IN THE COURT OF APPEALS OF MARYLAND

No. 57

September Term 2013

KEVIN J. SHANNON, M.D., et al.,

Petitioners,

vs.

MAFALDA FUSCO, et al.,

Respondents

On Writ of Certiorari to the Court of Special Appeals
for an Appeal from the Circuit Court for Prince George's County
(Honorable Leo E. Green, Jr.)

BRIEF OF AMICI CURIAE AMERICAN MEDICAL ASSOCIATION, MARYLAND STATE MEDICAL SOCIETY, AND MEDICAL MUTUAL LIABILITY INSURANCE SOCIETY OF MARYLAND IN SUPPORT OF KEVIN J. SHANNON, M.D.

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STATEMENT OF THE CASE

The Amici Curiae, American Medical Association, Maryland State Medical Society, and Medical Mutual Insurance Society of Maryland, adopt and incorporate by reference the Statement of the Case set forth in the Petitioner's Brief.

STATEMENT OF QUESTIONS PRESENTED

I. Whether the Court of Special Appeals erred when it determined that an expert who was not qualified to testify regarding any standards of practice applicable to a physician was still able to testify regarding the required contents of the informed consent conversation between a physician and a patient.

II. Whether the Court of Special Appeals erred when it mandated that physicians, as part of obtaining informed consent, advise patients regarding the status of FDA regulation of the medication's label and/or manufacturer's marketing of an FDA approved medication, regardless of the actual material risks known to the physician.

STATEMENT OF FACTS

The Amici Curiae adopt and incorporate by reference the Statement of Facts set forth in the Petitioner's Brief. In addition, the Amici Curiae highlight what they consider to be the salient facts:

1. The sole claim at issue brought by the Respondents, Plaintiffs below, is that the Petitioner, Kevin Shannon, M.D., a medical oncologist, failed to obtain informed consent to the administration of Amifostine, a prophylactic agent used to protect against collateral damage to healthy organs during a course of radiation treatment to address prostate cancer.

2. There is no allegation that Dr. Shannon breached any standards of care in selecting Amifostine as part of the treatment plan for his patient, Mr. Anthony Fusco.

3. Respondents claim that the following were materials risks that should have been conveyed to Mr. Fusco: the possibility of developing Stevens-Johnson Syndrome (SJS) and/or Toxic Epidermal Necrolysis Syndrome (TENS), that the package insert contains a precaution regarding the administration of Amifostine to elderly patients, and

that the United States Food and Drug Administration ("FDA") approved uses of Amifostine did not include treatment for prostate cancer.

4. Respondents offered the testimony of James Trovato, Pharm.D. as an expert witness to testify as to the known risks associated with the use of Amifostine, the benefits of its use, and alternative treatments.

5. On motion by the Petitioners, the Honorable Leo E. Green, Jr., excluded the testimony of Dr. Trovato, as he lacked the training and experience to testify regarding what a physician is required to tell a patient such as Mr. Fusco in order to obtain informed consent.

6. Dr. Shannon testified at trial regarding the material risks of Amifostine, including the risk of dermatologic reactions. The evidence at trial demonstrated that after 23 treatments with Amifostine, Mr. Fusco developed an acute rash that advanced to SJS and TENS. The jury determined that a reasonable patient, informed of the material risks, would not have refused consent to the use of Amifostine.

STANDARD OF REVIEW

The Amici Curiae adopt and incorporate by reference the Standard of Review set forth in the Petitioner's Brief.

STATEMENT OF INTENT OF AMICI CURIAE

The Amici Curiae are concerned that the holding of the Court of Special Appeals will have a detrimental effect upon the practice of medicine. By stating that a pharmacist is qualified to render opinions regarding the material risks of a treatment, the court is allowing him to dictate the terms of an informed consent conversation when he lacks the fundamental information necessary to properly advise any such patient on his own, including the training in the practice of medicine and the treatment of patients, knowledge of patient ailments and comorbidities, and knowledge of the relative risks and benefits of the complete treatment options. This holding, coupled with the court's ruling that FDA regulatory status must be part of an informed consent conversation, leads to a single element of a treatment plan, a single drug, overshadowing the totality of the

medical condition of the patient. This will transform the informed consent discussion from a considered effort to educate a patient about his treatment options into a dissertation regarding FDA regulations, drug labeling and package inserts, approved and unapproved uses, justifications for off-label use, and the like. The meaningful and useful information will ultimately be lost in such a surfeit of information and rather than be informed, a patient will end up confused and will cease making informed decisions. The quality of patient care can only be harmed by patients being so overwhelmed with extraneous information that they ultimately abandon their own self-determination.

ARGUMENT

I. A Pharmacist Lacks the Knowledge, Skill, and Training to Second Guess a Physician's Determination of the Risks that a Treatment Poses to a Patient and Should Not Be Permitted to Testify in a Lack of Informed Consent Claim Against a Physician.

A. The Doctrine of Informed Consent Arises from the Physician-Patient Relationship and Encapsulates both the Physician's Knowledge and the Patient's Need to Understand a Treatment.

It is a fundamental premise in the practice of medicine that a patient has a right to self-determination in electing to undergo medical treatment, and a physician may not treat a patient without that patient's consent. *Schloendorff v. Society of N. Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914) ("Every human being of adult years and sound mind has a right to determine what shall be done with his own body."). When Maryland's highest court, in *Sard v. Hardy*, 281 Md. 432, 379 A.2d 1014 (1977), adopted lack of informed consent as a distinct cause of action, it recognized that part and parcel to this fundamental right held by the patient was a duty imposed upon a physician. That duty mandates that the physician provide the patient with the information the patient needs to exercise that right and to make an informed decision about his own healthcare. *Sard*, 281 Md. at 432. *See also, Dingle v. Belin*, 358 Md. 354, 369, 749 A.2d 157 (2000) ("the patient will ordinarily be unable to make an intelligent decision whether to proceed without a clear and adequate explanation by the physician of the nature, benefits, and risks of, and alternatives to, the contemplated procedure.")

The *Sard* court identified what information needed to be conveyed to the patient by the physician as follows: "This duty to disclose is said to require a physician to reveal to his patient the nature of the ailment, the nature of the proposed treatment, the probability of success of the contemplated therapy and its alternatives, and the risk of unfortunate consequences associated with such treatment." *Sard,* 481 Md. at 440. Additional information may be required to be disclosed by the physician in certain situations. *See, e.g., McQuitty v. Spangler*, 410 Md. 1, 976 A.2d 1020 (2009) (change in patient's clinical status that affects the risks and benefits of treatment must be disclosed); *Goldberg v. Boone,* 396 Md. 94, 912 A.2d 698 (2006) (patient should be informed when physician administering the treatment lacks training and experience); *Dingle v. Belin*, *supra*, (patient should be advised that someone other than her physician will be performing surgery). A physician does not need to disclose all risks associated with the treatment, but only those risks "which a physician knows or ought to know would be significant to a reasonable person in the patient's position," which the *Sard* court referred to as "material risks." *Sard,* 281 Md. at 444.

The *Sard* court provided multiple exceptions to the duty of disclosure. As the *Sard* court stated, "there are definite limits on what a physician must communicate." *Id.* A physician need not inform a patient of "all possible complications" or "all risks" and need not provide the patient with "a mini-course in medical science." *Id.* The physician need not disclose a risk that "is either known to the patient or is so obvious as to justify presumption of such knowledge" or to inform a patient of "relatively remote risks inherent in common procedures . . . [that] are of very low incidence." *Sard*, 281 Md. at 445. A physician is not obligated to obtain informed consent "where the patient is incapable of giving his consent by reason of mental disability or infancy" or where "an emergency of such gravity and urgency exists that it is impractical." *Id.* The *Sard* court furthermore retained the therapeutic privilege, through which a physician may withhold information that is detrimental to a patient. *Id.* (A physician "retains a qualified privilege to withhold information on therapeutic grounds, as in those cases where a complete and candid disclosure of possible alternatives and consequences might have a detrimental

effect on the physical or psychological well-being of the patient."). Finally, a physician is under no obligation to disclose a risk of which, in the *exercise of ordinary care, he is unaware. Id.*

The focus in informed consent is on "the patient's need to obtain information." *Id*, 281 Md. at 444. The duty of a physician in providing informed consent is a duty of ordinary care, not professional care. *Id*., 281 Md. at 447. Consequently, expert testimony is not required to establish the physician's duty to disclose or a breach of that duty. *Id.* It is the jury that determines what information is material to a reasonable patient in making an informed decision about a particular treatment. *Smith v. Shannon*, 666 P.2d 351, 356 (Wash. 1983) ("Just as patients require disclosure of risks by their physicians to give an informed consent, a trier of fact requires description of risks by an expert to make an informed decision"). However, the jury still relies upon expert testimony in making that determination and, as the *Sard* court held, expert testimony cannot be dispensed with in an informed consent claim. Specifically, the *Sard* court stated that

> expert medical testimony . . . would be required to establish the nature of the risks inherent in a particular treatment, the probabilities of therapeutic success, the frequency of the occurrence of particular risks, the nature of available alternatives to treatment and whether or not disclosure would be detrimental to a patient.

