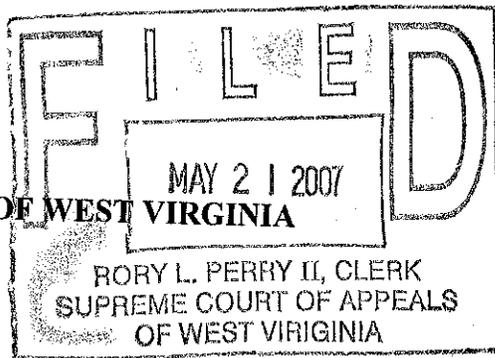


IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA



DONNA JOAN BLANKENSHIP, an individual, et al.,

Appellants/Plaintiffs,

APPEAL NO. 33224

v.

**CIVIL ACTION NO. 03-C-1313
Circuit Court of Kanawha County
(The Honorable Charles King)**

**ETHICON, INC., a New Jersey corporation;
et al.,**

Respondents/Defendants.

**JOINT RESPONSE OF HERBERT J. THOMAS MEMORIAL
HOSPITAL ASSOCIATION AND CHARLESTON AREA
MEDICAL CENTER, INC. TO BRIEF OF APPELLANTS**

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**TO THE HONORABLE JUSTICES OF THE
SUPREME COURT OF APPEALS OF WEST VIRGINIA:**

I. INTRODUCTION

This case arises solely out of surgical procedures the plaintiffs allege to have undergone at the two respondent hospitals. Whatever arguments appellants offer, however those arguments are packaged, whatever theories may have been or may be offered or articulated, the appellants simply cannot escape the fact that the hospitals' roles in the various surgical procedure dealt squarely and solely with the delivery of health care services. For appellants to argue that somehow what the hospitals did — or did not do — was not the delivery of health services, simply defies logic and is plainly wrong. Acceptance of appellants' arguments would emasculate the letter and spirit of the West Virginia Medical Professional Liability Act ("MPLA"), and expose the hospitals to liability for alleged defective products over which they had no control.

II. KIND OF PROCEEDING AND NATURE OF THE RULING BELOW

On May 18, 2004, the Circuit Court of Kanawha County granted Herbert J. Thomas Memorial Hospital Association ("Thomas Hospital") and Charleston Area Medical Center, Inc.'s ("CAMC") (collectively "the hospitals") Joint Motion to Dismiss appellants' complaint. At the time, appellants admitted they were not asserting claims against the hospitals under the MPLA. The Circuit Court properly ruled the exclusive remedy for any tort or breach of contract arising out of health care services rendered by health care providers or facilities is governed by MPLA. The Circuit Court also correctly ruled that product liability claims could not be asserted against the hospitals because they are not distributors in the chain of distribution of commercially manufactured products.

On July 23, 2004, appellants filed a Petition for Appeal of the Circuit Court's Order. On December 9, 2004, this Court issued an Order remanding this matter to the Circuit Court of Kanawha County for consideration of its opinion in *Boggs v. Camden-Clark Mem'l Hosp. Corp.*, 216 W. Va. 656, 609 S.E.2d 917 (2004) (which was issued on the same day this matter was remanded). The Court's remand order herein did not contain any analysis but merely a directive to the Circuit Court to consider *Boggs*.

After lengthy briefing, the hospitals and appellants appeared before the Circuit Court of Kanawha County on February 17, 2006, for a hearing on the hospitals' Joint Motion to Dismiss on Remand. On March 14, 2006, the Circuit Court, after considering this Court's decisions in *Boggs, supra*, and *Gray v. Mena*, 218 W. Va. 564, 625 S.E.2d 326 (2005), again correctly granted the hospitals' Joint Motion to Dismiss.

Appellants filed a Petition for Appeal on July 11, 2006. The hospitals responded jointly on August 10, 2006. This Court granted appellants' Petition on November 15, 2006 and, after an extension granted by this Court, appellants filed their appellate brief on March 19, 2007. The hospitals now respond in opposition. As set forth more fully below, the rulings by the Circuit Court of Kanawha County on remand were correct and appellants' claims against the hospitals were properly dismissed.

III. STATEMENT OF FACTS AND PROCEDURAL BACKGROUND

On June 3, 2003, appellants filed a putative class action complaint alleging injuries arising out of the use of defective Vicryl surgical sutures. Vicryl sutures are absorbable stitches which are left in the body to dissolve after surgery. The complaint alleges that the appellants were injured after being "implanted" with unsterilized Vicryl sutures manufactured by Ethicon, Inc. (Compl. ¶ 5.) The appellants sued the hospitals and Ethicon along with other

alleged suppliers and distributors of the sutures.¹ Appellants claim Ethicon produced and distributed the sutures even though they were contaminated. (*Id.* ¶ 7.) The complaint alleges multiple causes of action against all defendants, including negligence, intentional infliction of emotional distress, product liability, breach of express warranty, breach of implied warranty, violation of the West Virginia Consumer Credit and Protection Act, and fraud. The complaint made no attempt to distinguish which claims were being brought against which defendants.²

