IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

January 2003 Term

	FILED
No. 31147	July 3, 2003
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	SUPREME COURT OF APPEALS

OF WEST VIRGINIA

STATE OF WEST VIRGINIA EX REL. WEIRTON MEDICAL CENTER and LAWRENCE CALLAHAN, M.D., Petitioners

v.

THE HONORABLE JAMES P. MAZZONE,
Judge of the Circuit Court of Brooke County; and
REBECCA VILGA, Executrix and Fiduciary of the
Estate of Paul A. Vilga, Jr., deceased,
Respondents

WRIT OF PROHIBITION GRANTED

> Submitted: April 9, 2003 Filed: July 3, 2003

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The Opinion of the Court was delivered PER CURIAM.

JUSTICE McGRAW dissents and reserves the right to file a dissenting opinion.

SYLLABUS BY THE COURT

- "In determining whether to entertain and issue the writ of prohibition 1. for cases not involving an absence of jurisdiction but only where it is claimed that the lower tribunal exceeded its legitimate powers, this Court will examine five factors: (1) whether the party seeking the writ has no other adequate means, such as direct appeal, to obtain the desired relief; (2) whether the petitioner will be damaged or prejudiced in a way that is not correctable on appeal; (3) whether the lower tribunal's order is clearly erroneous as a matter of law; (4) whether the lower tribunal's order is an oft repeated error or manifests persistent disregard for either procedural or substantive law; and (5) whether the lower tribunal's order raises new and important problems or issues of law of first impression. These factors are general guidelines that serve as a useful starting point for determining whether a discretionary writ of prohibition should issue. Although all five factors need not be satisfied, it is clear that the third factor, the existence of clear error as a matter of law, should be given substantial weight." Syllabus Point 4, State ex rel. Hoover v. Berger, 199 W.Va. 12, 483 S.E.2d 12 (1996).
- 2. "In analyzing the admissibility of expert testimony under Rule 702 of the West Virginia Rules of Evidence, the trial court's initial inquiry must consider whether the testimony is based on an assertion or inference derived from the scientific methodology. Moreover, the testimony must be relevant to a fact at issue. Further assessment should then be made in regard to the expert testimony's reliability by considering its underlying scientific methodology and reasoning. This includes an assessment of (a) whether the scientific theory

and its conclusion can be and have been tested; (b) whether the scientific theory has been subjected to peer review and publication; (c) whether the scientific theory's actual or potential rate of error is known; and (d) whether the scientific theory is generally accepted within the scientific community." Syllabus Point 2, *Wilt v. Buracker*, 191 W.Va. 39, 443 S.E.2d 196 (1993).

Per Curiam:

Petitioners Weirton Medical Center and Dr. Lawrence Callahan, defendants below, seek to have this Court prohibit the Brooke County Circuit Court from enforcing an order limiting the testimony of one of their experts, Dr. Gerald Nuovo.¹ We grant the requested writ.

I.

Shortly after having a tooth extracted, Paul Vilga developed a high fever, muscle rigidity, uncontrollable shaking, abdominal pains, delusions, and seizures. Paramedics were called and they rushed Mr. Vilga to Weirton Medical Center on March 13, 2000.

At Weirton Medical Center, the attending emergency room physician Dr. Callahan diagnosed Mr. Vilga as suffering from malignant hyperthermia.² A short time later,

¹In the related case, *State ex rel. Weirton Medical Center v. Mazzone*, 212 W.Va. 128, 569 S.E.2d 204 (2002), this Court held that the West Virginia Medical Professional Liability Act does not require the disclosure of expert witnesses by either party before the statutorily required status conference has been held. The Court further held that once a trial court determines that expert witnesses are required in a medical malpractice case, a reasonable period of time must be provided for the retention of expert witnesses.

²Malignant hyperthermia, if left untreated, causes a very high body temperature that results in organ failure, multiple-system failure, and ultimately death.