Id, 281 Md. at 447-48.

When these topics of expert testimony are compared to the list of topics a physician must disclose to a patient, *Id.* at 440, the overlap demonstrates that in the trial of an informed consent claim, the expert medical witness assumes the role of the ordinary physician obtaining informed consent, while the jury assumes the role of the reasonable patient. This overlap, as well as the examples provided by the *Sard* court, demonstrate, as explained below, that this expert medical witness must hold the same or similar qualifications as the physician defendant.

B. The Informed Consent Conversation is a Distillation of a Physician's Knowledge and Experience and only an Expert Physician Can Properly Advise a Jury Considering a Lack of Informed Consent Claim.

Medicine is defined as the field of applied science related to the art of healing by diagnosis, treatment and prevention of disease. *Oxford English Dictionary.* The word medicine is derived from the Latin *medicina*, meaning the healing art. *Online Etymology Dictionary.*

i. Physician Education and Training.

Becoming a physician requires rigorous academic study followed by years of focused training. An aspiring physician must first obtain an undergraduate degree "with a strong emphasis on basic sciences, such as biology, chemistry, and physics."[1] The aspiring physician must then obtain admission to a medical school, where he will spend four years in both class room and clinical training.[2] During medical school,[3] the physician will have to complete a minimum of 130 weeks of instruction that includes anatomy, biochemistry, genetics, immunology, microbiology, pathology, pharmacology, physiology, public health sciences, and behavioral and socioeconomic subjects.[4] The medical student's curriculum will cover all organ systems, and include aspects of preventive, acute, chronic, continuing, rehabilitative, and end-of-life care.[5] The student will need to master contemporary scientific knowledge, concepts, and methods fundamental to acquiring and applying science to the health of individuals and

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[1] American Medical Association, *Requirements for Becoming a Physician*, http://www.ama-assn.org/ama/pub/education-careers/becoming-physician.page? ("Physician Requirements").

[2] *Id.*

[3] Medical schools in the United States and Canada are accredited by the Liaison Committee on Medical Education (LCME), which is jointly sponsored by the Association of American Medical Colleges (AAMC) and the Council on Medical Education of the American Medical Association (AMA). http://www.lcme.org/about.htm. Accreditation is voluntary and indicates compliance with LCME accreditation standards. Current standards are available at http://www.lcme.org/publications.htm#standards-section.

[4] LCME, *Accreditation Standards, Functions and Structure of a Medical School*, http://www.lcme.org/publications/functions2012may.pdf. ("Accreditation Standards").

populations, and engage in laboratory or other practical opportunities for the direct application of the scientific method, accurate observation of biomedical phenomena, critical analysis of data, and research.[6] The student must receive clinical experience in primary care and, by the time he graduates, have studied, and obtained clinical experience related to, each phase of the human life cycle, with the ability to: recognize wellness, determinants of health, and opportunities for health promotion; recognize and interpret symptoms and signs of disease; develop differential diagnoses and treatment plans; and assist patients in addressing health-related issues involving all organ systems.[7] Every medical student receives education and clinical training in the disciplines of family medicine, internal medicine, obstetrics and gynecology, pediatrics, preventive medicine, psychiatry, and surgery.[8] This core curriculum is supplemented by elective studies that reflect a student's individual career and/or academic interests.[9] In addition, medical school students must receive training and education in the social sciences that directly apply to the practice of medicine, such as communication skills, addressing violence and abuse, understanding cultural differences that impact health and illness, and ethical principles that dictate physician actions.[10]

Upon completing medical school, an aspiring physician must complete a residency program.[11] A residency program is "three to seven years or more of professional training under the supervision of senior physician educators. The length of residency training varies depending on the medical specialty chosen: family practice, internal medicine, and pediatrics, for example, require 3 years of training; general surgery requires 5 years."[12]

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[5] *Id.*
[6] *Id.*
[7] *Id.*
[8] *Id.*
[9] *Id.*
[10] *Id.*
[11] Physician Requirements, *supra*.
[12] *Id.*

After completing a residency program, physicians, such as the Petitioner,[13] often go on to complete a Fellowship, which is "one to three years of additional training in a subspecialty."[14] After completing their training, many physicians, including the Petitioner,[15] go on to become board certified. "The majority of physicians also choose to become board certified, which is an optional, voluntary process. Certification ensures that the doctor has been tested to assess his or her knowledge, skills, and experience in a specialty and is deemed qualified to provide quality patient care in that specialty."[16] Physicians are expected to continue their education throughout their careers and many states have mandatory minimum continuing medical education credit requirements.[17] Most board certifications must be renewed, and there are educational requirements associated with those renewals.[18]

ii. Licensing of Physicians in Maryland.

In order to practice medicine in Maryland, a physician must be licensed pursuant to MD. CODE ANN., HEALTH OCC. § 14-101, *et seq.* (West 2008). To obtain that license, a physician must have obtained a degree of doctor of medicine from an accredited medical school, have successfully completed at least one year of postgraduate medical training, and have passed an exam administered by the Board of Physicians. *Id.* at § 14-307. Maryland defines the practice of medicine as follows:

> (1) "Practice medicine" means to engage, with or without compensation, in medical:
> (i) Diagnosis;
> (ii) Healing;
> (iii) Treatment; or
> (iv) Surgery.

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[13] The Respondent, Dr. Kevin Shannon completed a dual fellowship in oncology and hematology. (E258.)
[14] Physician Requirements, *supra*.
[15] Dr. Shannon holds three board certifications: internal medicine, oncology, and hematology. (E260.)
[16] Physician Requirements, *supra*.
[17] *Id.*
[18] *Id.*

> (2) "Practice medicine" includes doing, undertaking, professing to do, and attempting any of the following:
>
> (i) Diagnosing, healing, treating, preventing, prescribing for, or removing any physical, mental, or emotional ailment or supposed ailment of an individual:
>
> 1. By physical, mental, emotional, or other process that is exercised or invoked by the practitioner, the patient, or both; or
>
> 2. By appliance, test, drug, operation, or treatment;
>
> (ii) Ending of a human pregnancy; and
>
> (iii) Performing acupuncture as provided under § 14-504 of this title.

Id. at § 14-101(o).

iii. <u>Application of Training and Knowledge to an Informed Consent Discussion.</u>

All of the training, knowledge, and experience of a physician, both about medicine and about the patient before him, is distilled into the informed consent conversation, in which the physician educates the patient about his medical condition and the treatment options available to him. Each element of an informed consent discussion identified by this court in *Sard,* 281 Md. at 440, is a piece of the practice of medicine and requires the knowledge and training of a physician. The compilation of information from the examination and assessment of the patient resulting in a diagnosis is contained within the required disclosure of "the nature of the ailment." *Id.* A physician's knowledge of all medical treatments including surgical, pharmaceutical, and radiological, whether conservative, aggressive, or alternative, is contained within "the nature of the proposed treatment." *Id.* This knowledge of the patient coupled with this knowledge of the treatments combine to provide "the probability of success of the contemplated therapy and its alternatives." *Id.* That knowledge furthermore combines to provide "the risk of unfortunate consequences associated with such treatment." *Id.* All of this information is interrelated; weighing and balancing the patient's medical condition and the state of medical knowledge regarding successes and failures associated with different treatment modalities.

Informing a patient about the material risks of a treatment is not limited to known complications of one element of a treatment, it includes interactions between the multiple

elements of a treatment. For example, because Amifostine protects healthy tissue from the effects of radiation therapy, a patient taking Amifostine is less likely to have the course of radiation therapy interrupted by complications such as mucositis. John R. Kouvaris et al., *Amifostine: The First Selective-Target and Broad-Spectrum Radioprotector,* The Oncologist 2007:12:738-747 (2007). An uninterrupted course of radiation therapy is more effective at shrinking cancerous tumors. *Id.* An informed consent discussion about Amifostine for a cancer patient undergoing radiation therapy will have to include not only the risks of Amifostine itself, but the risks of the radiation therapy with Amifostine and without it. The drug Amifostine does not stand in isolation, it is part of a treatment plan and impacts the other elements of that treatment plan.