On July 2, 2003, the hospitals moved to dismiss the complaint. Immediately thereafter, the manufacturing defendants removed the case to the United States District Court for the Southern District of West Virginia, arguing the hospitals (the only two West Virginia defendants) were fraudulently joined to destroy federal diversity jurisdiction. On November 5, 2003, United States District Judge Joseph R. Goodwin ruled the hospitals were not fraudulently joined and remanded the case to the Circuit Court of Kanawha County.³

On May 18, 2004, the Circuit Court granted the hospitals' Joint Motion to Dismiss. The Circuit Court properly ruled that the exclusive remedy for any tort or breach of contract arising out of health care services rendered by health care providers or facilities is under

¹ The suppliers and distributors named in the complaint are Johnson & Johnson Hospital Services, Inc.; Johnson & Johnson Health Care Systems, Inc.; Seneca Medical, Inc.; Skyland Hospital Supply, Inc.; Amerisource Medical Supply, Inc.; Baxter Healthcare Corporation; McKesson Medical-Surgical Medimart Inc.; and Owens & Minor, Inc.

² The complaint also fails to allege when the appellants' treatment occurred, where it occurred, why they believe they were implanted with "defective" surgical sutures, when they learned of their injuries, and why they can sue now for a recall that occurred over ten years ago. In fact, the complaint does not specifically allege the appellants were even treated at either of the hospitals.

³ The fact Judge Goodwin concluded the hospitals were not fraudulently joined does not in any way support the assertion that the Circuit Court improperly dismissed the claims against the hospitals. *See, Batoff v. State Farm Ins. Co.*, 977 F.2d 848, 852 (3d Cir. 1992) (stating that even though a party was not fraudulently joined, claims against that party may be dismissed for failure to state a claim upon which relief may be granted.) The Circuit Court applied the correct standard of review to appellants' complaint and correctly held that the complaint failed to state a claim upon which relief could be granted.

the MPLA. Additionally, the Circuit Court correctly ruled that product liability claims could not be asserted against the hospitals because they are not "distributors" in the chain of distribution of commercially manufactured products. On July 23, 2004, appellants filed their first Petition for Appeal. The hospitals responded on August 23, 2004. On December 9, 2004, this Court issued an Order remanding this matter to the Circuit Court for consideration of its opinion in *Boggs*, 216 W. Va. 656, 609 S.E.2d 917 (which was issued on the same day this matter was remanded).

After briefing by both sides, the hospitals and appellants appeared before the Circuit Court of Kanawha County on February 17, 2006, for a hearing on the hospitals' Joint Motion to Dismiss on Remand. After considering this Court's decisions in *Boggs, supra* and *Gray, supra*, the Circuit Court once again granted the hospitals' Joint Motion to Dismiss on March 14, 2006. It is from this ruling that appellants appeal.

IV. STANDARD OF REVIEW

The appellate standard of review for the granting of a motion to dismiss a complaint is *de novo*. See *State ex rel. McGraw v. Scott Runyan Pontiac-Buick, Inc.*, 194 W. Va. 770, Syl. Pt. 2, 461 S.E.2d 516 (1995). Dismissal is proper pursuant to Rule 12(b)(6) of the West Virginia Rules of Civil Procedure where "it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Chapman v. Kane Transfer Co., Inc.*, 160 W. Va. 530, Syl. Pt. 3, in part, 236 S.E.2d 207 (1977). Consistent with the well-established theory that the West Virginia Rules of Civil Procedure should be construed liberally to promote justice, a circuit court may look beyond the technical nomenclature of the complaint when ruling on a motion to dismiss pursuant to Rule 12(b)(6) of the West Virginia Rules of Civil Procedure to reach the substance of the parties' positions. *Harrison v. Davis*, 197 W. Va. 651, 658, 478 S.E.2d 104, 111 (1996) (citing *McGraw*, 194 W.

Va. at 776, n.7, 461 S.E.2d at 522 n. 7.) The trial court, consistent with notions of judicial integrity, thus may rely upon extrinsic information, such as statements and admissions of plaintiff's counsel at the hearing on a motion to dismiss, in ruling on a motion to dismiss pursuant to Rule 12(b)(6) of the West Virginia Rules of Civil Procedure. *Id.*

V. LAW AND ARGUMENT

This Court should affirm the Order of the Circuit Court on Remand for five reasons. First, the Circuit Court correctly ruled that appellants' exclusive remedy against the hospitals in this case is under the MPLA and appellants purposefully failed to state such a claim. Second, appellants failed to state a claim for any cause of action against the hospitals outside the MPLA. Third, the Order of the Circuit Court on Remand properly held that hospitals involved in the transfer of a healing material, like sutures, to a patient are not conducting a sale nor are they sellers in the chain of distribution of the product. Fourth, the hospitals do not have a duty to advise patients of recalls concerning the sutures in this case, but even if they did, such a claim could only be pursued under the MPLA, and appellants made no such claims in this case. Finally, it is improper for appellants to raise this issue, or any other issue not raised below, including seeking more time to comply with the MPLA, for the first time on appeal to this Court. For each of these reasons, as will be more fully developed below, the Order of the Circuit Court of Kanawha County on remand should be affirmed.

