

No. 061511

IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

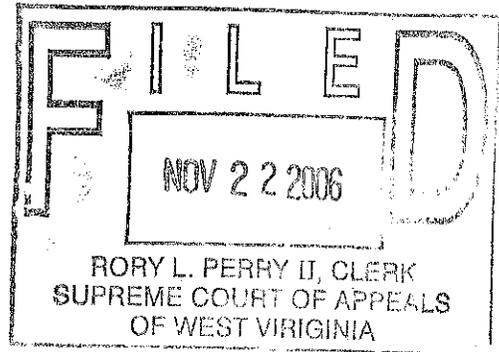
AUGUST EUGENE PHILLIPS and  
CHERYL PHILLIPS, his wife,

Petitioners/Plaintiffs below,

v.

LARRY'S DRIVE-IN PHARMACY,  
INC., a West Virginia corporation,

Respondent/Defendant below,



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BRIEF OF WEST VIRGINIA PHARMACISTS ASSOCIATION, INC.

*AS AMICUS CURIAE*

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## INTRODUCTION

This matter is before the Court pursuant to a certified question as follows:

In a civil action filed against a defendant licensed pharmacy for allegedly having negligently dispensed medication, is the pharmacy a "health care provider", as defined by West Virginia Code § 55-7B-2(c)?

The Circuit Court of Boone County answered this question in the affirmative and this brief supports that finding.

The West Virginia Pharmacists Association is a trade association consisting of approximately five hundred (500) pharmacists/pharmacies professionally licensed by the State of West Virginia under the provisions of W. Va. Code § 30-5-5 . The issue set forth above is of importance and critical interest to each of those members and the association.

West Virginia Code § 55-7B-1 *et seq.*, otherwise known as the Medical Professional Liability Act or "MPLA", was originally enacted in 1986. Significant amendments to the MPLA were made by the West Virginia Legislature sitting in Extraordinary Session later in 1986 and again in Regular Session in 2003. It is agreed that only provisions of the MPLA germane to this matter are those contained in the original act of 1986. While the facts and process that have led to this matter coming before the Court are fundamental to fully understanding why this matter is before the Court, it is the purpose of this *Amicus* Brief to provide the Court with additional argument and information that leads to the singular conclusion that pharmacies and pharmacists are indeed providers of health care under the MPLA and otherwise.

As to the certified question, the Court need look no further than to binding precedent found in the case of *Short v. Appalachian OH-9, Inc.*, 203 W. Va. 246, 507 S.E.2d 124 (1998). In that case one of the primary issues was whether or not emergency

medical services personnel were health care providers within the context of the MPLA. The only difference in the certified question now before the Court and the issue as presented in *Short*, is that rather than considering the issue as it relates to providers of emergency medical services, the Court must now consider it in relationship to those that provide pharmacy services.

In *Short*, even though providers of emergency medical services were not a health care provider specifically enumerated in the language of the MPLA as a "health care provider," the finding was clear that indeed emergency medical service personnel provided "health care" as defined in the act and therefore were "health care providers" as part of a general class. The identical logic applies in relationship to the certified question now before the Court.

Petitioners assert that pharmacists do not have a professional relationship with patients, but merely a retail relationship with a customer buying a product. See pages 9 and 10 of Petitioners' brief. Petitioners further contend that pharmacists do not engage in "independent medical treatment" as if that is some sort of requirement to be included as a health care provider under the terms of the MPLA. The irony in all of this is that the underlying claim of Petitioners in the Boone County Circuit Court Case is that the Respondent Pharmacy violated its professional duties to the Petitioners under West Virginia law – claiming in the underlying complaint that Respondent failed to "observe and correct the erroneous and incomplete drug order as a member of the plaintiff's healthcare team," Complaint at 30(c). Obviously, for purposes of the complaint in circuit court, the Petitioners believed the Respondent to be a provider of healthcare and now, as

a matter of convenience to have a chance at a larger recovery, Petitioners want to contend otherwise.

