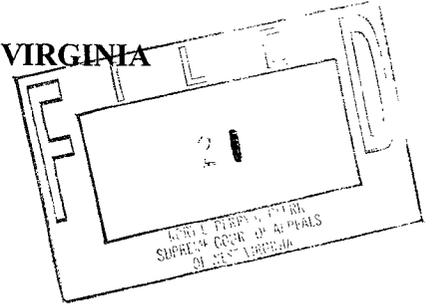


IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA



**LORETTA CLINE, Executrix of the Estate  
of Henry Cline, Plaintiff Below,**

**Petitioner,**

**v.**

**Supreme Court Docket No. 11-0351  
Trial Court Civil Action No. 09-C-2034**

**KIREN JEAN KRESA-RE AHL, M.D.,  
Defendant Below,**

**Respondent.**

**RESPONDENT'S BRIEF**

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## II. STATEMENT OF THE CASE

### Procedural History

Petitioner mailed Kiren Jean Kresa-Reahl, M.D., a “Notice of Claim” on July 6, 2009 (*See* Appendix, 000035), but failed to include a “screening certificate of merit” to support and substantiate the claim as required by West Virginia Code § 55-7B-6(b). Petitioner’s letter only stated, “No expert witness is needed as [decedent] did not receive adequate information regarding treatment options....” Petitioner did not further explain the absence of a screening certificate of merit.

Pursuant to West Virginia Code § 55-7B-6(e), and within 30 days of receiving the Notice of Claim, Dr. Kresa-Reahl responded by letter dated August 4, 2009. *See* Appendix, 000020. In her response, Dr. Kresa-Reahl made numerous specific objections to petitioner’s Notice of Claim and lack of screening certificate of merit and also requested more definite statements, details and/or information regarding the claim. Petitioner replied to this request in a brief letter dated August 5, 2009. *See* Appendix, 000022. Counsel asserted simply, “We feel we have fully complied with the statutory and case law requirements for the filing of our claim.” No further statement or support was made and no screening certificate of merit was provided. Instead, on October 29, 2009, petitioner filed her Complaint. *See* Appendix, 000001.

Dr. Kresa-Reahl timely answered petitioner’s Complaint, denied its substantive allegations, and preserved a number of affirmative defenses, including lack of subject matter jurisdiction and failure to state a claim upon which relief could be granted pursuant to Rules 12(b)(1) and 12(b)(6) of the West Virginia Rules of Civil Procedure, and also based upon petitioner’s failure to comply with the statutory pre-suit filing requirements of the Medical Professional Liability Act (“MPLA”). *See* Appendix, 000024. At the same time, Dr. Kresa-Reahl filed a Motion to Dismiss, further

detailing petitioner's failure to comply with the MPLA's pre-suit requirements and asking the lower court to dismiss petitioner's claim. *See* Appendix, 000009. Petitioner served a Response to Dr. Kresa-Reahl's Motion to Dismiss on March 31, 2010. *See* Appendix, 000036. Dr. Kresa-Reahl served a Reply on April 6, 2010. *See* Appendix, 000042. A hearing on Dr. Kresa-Reahl's Motion to Dismiss was held on April 7, 2010 before Judge Jennifer F. Bailey, Judge of the Circuit Court of Kanawha County, West Virginia.

The trial court entered an order dated February 3, 2011 granting Dr. Kresa-Reahl's Motion to Dismiss and dismissing, without prejudice, petitioner's Complaint. *See* Appendix, 000047. Judge Bailey found that petitioner had not asserted or specified a "well established legal theory of liability which did not require expert testimony" in her Notice of Claim on July 6, 2009 as required by West Virginia Code § 55-7B-6(c). Dr. Kresa-Reahl had not recommended, performed, or ordered thrombolytic therapy, or any other procedure. Therefore, because neither the thrombolytic therapy procedure nor any other procedure was performed or even recommended, the claim was not based on an informed consent theory.