A. The Circuit Court's Decision Should be Affirmed Because Appellants' Exclusive Remedy Against the Hospitals in This Case is Under the MPLA and Appellants Failed to State Such a Claim.

As the Circuit Court correctly concluded, the plaintiffs' claims arising out of health care services allegedly provided to the appellants⁴ and are therefore governed by the MPLA. The MPLA defines medical professional liability as "any liability for damages resulting from the death or injury of a person for any tort or breach of contract based on health care services rendered, or which should have been rendered, by a health care provider or health care facility to a patient." W. VA. CODE § 55-7B-2(d). Under the MPLA, hospitals are included within the definitions of health care provider and health care facility. W. VA. CODE § 55-7B-2(b)-(c). Thomas Hospital operates a hospital in South Charleston and CAMC operates a hospital in Charleston. The appellants allege they were "implanted with contaminated sutures" and that "[a]s a result of this exposure to contaminated sutures, appellants and class members suffer or were exposed to possible serious infections and injuries." (Compl. ¶ 20.) The appellants fit the definition of "patient" under the MPLA which includes "a natural person who receives or should have received health care from a licensed health care provider under a contract, expressed or implied." W. VA. CODE § 55-7B-2(e).

The MPLA applies to all actions which fit within its definitions. *See State ex rel. Weirton Med. Ctr. v. Mazzone*, 214 W. Va. 146, 587 S.E.2d 122 (2002) (stating "the provisions of the Medical Professional Liability Act . . . govern actions falling within its parameters. . ."). Recently, in *Boggs, supra*, and *Gray, supra*, this Court reaffirmed that the MPLA applies to claims arising out of health care services rendered or which should have been rendered by a

⁴ This is really an assumption in favor of the appellants, as the complaint does not specifically allege that any petitioner was treated at Thomas Hospital or CAMC.

health care provider or facility to a patient. Specifically in *Gray* this Court made clear that the MPLA applies to any “liability for damages...for any tort or breach of contract based on health care services rendered.” *Gray*, 625 S.E.2d at 331 (emphasis in original.) Accordingly, the Circuit Court correctly concluded that appellants’ claims must be dismissed because they arose, if at all, under the MPLA. Appellants failed to state such a claim because they admittedly failed to serve notices of claim and certificates of merit prior to initiating this lawsuit and failed to plead the required elements under the MPLA.⁵ Appellants consciously and knowingly chose to attempt to plead around the MPLA.

B. The Order of the Circuit Court Should be Affirmed Because Appellants Failed to State a Claim for Any Cause of Action Outside the MPLA

Appellants’ complaint fails to state a claim for any cause of action outside the MPLA including violation of the Consumer Credit and Protection Act,⁶ tort of outrage and fraud.⁷ In support of their contention that these claims were properly stated outside of the MPLA against the hospitals, appellants cite this Court’s decisions in *Boggs v. Camden-Clark, supra* and *Gray v. Mena, supra*. These cases, however, do not support appellants’ contentions. In *dicta* in *Boggs*, this Court stated:

The legislature has granted special protection to medical professionals while they are acting as such. This protection does not extend to intentional torts or acts outside the scope of health care services.⁸

⁵ Petition for Appeal at 21-22.

⁶ See also Section E, *infra*.

⁷ Appellants also claim that they properly stated a products liability claim against the hospitals. Such claim will be discussed below because the issue of whether a hospital can be an innocent “seller” in the chain of distribution of a commercially manufactured product is a separate and distinct issue.

⁸ 609 S.E.2d at 923-24.

This statement was later clarified in *Gray v. Mena*, where this Court stated:

We clarify *Boggs* by recognizing that the West Virginia Legislature's definition of medical professional liability, found in West Virginia Code § 55-7B-2(i), includes liability for damages resulting from the death or injury of a person for *any* tort based upon health care services rendered or which should have been rendered. To the extent that *Boggs* suggested otherwise, it is modified.⁹

Under *Boggs* and *Gray*, causes of action against health care providers, other than under the MPLA, can be brought in limited circumstances. The Circuit Court provided examples of such claims including: a claim that a hospital employee stole a patient's purse, or intentionally destroyed records or physically assaulted a patient. (Order p. 7, ¶10.) In order for a claim to properly be stated *outside* the MPLA, it cannot be premised upon the provision of health care services to patients as defined in the MPLA, like the appellants in this case. This was exactly the point of the holding in *Gray* – if the claim is premised (even arguably) upon the provision of health care services to a patient, a cause of action under the MPLA is the proper remedy for the aggrieved party.

As this Court has said, whether or not the MPLA applies in a particular case turns upon the allegations made by the plaintiff in the complaint. *See Gray*, 625 S.E.2d at 332 (relying upon *Burke v. Snyder*, 899 So.2d 336 (Fla. App. 2005) and *Buchanan v. Lieberman*, 526 So.2d 969 (Fla. App. 1998) and stating “[a] principal component of *Burke* is the recognition that the particular facts alleged by a plaintiff will impact the applicability of the statute. For instance, where the allegedly offensive action was committed within the context of the rendering of

⁹ 625 S.E.2d at 330. (Emphasis in original.)

medical services, the statute applies. Where, however, the action in question was outside the realm of the provision of medical services, the statute does not apply.”)