Not only are pharmacists required to be licensed as professionals and expansively regulated by the West Virginia Board of Pharmacy under W. Va. Code §§ 30-5-1. *et seq.*, it is plain and unambiguous throughout Article 5 of Chapter 30 that the intent of the article is to insure that the acts and services performed or furnished by pharmacists to or in behalf of patients is protective of the health, safety and welfare of the public. Persons using the services of a pharmacist and pharmacy are entitled to far more status than that of a mere "customer" in a store as Petitioner's brief would argue. Moreover, the licensure requirements for pharmacists established by Title 15, Legislative Rule, West Virginia Board of Pharmacy, further establishes the duties and professional responsibilities of pharmacists as health care providers.

The West Virginia Board of Pharmacy is authorized under the provisions of W. Va. Code § 30-5-19 to promulgate rules pursuant to the provisions of Chapter 29A "as are necessary to carry out the purposes and enforce the provisions of" Article 5 of Chapter 30. Contrary to the contentions of Petitioners, rules promulgated pursuant to the provisions of Chapter 29A do have the force and effect of law and, indeed, are ultimately approved by the legislature under the provisions of Chapter 29A.

Again, the irony is that Petitioner's complaint had it right and alleged that Respondent failed to "observe and correct the erroneous and incomplete drug order as a member of the plaintiff's healthcare team." Complaint at ¶ 30(c). Petitioner would allege that as a member of the "plaintiff's healthcare team" Respondent did not meet the duty of care required of a pharmacist or pharmacy in extending an "act" of "health care" "to or on

behalf of a patient during the patient's medical care, treatment or confinement," in the one instance for purposes of finding liability against the respondent, but would challenge the characterization of Respondent as a "health care provider" under the MPLA to avoid a limitation on liability provided by the MPLA for non-economic damages. Indeed, Exhibit 1 to Petitioner's Brief is a photocopy of the Board of Pharmacy Rules Regarding Licensure and the Practice of Pharmacy. There can be no misunderstanding that those rules define the activities of pharmacists as ones of health care to patients.

This *Amicus* Brief will address additional indicia of the nature of the practice of pharmacy and work of pharmacies that convincingly demonstrates their role as providers of health care in today's world – both practically and legally. Pharmacists are uniquely educated and continuously educated as the health care providers that have specialized knowledge on the appropriate use of the increasing number of medications, biologics, and medical devices prescribed as treatment for patients. They are recognized as health care providers in conjunction with a host of government sponsored programs including Medicare and Medicaid, programs of the federal government.

## ARGUMENT

### I.

#### **LICENSED PHARMACIES, PHARMACISTS AND PHARMACY TECHNICIANS ARE HEALTH CARE PROVIDERS UNDER W. VA. CODE § 55-7b-2, THE MEDICAL PROFESSIONAL LIABILITY ACT**

#### **A. PHARMACIES, PHARMACISTS AND PHARMACY TECHNICIANS PROVIDE "HEALTH CARE" AS DEFINED IN THE MPLA AND UNIVERSALLY WITHIN THE COMMON MEANING OF THE TERM**

The singular issue for consideration by the Court in this matter is whether licensed pharmacies and pharmacists are "health care providers" within the meaning of the MPLA. In order to answer that question one must first consider the definition of "health care", "health care facility", and "health care provider" as they appear in the provisions of W. Va. Code § 55-7B-2 (1986) which are next hereinafter set forth as follows:

- (a) "Health care" means any act or treatment performed or furnished, or which should have been performed or furnished, by any health care provider for, to or on behalf of a patient during the patient's medical care, treatment or confinement.
- (b) "Health care facility" means any clinic, hospital, nursing home, or extended care facility in and licensed by the state of West Virginia and any state operated institution or clinic providing health care.
- (c) "Health care provider" means a person, partnership, corporation, facility or institution licensed by, or certified in, this state or another state, to provide health care or professional health care services, including but not limited to, a physician, osteopathic physician, hospital, dentist, registered or licensed practical nurse, optometrist, podiatrist, chiropractor, physical therapist, or psychologist, or an officer, employee or agent thereof acting in the course and scope of such officer's, employee's or agent's employment.