The *Sard* court recognized this interplay of medical information when it concluded that expert medical testimony was required in an informed consent trial. *Sard,* 281 Md. at 447-48. In a case such as the one at issue here, which involves obtaining informed consent for a treatment to address prostate cancer in an elderly gentlemen, the expert medical witness logically must be a physician who is experienced in the treatment of cancer patients. *See, Robertson v. Iuliano*, CIV.A. RDB-10-1319, 2012 WL 6138441 (D. Md. Dec. 10, 2012) ("As in Maryland, other jurisdictions have held that the 'physician is uniquely qualified through education and training, and as a result of his or her relationship to the patient, to determine the information that the particular patient should have in order to give an informed consent.' *Sherwood v. Danbury Hosp.*, 278 Conn. 163, 896 A.2d 777, 792 (Conn. 2006) (quoting *Johnson v. Sears Roebuck & Co.*, 113 N.M. 736, 832 P.2d 797, 799 (N.M.App.1992))."); *See also, Festa v. Greenberg*, 511 A.2d 1371, 1378 (Pa. Super. Ct .1986) (discussing the need for physician expert testimony to provide the information relied upon by a jury in deciding the issue of informed consent).[19] To properly advise a jury on the topics identified by the *Sard* court requires

[19] The court should furthermore consider both the legislative intent and the explicit statutory language set forth in the Health Claims Act, MD. CODE ANN., CTS. & JUD. PROC. § 3-2A-01, *et seq*. which requires that all claims arising out of the rendering of health care go through arbitration. Although a claim arising solely from lack of informed

an expert who has knowledge of the principals of medicine and knowledge of all of the treatments available for prostate cancer. That knowledge will have to include the frequency of success or failure for the treatments, the rates of complication for those treatments, and what effect the patient's medical status has upon those statistics. Such an expert clearly needs to be capable of reviewing the medical records of Mr. Fusco and developing an opinion as to his medical conditions including not only the disease at issue, prostate cancer, but all of his co-morbidities. This entails the assessment and diagnosis that is uniquely within the province of a trained physician. This expert must be fully informed of the medical literature regarding every element of every treatment option applicable to treatment for prostate cancer, and it is only oncologists such as Dr. Shannon that have an obligation to keep abreast of this category of medical literature.

Only an expert physician with experience in the treatment of cancer will have the full set of skills and knowledge required to identify what are the characteristics of a patient in similar circumstances to Mr. Fusco and inform a jury as to the "nature of the risks inherent in [the] particular treatment" offered to Mr. Fusco, "the frequency of the

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consent is exempt from the requirement that the claim be supported by a certificate from a qualified expert contained in CJP § 3-2A-04(b), all other provisions of the statute apply. *Id*. This includes the following provision, "[i]n any action for damages filed under this subtitle, the health care provider is not liable for the payment of damages unless it is established that the care given by the health care provider is not in accordance with the standards of practice among members of the same health care profession with similar training and experience situated in the same or similar communities at the time of the alleged act giving rise to the cause of action." CJP § 3-2A-02(c)(1). The use of the phrase "standards of practice" in this provision is in contrast to the use of the term "standards of care" in the provisions associated with the requirements for an expert certificate, CJP § 3-2A-04, from which an informed consent claim is excluded, and the requirement that an expert with the same board certification testify in a medical negligence claim. CJP § 3-2A-02(c)(2)(ii). This suggests that "standards of practice" is a broader term that encompasses such standard physician practices as obtaining informed consent from a patient. The language and structure of this statutory provision, taken in context with the remaining provisions of the statute, suggests that the legislature intended it to apply to all claims arising from health care, including a lack of informed consent claim. Specifically, that a physician's attempt to obtain informed consent from a patient

occurrence of particular risks" in a patient such as Mr. Fusco, "the nature of available alternatives" including their risks for a patient such as Mr. Fusco, and "the probabilities of therapeutic success" in a patient such as Mr. Fusco, for both the treatment and the alternatives. *Id.*

C. A Pharmacist Lacks the Education, Training, or Experience to Educate a Jury on the Information that a Physician Can and Should Convey in an Informed Consent Conversation.

The practice of pharmacy is defined quite differently than the practice of medicine. The National Association of Boards of Pharmacy ("NABP") defines the practice of a pharmacist[20] as follows:

> The "Practice of Pharmacy" means the interpretation, evaluation, and implementation of Medical Orders; the accepting, processing, or Dispensing of Prescription Drug Orders; participation in Drug and Device selection; Drug Administration; Drug Utilization Review (DUR); the Practice of Telepharmacy within and across state lines; Drug or Drug-related research; the provision of Patient Counseling;[21] the provision of those acts or services necessary to provide Pharmacist Care in all areas of patient care, including Primary Care, Medication Therapy Management, Collaborative Pharmacy Practice,[22] the ordering, conducting, and

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should be compared with the similar practices among those in his profession with similar training and experience.

[20] National Association of Boards of Pharmacy, *Model State Pharmacy Act and Model Rules of the National Boards of Pharmacy*, § 104. Practice of Pharmacy, August 2013, available at www.nabp.net/publications/model-act. ("NABP Model Act").

[21] NABP defines "Patient Counseling" to mean "the oral communication by the Pharmacist of information, as defined in the rules of the applicable Board, to the patient or caregiver, in order to ensure proper use of Drugs and Devices." NABP Model Act, § 105(m4), Definitions. This definition is focused upon instructing a patient in the proper use of the medication in order to prevent self-administration errors. In no respect does this definition refer to advising a patient regarding the risks or benefits of a medication.

[22] A collaborative pharmacy practice is a reference to collaborative health care practice legislation which expands the role of pharmacists in patient care. Maryland adopted legislation associated with collaborative pharmacy practices that went into effect in 2008, several years after the care at issue. *See, e.g.*, MD. CODE ANN., HEALTH GEN. § 19-713.6; MD. CODE ANN., HEALTH OCC. § 12-6A-01 *et seq*. This practice permits a pharmacist to treat patients in a limited fashion, including administration of drugs and ordering tests. The pharmacist in this collaborative setting is acting under the direction of a physician, following treatment protocols prepared by the physician, and is acting under the auspices

> interpretation of appropriate tests, and the recommendation and administration of immunizations; and the responsibility for Compounding and Labeling of Drugs and Devices (except Labeling by a Manufacturer, Repackager, or Distributor of Non-Prescription Drugs and commercially packaged Legend Drugs and Devices), proper and safe storage of Drugs and Devices, and maintenance of required records. The practice of pharmacy also includes continually optimizing patient safety and quality of services through effective use of emerging technologies and competency-based training.

As this definition illustrates, the practice of pharmacy, at its core, is focused upon keeping the medications that physicians use to treat their patients safe and reliable. Pharmacists insure that the medication that a patient receives is what the physician intends to use to treat the patient. With limited exceptions inapplicable here, pharmacists do not assess and examine patients, quantify their physical conditions and ailments, make diagnoses, or develop treatment plans intended to resolve physical ailments and diseases. Rather, pharmacists help to carry out the treatment decisions made by a patient and his physician.

i. Pharmacist Education and Training.

Obtaining a doctor of pharmacy degree requires that a student complete 5-6 years of post-secondary education.[23] This includes two years of college-level course work on the basic sciences, such as general chemistry, organic chemistry, biology, mathematics, information technologies, or physical sciences, as well as general education in the humanities, behavioral sciences, social sciences, or communication. [24] The student can

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of a physician-pharmacist agreement approved by both the Board of Physicians and the Board of Pharmacy. *Id.*

[23] Council on Credentialing in Pharmacy, *Scope of contemporary pharmacy practice: Roles, responsibilities, and functions of pharmacists and pharmacy technicians*, Journal of American Pharmacists, 2010;50:e35-e69. doi:10.1331/JAPhA.2010.10510 (2003).

[24] Accreditation Council for Pharmacy Education, *Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree*, Adopted January 15, 2006, Effective July 1, 2007, available at https://www.acpeaccredit.org/pdf/ACPE_Revised_PharmD_Standards_Adopted_Jan152006.pdf. ("Pharmacy Education Standards").

then begin the four year doctor of pharmacy program.[25] The student must complete a curriculum of biomedical sciences that addresses the topics of anatomy and physiology, pathology and pathophysiology, microbiology, immunology, biochemistry, molecular biology, genetics and biostatistics; pharmaceutical sciences on the topics of medicinal chemistry, pharmacology, pharmacognosy and alternative and complementary treatments, toxicology, bioanalysis and clinical chemistry, pharmaceutics and biopharmaceutics, pharmacokinetics and clinical pharmacokinetics, pharmacogenomics and genetics, and extemporaneous compounding, parenteral and enteral; social, behavioral, and administrative sciences on the topics of health care delivery systems, economics and pharmacoeconomics, practice management, pharmacoepidemiology, pharmacy law, regulatory affairs, history, ethics, professional communications, and social and behavioral aspects of practice; and the clinical sciences including pharmacy practice and pharmacist-provided care, medication dispensing and distribution systems, pharmacotherapy, special populations, drug information, medication safety, patient assessment, literature evaluation, and research design.[26] The student must also complete a course of practical experiences under the supervision of pharmacist preceptors that include direct interaction with diverse patient populations in a variety of practice settings involving collaboration with other health care professionals.[27] Upon completing academic coursework, the student must complete a one year residency program.[28] If the student chooses to do so, he or she may also complete a second year of residency in a specialized area.[29]

ii. Licensing of Pharmacists in Maryland.

