THE STATE OF SOUTH CAROLINA
In the Court of Appeals

APPEAL FROM SPARTANBURG COUNTY
Court of Common Pleas

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.

INITIAL BRIEF OF APPELLANT

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Case Law

South Carolina

Other Jurisdictions

Statutes and Court Rules

Secondary Sources

STATEMENT OF THE ISSUES ON APPEAL

1. Whether Appellant presented a scintilla of evidence to show that Respondents' failure to diagnose the decedent's lung cancer was a proximate cause of his death.
2. Whether the circuit court erred in directing a verdict for Respondents and finding an expert unreliable despite the expert's microscopic examination of the tumor cells on which he based his testimony.

STATEMENT OF THE CASE

Decedent William Farr died from lung cancer two-and-a-half years after the cancer appeared on his January 2010 chest x-ray ordered and interpreted by Respondent Sau-Yin Wan, M.D. of Respondent Upstate Lung and Critical Care Specialists, P.C. ("Upstate Lung"). Although Dr. Wan is a pulmonologist and not a radiologist, she chose to interpret Mr. Farr's x-ray herself. (Tr. of Record at 338, lines 17-23). Appellant's radiology expert testified that Dr. Wan breached the standard of care when she failed to identify an "abnormal density" in Mr. Farr's right lung that was "readily apparent" on the x-ray. (Tr. of Record at 273, lines 15-21; 276, lines 5-16) Since Dr. Wan interpreted the x-ray as normal, no additional tests or treatment were ordered, and Mr. Farr's right lung tumor grew from 2-3 cm in diameter to approximately 9 cm when it was finally diagnosed by a different doctor in the fall of 2010. (Tr. of Record at 178-79). The tumor was surgically removed in December 2010 and his doctors recommended post-surgical adjuvant treatment including chemotherapy and radiation treatment. (GSO 142-44; Tr. of Record at 182, lines 17-25) A few months later, Mr. Farr's doctors discovered more cancer in Mr. Farr's left lung. (Tr. of Record at 184-87). Many of his medical records refer to the left lung tumor as a "recurrence" of cancer. (Tr. of Record at 248-50). Despite treatment and an additional surgery, Mr. Farr's condition deteriorated and he died on June 19, 2012. (State of South Carolina, Certificate of Death) The only ailment listed on his death certificate is "metastatic lung cancer." Id.

In May 2013, Appellant Lisa McKaughan, Mr. Farr's daughter and the personal representative of his estate, filed a Summons and Complaint against Dr. Wan and Upstate Lung alleging medical negligence claims. (Compl. ¶¶ 24-30). The Complaint alleged Dr.

Wan breached the standard of care in interpreting Mr. Farr's January 2010 x-ray and that her failures were a proximate cause of Mr. Farr's death. (Compl. ¶¶ 16-23). At trial, Appellant called three expert witnesses including radiologist Dr. William Woodruff, oncologist Dr. Barry Singer, and pathologist Dr. Willard Milby. Dr. Woodruff testified that Dr. Wan's failure to identify the abnormality on the x-ray and her report identifying the x-ray as essentially normal prevented follow-up testing to diagnose and treat the tumor at a small size and early stage. (Tr. of Record at 273-78). Dr. Singer and Dr. Milby testified that the nine months of unchecked tumor growth attributable to Dr. Wan's failure to properly interpret the x-ray was a proximate cause of Mr. Farr's death.

Dr. Singer concluded that the approximately 6 cm growth in Mr. Farr's right lung tumor following the January 2010 x-ray and before the tumor was diagnosed greatly increased the risk that the cancer would metastasize, an oncological term referring to instances where cancer cells from an existing tumor break off, relocate, and grow in another location. (Tr. of Record at 179-80; 181, lines 17-25). While Mr. Farr's right lung tumor was surgically removed and his left lung tumor was discovered later, Dr. Singer testified that the left lung tumor was a metastasis. (Tr. of Record at 189, lines 2-12). Dr. Singer reached this conclusion because both tumors were the same cancer type and because of the short time frame between the development of the right and left lung tumors. (Tr. of Record at 186, line 17 – 187, line 8). In short, Dr. Singer concluded that there was a 95% likelihood that Mr. Farr's cancer had metastasized, that the right and left lung tumors were "the same cancer," and that Dr. Wan's breaches of the standard of care caused Mr. Farr's death. (Tr. of Record at 186, lines 13-21; 192, line 25 - 193, line 6; 193, lines 10-17).

Dr. Milby also testified that Mr. Farr's left lung tumor was a metastasis. (Tr. of Record 473, lines 4-8). Dr. Milby explained to the jury that, just as he does in his clinical pathology practice, he conducted a microscopic, side-by-side comparison of tissue samples from Mr. Farr's right and left lung tumors. (Tr. of Record at 474, line 21 – 475, line 18). Dr. Milby presented the jury with images of the tumor cells and showed that precisely the same three cancer cell subtypes were present (in different proportions) in both tumors. (Tr. of Record at 506-14). He also presented higher magnification images of the cancer cells to demonstrate that the two tumors' cells had nearly indistinguishable nuclei. (Tr. of Record at 513, line 6 – 514, line 8). The appearance of the cancer cell nuclei was the "signature" of Mr. Farr's cancer. (Tr. of Record at 514, lines 3-8). His examination of the cells and other factors led Dr. Milby to conclude that there was a 95-99% likelihood that Mr. Farr's left lung tumor was a metastasis. (Tr. of Record at 515, lines 1-2).