Can there be any question but what a pharmacy or pharmacist – licensed by the State of West Virginia – furnishes treatment as part of a patient's medical care and thus is subject to the requirements and beneficial aspects of the MPLA? Pharmacies and pharmacists are required by the State of West Virginia to meet specific requirements,

including lengthy and highly specialized higher education, in order to be licensed under the provisions of Article 5 of Chapter 30 of the Code of West Virginia. The requirements for licensure are many and comprehensive as essential to the protection of the public health, safety and welfare. W. Va. Code § 30-5-1b(22) defines the term "pharmaceutical care" to be as follows:

(22) "Pharmaceutical care" is the provision of drug therapy and other pharmaceutical patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms or arresting or slowing of a disease process as defined in the rules of the Board.

As a practical matter and reflected by the definitions and various provisions throughout Article 5 of Chapter 30 of the West Virginia Code, pharmacists do far more than merely "dispense" an item to a "customer" as the Petitioner would have the Court rule in this matter. *See* Petition at pp. 9 and 10. Pharmacists may be responsible for mixing chemical compounds to produce the exact drug therapy needed for a patient. Pharmacists are responsible for evaluating prescription drug orders and patient records for known allergies, rational therapy contraindications, reasonable doses and route of administration, reasonable directions for use, duplication of drug therapies, interactions and adverse effects, and other important health care services. Moreover, pharmacists licensed by the State of West Virginia provide consultative services and review drug therapy regimens of patients for the purpose of evaluating and rendering advice to physicians regarding adjustment of drug therapies, and in some cases engage in collaborative practices with physicians to provide better patient healthcare. *See*, W. Va. Code § 30-5-1b and C.S.R. §15-1-19.1 et seq.

Among the many and various elements of health care that pharmacists provide their patients is that of Drug Therapy Management. See W. Va. Code § 30-5-1b (13). When providing drug therapy management services to a patient, a pharmacist reviews a patient's drug therapy regimens for the "purpose of evaluating and rendering advice to a physician regarding adjustment of the regimen." This might include the pharmacist doing such things as "collecting and reviewing patient histories; obtaining and checking vital signs, including pulse, temperature, blood pressure and respiration;" and, "ordering screening laboratory tests that are dose related and specific to the patient's medication or are protocol driven" in accordance with a collaborative pharmacy practice agreement between the pharmacist and a physician. Checking vital sign involves direct interaction with a patient well beyond the stereotypical notion that all a pharmacist does is count pills. Pharmacists work to help patients achieve optimum value in their prescription drug therapy, checking and then evaluating their vital signs and ordering laboratory tests. The duties and functions of a pharmacist in caring for their patients are undeniably acts of health care as used in common parlance and as defined in the statutes and rules governing the profession.

William T. Douglass, Jr., Executive Director and General Counsel of the West Virginia Board of Pharmacy, whose affidavit is appended hereto as Exhibit A, positively affirms that the profession of pharmacy in West Virginia is a function of extending health care serviced to patients. His affidavit is corroborated by one from Sam Kapourales, a licensed pharmacist and duly appointed member of the West Virginia Board of Pharmacy. His affidavit is appended hereto as Exhibit B. Both affidavits, without reservation, conclude that under the governing laws, rules and regulations of the

profession of pharmacy and which they are called upon to enforce from time to time, hold pharmacists to be providers of health care.

In fact, Petitioners originally made reference to the West Virginia Board of Pharmacy's legislative rules that detail the various responsibilities and professional standards to which pharmacists and pharmacies are held. *See* Petition Requesting Certified Question to be Docketed and the Circuit Court's Decision to be Reversed at pp.3-4. The Petitioners even recognize that pharmacists and pharmacies have responsibility for patient counseling, evaluation of prescriptions in relationship to the patient's health history, and a host of other items relating to a patients health and pharmaceutical care.

