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STATE OF WEST VIRGINIA
SUPREME COURT OF APPEALS

Loretta Cline, Executrix of the Estate of Henry Cline, Plaintiff Below

Petitioner,

v.

Case No. 11-0351
(Lower Court Case No. 09-C-2034)

Kiren Jean Kresa-Reahl, M.D., Defendant Below,

Respondent.

PETITIONER'S REPLY BRIEF

Richard D. Lindsay, M.D., J.D.
WV State Bar # 2216
Matthew C. Lindsay, M.D., J.D.
WV State Bar # 7896
Tabor Lindsay & Associates
Post Office Box 1269
Charleston, WV 25325
mlindsay@taborlindsay.com
304/344-5155

COUNSEL FOR PETITIONER

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III. ASSIGNMENTS OF ERROR (REPLY)

1. **Informed consent is not limited to only "procedures" but explicitly extends to medical treatment.**

2. **Informed consent claims do not require a screening certificate of merit.**

3. **The Respondent agrees with Petitioner that only the court has the authority to determine the sufficiency of, or need for, a screening certificate of merit.**

IV. STATEMENT OF CASE

Procedural History

On July 6, 2009 petitioner, Loretta Cline, Executrix of the Estate of Henry Cline, provided respondent a "Notice of Claim and Statement Pursuant to West Virginia Code §55-7B-6(c),"stating her intent to file suit against Dr. Kresa-Reahl for lack of informed consent. *(A.R.35.)* On August 4, 2009, respondent, via letter, objected to petitioner's Notice of Claim and asserted, among other things, that petitioner was required to provide a screening certificate of merit. *(A.R. 20.)* On August 5, 2009, petitioner responded in writing asserting that she met the statutory requirements for filing her claim. *(A.R.22.)*

On October 29, 2009, petitioner filed her Complaint. *(A.R.1.)* On December 22, 2009 respondent filed an Answer denying all substantive claims and Motion to Dismiss alleging petitioner failed to comply with pre-suit requirements of §55-7B-6. *(A.R.9.)* Petitioner filed a Response to Motion to Dismiss on April 1, 2010. *(A.R.36)*. Respondent filed a Reply on April 7, 2010. *(A.R.42.)* A hearing on respondent's Motion to Dismiss was held on April 7, 2010. On February 3, 2011, nearly a year later, the trial court entered an Order of Dismissal. *(A.R.47)*. This is an appeal from the final Order of Dismissal.

Statement of Facts

On or about February 22, 2009, petitioner's decedent, Henry Cline, presented to the emergency department at Charleston Area Medical Center by ambulance with complaints of headache followed by sudden onset right-sided weakness, partial paralysis, and decreased ability to speak. At approximately 10:30 p.m., well within the recognized window for lytic therapy, respondent, Dr. Kresa-Reahl, was consulted by telephone and declined to administer thrombolytic therapy based on Mr. Cline's history of prostate cancer. Dr. Kresa-Reahl never saw Mr. Cline, nor did she speak with Mr. Cline or his wife. Petitioner was never provided adequate information regarding treatment options for acute stroke. Mr. Cline was admitted to the Intensive Care Unit where he died the following morning.

Respondent has alleged a series of facts regarding, among other things, Mr. Cline's initial symptoms, the onset of those symptoms, discussions that took place in the emergency room between the Respondent and the emergency room physician, and factors considered by Respondent in her determination of the course of treatment for Mr. Cline. (*A.R. 11*) However, petitioner's claim was dismissed prior to any discovery or the taking of any testimony. These facts are not in evidence, nor has petitioner stipulated as to their authenticity or validity. Respondent has now alleged those same facts in her response.

The only facts that should be considered by the Court are those which have been alleged by Petitioner, and those facts must be construed in light most favorable to the Petitioner inclusive of all reasonable inferences which may be drawn from those facts.