Here, the Circuit Court properly ruled that appellants’ claims *in this case* arise, if at all, under the MPLA, stating:

There is no dispute that the plaintiffs received health care services and the complaint revolves around an integral part of the health care services rendered. The core allegations of the complaint center upon the performance of surgical procedures and the use of unsterile sutures during the procedures. Surgeries and the sutures used during surgery fit squarely within the definition of ‘health care’ which includes treatment furnished to a patient. Moreover, the MPLA expressly applies to ‘any liability for damages...for any tort or breach or contract based upon health care services rendered...’ . . . The court finds, therefore, that this action is governed by the MPLA, and the plaintiffs are bound by its requirements. (*Id.* at p.6, ¶ 7) (emphasis added; internal citations omitted.)

Careful review of appellants’ complaint supports the Circuit Court’s conclusion. Appellants’ claims of “outrage” are premised upon defendants’ alleged knowing, reckless and wrongful conduct which allegedly “exposed” appellants to the unsterile sutures. (Compl. ¶ 37.) The only actions of these defendants which would have resulted in the “exposure” of appellants to the allegedly defective sutures would have been in the provision of health care services and, more specifically, closure of wounds. As a result, the Circuit Court correctly ruled that such a cause of action fits within the MPLA, which was the exclusive remedy for the appellants for this claim.

Appellants’ claims related to the West Virginia Consumer Credit and Protection Act are premised upon appellants’ argument that the hospitals “sold” sutures and “services associated with said sutures.” (*Id.* ¶ 50.) Clearly, “services associated with said sutures” can only be referring to the provision of health care services (surgeries) to the appellants. Claims for

wrongful conduct in connection with these medical treatments can only arise under the MPLA as a claim related to the provision of health care services. Further, as set out in Section E, *infra*, hospitals are simply not merchants selling goods. The complaint also alleges the hospitals “failed to investigate all persons who were implanted with the defective sutures and to in good faith inform them or their patients’ guardians or estates.”¹⁰ (*Id.* ¶ 52.) As these allegations are related to an alleged omission by the hospitals in connection with health care services rendered, they fall squarely within the provisions of the MPLA.

Jurisdictions throughout the country have similarly held that medical malpractice claims may not be recast as claims under a consumer protection act. *See, e.g., Constant v. Wyeth*, 352 F. Supp.2d 847, 853-54 (M.D.Tenn. 2003) (*citing Simmons v. Stephenson*, 84 S.W.3d 926, 927-28 (Ky. App. 2002) (collecting cases); *Janusauskas v. Fichman*, 68 Conn.App. 672, 793 A.2d 1109, 1115-16 (2002) (collecting cases)).¹¹ To hold otherwise, as noted by the Supreme Court of Connecticut, “would transform every claim for medical malpractice into a [consumer protection act] claim.” *Sherwood v. Danbury Hosp.*, 252 Conn. 193, 213 (2000). A court of appeals in Texas, coming to the same conclusion, found that if a lawsuit is based on a breach of the standard of care, “the cause of action is nothing more than a health care liability claim, no matter how a plaintiff labels it. . . . We look to see whether the challenged act was ‘an inseparable part of the rendition of medical services.’” *Gomez v. Diaz*, 57 S.W.3d 573, 580 (Tex.App.-Corpus Christi 2001) (quoting *Walden v. Jeffery*, 907 S.W.2d 446, 448 (Tex. 1995)).

¹⁰ As a practical matter, the hospitals do not even know whether the appellants in this matter had surgery before or after the recalls at issue in this case (or at which hospital each petitioner had surgery) because such allegations were not made in the complaint in this case.

¹¹ *See also, Darviris v. Petros*, 442 Mass. 274 (2004); *Nelson v. Ho*, 564 N.W.2d 482 (Mich. App. 1997); *Henderson v. Gandy*, 623 S.E.2d 465 (Ga. 2005); and *Dorn v. McTigue*, 121 F.Supp.2d 17 (D.D.C. 2000).

Here, the appellants came to CAMC and Thomas Hospital to have surgery and an inseparable part of surgery was the use of absorbable sutures to close incisions required by the surgical procedures. These are, plainly and simply, MPLA claims which cannot be dressed up as “Consumer Credit and Protection Act” claims.

Appellants’ claims of fraud are similarly premised on the provision of health care services. The complaint alleges hospitals fraudulently “misrepresented the safety and effectiveness” of the sutures and that appellants relied upon such misrepresentations and/or omissions. (*Id.* ¶ 54-55.) Any claim that the hospitals misrepresented anything with respect to the sutures (which contention is expressly denied) falls within the MPLA.