Moreover, the Petitioners' Request for Certified Question advanced the notion that unless one makes a "diagnosis" they are not engaging in an act of "health care." Such a myopic view of the many and varied dynamics of what constitutes "health care" cannot be reasonably accepted. If so, the allegations of the Petitioner upon which it bases its claim for liability against the Respondent must fail, as they are based on an alleged failure of the Petitioner to have competently performed various elements of pharmaceutical care as part of the Petitioner's health care and as demanded by the standards established by the rules of the West Virginia Board of Pharmacy.

Still the act of dispensing the prescription, which obviously involves much more than the physical act of delivering prescribed medications to the patient is, under the clear and unambiguous language of W. Va. Code § 55-7B-2(a), "any act or treatment performed or furnished ... during the patient's medical care, treatment or confinement."

Without that act performed by the pharmacists or pharmacy, the patient would not receive his or her treatment, to the extent it is dependent on getting a prescription drug.

**B. LEGISLATIVE INTENT MUST BE DETERMINED FROM THE CLEAR AND UNAMBIGUOUS LANGUAGE OF THE OF W. VA. CODE § 55-7B-2(C) RELATING TO THE TERM "HEALTH CARE PROVIDER."**

The Petitioners brief would have the Court believe that because pharmacies, pharmacists and pharmacy technicians are not included as one of the specifically identified groupings of health care providers set forth in the MPLA's definition of a "health care provider" that they are therefore excluded. The definition of the term "health care provider" in the MPLA is as follows:

"Health care provider" means a person, partnership, corporation, facility or institution licensed by, or certified in, this state or another state, to provide health care or professional health care services, *including but not limited to* [emphasis added], a physician, osteopathic physician, hospital, dentist, registered or licensed practical nurse, optometrist, podiatrist, chiropractor, physical therapist, or psychologist, or an officer, employee or agent thereof acting in the course and scope of such officer's, employee's or agent's employment.

The Petitioner contends that unless specifically included as "a physician, osteopathic physician, hospital, dentist, registered or licensed practical nurse, optometrist, podiatrist, chiropractor, physical therapist, or psychologist, or an officer, employee or agent thereof acting in the course and scope of such officer's, employee's or agent's employment," that by definition any other provider or furnisher of "any act or treatment ... during the patient's medical care, treatment or confinement," being the furnishing of "health care" as defined by the MPLA, is excluded from the definition of "health care provider."

A question that must, therefore, be asked, is whether under Petitioners' logic, a pharmacist working for a hospital ("employee or agent thereof") or in a Federally Qualified Rural Health Center ("employee or agent thereof") would not be a provider of health care? What is it that would distinguish the actions of a pharmacist in a hospital or clinic setting as being a provider of health care versus the actions of an independent pharmacist doing exactly the same activity not being a provider of healthcare?

Petitioner argues that the language of the statute must be construed in light of legislative intent as determined by affidavits attached from Petitioner's counsel (who was a member of the legislature at the time of the enactment of W. Va. Code § 55-7B-1 et seq.) and four other legislators from twenty years ago as to what they believe the legislative intent to be or not be as it relates specifically to the profession of pharmacy being embraced within the term "health care provider." While such a self-serving approach may be novel, it is not the manor in which West Virginia law determines what the West Virginia Legislature, consisting of 134 elected members, intended within a given act. The West Virginia Legislature does not record legislative intent. It is long settled that legislative intent in West Virginia is derived from the plain wording of the acts passed by that body. The case of *State v. General Daniel Morgan Post 548, V.F. W., W. Va.*, 144 W. Va. 137, 107 S.E.2d 353 (1959) is one in which the Court has ruled that the only manner by which the will of the legislature is to be determined is contained in the words of the statute itself and further established "the general rule is that no intent may be imputed to the legislature other than that supported by the face of the statute itself. The courts may not speculate as to the probable intent of the legislature apart from the words employed."