In Maryland, pharmacists are licensed pursuant to MD. CODE ANN., HEALTH OCC. § 12-101, *et seq.* (West 2008). To obtain a license to practice pharmacy, an applicant must be a graduate of an approved school or one accredited by the Accreditation Council

[25] *Id.*, Standard No. 17, Guideline No. 17.1.
[26] *Id.*, Standard No. 13, and Appendix B – Additional Guidance to the Science Foundation for the Curriculum.
[27] *Id.*, Standard No. 14.
[28] Council on Credentialing in Pharmacy, *supra.*

for Pharmacy Education,[30] must complete a professional experience program, and must pass an exam administered by the Board of Pharmacy. *Id.* at § 12-302. The State of Maryland defines the practice of pharmacy as:

> (i) Providing pharmaceutical care;
> (ii) Compounding, dispensing, or distributing prescription drugs or devices;
> (iii) Compounding or dispensing nonprescription drugs or devices;
> (iv) Monitoring prescriptions for prescription and nonprescription drugs or devices;
> (v) Providing information, explanation, or recommendations to patients and health care practitioners about the safe and effective use of prescription or nonprescription drugs or devices;
> (vi) Identifying and appraising problems concerning the use or monitoring of therapy with drugs or devices;
> (vii) Acting within the parameters of a therapy management contract, as provided under Subtitle 6A of this title;
> (viii) Administering an influenza vaccination in accordance with § 12-508 of this title;
> (ix) Delegating a pharmacy act to a registered pharmacy technician, pharmacy student, or an individual engaged in a Board approved pharmacy technician training program;
> (x) Supervising a delegated pharmacy act performed by a registered pharmacy technician, pharmacy student, or an individual engaged in a Board approved pharmacy technician training program; or

Id. at § 12-101(s)(1).[31] Maryland requires that licensed pharmacists complete thirty hours of continuing education every two years in order to obtain a renewed license to practice pharmacy. *Id.* at § 12-309.

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[29] *Id.*

[30] Accreditation Council for Pharmacy Education was established in 1932 for the accreditation of professional degree programs in pharmacy. It is an autonomous and independent agency whose Board of Directors is appointed by the American Association of Colleges of Pharmacy, the American Pharmacists Association, the NABP, and the American Council on Education.

[31] Maryland has placed upon pharmacists a duty to provide prescription consultation services to recipients of medical assistance. *Id.* at § 12-507. The contents of the consultation are dictated by statute and include: the name and description of the medication; dosage, storage, and refill information; any special instructions for preparing or administering the medication; "common severe side or adverse effects or interactions and therapeutic contraindications," how to avoid them, and what to do if they occur; what

iii. Pharmacists Do Not Practice Medicine and Lack the Training and Knowledge Required to Engage in an Informed Consent Discussion.

There is no dispute that pharmacists such as Dr. Travato are highly qualified professionals who are valuable and critical contributors to the health care system. However, no matter how capable a pharmacist is, he is neither trained to nor seeks to practice medicine. *See*, *Nevada State Bd. of Pharm. v. Garrigus*, 496 P.2d 748, 749 (Nev. 1972) (holding that "[t]he profession of medicine calls for different requisites than the profession of pharmacy.") As illustrated above, the education, training, skill sets, and practices of pharmacists and physicians are distinctly different. A pharmacist does not have the ability to review patient medical records and arrive at a comprehensive diagnosis. A pharmacist is not trained in the interplay between disease, comorbidities, and treatment, and cannot testify, to a reasonable degree of medical probability, how this interplay effects the risks and benefits of treatment options for a specific condition. A pharmacist does not have the training, experience, and knowledge required to identify what are the characteristics of a patient in similar circumstances to Mr. Fusco and inform a jury as to the "nature of the risks inherent in [the] particular treatment" offered to Mr. Fusco, "the frequency of the occurrence of particular risks" in a patient such as Mr. Fusco, "the nature of available alternatives" including their risks for a patient such as Mr. Fusco, and "the probabilities of therapeutic success" in a patient such as Mr. Fusco, for both the treatment and the alternatives. *Sard*, 281 Md. at 447-48.

D. The Court of Special Appeals Relied Upon Case Law from Other Jurisdictions that is Inconsistent with Established Maryland Law and Should Not be Viewed as Persuasive.

To support its holding that Dr. Travato was qualified to render expert testimony as to the elements of a lack of informed consent claim, the Court of Special Appeals relied upon case law that is plainly distinguishable from the case at hand and/or inapposite of clear Maryland law. The appellate court relied upon a collection of cases that held that a

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to do if a dose is missed; and techniques for self-monitoring drug therapy. *Id.* However, this is not an informed consent communication and does not impose a duty upon a pharmacist to warn of material risks associated with a drug.

pharmacologist could testify as to the standards of care applicable to physicians prescribing medications. *See, Garvey v. O'Donoghue,* 530 A.2d 1141 (D.C. 1987) (malpractice in prescription of Tobramycin); *Thompson v. Carter,* 518 So.2d 609 (Miss. 1987) (malpractice in prescription of Bactrim). These cases are inapplicable as they do not address informed consent. Furthermore, the Maryland Legislature took action to curtail precisely the type of cross-discipline expert witness testimony these cases represent when it defined expert witness qualifications in a medical malpractice action. MD. CODE ANN., CTS. & JUD. PROC. § 3-2A-02(c). Case law from other states that is patently in contravention of Maryland statutory law should not be considered as persuasive, let alone dispositive, as to the propriety of permitting an expert from an unrelated profession to insert himself into the physician-patient relationship and dictate the terms of an informed consent conversation.

The appellate court further pointed to a series of cases in which a pharmacologist was permitted to testify on questions of causation associated with pharmaceuticals. *See, Sinkfield v. Oh*, 495 S.E.2d 94 (Ga. Ct. App. 1997) (effects of Motrin on pregnant women); *Tidwell v. Upjohn*, 626 So.2d 1297 (Ala. 1993) (effects of Halcion); *Goodman v. Lipman,* 399 S.E.2d 255 (Ga. App. 1990) (effects of Coumadin). In each of these cases, the pharmacologist was testifying as to the pharmacology topics well within their areas of expertise and were not addressing material risks or informed consent. Amici do not dispute that pharmacologists may testify regarding pharmacology, only that they may not provide, or testify regarding, informed consent.

Finally, the appellate court pointed to several criminal cases involving improper distribution of prescription narcotics, which also do not involve claims for informed consent. *United States v. Bek,* 493 F.3d 790 (7th Cir. 2007) and *United States v. Smith*, 573 F.3d 639 (8th Cir. 2009). The Amici do not dispute that there are circumstances where the expertise of a pharmacist or a pharmacologist would be helpful to a jury. However, that fact does not dictate the conclusion that the testimony of a pharmacist is helpful, relevant, or admissible in every case where a drug is at issue, let alone in a case

regarding a physician obtaining informed consent for a treatment plan that includes prescription medication.

The only case cited by the lower appellate court that appears consistent with the holding they propound does not withstand closer scrutiny. *Parker v. Harper*, 803 So.2d 76 (La. Ct. App. 2001), did not hold that a pharmacist could testify as to the material risks for a treatment regimen, as that term is used in Maryland. The *Parker* court's holding was far narrower, and only addressed whether a pharmacist's affidavit created a question of material fact as to whether the outcome the patient experienced was a known risk of the medication. In *Parker,* a child suffered an allergic reaction to Dilantin, developed SJS, lost total vision in one eye and partial vision in the other, and sustained permanent scarring. Her parents sued for medical malpractice and lack of informed consent. In Louisiana, informed consent is dictated by a statute which requires that a physician inform a patient of "the known risks" of certain specific adverse effects including "the loss or loss of function of any organ or limb" and also "of disfiguring scars." LA. REV. STAT. § 40:12:99.40. Under this statute, any risk of organ loss or disfiguring scars is a risk that must be disclosed, regardless of how remote that risk may be. There is no medical judgment called into question as to whether the risk may be material under the circumstances of a particular patient. The pharmacist's affidavit in *Parker* was offered solely to establish that the development of SJS, and its resulting scars, was a risk of Dilantin that was generally know, thereby establishing a dispute as to a material fact sufficient to survive summary judgment. Louisiana's statute sets a bright line test which Maryland's courts have rejected. *See, Goldberg, supra*. Not only is *Parker* inapplicable because the statute upon which it is based is inconsistent with Maryland's informed consent law, it is inapplicable because the statute upon which it is based has been repealed. LA. REV. STAT. § 40:12:99.40, repealed by La. Acts 2012, No. 759, §3, eff. June 12, 2012.