V. STATEMENT REGARDING ORAL ARGUMENT

Although the principle issue in this case, a claim predicated on lack of informed consent, has been reviewed by the Court in *Cross v. Trapp*, 170 W. Va. 459, 294 S.E.2d 446 (1982) and *Hicks v. Ghaphrey*, 212 W. Va. 327, 571 S.E.2d 317 (2002), it has not been reviewed by the Court in light of the Medical Professional Liability Act, *West Virginia Code* §55-7B-6. Therefore, to the extent that a claim of lack of informed consent is subject to or exclusive of the pre-suit requirement of a screening certificate of merit is an issue of first impression and is appropriate for Rule 20 argument.

VI. ARGUMENT

1. Informed consent is not limited to only "procedures" but explicitly extends to medical treatment.

A. Respondent erroneously contends, citing Cross v. Trapp, 170 W. Va. 459, 294 S.E.2d 446 (1982) and Hicks v. Ghaphrey, 212 W. Va. 327, 571 S.E.2d 317 (2002), that [i]nformed consent is a prerequisite to surgeries or other particular medical procedures that require invasive action or other physical contact." *See* Respondent's Brief 9. Justice McHugh opens the opinion in Cross by stating, "In this action, we are asked to consider the requirements of a consent given by a patient prior to surgery. **On a broader scale, we are asked to review a physician's duty to disclose to his patients methods of treatment, including surgery, and the risks incidental to such methods of treatment**." Id at 462 (*emphasis added*).

The fundamental basis of the patient need standard is that every patient, indeed every person, has a right to determine what is in their best interest. Id at 464. That is, each individual has the right to determine what medical treatment they receive. Canterbury v. Spence, 464 F.2d 772 (C.A.D.C. Cir. 1972), cert. denied. 409 U.S. 1064, 93 S.Ct. 560, 34 L.Ed.2d 518 (1972), the benchmark case used in the Court's analysis, represented a philosophical shift in the law by rejecting those standards imposed by physicians or the community. The court recognized that, if given adequate information, patients have ability and the right to chose a course of treatment that is best for them. The physician's duty is to provide adequate information so that the patient can make an educated decision. This couldn't be more clear than in the case of cancer. Those unfortunate individuals who are confronted with the diagnosis of cancer must often chose between surgery, chemotherapy, radiation, or a combination of all three. Some patients choose to forgo treatment completely. The physician's duty is to explain the potential success of each treatment, the risks and adverse effects inherent to each treatment, and the likely outcome should a patient refuse treatment. The patient's right to make an informed decision imposes the duty of informed consent, not the fact that surgery is an option for treatment.

Additionally, the "procedure" argument is one of semantics. It begs the question, "what is considered a medical procedure?" Respondent insinuates that a procedure involves some form of invasive treatment or offensive touching. Ironically, in her brief, respondent fails to meet that

standard by citing and heavily relying on *Vandi v. Permanente Medical Group, Inc.*, 7 Cal.App.4th 1064, 9 Cal.Rptr.2d 463 (1992). In that case, plaintiff sued the defendant physician for failing to perform a CT scan following a seizure. Plaintiff alleged that a CT scan would have revealed a intra-cranial abscess, the cause of the seizures. However, a CT scan is not surgery or a procedure, nor is it invasive. The reality is that the Court in *Vandi* declined to extend informed consent to include diagnostic tests that may have uncovered a particular condition. In essence, the Court declined to extend the physician's duty to disclose alternative treatments to include potential diagnostic procedures, opining that there are hundreds of potential diagnostic procedures available for a given condition and it is unreasonable to impose such a burden on a physician. However, the Court in *Vandi* reserved the potential for the duty to extend to non-recommended treatments, "In an appropriate case there may be evidence that would support the conclusion that a doctor should have disclosed information concerning a nonrecommended procedure." Id at 467.