The Circuit Court correctly held that the only cause of action available to appellants based on their complaint as filed was under the MPLA, and appellants simply failed to state such a claim. To the extent appellants contend the Circuit Court’s Order held that causes of action outside the MPLA could “never” be brought against a health care provider, they misread the Circuit Court’s decision. The Circuit Court’s Order on Remand was not attempting to make new law nor avoid this Court’s decisions in *Boggs* and *Gray*. Rather, the Circuit Court looked to those decisions and found support for its conclusions about the application of the law in this specific case. (Order at 7-8, ¶10.) The Circuit Court’s Order on Remand was correct and should be affirmed.

C. The Order of the Circuit Court on Remand Properly Held that Hospitals Involved in the Transfer of a Healing Material to a Patient are not Conducting a Sale nor are They Sellers in the Chain of Distribution of the Product.

The Circuit Court correctly ruled on remand that the transfer of a healing material, absorbable Vicryl sutures, from a health care provider to a patient during the course of medical

treatment does not constitute the "sale" of a product pursuant to West Virginia products liability and breach of warranty law.¹² The Circuit Court also correctly ruled that a health care provider is not a seller, or within the chain of distribution, of a product that is an incidental part of the medical treatment provided to a patient. Thus, it was proper for the Circuit Court to dismiss plaintiffs' claims against the hospital defendants concluding that plaintiffs' only valid cause of action against the hospitals (consistent with appellants' allegations) would be a negligence claim pursuant to the MPLA.

In order for the defendant health care providers to be held strictly liable in tort for an allegedly defective healing material, the transfer of the healing material from the health care provider to the patient would have to be a "sale" of that product. *See Star Furniture Co. v. Pulaski Furniture Co.*, 171 W. Va. 79, 297 S.E.2d 854 (1982). There is no existing law in the state of West Virginia which holds, acknowledges or even suggests that a health care provider that uses a healing material, as an incidental part of the health care services provided, has completed a "sale" of a product. In fact, this Court has declared the opposite to be the law of this state. *See Foster v. Mem'l Hosp. Ass'n*, 159 W.Va. 147, 219 S.E.2d 916 (1975). In *Foster*, this Court recognized that where an individual seeks professional services involving an incidental transfer of personal property as a necessary part of the services, there is no sale for product liability purposes. The transfer of property or title of certain items of medical material from a health care provider to a patient during the course of medical treatment does not constitute a "sale" nor does it serve to make the health care provider a seller of a product. *Id.*¹³

¹² See Sections B and E, herein.

¹³ Judge Irene Burger, relying on *Foster*, dismissed product liability claims against a defendant health care provider holding that insertion of a cervical spine locking plate during medical treatment "did not constitute a 'sale' as contemplated by West Virginia products liability law, but was incidental to the provision of medical services to a patient." *See Order, Lester v. Appalachian Reg. Healthcare, Inc.*,

Similarly, the appellants in this case did not seek implantation of absorbable sutures from the hospital, but were admitted to the hospitals for surgery. The sutures were a necessary part of the surgery – incisions have to be closed so they can heal. Thus, use of sutures in the surgery was not a “sale”, but merely the transfer of medical material as an integral and necessary part of the medical services provided to the appellants.

Before strict liability can attach to a health care provider for the transfer of medical materials during medical treatment, the health care provider must be a merchant, vendor, seller or distributor of the product. *See Star Furniture Co.*, 171 W.Va. 79, 297 S.E.2d 854. This Court addressed whether a hospital is a merchant in the chain of distribution of a product in *Foster*, 159 W.Va. 147, 219 S.E.2d 916, where it recognized a hospital does not fit the exact mold of a merchant, stating:

..[t]here is a reasonable difference between a merchant on the one hand who is engaged in the active promotion and sale of his product such as coca cola bottles, automobile axles, or standardized drugs and a doctor, dentist or lawyer on the other hand who supplies medicine, blood, tooth fillings, or legal briefs in the course of his professional relationship with a patient or client.

Foster, 159 W.Va. at 152, 219 S.E.2d at 921.

Hospitals purchase sutures so that patients will have everything necessary for a complete course of treatment. Sutures are just one type of medical material integrally related to the primary function of providing medical services and are not like a product sold in a hospital gift shop. Patients seek surgical treatment from health care providers, not the purchase of a

Circuit Court of Kanawha County, Civil Action No. 01-C-534, Jan 16, 2003 (Judge Berger). The plaintiff in *Lester* did not seek insertion of the cervical spine locking plate, but sought medical services from the health care provider aimed at resolving the plaintiffs’ medical condition. The insertion of the locking plate was merely incidental to the medical services provided.

suture.¹⁴ The hospitals were being paid for the health care services rendered, not for the purchase of sutures.

Thus, the hospitals are not in the business of selling sutures, nor are they in the chain of distribution of sutures, but rather are end users of sutures which are an incidental part of medical services which they provide. See *Order Lester v. Appalachian Reg. Healthcare, Inc.*, *supra*. See also, *Silverhart v. Mount Zion Hosp.*, 98 Cal. Rptr. 187, 191 (Cal. App. 1971). In *Silverhart*, the court recognized that the distribution process ended when the medical material, a needle, was sold to the hospital. The court noted the hospital did not sell the needle to its patients, but rather was the ultimate consumer of the needle.