E. The Distinctions Between the Knowledge Base of a Physician and that of a Pharmacist Have Been Acknowledged and Incorporated into Law in the Learned Intermediary Defense to a Pharmacy Liability Claim.

The learned intermediary doctrine is a well established legal premise that illustrates the distinctly different duties a pharmacist and a physician hold toward a patient, especially where conveying the information associated with informed consent is concerned. The learned intermediary doctrine, which is the law in Maryland, provides that a drug manufacturer, who has satisfied its duty to warn physicians of potential risks associated with a prescription drug, has no duty to warn a patient of those risks. *Nolan v. Dillon*, 261 Md. 516, 276 A.2d 36, 40 (1971); *Gourdine v. Crews*, 177 Md.App. 471, 935 A.2d 1146 (2006); *Doe v. Miles Labs., Inc.*, 927 F.2d 187, 194 (4th Cir.1991); *Lee v. Baxter Healthcare Corp.*, 721 F.Supp. 89, 94–95 (D.Md.1989), *aff'd*, 898 F.2d 146 (4th Cir.1990). Although not expressly addressed by Maryland's state courts, federal courts applying Maryland law have concluded that the learned intermediary defense applies to pharmacists, who likewise have no duty to warn patients of potential risks associated with prescription drugs. *Hofherr v. Dart Indus., Inc*., 853 F.2d 259, 263-64 (4th Cir. 1988) (applying Maryland law to find no duty of pharmacy to warn consumer); *Moore v. Wyeth-Ayerst Labs.*, 236 F.Supp.2d 509 (D. Md. 2002); *but compare, Rite Aid Corp. v. Levy-Gray*, 162 Md.App. 673, 876 A.2d 115 (2005) (pharmacy liable for breach of express warranty where package insert that pharmacy prepared and provided to consumer erroneously stated that medication could be safely taken with milk.)

One of the foundational elements of the learned intermediary doctrine is that a pharmacist, under usual circumstances, should not "set up his judgment against that of a licensed physician." *Peoples Serv. Drug Stores v. Somerville*, 161 Md. 662, 158 A. 12, 13 (1932). Maryland's Federal Courts have recognized that imposing a duty to warn about the risks of prescription drugs on a pharmacist "would create an intolerable confusion and foster obviously dangerous practices in the consumption of prescription drugs." *Hofherr*, 853 F.2d at 263. Specifically, these courts were concerned that such a law would lead to pharmacists second-guessing the treatment decisions of a physician

and that "only danger could result." *Id. at 263-64.* One such danger was expressed by the *Hofherr* court, which stated:

> A pharmacist or a manufacturer who advised a patient not to take a drug prescribed by a physician might easily cause death or serious injury, and we think the practice of medicine by pharmacists and pharmaceutical manufacturers is not a field in which we should even encourage them to engage, much less require it, as plaintiffs would have.

Hofherr, 853 F.2d at 264.

The learned intermediary doctrine is premised on the physician's "duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients" as well as the physician-patient relationship which results in the presumption that a patient places "primary reliance upon" the judgment of the physician. *McKee v. Am. Home Prods. Corp.*, 782 P.2d 1045, 1049 (Wash. 1989). The physician is the "learned intermediary" as he has examined the patient, reviewed the patient's complete medical history, and determined an appropriate drug treatment for that patient. "It is the physician who is in the best position to decide when to use and how and when to inform his patient regarding risks and benefits pertaining to drug therapy." *Kirk v. Michael Reese Hosp. & Med. Ctr.*, 513 N.E.2d 387, 395 (Ill. 1987), *cert. denied,* 485 U.S. 905, 108 S.Ct. 1077, 99 L.Ed.2d 236 (1988), citing W. Prosser & W. Keeton, The Law of Torts sec. 96, at 688 (5th ed. 1984). The physician has information about the patient that the pharmacist, dispensing the drug that the physician has prescribed, lacks. Consequently it is the physician, and not the pharmacist, who is in the best position to advise the patient about the risks of that drug. It is "only the physician who can relate the propensities of the drug to the physical idiosyncrasies of the patient." *McKee*, 782 P.2d at 1050; *Leesley v. West,* 518 N.E.2d 758, 762 (Ill. App. Ct. 1988) ("[t]he foreseeability of injury to an individual consumer in the absence of any particular warning also varies greatly depending on the medical history and condition of the individual-facts which we cannot reasonably expect the pharmacist to know.")

The doctrine furthermore emphasizes that a physician has an obligation to obtain informed consent to any treatment, including pharmaceutical treatment. Since the

physician has the duty to obtain informed consent from a patient, and the knowledge to advise the patient about the risks associated with any pharmaceutical therapy being contemplated, a pharmacist is absolved from any obligation to warn a patient about any risks associated with a prescription drug that the pharmacist is dispensing. The *McKee* court summarized the interplay between the manufacturer/pharmacist and the physician as to warning a patient of the risks of a medication as follows:

> Neither manufacturer nor pharmacist has the medical education or knowledge of the medical history of the patient which would justify a judicial imposition of a duty to intrude into the physician-patient relationship. In deciding whether to use a prescription drug, the patient relies primarily on the expertise and judgment of the physician. Proper weighing of the risks and benefits of a proposed drug treatment and determining what facts to tell the patient about the drug requires an individualized medical judgment based on knowledge of the patient and his or her medical condition.

McKee, 782 P.2d at 1051; *Wyeth Labs., Inc. v. Fortenberry*, 530 So. 2d 688, 691 (D.C. Cir. 1988) ("As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. . . . The choice he makes is an informed one, an individualized medical judgment bottomed on knowledge of both patient and palliative." (quoting *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974))); *Thomas v. Hoffman-LaRoche, Inc.*, 731 F. Supp. 224, 229 (N.D. Miss. 1989), *aff'd*, 949 F.2d 806 (1992) ("the physician through education, experience, and specialized training is in the best position to make a benefit/risk analysis in making the determination to prescribe a particular drug for a specific patient."); *Alm v. Aluminum Co.*, 717 S.W.2d 588, 592 (Tex. 1986) ("Generally, only the doctor could understand the propensities and dangers involved in the use of a given drug."); *Walker v. Jack Eckerd Corp.*, 434 S.E.2d 63, 67 (Ga. Ct. App. 1993) ("the fact that patients have different reactions to and tolerances for drugs coupled with the fact that the severity of the patient's condition may warrant a different level of risk acceptance, which factors are best monitored and evaluated by doctors.").

The learned intermediary doctrine is the established law in the vast majority of states. In fact, this defense to a duty to warn claim has been applied or at least recognized in 48 states, the District of Columbia and Puerto Rico. *See In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 806-809 (E.D. Tex. 2002) (listing cases in each jurisdiction); Diane Schmauder Kane, Annotation, *Constr. and Application of Learned-Intermediary Doctrine,* 57 A.L.R. 5th 1 (1998); *McKee, supra.*; *Larkin v. Pfizer, Inc.,* 153 S.W.3d 758, 761 (Ky. 2004); *McCombs v. Synthes (U.S.A.),* 587 S.E.2d 594, 595 (Ga. 2003); *Vitanza v. Upjohn Co.*, 778 A.2d 829, 836-38 (Conn. 2001); *Coyle v. Richardson-Merrell, Inc.,* 584 A.2d 1383, 1385 (Pa. 1991); *Jones v. Irvin*, 602 F.Supp. 399, 400-01 (S.D. Ill. 1985) (pharmacist has no duty to warn the customer or notify the physician that drug could cause adverse reactions to the customer). Several states have codified the doctrine. OHIO REV. CODE ANN. § 2307.76(C); N.C. GEN. STAT. ANN. § 99B-5(c); MISS. CODE ANN. § 11-1-63(c)(ii). New Jersey also has adopted a statutory presumption of an adequate warning in the case of drugs that have been approved by the FDA. *See* N.J. STAT. ANN. § 2A:58C-4. In adopting the learned intermediary doctrine, these courts have adopted the same reasoning espoused above, that it is the physician who best can say the risks a medication poses to a patient and therefore it is only the physician who can warn a patient about its use.

While not controlling of the issues before this court in this matter, the learned intermediary doctrine demonstrates that pharmacists and physicians have distinctly different roles and different obligations when it comes to patient care, including advising a patient in order to obtain informed consent to a recommended treatment. Pharmacists, unlike physicians, have no duty to warn a patient about risks associated with a particular medication. Pharmacists are absolved from liability arising from injury caused to an uninformed patient as that responsibility and liability lie exclusively with the physician. Allowing a pharmacist to testify against a physician in support of a lack of informed consent claim results in a pharmacist dictating what are appropriate practices in a field of medicine in which pharmacists, as a profession, play no role. Allowing a physician to be judged by standards espoused by an expert in a wholly unrelated profession who has no

duty in patient care comparable to the duty to obtain informed consent is illogical and manifestly unjust.