Although not affidavits from legislators, this Amicus Brief has appended the affidavits of two people knowledgeable of the position of the West Virginia Pharmacists Association relative to Senate Bill 714, the MPLA, which is the subject of the affidavits attached to the Petitioners' Brief. As the Court might well imagine, the recollection of the former legislators as to the matter in issue, i.e. the position of the West Virginia Pharmacists Association on the subject of Senate Bill 714, is diametrically different from that of the Executive Director of the Association, Richard Stevens, and the President Elect and Legislative and Government Affairs Committee Chairperson in 1986, Sandra Justice, whose positions are corroborated by official minutes of meetings of the Association and reports made to the Association by Mr. Stevens. Those affidavits are appended hereto as Exhibits C and D, respectively. They clearly describe the position of the West Virginia Pharmacy Association in 1986 as one of endorsing the salient provisions of Senate Bill 714. The passage of the measure was hailed by the Association in its official publications.

It is important to note from the affidavit of Mr. Stevens that the Conference Committee meeting referred to in the affidavits attached to the Petitioners' brief occurred in the waning moments of the 1986 Regular Session of the West Virginia Legislature. It consisted of an impromptu meeting near the entrance to the Senate chambers just minutes before midnight and the mandatory conclusion of legislative activity for the session. The meeting itself took only a matter of minutes according to the affidavit. Experience with such matters should convince the Court that there was little, if any, meaningful interaction between interested stakeholders and members of the conference committee at this meeting.

However, the effort to provide counter affidavits merely confirms the fallacy of trying to interpret legislative intent by any means other than from a reading of the actual words of the statute being construed and applying the applicable rules of statutory construction..

A discussion of the premise that legislative intent is not to be inferred from inaction by a legislative body is taken up in the case of *Pristavec v. Westfield Ins. Co.*, 184 W. Va. 331, 400 S.E.2d 575 (1990) citing *Sutherland on Statutes and Statutory Construction* §48.18, at 341 for the proposition that “rejection of a bill may occur because legislation already covers that point sufficiently, not because of disagreement with the merits of the bill.” The case further references W. Va. Code § 2-2-12, noting “abstracts of bills or changes proposed in existing statutes...shall not be construed or interpreted as indicating or expressing legislative intent.” One would certainly think that this principle of construction of statutes would prevail over the illogical and unpredictable course of having cases turn on the affidavits of former legislators, not only as to what they intended, but as if they were speaking for the entire 134 members of a given legislature.

At issue in this case is the use of the term "included but not limited to." Principles of statutory construction dictate against a narrow interpretation of that statutory language. This Court aptly noted in *State v. Zain*, 207 W. Va. 54, 528 S.E.2d 748 (1999):

West Virginia Code § 2-2-10 provides rules to be "observed in the construction of statutes, unless a different intent on the part of the Legislature be apparent from the context." Pursuant to subsection (i) "[t]he word 'person' or 'whoever' shall include corporations, societies, associations and partnerships, if not restricted by the context." Although this section of the code does not include the State within the definition of "person" it uses the term "include," which is a term of enlargement rather than of limitation. [Emphasis added.]

In W. Va. Code § 55-7B-2(a) the language is far broader than the word "include." Indeed, the operative words at issue are "including but not limited to ...," which clearly and unequivocally dictate that the class of entities enumerated as "health care providers" is subject to enlargement. Were the Court to follow the logic of the Petitioners and overturn the law as set forth in *Short v. Appalachian OH-9, Inc.*, 203 W. Va. 246, 507 S.E.2d 124 (1998) as discussed above, then such entities as nursing homes, extended care facilities, out patient or day surgery centers, imaging centers, laboratories where patients go with prescription in hand from a physician to have blood or urine analyzed, and various and other health care providers that have emerged in the market, would not be subject to the MPLA. In *Short*, providers of emergency medical services – not specifically listed within the definition of "health care provider" in the MPLA – were held to come within that definition and subject to the terms and provisions of the MPLA. The case of pharmacists and pharmacies is no different.

