, lines 10-11).

⁵ The medical records also supported the conclusion that the second tumor a metastasis of the first. Mr. Farr’s cause of death was metastatic lung cancer (R. p. 627) and his medical chart repeatedly referred to “recurrent” cancer. (R. pp. 273-75); see also R. p. 1058, 1073, 1108.

susceptible to more than one reasonable inference.” Proctor v. Dep’t of Health & Envtl. Control, 368 S.C. 279, 292, 628 S.E.2d 496, 503 (Ct. App. 2006). The circuit court was required to consider only the causation evidence that was actually before it when Respondents made their motion. The circuit court was not permitted to anticipate evidence Respondents planned to offer later and to direct a verdict for Respondents because Appellant’s evidence failed to offer what the circuit court believed to be a sufficient rebuttal.

CONCLUSION

Based on the arguments stated above and those in her earlier brief, Appellant respectfully requests the Court reverse the circuit court’s directed verdict. The circuit court abused its discretion in excluding Dr. Milby’s testimony because it committed an error of law by applying an improper per se literature requirement and because it focused on Dr. Milby’s conclusion rather than the sound pathological methodology underlying his conclusion.

Respectfully submitted,



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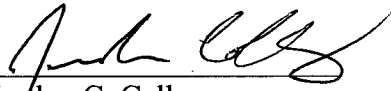
CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 11th day of April, 2016, he served counsel for the Respondents with a copy of the Final Brief of Appellant and Final Reply Brief in this matter by mailing a copy by United States Mail with first class postage prepaid to the following addresses:

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CERTIFICATE OF COUNSEL

Pursuant to Rule 211, SCACR, Appellant's counsel certifies that the Final Brief
of Appellant and Final Reply Brief comply with Rule 211(b), SCACR.


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