II. The Presence or Absence of FDA Approval is not a Material Risk and Should Not be a Mandatory Requirement of an Informed Consent Conversation.

The Court of Special Appeals held that whether a medication has been approved by the FDA for the particular use proposed by a physician is information material to a patient's consideration in deciding whether to undergo a proposed course of treatment. *Fusco v. Shannon*, 210 Md.App. 399, 436, 63 A.3d 145 (2013). The appellate court further held that the contents of a medication's package label regarding lack of testing in the elderly was also information material to a patient. *Id.* 210 Md.App. at 435-36. In so holding, the intermediate appellate court created a bright line requirement that a physician keep himself informed regarding labeling requirements and the regulatory status applicable to the manufacturers of the medications used in his practice and inform a patient of labeling and marketing regulations when recommending medications. The appellate court rejected established precedent in Maryland, rejected the opinions of the majority of courts that have considered the issue, placed upon physicians the unrealistic and unnecessary burden of staying abreast of regulatory activity to which they are not subject, and interfered with the ability of a physician and patient to have a meaningful conversation about actual risks and benefits of a proposed course of treatment.

A. Maryland has Historically Rejected a Bright Line Test of What Must be Included in an Informed Consent Conversation.

As discussed above, when Maryland's highest court first recognized a failure to obtain informed consent as a cause of action, it recognized that it was a conversation between a physician and a patient, the contents of which were dependent upon the circumstances. *Sard v. Hardy, supra*. The *Sard* court did not dictate what must be said during an informed consent conversation, only what categories of information must be shared, such as an explanation of the treatment, material risks, likelihood of success, etc. *Id.*, 281 Md. at 447-48. The risks to be disclosed are the "material risks" of the proposed treatment, which risks are based upon "the position of the patient." *Id.*, 281 Md. at 450.

The physician is not required to "divulge all risks" or to discuss "all possible complications." *Id.*, 281 Md. at 444. The *Sard* court included multiple exceptions to the obligation to obtain informed consent in order to address the needs of the patient and maintained "a qualified privilege to withhold information on therapeutic grounds." *Id.* All of the information dictated by the *Sard* court was focused upon the knowledge available to the physician about the treatment being rendered to the patient. *Id.*, 281 Md. at 444 ("a material risk is one which a physician knows or ought to know.") A physician is not required to disclose information he does not have. *Id.*, 281 Md. at 445. ("where the physician does not know of a risk and should not have been aware of it in the exercise of ordinary care, he is under no obligation to make disclosure.")

In subsequent cases, Maryland's appellate courts have emphasized that "there is no bright-line test for determining the scope of disclosure required." *Goldberg*, 396 Md. at 123. "[T]here is no . . . all-inclusive list of items that must be disclosed by a physician." *Id.*, 396 Md. at 125. The contents of the informed consent discussion is dependent upon the circumstances, specifically, the course of treatment being discussed, the patient's medical issues, and the physician's knowledge and clinical judgment. Despite this established precedent the appellate court below added a specific detail of information, a "bright-line test," to the informed consent discussion – the status of FDA regulation. In doing so, they reversed their own holding in *Waldt v. Univ. of Md Med. Sys. Corp.*, 181 Md.App. 217, 248, 956 A.2d 223 (2008) (proffered expert testimony that use of medical device was not approved was "not a proffer of a risk inherent to the procedure," but a proffer that the "procedure was contraindicated," which goes to an ordinary negligence claim, not to a lack of informed consent claim) and went contrary to this Court's precedent in *Univ. of Md Med. Sys. Corp. v. Waldt*, 411 Md. 207, 236, 983 A.2d 112 (2009) (testimony regarding FDA approved use of medical device is not testimony of a material risk.) As the *Waldt II* court acknowledged, the status of an FDA regulation bears no relation to the actual risks of a treatment, or even to the state of scientific knowledge among medical professionals regarding the proposed treatment.

Consequently, advising a patient of the regulatory status of a medication or medical device provides no material or meaningful information to a patient.

B. A Physician's Use of a Medication is Based Upon the Medical Knowledge Regarding the Risks and Benefits of the Medication, Not Upon Regulatory Status.

A physician's decision to use a medication in the treatment of his patient is based upon the state of medical knowledge regarding that medication. That knowledge is founded in literature reporting on medical science, such as case studies, epidemiological studies, studies on the efficacy of various drugs for treating specific conditions and/or in specific patient populations, and similar medical literature. This literature is subject to peer review that considers the scientific methodology and verifies the accuracy of the results.

Physicians have an affirmative obligation to further their medical education throughout their careers and to keep themselves apprised of developments in their field. American Medical Association ("AMA"), *Opinion 9.011 – Continuing Medical Education*, Code of Medical Ethics. This plainly includes keeping themselves apprised of medical literature reporting on developments in medications. The AMA advises physicians to rely upon their professional knowledge base and clinical judgment in making treatment recommendations, not upon the regulatory status of a drug or its product label. As the AMA has stated,

> The official labeling should not be regarded as a legal standard of acceptable or accepted medical practice nor as a substitute for clinical judgment or experience nor as a limitation on usage of the drug in medical practice. The official labeling statements approved by the FDA establish the parameters governing advertising or promotion of the drug product.

AMA, *Policy H-115.994 - Prescription Product Labeling*. The AMA has further stated:

> The AMA confirms its strong support for the autonomous clinical decision-making authority of a physician and that a physician may lawfully use an FDA approved drug product or medical device for an unlabeled indication when such use is based upon sound scientific evidence and sound medical opinion.

AMA, *Policy H-120.988 - Patient Access to Treatment Prescribed by Their Physicians*. The AMA recommends several sources for obtaining that "sound scientific evidence," including peer-reviewed literature. *Id.* The knowledge base that informs a physician's treatment decision is also the foundation of his informed consent discussion. That knowledge base, which is current and based upon established medical practice, should remain the sole foundation of an informed consent discussion, not FDA labeling and marketing regulations.

Furthermore, as the policy statements of the AMA demonstrate, physicians have a professional obligation to keep themselves informed of medical knowledge about their field of practice, including the medications they use. Their practice is not dictated by official labeling statements approved by the FDA and they have, historically, not been obligated to keep themselves informed of those labeling requirements. Consequently, FDA regulations regarding marketing and labeling have not been "information which a physician knows or ought to know," the standard enunciated in *Sard*, 281 Md. at 444. The intermediate court's new requirement that a patient be advised of FDA status for a medication has not only created a new bright-line requirement for the contents of an informed consent conversation, it dictates a new category of knowledge which a physician must possess. Physicians must now memorize the labels of all of the medications they prescribe and communicate the contents of those labels to the patient, in addition to knowing current scientific knowledge about the medications and conveying that information to the patient.

i. The FDA Regulates How Drug Manufacturers May Label and Market Their Products; Not How Physicians May Use Them.

The FDA regulates prescription drugs and medical devices, among other things, pursuant to the Food, Drug, and Cosmetic Act ("FDCA"), Pub.L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. §§ 301 *et seq*. (1994)). This law prohibits a manufacturer from marketing or selling a new prescription drug without first obtaining FDA approval. 21 U.S.C.A. § 355(a). The FDCA does not regulate the practice of medicine. "The legislative history of the federal Food, Drug and Cosmetic Act reveals

that Congress recognized that the act was 'not intended as a medical practices act and [would] not interfere with the practice of the healing art.' Senate Rep. No. 361, 74th Congress, 1st Session, at 3 (1935)." *Klein v. Biscup*, 673 N.E.2d 225, 231 (Ohio Ct. App. 1996).

The interplay between the regulatory process and use of medications by physicians was explored in depth in the case of *Richardson v. Miller*, 44 S.W.3d 1 (Tenn. Ct. App. 2000), where the court held that evidence regarding off-label use was admissible in a medical malpractice action to determine if there had been a breach in the standard of care. As the *Richardson* court explained. The term "off-label" use, "as customarily used by health care providers, is medically neutral and refers to a circumstance in which a patient uses a prescribed drug or device in a manner that varies in some way from the drug's or device's FDA-approved labeling." *Id.*, 44 S.W.3d at 9 (*citing* James M. Beck & Elizabeth D. Azari, *FDA, Off–Label Uses, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71, 85 (1998)). As the *Richardson* court observed, "the director of the FDA's Center for Drug Evaluation and Research describes off-label use as '[u]se for indication, dosage form, dose regimen, population of other use parameter not mentioned in the approved labeling.'" *Richardson*, 44 S.W.3d at 9 n.3 (*citing* Janet Woodcock, *A Shift in the Regulatory Approach* (Presentation to DIA Montreal June 23, 1997)); *see also Washington Legal Found. v. Friedman*, 13 F.Supp.2d 51, 55 (D.D.C.1998); Steven R. Salbu, *Off–Label Use, Prescription and Marketing of FDA–Approved Drugs: An Assessment of Legislative and Regulatory Policy*, 51 Fla.L.Rev. 181, 188-92 (1999).