Here, the defendant hospitals did not "sell" the absorbable sutures to the appellants. The hospitals were the actual consumers of the sutures, using them as an incidental part of the medical services provided, and the sutures were merely transferred to the appellants as an incidental part of those medical services provided. Specifically, the sutures were used to close an opening, and then disintegrated after complete closure.

Accordingly, the transfer of the sutures from the hospital to the patient during medical services is not a "sale." Nor is a hospital a seller or within the chain of distribution of sutures when sutures are used as an incidental part of the medical services provided.

D. There is No Duty on the Hospitals to Notify Patients Concerning a Recall of Sutures and, Even if There Were, Plaintiffs Claims Are Governed by the MPLA, Claims Which Appellants Did Not Assert.

Despite the fact appellants did not raise this issue before the Circuit Court (which will be further addressed in Part E, *infra*), they argue Judge King erred in dismissing the

¹⁴ Defendants acknowledge there may be extraordinary cases where patients do seek a particular product from a health care provider. This did not happen here.

hospitals because they had a duty to notify patients about the suture recall. This duty simply does not exist under West Virginia law and the facts of this case, but even if it did, the proper action would be under the MPLA – a claim appellants purposefully chose not to make in this case.

In their brief, appellants attempt to rely upon *Pumphrey v. C.R. Bard, Inc.*, 906 F. Supp. 334, 338 (N.D.W.Va. 1995), for the proposition that “a medical facility has an independent obligation to keep informed with respect to safety and potential problems prescription drugs and/or medical devices and products.” (Brief of Appellants at 16.) This argument stretches *Pumphrey*, which dealt with the Learned Intermediary Doctrine. The Learned Intermediary Doctrine essentially says it is sufficient for a manufacturer of a drug or medical device to give warnings to the doctor or health care provider and expect that the health care provider will pass along warnings to the end user as they deem appropriate. As a starting point, *Pumphrey* expressly recognizes that the Learned Intermediary Doctrine has not yet been recognized as a defense in West Virginia. Nonetheless, a manufacturer’s defense in a products liability case cannot be affirmatively used here to establish a separate duty on the part of the hospitals to notify every person who may have had recalled sutures utilized during their surgery.

Appellants also cite *Pumphrey* (in their Points and Authorities Relied Upon) for the proposition that “medical facilities have affirmative legal duties, once informed of defective devices or medical supplies being implanted in a patient, to make reasonable efforts to inform the patient.” (*Id.* at 13.) *Pumphrey* does not establish this principle of law. At best, *Pumphrey* and the Learned Intermediary Doctrine stand for the proposition that health care providers must provide warnings to end users *prior* to their use of a product. The hospitals can find no West

Virginia case law to suggest that they have any such *post-recall duty*, particularly under the facts of this case.¹⁵

Appellants fail to cite any West Virginia authority to establish a post-recall duty, and instead rely on a selection of medical malpractice cases from other jurisdictions. (Brief of Appellants at 13-14, 16 citing *Harris v. Raymond*, 715 N.E.2d 388 (Ind. 1999); *Brawn v. Oral Surgery Associates*, 819 A.2d 1014 (Me. 2003); *Cox v. Paul*, 828 N.E.2d 907 (Ind. 2005); *Monahan v. Weichert*, 82 A.D.2d 102, 442 N.Y.S.2d 295 (N.Y.A.D. 4th Dep't 1981)). *Harris*, *Brawn*, and *Cox* all involve a recall of Vitek Proplast Teflon temporomandibular ("TMJ") implants.

As an initial matter, these cases relied on by the appellants are medical malpractice cases. Here, appellants' consistent position has been that this is not a medical malpractice case; it follows that there is little relevance to any cases here.¹⁶

Notably, in *Cox, supra*, the Supreme Court of Indiana specifically held that a health care provider is not strictly liable for a failure to warn, which is apparently what appellants seek in this case. These TMJ cases are also factually distinguishable from this case. Plaintiffs who had surgery to get the TMJ implants contracted to receive the devices, and the

¹⁵ The impracticality and impossibility of this suggestion is easily demonstrated. There are many medical products and drugs that are used during the course of a routine surgery. Some examples would include pain killers like Tylenol, band-aids, rubber gloves, and sutures. These types of products are used for patient care but are not routinely tracked in any specific way to any particular patient. Thus, if there were another Tylenol recall, similar to that in the 1980's, there would be no way for the hospitals to know which patients might have received the contaminated products, and there would be no way for the hospital to know who to notify.

¹⁶ *Monahan v. Weichert*, 82 A.D.2d 102, 442 N.Y.S.2d 295 (1981), is a medical malpractice case. It does not appear to address a duty to warn post-recall. Rather, the case appears to be about distinguishing the effects of medical negligence from the natural progression of plaintiff's condition and discusses establishing proximate cause.

health care providers knew which of their patients received the TMJ implants, and they could be identified and notified.