Judge Bailey also ruled that even if the case could be based upon a theory of informed consent, expert medical opinion would be required to establish that the treatment which was not offered was medically reasonable or indicated and, accordingly, should have been disclosed or recommended to meet the applicable standard of medical care. The reasonableness of a treatment, including alternative treatments, must be left to the medical judgment of trained physicians, and must be assessed based upon the particular circumstances and conditions known when patient care is rendered. The trial court concluded that physicians are not legally obligated under an informed consent theory to disclose treatments, against their discretion and medical judgment, which are not indicated under the circumstances. The trial court also concluded expert opinion was necessary in

this case, in the form of a certificate of merit, to establish whether the thrombolytic therapy procedure was medically indicated under the circumstances of Mr. Cline's care and such testimony also would be necessary to establish whether this therapeutic procedure would have altered the ultimate outcome for Mr. Cline. Judge Bailey held that petitioner's filing of her Complaint without a screening certificate of merit was premature and ordered the dismissal of petitioner's Complaint without prejudice.

From this order, petitioner filed this appeal and requested an order reversing the trial court's ruling.

#### Statement of the Facts

This is a professional liability claim against Dr. Kresa-Reahl, a licensed health care provider and board-certified neurologist, who previously maintained a practice in neurology at Capitol Neurology in Charleston, West Virginia.<sup>1</sup> Petitioner's decedent, Henry Cline, developed a headache, then weakness and difficulty speaking, at his home on February 22, 2009, at approximately 7:30 p.m., which was the onset of his symptoms. His complaints progressed to staring, one-sided weakness and difficulty speaking. Petitioner and plaintiff below, Loretta Cline, decedent's wife, called for an ambulance at 9:05 p.m. The crew noted after their arrival at 9:13 p.m. that Mr. Cline was unable to speak, had right sided weakness, was lying in bed and had a decreased level of consciousness. He would not obey commands and was unable to move his right arm and leg to command. His history of prostate cancer also was documented. The ambulance immediately took Mr. Cline to the Emergency Department at Charleston Area Medical Center General Division ("CAMC"), where he arrived shortly before 10:00 p.m.

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<sup>1</sup> In July 2010, Dr. Kresa-Reahl moved to Portland, Oregon, where she is affiliated with Providence Brain Institute, part of Providence - St. Vincent's Medical Center. Dr. Kresa-Reahl's current practice is located at the Providence Multiple Sclerosis Center.

The emergency physician and CAMC staff began their patient evaluation immediately, and noted Mr. Cline's medical history, symptom onset, and absence of prior neurological complaints. Laboratory studies and a head CT scan also were obtained immediately. The head CT did not indicate hemorrhage, brain swelling, or acute indications of a stroke.

The emergency physician telephoned Dr. Kresa-Reahl, who was on call for the neurology service, with his assessment of an acute ischemic stroke and spoke with her between 10:30 and 10:45 p.m. He reviewed with her Mr. Cline's condition including the timing, onset and progression of his severe symptoms, his obtunded (markedly dulled or decreased) level of consciousness and cancer history and she concluded, based on this verbal report, that a thrombolytic therapy procedure was not appropriate for Mr. Cline. (A thrombolytic therapy procedure is a general reference to administering the drug "tPA" to a patient in an effort to "lyse" or break up a blood clot in the heart, brain or other body part. A consent form generally is utilized with the procedure because of the significant risks of injury and death which accompany the use tPA.) Dr. Kresa-Reahl immediately admitted him to the Intensive Care Unit for close monitoring based upon his presentation, where he was seen promptly by in-hospital intensivist physicians, and specifically trained nurses.

Mr. Cline received intensive medical care and monitoring throughout the night. He nevertheless developed cardiac and respiratory arrest at 6:50 a.m. (his heart and breathing stopped) and resuscitation efforts were undertaken. He could not be revived and was pronounced dead at 7:32 a.m., on February 23, 2009, twelve hours after symptom onset.

### **III. SUMMARY OF ARGUMENT**

1. The MPLA has required claimants to provide health care providers with a screening certificate of merit unless their claim is based upon a "well-established legal theory of liability which does not require expert testimony." Petitioner's claim did not meet the exception.

Her claim was not an informed consent claim because, under West Virginia law, informed consent claims involve the performance of a particular medical procedure and Dr. Kresa-Reahl did not perform, or even recommend, such a procedure. The patient need standard would not apply, as this standard is applicable only to informed consent claims. Rather, petitioner's claim was an ordinary negligence claim and a certificate of merit was required to establish a breach of the applicable standard of care. Judge Bailey correctly held that the claim was not based upon a theory of informed consent and properly concluded a certificate of merit was required.