Respondents moved in limine to exclude Dr. Milby's causation opinions. (Tr. of Record at 8-13). The circuit court declined to rule on the motion before hearing Dr. Milby's testimony. (Tr. of Record at 15, lines 3-15). Following Appellant's case-in-chief, Respondents moved for a directed verdict on the causation element of Appellant's medical negligence claim. (Tr. of Record at 572, line 14 – 575, line 20). Respondents asked the circuit court to find that there was no evidence of causation by first asking the circuit court to exclude Dr. Milby's testimony as unreliable under Rule 702, SCRE. The circuit court accepted Respondents' argument, excluded Dr. Milby's causation testimony from consideration, and granted a directed verdict by finding no causation evidence. (Tr. of Record at 591-94). The circuit court specifically cited as the basis for its ruling one

exchange between Respondents' counsel and Dr. Milby regarding medical literature on lung cancer metastasis. (Tr. of Record at 593, line 23 – 594, line 13).

The circuit court made its ruling on July 29, 2015 and Appellant received written notice of the order on July 30, 2015. Appellant served a timely notice of appeal on August 20, 2015. (Notice of Appeal, dated Aug. 20, 2015).

STANDARD OF REVIEW

A directed verdict is appropriate only if the evidence in the record is susceptible to only one reasonable inference. Proctor v. Dept. of Health & Envtl. Control, 368 S.C. 279, 292, 628 S.E.2d 496, 503 (Ct. App. 2006) (citing Adams v. G. J. Creel & Sons, Inc., 320 S.C. 274, 277, 465 S.E.2d 84, 85 (1995)). A directed court is improper if the non-movant presents a scintilla of evidence to support her position on a disputed factual matter. Williams v. Haverty Furniture Co., 182 S.C. 100, 188 S.E. 512, 512 (1936). A directed verdict may not be entered if a verdict in favor of the non-movant "would be reasonably possible under the facts as liberally construed" in favor of the non-movant. Proctor, 368 S.C. at 292, 628 S.E.2d at 503 (quoting Harvey v. Strickland, 350 S.C. 303, 309, 566 S.E.2d 529, 532 (2002)). A circuit court's ruling on expert witness testimony is reviewed for an abuse of discretion. Watson v. Ford Motor Co., 389 S.C. 434, 447, 699 S.E.2d 169, 176 (2010). A circuit court abuses its discretion when its ruling "either lacks evidentiary support or [is] controlled by an error of law." State v. Pagan, 369 S.C. 201, 208, 639 S.E.3d 262, 265 (2006). In its review of a directed verdict, an appellate court must apply the same standard as the trial court. Wright v. Craft, 372 S.C. 1, 18, 640 S.E.2d 486, 495 (Ct. App. 2006).

ARGUMENTS

I. Appellant's evidence demonstrated the required causal connection between Respondents' conduct and Mr. Farr's death.

The circuit courted directed a verdict for Respondents based on a perceived lack of evidence to establish the required causal connection between Respondents' conduct

and Mr. Farr's death.[1] This ruling was erroneous because Appellant presented evidence demonstrating that Dr. Wan's failure to properly diagnose and respond to Mr. Farr's abnormal chest x-ray in January 2010 most probably resulted in the lung cancer that caused Mr. Farr's death. The testimony from oncology and clinical pathology experts met all requirements for causation evidence in medical malpractice cases under South Carolina law and was corroborated by the death certificate which indicated that Mr. Farr died of metastatic lung cancer. Since a mere scintilla of evidence was sufficient to defeat Respondents' motion and since Appellant presented substantial causation evidence, the circuit court erred in directing a verdict in Respondents' favor.

South Carolina law limits expert causation testimony admissibility in medical malpractice cases through the "most probably" rule of causation. This rule simply requires a medical malpractice plaintiff to meet the same requirement for causation evidence that all negligence plaintiffs face. Jones v. Owings, 318 S.C. 72, 74, 456 S.E.2d 371, 372 (1995). The "most probably" rule is premised on the fact that medical litigation is "highly technical" and determining the cause of a medical condition is almost always impossible without expert assistance. Ellis v. Oliver, 323 S.C. 121, 125, 473 S.E.2d 793, 795 (1996). If a party expects to introduce expert testimony on causation, then the "experts must, with reasonable certainty, state that in their professional opinion, the

[1] Respondents also moved for a directed verdict on the breach element of Appellant's medical negligence cause of action. (Tr. of Record at 572, lines 1-13). The circuit court was correct to deny that motion. (Tr. of Record at 577, lines 10-15). The alleged breaches underlying Appellant's claims related to Dr. Wan's interpretation of Mr. Farr's January 2010 chest x-ray and her failure to follow up on its abnormal results. (Compl. ¶¶ 16-22, 27). Appellant called radiology expert Dr. William Woodruff who testified that the January 2010 x-ray was "absolutely" abnormal and that a reasonably prudent doctor was required treat the abnormality as cancer "until proven otherwise." (Tr. of Record at 273, line 15; 276, line 8). Dr. Woodruff concluded that Dr. Wan's interpretation of the x-ray represented a breach in the standard of care. (Tr. of Record at 279, lines 1-4).

injuries complained of most probably resulted from the defendant's negligence." Id. at 125, 473 S.E.2d at 795. An expert's testimony "must provide a significant causal link" between the negligence and the injury. Martasin v. Hilton Head Health System, 364 S.C. 430, 613 S.E.2d 795 (Ct. App. 2005). The South Carolina Supreme Court has concluded that "[i]t is not sufficient for the expert to testify merely that the ailment might or could have resulted from the alleged cause." Baughman v. Am. Tel. & Tel., Co., 306 S.C. 101, 111, 410 S.E.2d 537, 543 (1991).