Unlike the TMJ case, appellants here contracted to have surgery (the exact nature of which is unknown due to the lack of any factual support in appellants' pleadings). As part of their respective surgeries, absorbable sutures had to be used to close incisions. Put simply, appellants did not contract for sutures, but contracted for surgery. The sutures, then, were an integral and necessary part of the surgery, as correctly recognized by Judge King. (See discussion in Section E, *infra*.)¹⁷

As an integral part of the surgeries, the provision of sutures falls squarely within the confines of medial professional liability as defined in the MPLA. W. VA. CODE § 55-7B-2(i). The post recall duty to warn, if there is such a claim, is therefore governed by the MPLA, and plaintiffs' admitted failure to comply with the Notice of Claim and Certificate of Merit provisions of W.Va. Code § 55-7B-6(a) and (b) requires affirmance of the circuit's court's order dismissing this action with prejudice. See *Davis v. Mound View Health Ctr.*, 220 W. Va. 28, 640 S.E.2d 91 (2006).

E. It is Improper for Appellants to Raise New Issues on Appeal That Were Not Raised Before the Circuit Court Below.

Generally, non-jurisdictional questions that have not been decided at the circuit court level and are first raised on appeal should not be considered.

¹⁷ It is proper for this Court to consider the hospitals' arguments on this claim as an alternate ground for affirming the Circuit Court's Order on Remand. See *Keller v. Prince Georges County*, 923 F.2d 30, 32 (4th Cir. 1991). See also, *Dandridge v. Williams*, 397 U.S. 471, 475 n.6, 90 S. Ct. 1153, 1156 n.6 (1970) (stating "[t]he prevailing party may, of course, assert in a reviewing court any ground in support of his judgment, whether or not that ground was relied upon or even considered by the trial court.") An appellate court has the power and duty to affirm an award of summary judgment on any ground supported in the record. See *Yale v. Nat'l Indem. Co.*, 602 F.2d 642 (4th Cir. 1979) (stating "we review judgments, not reasons.")

The rationale behind this rule is that when an issue has not been raised below, the facts underlying that issue will not have been developed in such a way so that a disposition can be made on appeal. Moreover, we consider the element of fairness. When a case has proceeded to its ultimate resolution below, it is manifestly unfair for a party to raise new issues on appeal. Finally, there is also a need to have the issue refined, developed and adjudicated by the trial court, so that we may have the benefit of its wisdom.

Whitlow v. Bd. of Educ. of Kanawha County, 190 W. Va. 223, 438 S.E.2d 15, 18 (1993).

Appellants improperly raise two issues before this Court not raised in the Circuit Court below. First, appellants did not argue before the Circuit Court, nor did they argue in any Petition for Appeal before this Court, that the hospitals had a duty to warn patients of recalls. Second, appellants never asked, nor raised on appeal, the new argument that the Circuit Court committed reversible error by not allowing them "additional time" to comply with the MPLA. Neither argument was raised below, and neither should be considered by this Court.

1. Appellants' post-recall duty to warn argument has never been argued below or in any Petition before this Court and is improper.

Appellants did not argue before the Circuit Court, nor did they argue in any Petition for Appeal before this Court, that the hospitals should not be dismissed from this case because they had a duty to warn patients of recalls and breached that duty. Even if such an argument is to be considered, a claim against the hospitals for failure to warn arises under the MPLA, and appellants have failed to state such a claim in this case.

To the extent appellants rely upon the Consumer Credit Protection Act ("CCPA") as the basis for their "failure to warn post-recall" claim, their claims are improper and not supported by law. The CCPA claim appears to be based upon West Virginia Code §46A-6-102(f), (*see* Compl. ¶¶ 50-53.), which defines terms used throughout the Act. West Virginia

Code §46A-6-102(f) defines “unfair methods of competition and unfair or deceptive acts or practices” in pertinent part, as follows:

[t]he act, use or employment by any person of any deception, fraud, false pretense, false promise or misrepresentation, or the concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, *in connection with the sale or advertisement of any goods or services*, whether or not any person has in fact been misled, deceived or damaged thereby.

W. VA. CODE §46A-6-102(f) (emphasis added).¹⁸ Appellants assert the CCPA created a duty that required the hospitals to investigate all persons who may have had the allegedly contaminated sutures used during their *operations*, and advise them of the recall. Despite the fact this issue was not raised before the Circuit Court, it cannot support a reversal of the Circuit Court’s Order because this section of the West Virginia Code specifically contemplates a sale of a product and, as was found by the Circuit Court, there was no sale. The essence of the transaction with plaintiffs was the delivery of health care services and the use of sutures was incidental to the surgeries. This finding is precisely in line with and supported by *Foster*, which recognized and held that hospitals are not merchants engaged in the sale of goods. 159 W.Va. 147, 219 S.E.2d 916.¹⁹ Where an individual seeks professional services involving an incidental transfer of personal property as a necessary part of the services, there is no “sale.” *See id.* *See also*, Section C, *supra*. Thus, even if appellants are permitted to raise this issue for the first time before this Court, the argument is without merit and does not support a reversal of the Circuit Court’s ruling. The Order of the Circuit Court on Remand should be affirmed.

¹⁸ W. Va. Code §46A-6-104 prohibits unfair methods of competition and unfair or deceptive acts or practices.