The reason for that reservation by the Court in *Vandi* is illustrated by the case at bar. While in the emergency room, Mr. Cline was diagnosed with an acute stroke. There are only two potential treatments for this type of acute stroke: (1) thrombolytics and (2) conservatives measures.[1] The emergency room physician contacted Respondent by phone and she declined to recommend thrombolytics. Instead, Respondent recommended admission to the ICU and conservative treatment. Petitioner's claim for informed consent is based on the fact that no one discussed the potential treatments for acute stroke, the relative risks inherent to those treatments, or reasonable alternatives to those treatments. In fact, Respondent never actually saw Mr. Cline. Dr. Kresa-Reahl simply ordered a treatment (conservative measures) without obtaining informed consent. At that point, petitioner was entitled to receive adequate information about his care and treatment.[2] Mr. Cline was entitled to decide what course of treatment was in his best interest.

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[1]CT scan confirmed that Mr. Cline's stroke was due to a clot. Conservative measures include admission to the ICU for bed rest and observation, medications, and necessary life support intervention.

[2]At the time, Mr. Cline was unable to make medical decisions. His wife, Petitioner herein, had the proper authority to make medical decisions on behalf of Mr. Cline.

There is no way of knowing what decision would have been made, but there were other options available including, but not limited to, choosing thrombolytic therapy, getting a second opinion, or refusing treatment altogether. The breach of duty to obtain informed consent occurred when Mr. Cline was not provided the information necessary to make an informed decision. That exemplifies the foundation of the patient need standard adopted by this Court in *Cross*. Petitioner is not seeking expansion of the informed consent doctrine, only its proper application.

B. Even if the Court upholds the standard in *Hicks* (that informed consent only applies to recommended procedures), that would still require a physician to disclose reasonable alternatives.

In *Hicks*, the plaintiff had been injured in a motor vehicle accident which left him paralyzed. Weeks after his discharge from the hospital, Mr. Hicks developed a blood clot and subsequent pulmonary embolism and died. The claim in that case was one of medical negligence for the failure of the physician to insert a vena cava filter (designed specifically to prevent pulmonary embolism) during the initial hospitalization. That case resulted in a jury verdict in favor of the defendant. On appeal, Hicks alleged that, among other things, the lower court erred by not giving an instruction on informed consent. The Court reasoned, relying on *Vandi* and distinguishing the case from *Matthies v. Mastromonaco*, 160 N.J. 26, 733 A.2d 456(1999), that because the physician did not recommend insertion of a vena cava filter, the physician was did not have a duty to disclose the vena cava filter as a potential method of treatment. Id at 325.

The oversight in the *Hicks* analysis is two-fold. First, requiring a physician to only disclose information about a method of treatment which is recommended virtually destroys the patient need standard to obtain informed consent. The physician is then only required disclose the risks, efficacy, and anticipated outcome of the recommended treatment. That is, a physician is only required to obtain informed consent for those methods of treatment that the physician deems appropriate. This is simply a recapitulation of the reasonable physician standard explicitly rejected by this Court in *Cross*.

> "We find the patient need standard to be the standard most likely to make certain that a patient's consent to a particular method of treatment, such as surgery, was, in fact, an

> informed consent. Unlike the patient need standard, the focus of the national and local standards of disclosure is upon the medical profession, rather than upon the patient. As stated in *Canterbury*, supra: 'Respect for the patient's right of self-determination on a particular therapy demands a standard set by law for physicians rather then one which physicians may or may not impose upon themselves.' 464 F.2d at 784."Id at 467-468.

Secondly, the analysis in *Hicks* ignores the fact that even if a treatment is recommended by the physician, according to *Cross*, the physician still has a duty to disclose reasonable alternatives and the risks associated with those alternatives. Using the facts in *Hicks* as an example, the defendant physician did not recommend insertion of the vena cava filter, but instead ordered multiple ultrasounds to check for blood clots. Essentially, the physician recognized the risk of Mr. Hicks developing blood clots and chose to monitor that risk via ultrasound. However, even according to the Court's analysis, the physician would still be required to obtain informed consent for the treatment that was recommended. That is, he is required to discuss alternative treatments and the risks inherent to those alternative treatments. Therefore, assuming insertion of the vena cava filter is an alternative treatment, it should have been discussed with Mr. Hicks.