Appellant's expert testimony met the "most probably" standard. The record indicates that Mr. Farr had lung cancer when he presented to Dr. Wan's office for a chest x-ray in January 2010. (Tr. of Record at 178, line 17 – 179, line 7). The tumor in Mr. Farr's right lung was immediately and easily visible on the x-ray film Dr. Wan ordered and interpreted. At that time, the tumor was relatively small and at an early stage. (Tr. of Record at 179, lines 5-7) (describing the tumor as 2-3 cm). If the abnormality readily apparent on the January 2010 x-ray been further probed through diagnostic testing, then the relatively small tumor could have been surgically removed, and Mr. Farr would likely not have required adjuvant treatment such as chemotherapy or radiation. (Tr. of Record at 182, lines 17-25). According to oncology expert Dr. Barry Singer, if the cancer had been properly diagnosed in January 2010, then Mr. Farr had a 70-75% chance of being fully cured. (Tr. of Record at 183, lines 11-14).

However, since Dr. Wan failed to properly identify the abnormality and failed to order the follow up tests needed to diagnose it as cancer, the tumor was allowed to grow unchecked for the next nine months. The risk of metastasis has a direct correlation with tumor size. The likelihood of cancer spreading from a primary tumor to another location

in the body increases as the primary tumor increases in size. Dr. Singer explained the mechanism behind this increased risk. Metastasis occurs when cells break off from an existing tumor and relocate to another part of the body. (Tr. of Record at 181, lines 17-18). While the body's immune system can destroy some of the migrant cancer cells, if enough cells break off, then a new "metastatic" tumor can develop in a different area or even a different organ. (Tr. of Record at 181, lines 19-25). As Mr. Farr's right lung tumor progressed, its surface area increased from 2-3 cm in diameter to 9 cm. For a tumor growing to that "very large" size, "there's a greater risk of developing metastasis." (Tr. of Record at 180, lines 18-19; 184, line 2).

Once the right lung tumor was finally diagnosed in the fall 2010, Mr. Farr was still a candidate for surgical resection. The December 2010 surgery was successful. (GSO 142-44). However, the tumor's increase in size made the surgery more extensive than would have been required in January 2010 and Mr. Farr was required to undergo post-operative adjuvant treatment due to the tumor's large size. (Tr. of Record at 180, line 20 - 181, line 4). Crucially, the fact that the tumor was removed **did not** mean that it could not metastasize to another part of the body. As Dr. Singer explained, surgical resection does not remove every cancer cell. (Tr. of Record at 251, lines 10-14). In fact, even in patients who undergo surgical resection (and even when post-operative pathology results indicate no lymphatic involvement and negative surgical margins), a sizable percentage of patients "die [be]cause they have metastatic disease that turns up within a year or two." (Tr. of Record at 251, lines 13-14). Dr. Singer testified that, more likely than not, Mr. Farr fell in this category. (Tr. of Record at 251, lines 15-17).

Dr. Singer concluded that the left lung tumor Mr. Farr developed was a metastasis and that Mr. Farr died from metastatic lung cancer. Tr. of Record at 189, lines 2-12. Dr. Singer also testified that Dr. Wan's failure to diagnose the right lung tumor was a proximate cause of Mr. Farr's death. Tr. of Record at 192, line 25 – 193, line 3. Dr. Singer ably supported these conclusions by reference to Mr. Farr's medical records and widely-understood oncological principles. For example, Dr. Singer reviewed pathology reports that described both the right and left lung tumors as adenocarcinoma, one of three main types of lung cancer. When two lung tumors in the same person are both adenocarcinoma, there is a 95% chance that the tumors are the "same cancer" rather than independently arising tumors. (Tr. of Record at 186, lines 13-21). Dr. Singer's conclusion was also supported by the timing in which the left lung tumor developed and was discovered. The left lung tumor was diagnosed approximately 1 ½ years after the right lung tumor appeared on the January 2010 x-ray. In his experience as an oncologist, Dr. Singer has found that a second lung tumor appearing less than two years after the first "strongly indicate[s]" metastasis. (Tr. of Record at 187, lines 1-8). Dr. Singer also testified that Mr. Farr's medical records indicate that the left lung tumor was treated as a metastasis rather than a tumor of independent origin. The left lung tumor was often referred to as "recurrent," a term understood to refer to metastatic disease, and the death certificate indicated that Mr. Farr died of metastatic cancer. (Tr. of Record at 248-50).

Dr. Willard Milby, appellant's anatomic and clinical pathology expert, also testified that Mr. Farr's left lung tumor was a metastasis of the right lung tumor evident on the chest x-ray ordered by Dr. Wan in January 2010. Tr. of Record at 473, lines 7-8 ("the tumor from the right did metastasize to the left"). Dr. Milby is a board-certified

pathologist who has examined thousands of lung cancers in his career. He is the only medical professional to perform a pathological examination of tissue from both of Mr. Farr's lung tumors. Dr. Milby examination of Mr. Farr's tissue was conducted using the usual pathology standards that he applies on a day-to-day basis in his clinical practice. (Tr. of Record at 474-75). Dr. Milby looked at slides under a microscope containing tissue samples from both tumors. A microscopic examination is the best way to determine whether a later-arising tumor is a metastasis or a tumor of independent origin. (Tr. of Record at 475, lines 14-18).