Dr. Callahan had Mr. Vilga transported by helicopter to Allegheny General Hospital in Pittsburgh, Pennsylvania.³

After Mr. Vilga's arrival at Allegheny General, the treating physician who examined Mr. Vilga concluded that Mr. Vilga did not have malignant hyperthermia. Instead, the treating physician concluded that Mr. Vilga suffered from sepsis, a bacterial or viral infection of the blood. Although Mr. Vilga underwent treatment for sepsis, he died several hours later-- approximately ten hours after the onset of his first symptoms.

Approximately one year later, Mr. Vilga's executrix and widow, Rebecca Vilga, filed a medical malpractice action and a wrongful death action against Weirton Medical Center and Dr. Callahan in Brooke County Circuit Court.

The petitioners hired Dr. Gerard Nuovo to review Mr. Vilga's medical records to determine the cause of his death. Dr. Nuovo currently teaches at the Ohio State University Medical Center in the Department of Pathology. Dr. Nuovo also directs the University's Department of Cytopathology (the study of disease in cells) and the University's Molecular Histopathology (the study of molecular changes in diseased tissues) laboratory. Dr. Nuovo is also board-certified in anatomic pathology.

Dr. Nuovo sits on the editorial review boards of several respected scientific journals including: the Journal of Histochemistry and Cytochemistry, the Journal of Histotechnology, the American Journal of Surgical Pathology, and the journal Frontiers in

³Whether it was medically necessary to transfer Mr. Vilga to Allegheny Hospital is factually disputed below.

Biotechnology. Dr. Nuovo has published more than 149 articles in peer-reviewed journals, has been invited to contribute to thirty-two chapters in peer-reviewed journals and texts, and has written or co-authored five books. Dr. Nuovo has also received several awards for his research. He received the LR Jones Award for Basic Research, the ASCAP award for resident research in 1993 and 1994, and the National Cancer Institute's Third Annual Howard M. Temin Award in Clinical Science for HIV/AIDS.⁴

To analyze Mr. Vilga's cells, Dr. Nuovo used a procedure called "Reverse Transcriptase *in situ* Polymerase Chain Reaction" (hereinafter "RT *in situ* PCR").⁵ The relatively new procedure differs from traditional testing procedures in that RT *in situ* PCR allows the examiner to test a cell for viruses while leaving the cell intact. Using traditional methods, the search for a virus' markers destroys the tested cells.

Using the RT *in situ* PCR method, Dr. Nuovo tested Mr. Vilga's spleen for different types of viral and bacterial infections. Ultimately Dr. Nuovo concluded that Mr. Vilga died as the result of rotaviral sepsis for which, in Dr. Nuovo's opinion, there is no cure.⁶

⁴According to the National Institute of Health's website, "[t]he major objective of the [Howard M. Temin] award is to sustain and advance the early research careers of the most promising M.D.s and Ph.D.s while they consolidate and focus their independent research programs, and obtain their own research grant support."

⁵Dr. Nuovo was involved in the invention and patenting of RT *in situ* PCR method for detecting rotaviruses.

⁶According to the circuit court's order, a rotavirus is "a children's disease [viral infection] commonly associated with diarrhea." In the United States and other industrialized (continued...)

Pre-trial, Mrs. Vilga moved to exclude the testimony of Dr. Nuovo on the basis that the testing procedure utilized by Dr. Nuovo was not a sufficiently reliable method for detecting rotaviruses. The trial court ordered that Dr. Nuovo's testimony be excluded, finding that the methodology used by Dr. Nuovo as a basis for his conclusion lacked sufficient indicia of reliability⁷ to be admitted into evidence.

In response to the circuit court's ruling, the petitioners filed the instant petition for a writ of prohibition with this Court. Petitioners seek to prohibit the circuit court from enforcing its order excluding Dr. Nuovo's testimony regarding a rotavirus as the cause of Mr. Vilga's death.

II.

This Court has established the following standard to apply when determining whether a writ of prohibition should issue:

In determining whether to entertain and issue the writ of prohibition for cases not involving an absence of jurisdiction but only where it is claimed that the lower tribunal exceeded its legitimate powers, this Court will examine five factors: (1) whether the party seeking the writ has no other adequate means,

⁶(...continued) countries, rotaviruses are typically not fatal except in the very young or those with severely compromised immune systems. Only two cases of adult rotavirus deaths have been documented in the United States, and both were diagnosed by Dr. Nuovo and his associates.