The Court applied the confirmed rules of statutory construction in *Short* and held that the definition of "health care provider" in W. Va. Code § 55-7B-2(c) is subject to enlargement and flexibility in relationship to the specific entities that are provided for in the subsection. It applied the notion that "included but not limited to" language is wording of enlargement and not limitation. The United States Court of Appeals for the Ninth Circuit held in *U. S. v. Gertz*, 249 F2d 662 (9<sup>th</sup> Cir. 1957), citing *Federal Land Bank of St. Paul v. Bismarck Lumber Co.*, 314 U. S. 95, 100 (1941) that the word "includes" is usually a term of enlargement and not of limitation.

In examining the language of W. Va. Code § 55-7B-2(c), we find language that is general at first – basically opening an entire class of entities or persons licensed or

certified by the State of West Virginia to provide health care services. The language creating the general class is then followed by open-ended language more specifically enumerating or providing examples of those who may be licensed or certified by the State of West Virginia to provide health care services is set forth as follows: *“including but not limited to a physician, osteopathic physician, hospital, dentist, registered or licensed practical nurse, optometrist, podiatrist, chiropractor, physical therapist, or psychologist, or an officer, employee, or agent thereof acting in the course and scope of such officer’s, employee’s or agent’s employment.”*

For reasons set forth in this brief, there can be no question that pharmacists are part of the general class due to the facts that they are licensed by the State of West Virginia and they provide health care services. None of the enumerated entities would serve to deny pharmacists from being excluded from the general class. All are part of the same general class, the same as pharmacists. By providing the language “including but not limited to” the legislature has certainly provided for the opening of the class in the future for other health care providers not originally enumerated – perhaps recognizing that medical science is a dynamic field in which therapies and treatments yet to be discovered might be administered by professional who are yet to emerge in the health care delivery world.

Reliance on the affidavits of former members of the West Virginia Legislature to determine legislative intent in this matter would require the Court to abandon its own precedent that "Ordinarily, a court cannot consider the individual views of members of the Legislature or city council which are offered to prove the intent and meaning of a

statute or ordinance after its passage and after litigation has arisen over its meaning and intent." *Cogan v. Wheeling*, 166 W. Va. 393, 396, 274 S.E.2d 516, 518 (1981).

If the Court were to now abandon the rules of statutory construction it has often applied<sup>1</sup> and determination of legislative intent through the actual words of an enactment, all West Virginia courts, when challenged as to the intent of the legislature, would be faced with the added dimension of securing the testimony of legislators as to what was intended by a particular statute. Not only would this be impractical in virtually all cases, but it would be impossible in some when dealing with older statutes after those responsible for legislating the same have long departed this life.

## II.

### **PHARMACISTS, PHARMACIES, AND PHARMACY TECHNICIANS ARE "HEALTH CARE PROVIDERS" AS THAT TERM IS COMMONLY USED THROUGHOUT THE HEALTH CARE COMMUNITY AND IN WEST VIRGINIA LAW GOVERNING PHARMACISTS AND PHARMACIES**

One of the most discussed and debated actions in the nationwide effort to improve affordability and access to prescription drugs for senior citizens is that of the Medicare Part D prescription drug benefit provided within *The Medicare Prescription Drug, Improvement, and Modernization Act of 2003* (Public Law Number 108-173; MMA 2003). Within the confines of this law that provides prescription drug benefits to as many as 356,000 West Virginians<sup>2</sup> it is found that those that enroll in the benefit become subject to medication therapy management (MTM) services. Prescription drug plans

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<sup>1</sup> See *Helton v. REM Community Options, Inc.*, \_\_\_ W.Va. \_\_\_, 624 S.E.2d 512 (2005); *State v. Zain*, 207 W.Va. 54, 528 S.E.2d 748 (1999); and, *Short v. Appalachian OH-9, Inc.*, 203 W.Va. 246, 507 S.E.2d 124 (1998)

<sup>2</sup> See statistical data at U. S. Department of Health & Human Services, Centers for Medicare & Medicaid Services – <http://www.cms.hhs.gov>

under MMA 2003 must provide MTM services to serve the needs of certain beneficiaries with chronic conditions. While other providers are not precluded from performing MTM services, pharmacists are the only health care professionals specified in the law as eligible to provide such services. The MMA 2003 also contemplates that pharmacists will play a vital role in chronic care improvement programs. Thus, pharmacists again are directly involved in a component of health care that is unique to them and no others.