2. Alternatively, in the event this Court should expand the informed consent theory to include non-performed and/or non-recommended treatments, a certificate of merit was needed to establish that Dr. Kresa-Reahl's decision not to order the thrombolytic therapy procedure was a breach of the applicable standard of care. Under existing West Virginia law, informed consent cases have involved a physician's duty to disclose medical information in relation to particular medical procedures performed. With an expanded theory, expert medical opinion would be required to establish duty and breach, particularly to establish that a non-performed procedure was medically reasonable or indicated under the circumstances. Judge Bailey correctly held that an expert opinion and, therefore, a certificate of merit, were required in this matter even if the claim was based upon a theory of informed consent.

3. Judge Bailey did not find that Dr. Kresa-Reahl had the authority to determine the sufficiency of petitioner's Notice of Claim. The trial court retained this authority and properly exercised it in holding that petitioner's claim did, in fact, require a certificate of merit. Dr. Kresa-Reahl maintained her right to contest the sufficiency of pre-suit papers and, upon proper motion, Judge Bailey was within her discretion in dismissing the claim without prejudice.

#### **IV. STATEMENT REGARDING ORAL ARGUMENT AND DECISION**

The present case does not present unique or complicated questions of law or fact necessitating oral argument in view of the Court's prior decisions in Cross v. Trapp, 170 W.Va. 459, 294 S.E.2d 446 (1982), and Hicks v. Ghaphery, 212 W.Va. 327, 571 S.E.2d 317 (2002). The trial court's decision also was consistent with the decision of the United States District Court for the Southern District of West Virginia in Sayre v. United States of America, No. 2:09-0295, 2009 U.S. Dist. LEXIS 114864 (S.D.W. Va. Dec. 9, 2009).

#### **V. ARGUMENT**

**I. The trial court correctly held that petitioner's claim required a screening certificate of merit, as her claim was not based upon an informed consent theory of liability.**

The trial court correctly dismissed petitioner's claim because she failed to comply with the statutory prerequisites for filing an action against a health care provider as set forth in the MPLA. The MPLA was enacted as a comprehensive statutory scheme to reduce the number of frivolous lawsuits and reduce costly litigation by requiring that certain minimum prerequisites be met before a civil action can be filed against a health care provider, such as Dr. Kresa-Reahl. Westmoreland v. Vaidya, M.D., 222 W.Va. 205, 664 S.E.2d 90 (2008); Hinchman v. Gillette, 217 W.Va. 378, 618 S.E.2d 387 (2005). This set of statutes has required claimants to obtain and provide a signed pre-suit certification from a qualified expert confirming the applicable standard of care was breached. The applicable portion of the relevant section has provided the following:

At least thirty days prior to the filing of a medical professional liability action against a health care provider, the claimant shall serve by certified mail, return receipt requested, a notice of claim on each health care provider the claimant will join in litigation. The notice of claim shall include a statement of the theory or theories of liability upon which a cause of action may be based, and a list of all health care providers and health care facilities to whom notices of claim are being sent, *together with a screening certificate of merit.*

W. Va. Code, § 55-7B-6(b) (emphasis added).

The MPLA has an exception to the requirement of a screening certificate of merit, although the facts of this case did not meet it. To qualify for the exception, a claim must be based upon a “well-established legal theory of liability which does not require expert testimony supporting a breach of the applicable standard of care.” W. Va. Code, § 55-7B-6(c). Petitioner did not meet the exception and Dr. Kresa-Reahl was entitled to a screening certificate of merit.

Petitioner’s claim was not based upon a theory of informed consent, but rather upon a theory of ordinary negligence. Informed consent is a prerequisite to surgeries or other particular medical procedures that require invasive action or other physical contact. The doctrine evolved in West Virginia from legal principles related to battery, assault, and unlawful touching. Cross v. Trapp, 170 W.Va. 459, 463, 294 S.E.2d 446, 450 (1982). Cross and other informed consent cases in West Virginia have involved an operation or particular medical procedure performed on a patient by a physician. In contrast, an informed consent is not required if the physician does not perform a procedure. Cross; Hicks v. Ghaphery, 212 W.Va. 327, 571 S.E.2d 317 (2002). Claims for an alleged failure to recommend or perform a procedure are based in negligence and ordinary negligence principles are applied. Hicks, 571 S.E.2d at 325.