The lack of FDA approval of a drug or device for a particular use does not imply that using the drug or device for that use is either disapproved or improper. *Richardson*, 44 S.W.3d at 12; *see also, Holland v. Smith & Nephew Richards, Inc.*, 100 F. Supp. 2d 53, 56 (D. Mass. 1999) ("The mere fact that the FDA has not cleared a product for a particular use does not mean that the product is not in fact suitable for that purpose; it simply means that the FDA has not cleared it."); *Southard v. Temple Univ. Hosp.*, 781 A.2d 101, 107 (Pa. 2001). "Thus, the fact that the FDA has not approved labeling of a

drug for a particular use does not necessarily bear on those uses of the drug that are established within the medical and scientific community as medically appropriate." *Weaver v. Reagen*, 886 F.2d 194, 198 (8th Cir. 1989). It is the physician's obligation to determine if the off-label use is appropriate for his patient. "[A] physician who engages in off-label uses has the responsibility to be well informed about the device, and to base the decision to use it on sound medical evidence." *Femrite v. Abbott Northwestern Hosp*., 568 N.W.2d 535, 542 (Minn. Ct. App. 1997). "The term 'unapproved uses' is, to some extent, misleading. It includes a variety of situations ranging from unstudied to thoroughly investigated drug uses. . . . [A]ccepted medical practice often includes drug use that is not reflected in approved drug labeling. With respect to its role in medical practice, the package insert is informational only." *Weaver v. Reagen, supra, citing* U.S. Food and Drug Administration FDA Drug Bulletin, *Use of Approved Drugs for Unlabeled Indications*, 12 FDA Drug Bull. 4 (1982).

The *Richardson* court explained the FDA's drug approval process as follows:

> The FDA's approval process begins when a manufacturer submits a new drug application. This application must include detailed information regarding the drug, including (1) its components, (2) its manufacturing process, (3) samples of the drug, (4) studies conducted to determine the drug's safety and efficacy for a particular use or uses, and (5) the proposed labeling for the drug. *See* 21 U.S.C.A. § 355(b)(1); 21 C.F.R. §§ 314.50, 807.87(e) (1999). The FDA's consideration of a new drug application is limited to the use or uses for which the manufacturer has conducted safety and efficacy studies. *See* 21 U.S.C.A. § 360e(d)(1)(A) (West 1999); 21 C.F.R. §§ 314.50-54, 807.92(a)(5), 807.100(b)(1) (1999). After receiving the new drug application and the supporting data, the FDA conducts a risk-benefit analysis to ascertain the new drug's safety and therapeutic effectiveness for the intended use or uses specified by its manufacturer. Once the FDA determines that the new drug is safe and effective, the FDA and the drug's manufacturer negotiate the language to be included in the drug's labeling.

Richardson, 44 S.W.3d at 10. If subsequent information indicates that a drug is not safe and effective for use as stated on its label, the FDA may withdraw its approval or it may require changes to the drug's label to indicate that certain uses are contraindicated. *See*

21 C.F.R. §§ 314.150(a)(2)(i), 201.57(d), 801.109. The manufacturer's marketing of the drug is limited to the uses contained on the label.

Once a drug has been approved for any use by the FDA, physicians have wide latitude to prescribe the drug to their patients. "Neither Congress nor the FDA has attempted to regulate the off-label use of drugs by doctors and consumers." *Washington Legal Found. v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000). The FDA has explicitly recognized that physicians have a right to engage in this practice:

> Once a drug has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. Such "unapproved" or, more precisely, "unlabeled" uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature.

U.S. Food and Drug Administration, FDA Drug Bulletin, 12 FDA Drug Bull. 1, 5 (1982), *see also, United States v. Caronia*, 703 F.3d 149, 153 (2d Cir. 2012). "A physician may prescribe a legal drug to serve any purpose that he or she deems appropriate, regardless of whether the drug has been approved for that use by the FDA." *Washington Legal Found.* 202 F.3d at 333. "'[O]ff-label' usage of medical devices 'is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine.'" *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350, 121 S.Ct. 1012, 1018 (2001). The FDCA expressly provides that "[n]othing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient ... within a legitimate health care practitioner-patient relationship." 21 U.S.C.A. § 396.3. *See, Blazoski v. Cook*, 787 A.2d 910, 918 (N.J. Super Ct. App. Div. 2002).

If the drug manufacturer wants to market the drug for any off-label use, it must resubmit the drug for another series of clinical trials similar to those required for obtaining initial approval of the drug. 21 C.F.R. §§ 314.54, 314.70-.71. Since the FDA approval only applies to marketing and labeling for the drug, not to its actual use, and obtaining that approval is a substantial expense, there is little incentive for manufacturers

to seek FDA approval for off-label uses. *See, Richardson,* 44 S.W.3d at 12 ("Because of the time and expense of obtaining FDA approval of new uses for an already approved drug, drug manufacturers frequently do not voluntarily request FDA approval for a new use unless the change in the labeling will pay for itself in increased profits."); *see also* J. Howard Beales, III, *Economic Analysis and the Regulation of Pharmaceutical Advertising,* 24 Seton Hall L.Rev. 1370, 1387, 1392–93 (1994).

There is an increasing trend toward allowing and even encouraging dissemination of information to physicians about off-label drug use. *See, e.g.,* AMA Policy H-120.988, which states that the "AMA supports the dissemination of independently derived scientific information about unlabeled uses by manufacturers to physicians" and recommends guidelines for what information may be so distributed; Department of Health and Human Services, Food and Drug Administration, Office of the Commissioner, Office of Policy, *Guidance for Industry – Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* (January, 2009); *see also*, *U.S. v. Caronia*, *supra*, which overturned, on First Amendment grounds, a conviction for violation of the FDCA by a pharmaceutical sales representative who was promoting the off-label use of a medication.

Due to the pace of developments in medicine, it is not uncommon that an "off-label" use of a medication in a particular circumstance is the standard of care. The corollary is also true – it may be a violation of a standard of care to use an FDA approved treatment if the state of medical knowledge demonstrates that another treatment, which is not FDA approved, is more beneficial and poses fewer risks to the patient. It is well known that regulatory action falls far behind the progress of medical development and knowledge. It is the state of medical science and knowledge that informs medical standards of practice, and those standards of practice that inform the patient's treatment considerations and decisions, not regulatory compliance in pharmaceutical labeling.

ii. The Regulatory History of Amifostine Reflects Pharmaceutical Marketing, Not Medical Knowledge.

Amifostine was originally developed as a radioprotective agent in a classified nuclear war project, to protect normal tissues against the toxicities of radiation. Valeria Santini & Francis J. Giles, *The Potential of Amifostine: from Cytoprotectant to Therapeutic Agent*, Haematologica, 84:1035-1042 (1999). It was shown to act as a radioprotective agent, protecting normal tissues from the damaging effects of irradiation. CM Spencer & KL Goa, *Amifostine. A Review of its Pharmacodynamic and Pharmacokinetic Properties, and Therapeutic Potential as a Radioprotector and Cytotoxic Chemoprotector*, Drugs, Dec. 50(6): 1001-31 (1995). After it was declassified, clinical studies demonstrated that Amifostine protected against a variety of chemotherapy-related toxicities. Santini & Giles, *supra.* "By the early 1990's, it was known that Amifostine could be beneficial for cancer patients to alleviate the severity of the side effects associated with radiation and chemotherapy." *Medimmune Oncology, Inc. v. Sun Pharm. Indus., Ltd.*, CIV.A. MJG-04-2612, 2007 WL 6137013 (D. Md. Oct. 29, 2007). Amifostine "exerts a protective effect from toxicity induced by chemo- or radiotherapy on normal tissues, through free radical scavenging, hydrogen donation and inhibition of DNA damage." M. Orditura et al., *Amifostine: A Selective Cytoprotective Agent of Normal Tissues from Chemo-radiotherapy Induced Toxicity (Review),* Oncology Reports 6.6: 1357-1419 (1999). It protects a broad range of organs that are adversely affected by systemic cancer chemotherapy and obtains a better quality of life in patients receiving oncological treatment. *Id.*[32]

The FDA designated Amifostine as an "orphan drug" on May 30, 1990 at the request of MedImmune Oncology, Inc. ("MedImmune"), a pharmaceutical manufacturer. *See,* FDA Publication, *Orphan-designated Products with at Least One Marketing*