⁷The circuit court noted that while the use of techniques similar to RT *in situ* PCR has gained widespread acceptance for detecting other viruses, RT *in situ* PCR has not yet gained general acceptance for its use in detecting rotaviruses.

such as direct appeal, to obtain the desired relief; (2) whether the petitioner will be damaged or prejudiced in a way that is not correctable on appeal; (3) whether the lower tribunal's order is clearly erroneous as a matter of law; (4) whether the lower tribunal's order is an oft repeated error or manifests persistent disregard for either procedural or substantive law; and (5) whether the lower tribunal's order raises new and important problems or issues of law of first impression. These factors are general guidelines that serve as a useful starting point for determining whether a discretionary writ of prohibition should issue. Although all five factors need not be satisfied, it is clear that the third factor, the existence of clear error as a matter of law, should be given substantial weight.

Syllabus Point 4, *State ex rel. Hoover v. Berger*, 199 W.Va. 12, 483 S.E.2d 12 (1996).

In *State ex rel. Wiseman v. Henning*, 212 W.Va. 128, 569 S.E.2d 204 (2002) (*per curiam*), the testimony of expert witness Dr. Hussein was contested. Dr. Hussein, an expert in cancer research and treatment, proposed to testify to the novel theory that the impact from a physical trauma could cause multiple myeloma cancer at the site of impact. In *Wiseman*, this Court prohibited the circuit court from categorically excluding testimony from a well-credentialed medical expert on a novel theory.

The instant case is similar to *Wiseman*. In both instances, well-credentialed medical experts were presented to testify regarding theories that are relatively untested, and do not as yet enjoy widespread acceptance in the scientific community.

In the instant case, if we were to allow the trial court's ruling to stand, both parties would be compelled to go through an expensive, complex trial, and appeal from the final judgment — an appeal that would likely address this issue. Based on our review of the record before us, we determine there is a likelihood of reversal on appeal based on the circuit

court's exclusionary ruling; we further find that the petitioner has no plain, speedy, and adequate remedy in the ordinary course of law. *Wiseman*, 212 W.Va. at 132, 569 S.E. 2d at 208. Therefore, prohibition is appropriate.

Having decided that prohibition is appropriate, we move to the substance of the petitioner's claim — that the circuit court erred in excluding Dr. Nuovo's testimony that a rotavirus, and not the petitioners' negligence, had caused Mr. Vilga's death.

In reviewing an expert witness' testimony, circuit courts are guided by Rule 702 of the *West Virginia Rules of Evidence*. 8 Interpreting Rule 702, this Court has stated:

In analyzing the admissibility of expert testimony under Rule 702 of the West Virginia Rules of Evidence, the trial court's initial inquiry must consider whether the testimony is based on an assertion or inference derived from the scientific methodology. Moreover, the testimony must be relevant to a fact at issue. Further assessment should then be made in regard to the expert testimony's reliability by considering its underlying scientific methodology and reasoning. This includes an assessment of (a) whether the scientific theory and its conclusion can be and have been tested; (b) whether the scientific theory has been subjected to peer review and publication; (c) whether the scientific theory's actual or potential rate of error is known; and (d) whether the scientific theory is generally accepted within the scientific community.

Syllabus Point 2, Wilt v. Buracker, 191 W.Va. 39, 443 S.E.2d 196 (1993).

⁸Rule 702 states that:

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.

West Virginia Rules of Evidence, Rule 702.

We further held in Syllabus Point 3 of *Gentry v. Mangum*, 195 W.Va. 512, 466 S.E.2d 171 (1995), that an expert's testimony must be relevant and reliable. "The first and universal requirement for the admissibility of scientific evidence is that it be both 'reliable' and 'relevant." In *Gentry*, this Court required that "a *preliminary assessment* [be made] at the outset pursuant to Rule 104(a) of whether the reasoning or methodology underlying the testimony is scientifically valid." *Gentry*, 195 W.Va. at 521, 466 S.E.2d at 180. Circuit court judges have the discretion and authority under the *Rules of Evidence* to determine whether scientific expert testimony is "trustworthy, even if the technique involved has not yet won general scientific acclaim." *Gentry*, 195 W.Va. at 521, 466 S.E.2d at 180. Although the circuit court serves as the initial gatekeeper, questions of fact are ultimately for the jury to resolve. *Wiseman*, 212 W.Va. at 134, 569 S.E.2d at 210.