2. Informed consent claims do not require a screening certificate of merit.

As set forth in Petitioner's brief, as a prerequisite to filing a claim in medical negligence *West Virginia Code* §55-7B-6, the Medical Professional Liability Act (herein "MPLA"), mandates that a potential plaintiff first provide a notice of claim and screening certificate of merit to each subject defendant. However, in anticipation of those cases that are founded upon well-established common law theories of liability and do not require an expert to opine as to the breach of the applicable standard of care, the MPLA provides an exception in §55-7B-6(c). Contrary to Respondent's brief, a claim for lack of informed consent squarely falls within the language and intent of §55-7B-6(c).

Respondent admits that *Cross* supports the contention that expert testimony is not needed to establish the scope of the physicians duty or the breach of that duty. However, Respondent then argues because expert testimony may be needed during the course of the claim, then, by default, informed consent must require a certificate of merit. This is the same argument that was presented in *Sayre v. United Sates of America*, No. 2:09-0295, 2009 U.S. Dist. LEXIS 114864

(S.D.W. Va. Dec. 9, 2009) and is Respondent's only support for her position.[3] The issue of whether a claim for informed consent requires a certificate of merit has never been addressed by this Court. According to Cross, expert testimony is not required to establish the scope of a physicians duty, nor the breach thereof. Therefore, since it is the patient who determines the physician's duty to disclose, Petitioner is not required to provide a certificate of merit to satisfy the pre-suit requirements of the MPLA. Moreover, the court in Sayre failed to recognize the actual language in §55-7B-6(c), which specifically includes those claims which do "not require expert testimony supporting a breach of the standard of care." The patient need standard in Cross explicitly states that expert testimony is not necessary to prove a breach of the standard of care. If the legislature had intended that plaintiffs provide a certificate of merit for some other purpose, *i.e.* on risks and alternative methods of treatment, it would have certainly added that language. However, the wisdom of the legislature was to limit the certificate of merit exception to those case which do not require expert testimony to establish a breach of the standard of care.

The patient need standard adopted in Cross represents the last bastion of lay a person's right to access the courts in medical malpractice. The standard arose from common law to hold physicians accountable for the information they provide patients. In fact, it is difficult to imagine another well-established common law theory of liability that would meet the exception to the certificate of merit in §55-7B-6(c). If the Court determines that a certificate of merit is required in claims for lack of informed consent, it would not only undermine the decision in Cross, but would essentially bar *pro se* medical malpractice litigants from the courts.

3. The Respondent agrees with Petitioner that only the court has the authority to determine the sufficiency of, or need for, a screening certificate of merit.

Although Respondent concedes this point, she alleges that Petitioner had numerous opportunities to "cure the defect" by obtaining a certificate of merit. Procedurally, potential

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[3]The plaintiff in Sayre was represented by the same counsel as Petitioner herein. Although Petitioner has no knowledge of that case, counsel for Petitioner asserts that the Court erred by dismissing the claim for lack of a certificate of merit. However, due to other factors not at issue here, an appeal was not filed in that case.

defendants in a medical malpractice claim must note their objections to the notice of claim or screening certificate within thirty days of receipt in order to preserve the right to challenge the validity or sufficiency of those documents once the Complaint has been filed.

As a practical matter, this creates an atmosphere where potential defendants object to the notice of claim or certificate of merit, regardless of quality or content, simply to preserve that right. A prime example is the objection made in the case at bar. Respondent demanded that petitioner identify, among other things, how she intended to establish Mr. Cline had a stroke, the last "clock time" Mr. Cline was normal, and the National Institute of Health Stroke Score assigned to Mr. Cline. *(A.R.20-21)*. The pre-suite requirements do not contemplate nor require a potential plaintiff to provide such a detailed description of facts, which may or may not be known, at the time of service of the notice of claim and certificate of merit. In other words, a potential plaintiff is not required to try her case in the notice of claim and certificate of merit before the Complaint has been filed or discovery has commenced.