Dr. Milby's examination revealed substantial and conclusive evidence that the left lung tumor was a metastasis. First, in general, a second lung tumor is far more likely to be a metastasis than a tumor of independent origination. (Tr. of Record at 473, lines 23-25). More than 95% of second lung tumors are metastases. (Tr. of Record at 474, lines 1-5). Second, the fact that both tumors were adenocarcinoma supported Dr. Milby's causation opinion. (Tr. of Record at 473, lines 11-14; 515, line 3). Third, Dr. Milby's microscopic examination revealed that both tumors had the same three cancer cell subtypes. Dr. Milby testified that there are approximately ten different subtypes of adenocarcinoma classified based on the cancer cell shape. (Tr. of Record at 506-07). Mr. Farr's tumors had precisely the same three subtypes of cancer cells (i.e. acinar, lepidic, and papillary). (Tr. of Record at 509-11). One of the subtypes, known as papillary cells, is relatively rare in adenocarcinoma and the presence of the papillary pattern in both tumors was "compelling" evidence that the left lung tumor was a metastasis. (Tr. of Record at 515, lines 7-12).

Fourth, the microscopic slides (presented to the jury at trial) depicted the free floating cancer cells Dr. Singer described as often breaking off from a primary tumor and migrating to other parts of the body. (Tr. of Record at 510, lines 20-24). Finally, an even closer examination of the cells from each tumor revealed the "signature" feature of Mr. Farr's lung cancer. (Tr. of Record at 514, line 7). Under high magnification, the cells' nuclei "look[ed] exactly alike." (Tr. of Record at 514, line 4). This comparison extended to all three cancer cell subtypes present in Mr. Farr's tumors. In other words, the papillary cell nuclei appeared similar to the acinar cell nuclei to the lepidic cell nuclei. (Tr. of Record at 514, lines 1-3; 515, lines 13-17). Based on this standard pathology examination, the results of which were presented for the jury's observation, Dr. Milby concluded that Mr. Farr's left lung cancer most probably was a metastasis of the right lung tumor Dr. Wan should have identified during the January 2010 chest x-ray. (Tr. of Record at 515, lines 13-23).

II. The circuit court erred in disregarding Dr. Milby's testimony when ruling on Respondents' directed verdict motion.

Respondents proposed an excessively stringent reliability standard that goes far beyond Rule 702, SCRE, pursued its novel standard during the cross-examination of Appellant's pathology expert, and seized on the expert's inability to meet this elusive non-standard to persuade the circuit court to direct a verdict in its favor. Ultimately, the circuit court applied a reliability standard that Rule 702 does not impose and overlooked reliable evidence establishing the required causal connection between Respondents' conduct and Mr. Farr's death. Instead of attacking Appellant's expert testimony on metastasis, Respondents convinced the circuit court to focus on the pathway by which the cancer cells traveled from one lung to the other. This argument is a red herring that

ignores the substantial evidence of metastasis offered by Appellant's experts. The circuit court's ruling was an error of law that should be reversed.

A. The circuit court directed a verdict in Respondents' favor after excluding or disregarding Appellant's expert causation testimony.

Following Appellant's case-in-chief, Respondents moved for a directed verdict on the causation element of Appellant's negligence claim. Since the tumor Dr. Wan allegedly misdiagnosed was later removed and Mr. Farr died of a second lung tumor, Appellant's causation burden required her to present evidence that the second tumor most probably resulted from the misdiagnosis of the first. During his directed verdict argument, defense counsel acknowledged that evidence of metastasis was the essence of the causation issue. Tr. of Record at 574, lines 16-18. As discussed in Section I above, Appellant met that burden with the testimony of oncology and pathology experts, each of whom testified that the second tumor was a metastasis of the first.

Yet, when the circuit court granted the motion, it overlooked the proof of metastasis Appellant put in evidence. The circuit court gave no consideration to substantial evidence of metastasis offered by Dr. Singer including his testimony that tumor progression (in size and stage) increases the likelihood of metastasis, that the timing of the second tumor is a strong indication that it was a metastasis, and that, after fully considering Mr. Farr's medical record, Dr. Singer believed the first and second tumors were "the same cancer." Tr. of Record 179, line 21 – P. 180, line 19; P. 187, lines 5-8; P. 193, lines 14-17. The circuit court acknowledged Dr. Milby also concluded the second tumor was a metastasis but excluded Dr. Milby's causation testimony in full based on a single exchange with defense counsel during cross-examination. Tr. of Record

at 593, line 23 – P. 594, line 13. The circuit court concluded that Dr. Milby left the jury to speculate as to whether the second tumor was a metastasis. Tr. of Record at 594, line 10.