Central to Mrs. Vilga's medical malpractice action and wrongful death action is proving that the petitioners could have diagnosed and treated Mr. Vilga in a way that could have prevented his death. The parties in the instant case do not dispute the relevance of Dr. Nuovo's testimony. Instead, Mrs. Vilga disputes the reliability of Dr. Nuovo's testimony under a *Wilt* analysis.

The *Rules of Evidence* do not require that a scientific opinion be "generally accepted," because such a requirement is "at odds with the liberal thrust of the . . . Rules and their general approach of relaxing the traditional barriers to opinion testimony." *State v. Leep*, 212 W.Va. 57, 66, 569 S.E.2d, 133, 141 (2002) (citations and internal quotations omitted); *accord Wiseman*, 212 W.Va. at 134, 569 S.E.2d at 210. When analyzing expert

testimony, trial courts are to focus on the soundness of the principles and methodologies used, not the conclusions ultimately reached. "The problem is not to decide whether the proffered evidence is right, but whether the science is valid enough to be reliable." *Gentry*, 195 W.Va. at 523, 466 S.E.2d at 182; *see Wiseman*, 212 W.Va. at 134, 569 S.E.2d at 210. This Court further stated in *Gentry* that "[o]nce an expert witness passes the minimal threshold, further credentials affect the weight of the testimony not its admissibility." *Gentry*, 95 W.Va. at 523 fn. 14, 466 S.E.2d at 182, fn. 14 (1995).

This Court takes notice of the small sample of patients in whom Dr. Nuovo has detected rotaviruses using the RT *in situ* PCR technique, and of the circuit court's finding that four patients was too small a number to be a representative sample for scientific purposes. However, a small sample and the other concerns cited by the circuit court in its order are not a hindrance to admissibility, but instead go to the weight given to the evidence.

This Court further recognizes that Dr. Nuovo's opinion may be novel and unorthodox, and may not have yet received, as the circuit court found, "general acceptance

⁹As Dr. Nuovo testified at his deposition, no other doctor outside of his medical group has used the technique to detect a rotavirus.

¹⁰No doctors outside of Dr. Nuovo's medical group have written about RT *in situ* PCR in a publication subject to peer review. At the time of the circuit court's order, Dr. Nuovo and other doctors in his medical group had written one article that had appeared in two separate peer-reviewed journals.

As for the rate of error, Dr. Nuovo testified that the rate of error for the RT *in situ* PCR is practically zero, but no other publications exist to which the circuit court could compare Dr. Nuovo's assertion.

Finally, RT *in situ* PCR is not widely used to diagnose rotaviruses, but is generally accepted in the scientific community for the diagnosis of most viral infections.

in the scientific community." However, the record suggests a substantial degree of reliability underlying the formation of Dr. Nuovo's opinion. Even one of the respondent's experts, Dr. Keith B. Armitage, recognized in his deposition that Dr. Nuovo is a "mainstream scientist," meaning that "[h]e's a professor at a major academic center and he has publications that have been published in peer reviewed journals." Dr. Armitage further acknowledges that PCR is the "gold standard for most viral infections." When asked in his deposition: "Well, is there a difference between PCR and RT *in situ* PCR?" Dr. Armitage replied: "No, not really."

While Dr. Nuovo's theory may be novel, his theory is that of a "mainstream scientist" at "a major academic center" who has "publications that have been published in peer reviewed journals." Dr. Nuovo's credentials and the RT *in situ* PCR procedures combine to make Dr. Nuovo's proffered opinion "valid enough to be reliable." Whether "the proffered evidence is right" is a question for the finder of fact.

Accordingly, we find that the circuit court exceeded its authority in its decision to exclude the testimony of Dr. Nuovo.

III.

Therefore, we grant the requested writ of prohibition. The circuit court is precluded from enforcing its order excluding the expert's testimony.

Writ of Prohibition Granted.