Pharmacists are the only health care professionals who receive specialized training on the appropriate use of the increasing numbers of medications, biologics, and medical devices available today. America's reliance on medications for treating and managing health problems has increased dramatically in the past several decades. In 1966, \$4 billion was spent on pharmaceuticals; in 2003, \$180 billion was spent.<sup>3</sup> When patients use multiple medications, the pharmacist's expertise is critical in determining the dosages that should be adjusted to meet changes in a patient's condition. Pharmacists can also evaluate or recommend alternative medications that may be appropriate if a certain medication or combination is not well tolerated by the patient or not covered by insurance. Further, pharmacists monitor for adverse drug reactions that may cause patients to interrupt their pharmacotherapy.

In the report *To Err Is Human: Building a Safer Health System*, the Institute of Medicine stated, "Because of the immense variety and complexity of medications now available, it is impossible for nurses and doctors to keep up with all the information required for safe medication use. The pharmacist has become an essential resource ...

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<sup>3</sup> American Enterprise Institute for Public Policy Research. *Medicare After Reform: What Happens Next?*. December 2003. Available at [http://www.aei.org/events/eventID.681,filter.all/event\\_detail.asp](http://www.aei.org/events/eventID.681,filter.all/event_detail.asp)

and thus access to his or her expertise must be possible at all times.<sup>4</sup> Unquestionably, pharmacists play an integral role in a patient's health care.

In the interest of health, safety and welfare, West Virginia has an entire body of statutory and regulatory law to govern the practice of pharmacy. West Virginia Code §§ 30-5-1-29 embraces the statutory framework governing the profession of pharmacy in the state. It is comprehensive in its approach. Not only does it establish educational and other requirements for professional licensure, but it also addresses standards of care to be observed by pharmacists and sets forth the legislative purpose for the statute, i.e. to protect the public health, safety and welfare by the effective regulation of the practice of pharmacy. See W. Va. Code § 30-5-1a. Moreover, a brief review of the definitional section of Article 5, being W. Va. Code § 30-5-1b contains a myriad of terms clearly indicating the role of pharmacists and pharmacies as providers of health care. "Collaborative pharmacy practice" found at W. Va. Code § 30-5-1b(3) is where pharmacists work collaboratively with physicians under written protocol where the pharmacist or pharmacists may perform certain patient care functions authorized by the physician.

In W.Va. Code § 30-5-12 (12), the term "Drug regimen review," a standard of practice for pharmacists, is defined. Substantially more than just "dispensing" a product to a "customer," as Petitioners would have the Court believe, "drug regimen review" means the evaluation of the prescription drug orders and patient records for (i) known allergies; (ii) rational therapy contraindications; (iii) reasonable doses and route of administration; and (iv) reasonable directions for use. It further means evaluation of the

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<sup>4</sup> Kohn LT, Corrigan JM, Donaldson MS, eds.; Committee on Quality of Health Care in America, Institute of Medicine. *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 2000

prescription drug orders and patient records for duplication of therapy, along with evaluation of the prescription drug "for interactions and/or adverse effects which may include but are not limited to any of the following: (i) drug-drug; (ii) drug-food; (iii) drug-disease; and (iv) adverse drug reactions." If these are not sufficient indications of a function that includes the basic concept of health care, the definition of "drug regimen review" contains the further point of "Evaluation of the prescription drug orders and patient records for proper use, including over use and optimum therapeutic outcomes."

In W. Va. Code § 30-5-12(13) the term "drug therapy management" is defined. Drug therapy management is performed by a pharmacist in conjunction with duties associated with a pharmacy collaborative practice with a physician. Without quoting, suffice it to say that it contemplates review of drug therapy regimens of patients by a pharmacist for purposes of rendering advice to a physician. It embraces the concept that decisions about a patient's drug therapy will be based on collecting and reviewing patient histories, obtaining and checking vital signs including pulse, temperature, blood pressure and respiration, thus requiring pharmacists to be learned in these elements of a patient's health care.