The circuit court reached this conclusion despite Dr. Milby's detailed microscopic comparison of the two tumors. That comparison revealed that the two tumors were the same type of lung cancer, that both tumors included precisely the same three cancer cell subtypes, and that the tumor cells' nuclei were indistinguishable. More generally, Dr. Milby testified that there was a 95-99% probability that Mr. Farr's second tumor was a metastasis. Despite all of this evidence and the death certificate's indication that Mr. Farr died of metastatic lung cancer, the circuit court declared Dr. Milby's testimony unreliable based on a perceived lack of medical literature support for his conclusions. Tr. of Record at P. 593, line 23 – P. 594, line 3.

B. The circuit court's "gatekeeping" rule is limited to expert admissibility standards imposed by the South Carolina Rules of Evidence.

For all forms of expert testimony, a circuit court has "an affirmative and meaningful gatekeeping duty." State v. White, 382 S.C. 265, 676 S.E.2d 684, 686 (2009). Every expert's testimony must "meet a reliability threshold for the jury's ultimate consideration." Id. Since Rule 702, SCRE requires expert testimony to be reliable,[3] the gatekeeper must "evaluate the substance of the testimony and determine whether it is reliable." Watson v. Ford Motor Co., 389 S.C. 434, 446, 699 S.E.2d 169, 175 (2010) (citing State v. Council, 335 S.C. 1, 20, 515 S.E.2d 508, 515 (1999)). Fundamentally, a trial court's gatekeeping duty is to ensure the expert "employs in the courtroom the same

[3] Rule 702 also imposes qualification and helpfulness requirements but neither of those is at issue in this case. Respondents did not object to any of Appellant's experts' qualifications and the experts' testimony regarding lung cancer characteristics meets the helpfulness requirement because it is beyond the general knowledge of lay jurors.

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). Crucially, the gatekeeper role only requires that the circuit court "decide whether the evidence submitted by a party is admissible pursuant to the Rules of Evidence as a matter of law." Watson, 389 S.C. at 445, 699 S.E.2d at 174. Thus if a circuit court applies an admissibility requirement that exceeds the standards imposed by rule, then it has strayed from its gatekeeping responsibilities to a role reserved for the fact finder.

C. The circuit court applied a requirement beyond Rule 702 when it disregarded Dr. Milby's testimony based on a perceived lack of medical literature support.

Respondents' entire argument in support of a directed verdict and the circuit court's sole basis for directing a verdict focused on lung cancer metastasis methods. However, the causation question in this case is simply whether the left lung tumor was in fact metastatic. The fact that Dr. Wan and her practice chose to defend the suit by alleging the left lung tumor arose independently cannot change the fundamental causation question Appellant and her experts were required to address. Respondents also attempted to change the Rule 702 reliability standard by improperly reducing the Council reliability analysis to a single-issue proposition focused solely on medical literature. The circuit court accepted Respondents' argument and concluded Appellant's evidence failed a medical literature litmus test. As discussed below, that conclusion is faulty because it misinterpreted Dr. Milby's medical literature testimony. More fundamentally, however, the circuit court's ruling represents an error of law because Dr. Milby applied reliable pathology methods and Rule 702's reliability analysis cannot be reduced to any single factor.

Traditionally, South Carolina courts examined expert testimony to determine "the degree to which the trier of faith must accept, on faith, scientific hypotheses not capable of proof or disproof in court and not even generally accepted outside the courtroom." State v. Jones, 273 S.C. 723, 731, 259 S.E.2d 120, 124 (1979). After Jones, South Carolina adopted Rule 702, SCRE, which permits "a witness qualified as an expert by knowledge, skill, experience, training, or education" to offer opinions that will "assist the trier of fact to understand the evidence or to determine a fact in issue." Rule 702, like its federal court counterpart, has been interpreted to impose a reliability requirement. Council, 335 S.C. at 20, 515 S.E.2d at 518 (citing Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993)). Since Rule 702 does not define reliability, Council reached back to Jones and other South Carolina precedent to give substance to the requirement. Council, 335 S.C. at 20, 515 S.E.2d at 518 (discussing the "Jones factors"). Council identified multiple factors relating to the reliability of scientific expert testimony such as (1) publication and peer review; (2) prior application of the method to the type of evidence involved in the case; (3) quality control procedures used to ensure reliability; and (4) consistency of the method with recognized scientific laws and procedures. 335 S.C. at 19, 515 S.E.2d at 517 (citing State v. Ford, 301 S.C. 485, 392 S.E.2d 781 (1990)).

Rule 702's reliability requirement "does not lend itself to a one-size-fits-all approach." Watson, 389 S.C. at 450 n. 1, 699 S.E.2d at 177 n. 1. The four considerations that have become known as the "Council factors" are non-exhaustive. Council held that the reliability of scientific expert testimony is based on "several factors" which "include[e]" the Council factors. 335 S.C. at 19, 515 S.E.2d at 517. In practice, this means that the reliability standard cannot be reduced to any single one of the traditional

Council factors and none of those factors can be elevated to a litmus test for scientific expert testimony. For example, in State v. Cain, ___ S.C. ___, 776 S.E.2d 374 (Ct. App. 2015), this Court found scientific expert testimony reliable without discussing the Council factor relating to "publication and peer review." The expert in Cain testified on the theoretical yield of methamphetamine based on the quantity of component chemicals present at a crime scene. 776 S.E.2d at 379. In a thorough discussion, this Court considered the prior application, consistency with scientific procedures, and quality control factors from Council. Id. at 381-82. However, Cain did not discuss the publication and peer review factor. Instead, after applying some but not all of the Council factors, Cain concluded that its gatekeeping duties were complete and the expert testimony was reliable. Id. at 382. Cain's omission of the publication and peer review factor is especially noteworthy because a perceived lack of publication/peer review was the opponent's expressed objection to the expert testimony. Id. at 379 (noting objecting party's doubt as to "whether 'some learned treatise' supported the theory").