In Cross, the physician performed a transurethral resection of the prostate gland procedure, allegedly without the patient’s consent. At the time Cross was decided, West Virginia had not adopted a standard for evaluating the adequacy of a physician’s disclosure of information relative to whether a patient had given informed consent to a particular medical procedure. The Supreme Court discussed three principal standards for making this evaluation and of the three, adopted the “patient need standard.” This patient need standard was to be used in evaluating the adequacy of the information provided by the physician to the patient for the “particular medical procedure,” not to determine whether a claim was based on an informed consent theory of liability. A central

element of the Cross analysis and “patient need standard” was that some type of procedure or operation was performed by the physician. Where no procedure or surgery was performed, informed consent was not at issue. Where informed consent was not at issue, the “patient need standard” would not be applicable.

West Virginia law on “informed consent” was developed further in Hicks, a case in which the physician decided *not* to perform a certain procedure, i.e., insertion of a vena cava filter (a filter in the body’s largest vein which sifts blood clots out of the bloodstream). Plaintiffs argued in Hicks that they were entitled to an informed consent jury instruction at trial, but the Supreme Court of Appeals disagreed. The Supreme Court ruled such an instruction would have required an expansion of the duty, which it had placed on physicians for performed procedures, to disclose information regarding procedures the physician did not perform. This Court expressly refused to expand the informed consent doctrine to such an extent. Rather, this Court held that a physician’s decision *not* to recommend a procedure must be assessed in terms of whether the physician violated the applicable standard of care, not any “patient need standard.” Id. at 325. The Court concluded, “[I]f the procedure is one which should have been proposed, then the failure to recommend it would be negligence under ordinary medical negligence principles and there is no need to consider an additional duty of disclosure.” Id., citing Vandi v. Permanente Medical Group, Inc., 7 Cal.App.4<sup>th</sup> 1064, 9 Cal.Rptr.2d 463 (1992).

West Virginia law, pursuant to Hicks and now in place for nearly the last decade, has required physicians who do not recommend certain procedures to patients to respond to allegations based in ordinary negligence. Petitioner has claimed Dr. Kresa-Reahl did not recommend a thrombolytic therapy procedure; therefore, petitioner’s claim is an ordinary negligence claim and not an informed consent claim. Accordingly, the “patient need standard” does not apply to this case

and a pre-suit expert opinion is required to certify Dr. Kresa-Reahl breached the applicable standard of care.

Plaintiff's reliance on Matthies v. Mastromonaco, 160 N.J. 26, 733 A.2d 456 (1999), is misplaced. New Jersey's approach to informed consent has used ordinary negligence principles, not the battery principles utilized by West Virginia courts and as set forth in Cross. The West Virginia Supreme Court in Hicks did not rely on Matthies and chose to distinguish it because the underlying facts involved a chosen *course of treatment*, not the performance of a particular medical procedure. The case at bar is the same case as Hicks in that it involved a physician's decision not to perform a procedure, and Matthies again is not applicable.

West Virginia's Supreme Court of Appeals not only distinguished Matthies in Hicks, but it expressly adopted the analysis of Vandi, which involved a patient who sued his physician for failing to perform a CT scan after he had a seizure. This Supreme Court concluded that it would not adopt a law which would burden physicians with disclosing and offering medical procedures which, in the exercise of the physician's judgment, were not medically indicated. To do otherwise would forever require defendants to address "medical hindsight." The Court recognized that, with such a legally imposed duty, fact finders easily could look back and identify a procedure which would identify or treat a condition, but which was not medically indicated at the time. Such a hindsight analysis in the context of informed consent was fundamentally flawed. Hicks, at 571 S.E.2d at 325.

Claims related to non-performed procedures are not informed consent claims and no need exists "to consider an additional duty of disclosure." Ordinary negligence principles apply. Hicks, 571 S.E.2d at 325, citing Vandi, 7 Cal.App.4<sup>th</sup> at 1070-71, 9 Cal.Rptr.2d at 467. Accordingly, petitioner's claim that Dr. Kresa-Reahl should have recommended or performed a thrombolytic therapy procedure, which was not done or recommend, is based in ordinary

negligence and a certificate or merit from a qualified expert is required to establish the applicable standard of care which existed, and that it was breached.