In as much as a potential defendant has a right to object to the notice of claim or screening certificate of merit, a potential plaintiff has the right to assert that the notice and certificate provided satisfy the requirements as set forth in the MPLA. At that point, only the Court, upon proper motion, has the authority to determine the sufficiency of a certificate of merit. Therefore, assuming the Court determines a defect exists, this is the first opportunity for a potential plaintiff to correct any insufficiency. *Westmoreland v. Vaidya*, 222 W. Va. 205, 664 S.E.2d 90 (2008). Upon such determination by the court, Petitioner must be granted a reasonable amount of time to cure any deficiencies.

Respondent contends that petitioner had numerous opportunities to cure any defect in the notice of claim and certificate of merit. These alleged "opportunities" are artificially created based on Respondent's initial objections to the certificate of merit and are prior to the court's review. Therefore, Petitioner did not have an opportunity to cure any defects until the court ruled that there was a defect. To assert that Petitioner had an opportunity to cure prior to the court's review essentially subjects the Petitioner to the whim of the Respondent. That is, any potential defendant then has the authority to determine the sufficiency of the notice or certificate. West Virginia law, as respondent concedes, exclusively provides that only the Court can determine the

sufficiency of or need for a certificate of merit.

VII. CONCLUSION

The lower court erred in granting respondent's motion to dismiss. the common law doctrine of informed consent is a well-established principle of law. In *Cross*, West Virginia adopted the patient need standard which does not require expert testimony to establish the scope of a physician's duty to disclose. The need for expert testimony to prove certain matters beyond or outside the scope of a physician's duty does not impose a duty upon petitioner to provide a screening certificate of merit. Therefore, a claim of lack of informed consent made pursuant to West Virginia Code §55-7B-6(c), does not require that petitioner provide a screening certificate of merit. Furthermore, a physician has a duty to provide reasonable information regarding multiple treatment options, which is generally construed to include the possibility of treatment, the risks inherent to recommended treatment, alternative treatments, risks inherent to alternative treatments, and the likely outcome of a chosen course of treatment regardless of whether the physician recommends a particular treatment. Therefore, petitioner requests that ruling of the lower court be reversed, and this case remanded for further proceedings. In the alternative, should this Court affirm the trial court ruling above, petitioner should be provided adequate time to obtain a certificate of merit before dismissal of her claim.

Loretta Cline, Executrix of the
Estate of Henry Cline
By Counsel:

Richard D. Lindsay, M.D., J.D.
WV State Bar # 2216
Matthew C. Lindsay, M.D., J.D.
WV State Bar #7896
Tabor Lindsay & Associates
Post Office Box 1269
Charleston, WV 25325
mlindsay@taborlindsay.com
304/344-5155

CERTIFICATE OF SERVICE

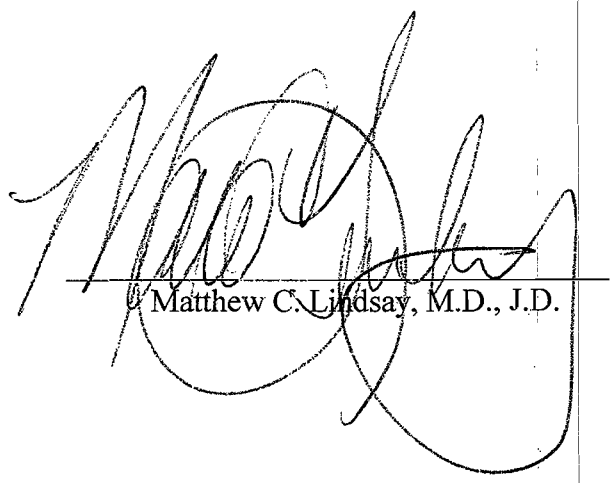
I hereby certify that on this 10th day of August, 2011, true and accurate copies of the foregoing Petitioner's Brief were deposited in the U.S. Mail contained in postage-paid envelope addressed to counsel for all other parties to this appeal as follows:

Barry M. Taylor, Esquire

Jenkins Fenstermaker, PLLC

Post Office Box 2688

Huntington, WV 25726-2688



Matthew C. Lindsay, M.D., J.D.