The reliability standard imposed by the similarly worded federal rule has been interpreted the same way. Daubert, 509 U.S. at 594 ("The inquiry envisioned by Rule 702 is, we emphasize, a flexible one").[4] Daubert's list of factors "neither necessarily nor exclusively applies to all experts or in every case." Kumho, 526 U.S. at 141. Like Watson's refusal to apply a one-size-fits-all approach in South Carolina, the U.S.

[4] Admittedly, Council refused to adopt the Daubert standard. 335 S.C. at 20, 515 S.E.2d at 518. However, both standards rely on their respective Rule 702s and both propose similar sample reliability factors. Compare Council, 335 S.C. at 19, 515 S.E.2d at 517 with Daubert, 509 U.S. at 593-94. In fact, this Court has noted in the past that the Council and Daubert standards are often deemed "very similar." In re Robert R., 340 S.C. 242, 531 S.E.2d 301 n. 3 (Ct. App. 2000) (citing G. Ross Anderson, Jr., Evidence Eggshells—A New Walk for Experts, The Bulletin, Fall 1999 at 7, 9). At trial, Respondents argued that Council is Daubert progeny. Tr. of Record at 581, lines 1-3.

Supreme Court has held that "the factors identified in Daubert may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." Kumho, 526 U.S. at 150. Kumho not only refused to require trial courts to consider all factors Daubert suggested in every case, it also refused to define which Daubert factors should be considered for any particular type of expert testimony.[5] In other words, Kumho refused to say that, for example, all medical experts must be judged by all Daubert factors or any particular subset of those factors. The reality is that "[t]oo much depends upon the particular circumstances of the particular case" to impose rigid restraints on the reliability analysis. Id.

Kumho also expressly rejected the type of reliability litmus test the circuit court applied to Appellant's expert testimony. It would be an error to mechanically exclude medical expert testimony based on a lack of peer review studies confirming the expert's conclusion. The absence of studies may be attributable to a variety of factors wholly unrelated to the reliability issue. Id. at 151 (recognizing that some scientific issues may lack peer reviewed studies because the issue "may never previously have interested any scientist"). Building on Daubert and Kumho, many federal courts have admitted medical expert testimony where no publications or studies were offered. In Westberry v. Gislaved Gummi AB, 178 F.3d 257, 262 (4th Cir. 1999), the court rejected the argument that a medical expert's conclusion was unreliable simply because no peer reviewed studies supported his conclusion. The Third Circuit has also held that "we do not believe that a

[5] While Kumho was primarily concerned with the proper reliability analysis for technical or experiential expert testimony, its focus on the analysis' flexibility applies equally to scientific experts. 526 U.S. at 151 (noting Daubert's factors "do not all necessarily apply even in every instance in which the reliability of scientific testimony is challenged").

medical expert must always cite published studies on general causation in order to reliably conclude that a particular objet caused a particular illness." Heller v. Shaw Indus., Inc., 167 F.3d 146, 155 (3d Cir. 1999).

A per se rule requiring studies is too rigid and expert testimony "must be evaluated practically and flexibly without bright line exclusionary (or inclusionary) rules." Id.; see also Turner v. Fire Equip. Co., 229 F.3d 1202, 1208-09 (8th Cir. 2000) (adopting the Heller rule and citing Westberry). In the Second Circuit, the court has affirmed admission of expert testimony "despite the fact that the expert could not point to a single piece of medical literature" that specifically supported the expert's opinion. Amorgianos v. Nat'l R.R. Passenger Corp., 303 F.3d 256, 266 (2d Cir. 2002) (citing McCullock v. H.B. Fuller Co., 61 F.3d 1038, 1043 (2d Cir. 1995)). The Fifth Circuit had held that "we do not suggest that an expert must back his or her opinion with published studies that unequivocally support his or her conclusions." Knight v. Kirby Inland Marine Inc., 482 F.3d 347, 354 (5th Cir. 2007) (citing Bonner v. ISP Techs., Inc., 259 F.3d 924, 929 (8th Cir. 2001)). Noting the widespread consensus on this point, the Ninth Circuit found that the U.S. Supreme Court has specifically recognized that "[p]ublication . . . is not the *sine qua non* of admissibility." Clausen v. M/V New Carissa, 339 F.3d 1049, 1060 (9th Cir. 2003) (quoting Daubert, 509 U.S. at 593).

Cain, therefore, confirms South Carolina's at least tacit recognition of what the Fourth Circuit and most federal courts have stated explicitly—literature specifically approving the expert's precise conclusion may be important but is not a *sine qua non* for reliability. In this case, Respondents moved for a directed verdict based on a perceived lack of medical literature supporting Dr. Milby's testimony. Tr. of Record at 572. The

circuit court granted a directed verdict on that basis. Tr. of Record at 593-94. In doing so, the circuit court applied a requirement that the South Carolina Rules of Evidence do not impose and strayed from its gatekeeping duty. This decision represents an error of law and an abuse of the circuit court's discretion.