**II. Even if West Virginia law on informed consent is expanded to include a non-performed and non-recommended procedure, a screening certificate of merit still would be required.**

This alternative argument is set forth in the event this Court should expand West Virginia's informed consent theory to include non-performed and/or non-recommended medical procedures, and thereby overrule Hicks. Even in that circumstance, a pre-suit certificate of merit would be necessary to meet the threshold requirements of the exception set forth in W.Va. Code §55-7B-6(c).

The traditional informed consent analysis utilized for a performed procedure, as set forth in Cross and Hicks, cannot be applied to this alternative argument because the traditional analysis has been based upon a particular medical procedure which a physician has established as reasonable and necessary through his/her performance of it. An informed consent claim based on a non-performed and non-recommended procedure has no such physician-established basis on which to base duty and/or breach. Such a physician-established medical basis is a pre-requisite to asserting an informed consent medical liability claim in West Virginia, consistent with Cross and the MPLA. A claimant, such as this petitioner, should not be permitted to circumvent this physician-established basis for a procedure simply by arguing that her claim is "informed consent." Such a bypass would allow any lay claimant to establish procedures and treatments as medically sound alternatives when, in fact, no medical basis exists for their consideration in an informed consent situation.

This Supreme Court has warned of the danger of lay testimony establishing medical duty and medical breach. Cross generally discussed the scope of a physician's duty to disclose medical information related to a performed procedure and also established that an expert opinion may not be necessary to determine whether informed consent was obtained, again for performed procedures.

The question, however, of *which* alternative treatments were medically reasonable or indicated in a given situation, and their risks, even if not recommended by the defendant physician, would require an expert medical opinion. The Supreme Court discussed this duty and the role of expert testimony in informed consent cases as follows:

Finally, we hold that although expert medical testimony is not required under the patient need standard to establish the scope of a physician's duty to disclose medical information to his or her patient, expert medical testimony would ordinarily be required to establish certain matters including: (1) the risks involved concerning a particular method of treatment, (2) alternative methods of treatment, (3) the risks relating to such alternative methods of treatment and (4) the results likely to occur if the patient remains untreated.

Cross, 294 S.E.2d at 455.

Cross was applied in a MPLA case recently decided in the United States District Court for the Southern District of West Virginia by Judge John T. Copenhaver, Jr. Sayre v. United States of America, No. 2:09-0295, 2009 U.S. Dist. LEXIS 114864 (S.D.W. Va. Dec. 9, 2009). Judge Copenhaver found that expert testimony was necessary to establish an informed consent cause of action against a Veteran's Administration doctor for allegedly failing to disclose information regarding a surgical procedure. Specifically, plaintiffs, represented by the same law firm as counsel for petitioner herein, had "overlooked a crucial aspect of the court's discussion in Cross," namely that expert testimony ordinarily is required to establish certain matters, including the risks involved in a particular method of treatment. Judge Copenhaver dismissed the claim without prejudice for failure to serve a certificate or merit.

Judge Copenhaver's analysis was that whenever a claimant makes an informed consent claim relating to the adequacy of information, including alternatives and risks, a certificate of merit is required. Applying this analysis to the case at bar, petitioner has argued she did not receive adequate information regarding an alternative procedure. In such a circumstance, a

certificate of merit would be necessary. Therefore, even if informed consent would be expanded to include non-performed and/or non-recommended procedures, a certificate of merit still was required to pursue a claim against Dr. Kresa-Reahl.

This legal reasoning is sound. Again, the filing and pursuit of medical liability lawsuits for medical procedures which neither were performed nor recommended by a defendant physician, in the absence of a certificate of merit, would allow lay plaintiffs to establish both medical duty and medical breach. Applying plaintiff's argument, a physician who did not perform or recommend a particular procedure would face claims by a lay plaintiff who, in hindsight, deemed the non-performed and non-recommended procedure to be the very one which would have been beneficial to her, and to then proceed to a lawsuit without a medical foundation.

The Supreme Court's analysis in Cross has remained applicable: Expert opinion is required to establish whether an alternative method of treatment is medically reasonable. Even if this Supreme Court should overrule Hicks and concluded this matter was an informed consent claim, a certificate of merit still would be required to establish whether a thrombolytic therapy procedure was an alternative method of treatment under the circumstances and to establish a viable claim against Dr. Kresa-Reahl.