A pharmacist is expected to provide counseling to a patient to improve therapy by helping the patient better understand the proper use of drugs and devices. This is so much true that the term "Patient counseling" is set out in W. Va. Code § 30-5-1b(20).

As discussed above, the term "Pharmaceutical care" is defined in a way that makes it compelling that the work of a pharmacists is clearly a function of providing health care. The term is found at W. Va. Code 30-5-1b (22), where it says: "*Pharmaceutical Care* is the provision of drug therapy and other pharmaceutical patient

care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms or arresting or slowing of a disease process as defined by the rules of the Board. (emphasis added). It is worth noting that the statute quoted refers to "patients" of pharmacists and not "customers" of pharmacists. Common logic beyond the reading of the definition for pharmaceutical care tells us that one who administers or provides therapy to a patient for the cure or prevention of a disease, eliminating or reducing symptoms or arresting or slowing of a disease process is administering health care to that patient.

Thus, without question, the work of a pharmacist is far more than merely delivering a product to a customer as if he or she were selling bolts in a hardware store as Petitioners would have the Court believe. Pharmacists are highly educated, must meet ongoing continuing education requirements, engage in collaborative practices with physicians, are responsible for managing a patient's drug therapy and are on the front line of communications with patients subsequent to their diagnosis by a physician and prescribed drug therapy. They are the implementers of the prescription drug therapy that physicians order. Under certain conditions they also are adjusters of that drug therapy. It is not something entrusted to an uneducated, untrained, or unlicensed professional. Rather, it is the delivery of a component of health care by someone who is educated, trained and licensed by the State of West Virginia as a professional.

Unquestionably, the West Virginia Legislature, through its actions in providing for the licensure and regulation of pharmacists, has considered pharmacists to be health care providers. Petitioner's argument that the failure of movement of House Bill 2871 in the 2005 Regular Session of the West Virginia Legislature somehow constitutes an

expression by the legislature that pharmacists and pharmacies were not to be included within the definition of "health care provider" should be ignored. A review of the legislative history of House Bill 2871 indicates that upon its introduction in the 2005 Regular Session, it was referred to the House Committee on the Judiciary and from that point was never acted on. In fact, no votes were ever taken on the measure. The members of the legislature never expressed anything with respect to the bill. It is just as plausible for one to think that the Judiciary Committee Chairman or committee staff were of the opinion that there was no utility to the legislation since pharmacists and pharmacies would certainly be included in the definition of "health care provider" under the "included but not limited to" language. In West Virginia, the rule is that inaction by the Legislature on a subsequent attempt to amend a statute, is not an indication of legislative intent one way or the other. *Miners in General Group v. Hix*, 123 W.Va. 637, 656-657, 17 S.E.2d 810, 820 (1941) overruled on other grounds by *Lee-Norse Co. v. Rutledge*, 170 W.Va. 162, 291 S.E.2d 477 (1982).

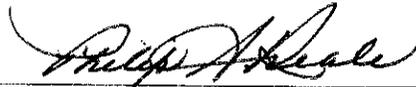
### CONCLUSION

The crux of this matter is one of statutory construction. Well established rules of statutory construction should be employed as opposed to the Court evaluating competing affidavits about what may or may not have been in the minds of a few legislators as opposed to the entire legislature, as well as interested stakeholders, in a given piece of legislation. Obviously, that would initiate a practice for the future that would effectively eliminate any predictability in the statutory law of West Virginia.

The Circuit Court of Boone County made a proper decision in its determination that the Respondent pharmacy was a "health care provider" as defined in the MPLA and therefore covered under the provisions of that statute. The application of principles of statutory construction routinely applied and often confirmed by this Court resulted in that determination. Accordingly, this Court should deny the Petition on Certified Question to overturn the proper decision of the Circuit Court of Boone County.

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