D. The circuit court's exclusion of Dr. Milby's testimony is not supported by Graves v. CAS Medical Systems, Inc.

Respondents relied on Graves v. CAS Medical Systems, Inc., 401 S.C. 63, 735 S.E.2d 350 (2012), to support the Council argument underlying their directed verdict motion. Graves affirmed the exclusion of multiple computer software experts in a products liability suit based on an allegedly defective medical device that may have contributed to an infant's death. Id. at 68, 735 S.E.2d at 652. Graves is distinguishable because Dr. Milby's methodology was far more reliable than the one employed by the experts in Graves. Those experts concluded that the defendant's vital sign monitor failed to sound its alarm in response to the decedent's increasingly dire breathing and heartrate. However, this conclusion was not grounded in sound scientific methodology. While the experts concluded that the monitor's software was defective, none of them actually tested the software. Id. at 70, 735 S.E.2d at 653. Their conclusions were based on the computer science equivalent of a differential diagnosis which, although a potentially reliable method for forming a causation opinion, was not reliably applied by the experts. Id. Despite objective evidence indicating that the monitor's alarm sounded properly, the experts rejected this evidence based solely on the plaintiffs' testimony that they did not hear the alarm. Id. at 71, 735 S.E.2d at 654. The objective evidence suggested that the monitor functioned properly and that the plaintiffs unfortunately slept through the alarm. Before settling on the conclusion that the monitor was faulty, the experts offered nothing

to discount the evidence suggesting that the device functioned properly. Id. at 76, 735 S.E.2d at 656. Their differential diagnosis was unreliable because it did not demonstrate the intellectual rigor used for similar processes outside of litigation.

Dr. Milby's testimony is different in several ways. For example, Dr. Milby's causation conclusion was not the product of a differential diagnosis. A differential diagnosis is the "process of identifying a cause by 'eliminating the likely causes until the most probable one is isolated.'" Id. at 77, 735 S.E.2d at 656 (quoting Westberry, 178 F.3d at 262). Dr. Milby concluded that Mr. Farr's second tumor was a metastasis not by ruling out possible alternative causes but by physically examining both tumors and identifying substantial, definitive evidence confirming metastasis. The cancer type, cell subtypes, and identical nuclei all supported Dr. Milby's conclusion that the second tumor was most probably a metastasis.

Dr. Milby's microscopic exam of the tumor cells is another factor that distinguishes Graves. The Graves experts did not even examine the software they concluded to be defective. In contrast, Dr. Milby conducted a detailed examination of Mr. Farr's tumors and presented the results to the jury. (Tr. of Record at 506-14). In fact, Dr. Milby was the only medical provider to examine both tumors. Dr. Milby based his conclusions on the objective results of his examination and, unlike the Graves experts, did not credit or rely on the disputed testimony of an interested party. Finally, Graves is different because the products liability claims at issue there impose a different causation standard than applies to Appellant's medical negligence claim. To prevail in the design defect claim at issue in Graves, a plaintiff must demonstrate product failure and a feasible alternative design. Branham v. Ford Motor Co., 390 S.C. 203, 225, 701 S.E.2d 5, 16

(2010). In other words, a products liability plaintiff must prove both that the product failed and prove how it failed by offering the factfinder a design in which the failure would have been avoided. The medical negligence causation standard is different. Appellant was only required to prove that "the injuries complained of most probably resulted from the defendant's negligence." Ellis, 323 S.C. at 125, 125, 473 S.E.2d at 795. Dr. Milby met this standard by testifying that Mr. Farr's second tumor was most probably a metastasis of the tumor Dr. Wan failed to diagnose on the January 2010 x-ray. This conclusion was reliable under Council because, unlike Graves, it was reached as part of a detailed, hands-on, and objective analysis of the actual tissue in question.

E. Dr. Milby's causation testimony was supported by medical literature.

The circuit court's exclusion of Dr. Milby's testimony was also in error because it misstated the evidence in the record. Even though his causation opinion was not dependent on the mechanism by which Mr. Farr's cancer metastasized, Dr. Milby discussed literature confirming that lung cancer can spread through the airways (i.e. aerogenous spread) in anticipation of Respondents' independent origination defense. The circuit court acknowledged that its directed verdict ruling focused on one exchange between Dr. Milby and defense counsel during cross-examination. (Tr. of Record at 593, line 23 – 594, line 13). That exchange is not representative of Dr. Milby's testimony either on direct or cross-examination. Moreover, Dr. Milby's testimony during this exchange was in response to questions that imposed restraints that were not a part of Dr. Milby's examination of Mr. Farr's case and not a part of the normal pathological process of examining microscopic lung cancer samples. In short, Respondents' counsel got Dr. Milby to admit that there is a lack of literature to support counsel's proposition but that

proposition was not the one underlying Dr. Milby's testimony and the absence of literature to support it could not render Dr. Milby's testimony unreliable.

The circuit court was incorrect in concluding that there is no medical literature to support aerogenous spread of lung cancer. Dr. Milby cited and read into the record multiple authoritative texts documenting this mechanism of lung cancer metastasis. Aerogenous spread of lung cancer is so well recognized among pathology practitioners that it is taught during pathology residency and appears prominently in leading lung pathology textbooks. (Tr. of Record at 488, lines 19-22). Dr. Milby cited Dail and Hammar's Pulmonary Pathology, an authoritative medical text devoted solely to pathology issues involving the lungs. (Tr. of Record at 489, lines 3-23). The Dail and Hammar text indicates that certain lung cancers "can spread aerogenously and . . . avoid the lymphatic pathways or regional nodes." (Tr. of Record at 490, lines 8-11). The same text indicates that some lung cancers are subject to "bilateral" aerogenous spread, which means that lung cancer cells can migrate through the air from one lung to the other. (Tr. of Record at 490, lines 8-13).