¹⁹ For this Court to hold, for the first time, that the CCPA applies to hospitals which provide medical products for use by surgeons, is a monumental shift in the law and the imposition of new liability that directly contradicts the protections afforded under the MPLA.

2. Appellants' request for more time to comply with the W. VA. CODE § 55-7B-6 was not argued before the trial court and cannot be raised here.

Appellants never asked the Circuit Court to grant them more time to comply with W. Va. Code §55-7B-6.²⁰ In fact, appellants argued, time and time again, that they were not making any MPLA claims, and did not have to comply with the Notice of Claim and Certificate of Merit provisions of §55-7B-6.

Appellants now seek to argue for the first time that they are entitled to more time to comply with §55-7B-6. This argument surfaced for the first time in their July 2006 Petition for Appeal, having not been previously made in the Circuit Court. Appellants rely upon *Gray v. Mena* for the assertion they should have been given more time to comply with the MPLA before having their claims against the hospitals dismissed. *Gray*, 218 W. Va. 564, 625 S.E.2d 326. Both the hospitals and the appellants discussed *Gray* in their briefing to the Circuit Court on remand and were well aware of its holdings. Appellants, even with full knowledge of *Gray*, stuck with the position the MPLA did not apply and failed to ask the Circuit Court for time to comply with the MPLA filing requirements. It is improper for them to request it now.

Even if this Court considers appellants' request for more time, the hospitals submit that *Gray* does not give the appellants the time they seek. In *Gray*, this Court issued a strong caution to litigants when pleading causes of action which may be construed as falling within the MPLA:

²⁰ Appellants cite to a reference in the Transcript of the February 16, 2006 hearing, at page 8, apparently suggesting that they raised this issue in the trial court. In fact, what the transcript reveals is that while appellants' counsel did explain to the Circuit Court that *Gray* addressed the timing of the dismissal of a case that did not comply with the MPLA, counsel never asked the Circuit Court for time to comply with the MPLA before dismissal.

[w]e caution all litigants preparing a complaint in such matters to be diligent in adhering to the requirements of the Medical Professional Liability Act *where the healthcare provider's action could possibly be construed as having occurred within the context of the rendering of health care services.*

Gray, 218 W. Va. at 570, 625 S.E.2d at 332 (emphasis added).

Gray was decided in November of 2005, well over a year ago. Appellants were familiar with the opinion and the Court's caution to litigants attempting to plead around the MPLA, and have had more than enough time to comply with the MPLA had they truly desired to do so. Certainly, appellants had the opportunity to ask the Circuit Court for additional time. Failure to comply with W.Va. Code 55-7B-6 was the subject of the hospital's motion to dismiss filed July 2, 2003. At no time did plaintiffs cure their failure or ask for time to cure it, choosing instead to argue the MPLA does not apply. The appellants strategically chose not to state an MPLA claim and affirmatively tried to plead around it. They are not entitled now, on appeal, to more time to comply simply because they have changed their strategy.

VI. RELIEF PRAYED FOR AND CONCLUSION

The Circuit Court was correct in dismissing all of the appellants' claims against Herbert J. Thomas Memorial Hospital Association and Charleston Area Medical Center, Inc. The Circuit Court correctly ruled that appellants' exclusive remedy against the hospitals in this case is under the MPLA and appellants failed to state such a claim and further, appellants failed to state a claim for any cause of action outside the MPLA. The Order of the Circuit Court on Remand properly held that hospitals involved in the transfer of a healing material, like sutures, to a patient are not conducting a sale nor are they sellers in the chain of distribution of the product. The hospitals did not have a duty to advise patients of the recall concerning the sutures in this case, but even if they did, a breach of any such duty could only be pursued under the MPLA, and

appellants made no such claim in this case. Further, it is improper for appellants to raise this issue, or any other issue not raised below, including seeking more time to comply with the MPLA, for the first time on appeal to this Court. For each of these reasons, the hospitals respectfully request that the Order of the Circuit Court on Remand be affirmed.

Respectfully submitted,

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IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

**DONNA JOAN BLANKENSHIP, an
individual, et al.,**

Appellants/Plaintiffs,

APPEAL NO. 33224

v.

**CIVIL ACTION NO. 03-C-1313
Circuit Court of Kanawha County
(The Honorable Charles King)**

**ETHICON, INC., a New Jersey corporation;
et al.,**

Respondents/Defendants.

CERTIFICATE OF SERVICE

I, Laurie K. Miller, counsel for Herbert J. Thomas Memorial Hospital Association, do hereby certify that the foregoing Joint Response of Herbert J. Thomas Memorial Hospital Association and Charleston Area Medical Center, Inc. to Brief of Appellants was made on the 21st day of May, 2007, by causing a true and exact copy thereof to be mailed by First-Class United States mail, postage prepaid, to:

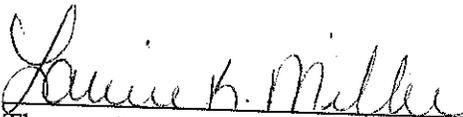
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