Permitting this petitioner to pursue an informed consent claim related to a non-performed and/or non-recommended procedure is to allow a lay person with no medical background or training to establish that Dr. Kresa-Reahl breached a legal duty to Mr. Cline. The claim at bar proceeded into a lawsuit by circumventing the certificate of merit process and with absolutely no medical basis, which is unfair to Dr. Kresa-Reahl and to any health care provider in the same situation.

**III. The trial court acted within its discretion in determining that a certificate of merit was necessary, that petitioner's Notice of Claim was insufficient, and that dismissal was appropriate.**

The courts only, and not the parties, have final authority to determine the sufficiency of pre-suit papers required by the MPLA. Health care providers are required by decisions of this Supreme Court, however, to raise objections to Notices of Claim and certificates of merit pursuant to West Virginia Code § 55-7B-6(c) in order to preserve their rights. *See Westmoreland*, 222 W.Va. 205, 664 S.E.2d 90 (2008) (reversing, in part, a dismissal for lack of certificate of merit because defendant did not provide plaintiff with any pre-suit notice specifying defects or insufficiencies); *Hinchman*, 217 W.Va. 378, 618 S.E.2d 387 (2005) (reversing dismissal by trial court because plaintiff did not receive specific pre-suit notice of defects and insufficiencies in a notice of claim and certificate of merit and an opportunity to correct them). The trial court herein simply held that petitioner did not take the opportunity to address issues timely raised by Dr. Kresa-Reahl in her response letter of August 4, 2009 or her Motion to Dismiss and that a certificate or merit was needed.

Dismissal of petitioner's Complaint without prejudice was appropriate. Petitioner had an opportunity to obtain a certificate of merit prior to serving her Notice of Claim, and chose not to do so. She then had a second opportunity to cure the defect after Dr. Kresa-Reahl raised the specific issue and before filing her Complaint, and again chose not to do so. Finally, she had a third chance to obtain such a certificate after review of Dr. Kresa-Reahl's legal argument and prior to the April 2010 hearing, and again chose not to do so. Dismissal of such actions has remained a remedy which trial courts may utilize to enforce the MPLA's pre-suit requirements when one or more opportunities are provided to claimants to correct their errors. Four chances to correct such errors neither are required by this Court nor the MPLA. Dismissal without prejudice was appropriate. *See*

Westmoreland, 222 W.Va. 205, 664 S.E.2d 90 (2008) (dismissal with prejudice reversed to give plaintiff an opportunity to correct the error and obtain a certificate of merit); Sayre, No. 2:09-0295, 2009 U.S. Dist. LEXIS 114864 (2009) (claim dismissed without prejudice for failure to serve certificate of merit).

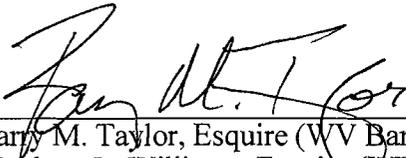
Petitioner has not been prejudiced from refileing within one year. Davis v. Mound View Health Care, Inc., 220 W.Va. 28, 640 S.E.2d 91 (2006); West Virginia Code § 55-2-18. Judge Bailey's order enforced the MPLA and petitioner may pursue her claim if and when she chooses.

#### **VI. CONCLUSION**

The trial court's dismissal of petitioner's Complaint should be upheld. The dismissal order is based on this Court's prior decisions, including Cross and Hicks, as well as supported by the U.S. District Court's decision in Sayre. Application of West Virginia law was appropriate and without error. For the foregoing reasons, Dr. Kresa-Reahl requests that the ruling of the lower court be affirmed.

**KIREN JEAN KRESA-RE AHL, M.D.**

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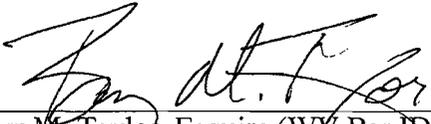
KIREN JEAN KRESA-RE AHL, M.D.,  
Defendant Below,

Respondent.

CERTIFICATE OF SERVICE

I, Barry M. Taylor, counsel for Kiren Jean Kresa-Reahl, M.D., certify that I served a true and correct copy of the foregoing *Respondent's Brief* by mailing the same, first class postage prepaid, in an envelope addressed to the following counsel of record this *20<sup>th</sup> day of July 2011*:

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