Dr. Milby referred to a second medical textbook entitled Lung and Mediastinum Cytohistology which read in part:

> Lung adenocarcinoma spread via the lymphatic systems, the regional lymph nodes, hematogenously to distant sties, **and/or aerogenously** to other regions of the lung. Aerogenous dissemination occurs in tumors with lepidic growth forming legions separate from the main mass involving from the same lobe or different lobes in the ipsilateral or the contralateral lung resulting in multi-centricity.

(Tr. of Record at 503, line 19 – 504, line 2) (emphasis added). Dr. Milby explained that this passage documents that some lung cancers can spread through the breathing process. (Tr. of Record at 504, lines 13-17). Dr. Milby also acknowledged a medical journal

article entitled "Neutrophils Promote Aerogenous Spread of Lung Adenocarcinoma with Bronchoalveolar Carcinoma Features." (Tr. of Record at 504, line 18 – 505, line 13).

The circuit court acknowledged that its ruling on the reliability of Dr. Milby's testimony on aerogenous spread focused on one question-and-answer during Dr. Milby's cross-examination. (Tr. of Record at 593, line 23 – 594, line 3). This exchange was part of an increasingly narrow and decreasingly relevant line of questioning regarding the basis for Dr. Milby's causation testimony. After Dr. Milby read from the authoritative texts cited above, Respondents' counsel asked Dr. Milby to cite literature supporting aerogenous spread for lung adenocarcinoma where the second tumor has a different proportion of cancer cell subtypes from the first tumor. (Tr. of Record 546, lines 4-9). This line of questioning misconstrued a fundamental aspect of Dr. Milby's opinions. For purposes of Dr. Milby's testimony on metastasis, the varying proportions of cell subtypes from the first tumor to the second was immaterial. (Tr. of Record at 475, line 19 – 476, line 2; 566, lines 1-13). From a pathological perspective, "with adenocarcinoma, subtypes don't really matter." (Tr. of Record at 554, lines 6-7). The same is true from a oncological perspective. (Tr. of Record at 187, line 25 – 188, line 4) (Dr. Singer testifying that "metastases in primaries often don't have the same histology" and "it's a regular finding"). Thus, defense counsel's questions were grounded in a distinction without a difference.

Even so, Dr. Milby took on Respondents' counsel's trifling challenge to prove a point that was not necessary to support his conclusion. He pointed to another portion of the Dail and Hammar text, and Respondents' counsel replied only with a quibble about the age of the footnotes supporting the proposition. (Tr. of Record at 546-47). This is the

context in which Respondents' counsel elicited the response on which the circuit court declared Dr. Milby's testimony unreliable and directed a verdict in Respondents' favor. But, counsel's disagreement with Dr. Milby's conclusions or with the pulmonary pathology texts that support them is a not a proper basis for excluding Dr. Milby's testimony.[6]

CONCLUSION

Based on the arguments stated above, Appellants respectfully request that the Court reverse the circuit court's order. Appellant offered competent expert testimony linking Respondents' breaches in the standard of care to the formation and progression of the lung cancer that took Mr. Farr's life. Oncologist Barry Singer testified that the type of cancer Mr. Farr had and the speed at which the second tumor developed demonstrated that the second tumor was a metastasis. Pathologist Willard Milby likewise testified that there was a 95-99% likelihood that Mr. Farr's second lung tumor was a metastasis. To support this conclusion, Dr. Milby presented the jury with the results of a microscopic pathological examination of Mr. Farr's cancer cells showing both tumors contained the same cancer cell subtypes and indistinguishable nuclei.

The circuit court's finding that Dr. Milby's testimony was unreliable was based on a misunderstanding of his testimony and the evidence offered to support it. Dr. Milby's testimony complied with Rule 702, SCRE and should have been considered in

[6] Nor is Respondents' insistence that their experts disagree with Dr. Milby and do not believe aerogenous spread is a recognized mechanism of lung cancer metastasis. (Tr. of Record at 11, lines 11-18). In Moriarty v. Garden Sanctuary Church of God, 341 S.C. 320, 331, 534 S.E.2d 672, 677 (2000), the court based its ruling in part on the recognition of a psychological condition even though some in the psychological community "believe there is no empirical evidence" that the concept is real. There may have been a "battle of experts" on the subject but the prospect of that battle certainly did not disqualify either side. Id. at 331-32, 534 S.E.2d at 677-78.

opposition to Respondents' directed verdict motion. Both with and without Dr. Milby's testimony, Appellant provided a scintilla of evidence on causation and her claim should have been presented to the jury.

Respectfully submitted, w/ express permission
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CERTIFICATE OF SERVICE BY MAIL

I, Kennardy Jones, employee of McGowan, Hood & Felder, LLC, attorney(s) for the Plaintiff, do hereby certify that I have served copy(s) of the **Initial Brief of Appellant,** on the parties listed below by depositing them in the United States Postal Service, with proper postage affixed thereto, on this 20th day of October, 2015, addressed to the attorney(s) listed below:

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