[32] *See also*, John R. Kouvaris et al., *Amifostine: The First Selective-Target and Broad-Spectrum Radioprotector*, The Oncologist 2007:12:738-747 (2007); Cynthia Menard et al., *Clinical Trial of Endorectal Amifostine for Radioprotection in Patients with Prostate Cancer: Rationale and Early Results*, Seminars in Oncology, Vol. 30, No. 6, Suppl 18: pps 63-67 (2003); Luis A. Linares & Deborah Echols, *Amifostine and External Beam Radiation Therapy and/or High-Dose Rate Brachytherapy in the Treatment of Localized*

Approval for a Rare Disease Indication,"[33] ("Orphan Products"). The Orphan Drug Act, Public Law 97-414, seeks to encourage development of medications to treat rare diseases by providing financial incentives to manufacturers.[34] Those incentives include grants to encourage development, special handling in the regulatory process, and protection for unpatented drugs, specifically, the right to exclusively market the drug for the disease as approved for seven years. *Id.* The objective of the orphan designation of Amifostine was "for use as a chemoprotective agent for cyclophosphamide in the treatment of advanced ovarian carcinoma." *See*, Orphan Products. Through the orphan drug program, MedImmune sought FDA approval for an injectable form of Amifostine it called "Ethyol" as a new drug, and obtained that approval on December 8, 1995. *See*, Label and Approval History for FDA Application (NDA) 020221, ("Approval History").[35] Its approved indication was "to reduce the cumulative renal toxicity associated with repeated administration of cisplatin in patients with advanced ovarian cancer." *See*, Orphan Products. MedImmune subsequently applied for, and obtained in 1999, approval through the orphan drugs program allowing it to exclusively market Ethyol to reduce the incidence and severity of radiation-induced xerostomia in patients with head and neck

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Prostate Carcinoma: Preliminary Results of a Phase II Trial, Seminars in Oncology, Vol. 30, No. 6, Suppl 18: pps 58-62 (2003).

[33] Orphan Products is available at http://www.fda.gov/downloads/aboutfda/centers offices/officeofmedicalproductsandtobacco/officeofscienceandhealthcoordination/ucm215812.xls. Orphan drug status provides financial incentives for development of drugs to treat rare diseases or conditions. *See*, http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/HowtoapplyforOrphanProductDesignation/default.htm. Specifically, among other benefits, manufacturers are given exclusive marketing rights for older medications that are not protected by patents.

[34] In passing the Orphan Drug Act, Congress found that "because so few individuals are affected by any one rare disease or condition, a pharmaceutical company which develops an orphan drug may reasonably expect the drug to generate relatively small sales in comparison to the cost of developing the drug and consequently to incur a financial loss." Orphan Drug Act, Pub. L. No. 97–414 (HR 5238), Pub. L. No. 97–414, January 4, 1983, 96 Stat. 2049.

[35] Label and Approval History for FDA Application (NDA) 020221, available at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/ .

cancers. *Id.*[36] Since 1995, the FDA has approved labeling revisions for MedImmune's Ethyol on eight separate occasions. *See*, Approval History. These approvals applied to such things as reorganizing the label to comply with FDA guidelines,[37] adding a "Geriatric Use" subsection,[38] removing the non-small cell lung cancer indication,[39] and updating safety information.[40]

In the instant case, the appellate court below took particular note of the language in the package insert for Amifostine that indicated "that it lacked testing on elderly patients" and considered this to be material information that should have been conveyed to the patient, Mr. Fusco. *Fusco, supra*, 210 Md.App. at 435-36. The regulatory history for how this language was added to the package insert, while not before the court below, illustrates the danger inherent in requiring FDA regulatory status to be part of an informed consent conversation. On November 12, 2001, MedImmune submitted a supplemental new drug application to update safety information on its package insert for Ethyol.[41] When it approved those changes, the FDA requested that MedImmune delete the following statement from the "Adverse Reactions" section of the label: "Although clinical trials of ETHYOL included elderly patients, no clinical studies have been performed specifically evaluating the safety of ETHYOL in patients with preexisting cardiovascular or cerebrovascular conditions."[42] The FDA furthermore requested that MedImmune analyze its existing clinical data "to evaluate any age differences in

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[36] *See also*, FDA approval letter dated June 24, 1999, available at http://www.accessdata.fda.gov/drugsatfda_docs/appletter/1999/20221s12ltr.pdf.
[37] FDA approval letter dated February 20, 2002, available at http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/20221s15ltr.pdf.
[38] FDA approval letter dated March 27, 2003, available at http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2003/20221slr017ltr.pdf.
[39] FDA approval letter dated March 28, 2006, available at http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2006/020221s020ltr.pdf.
[40] FDA approval letter dated February 20, 2002, *supra;* FDA approval letter dated November 7, 2008, available at http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2008/020221s024ltr.pdf.
[41] FDA approval letter dated February 20, 2002, *supra.*
[42] *Id.*

response and toxicity" and requested that "if significant differences cannot be determined" the following be added to the label:

> Clinical studies did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy in elderly patients.[43]

This request by the FDA resulted in another supplemental application that was submitted on March 11, 2003 and approved on March 27, 2003.[44] The March 27, 2003 approval resulted in adding the precise language requested by the FDA, a warning that the medication "lacked testing in the elderly," to future drug labels. The new language appears under a section of the label marked "Precautions," not in the section marked "Warnings" and states as follows:

> **Geriatric Use**
> The safety Clinical studies did not include sufficient number of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy in elderly patients.[45]

This is significant in two respects. First, this language was added at the request of the FDA because the existing data did **not** show a difference in response and toxicity when age was taken into consideration. If the data had shown a difference based on age, that information would have been reflected in the label. It did not. The FDA requested this warning not because the risks were different for elderly patients, as there is no evidence they were, but because the size of the statistical sample was not large enough based on FDA criteria. The presence of this "Precaution" might seem to suggest that the drug is

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[43] *Id.*
[44] FDA approval letter dated March 27, 2003, *supra*.
[45] The approved label is available at http://www.accessdata.fda.gov/drugsatfda_docs/

more dangerous for elderly patients, when that is not what the data states, and may tend to deter elderly patients from using this beneficial medication. A physician familiar with the medical literature is in the best position to inform a patient if his age, in and of itself, effects the risks he faces from this procedure.[46]

The second item of significance is that this addition to the label was approved on March 27, 2003, more than two weeks **after** Dr. Shannon discussed the risks and benefits of the use of Amifostine with Mr. Fusco. There is no indication of when this new language started to appear in the package inserts and it would be pure speculation to suggest that it was part of the insert for the medications administered to Mr. Fusco.[47] At what point in time is a physician such as Dr. Shannon required to be aware of this change? When is he required to inform he patient about this new regulation, which is not a reflection of any change in the medical literature? Was the physician supposed to know about the label change as soon as it was approved by the FDA, or when it started to appear in the package insert? Does the physician need to redo the informed consent conversation to address the new FDA approved label? Must the physician interrupt an ongoing course of medical therapy to inform the patient that the label for his medication has changed? This one detail clearly illustrates the fallacy of choosing a regulatory label in lieu of, or as a supplement to, established medical knowledge, as well as the fact that it is unrealistic to expect a physician to keep abreast of these kinds of regulatory changes.

Finally, in March, 2008, Sun Pharmaceutical Industries obtained FDA approval to market a generic version of Amifostine solely "for reduction of kidney damage in patients who have advanced ovarian cancer and are being given repeat doses of cisplatin." "Sun Pharma gets FDA nod to market generic Ethyol in U.S.," The Economic

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label/2003/20221slr017_ethyol_lbl.pdf.

[46] It is noteworthy that this precaution regarding geriatric patients refers to their increased frequency of comorbidities such as decreased hepatic, renal, or cardiac function, comorbitities of which a treating physician should be aware, and makes no reference to dermatological reactions such as that experienced by Mr. Fusco.

Times, March 18, 2008. The FDA approved label for Sun Pharmaceutical Industries' version of Amifostine carves out the reference to the use of Amifostine for head and neck cancers and only refers to its use in treating ovarian cancer.[48] Consequently, Sun Pharmaceutical Industries has an FDA approved package insert for their generic drug that is different than the package insert that MedImmune has FDA approval to use. If, in the future, either company obtains approval for another use pursuant to the Orphan Drug Act, *supra*, including exclusive marketing rights, the labels will have even greater differences, even though the properties of the drugs and the status of the medical literature for the drugs are unchanged. The requirement that a physician advise a patient of the FDA approved uses of a drug will, under this regulatory history, require that a physician's informed consent conversation be based upon whether the patient will be buying the name brand or the generic version of the drug, even though it is essentially the same drug, with the same material risks.

The FDA regulatory status of a device is merely a legal expression of a process that changes over time, even while the actual characteristics of the medication at issue are unchanged. A change on a label does not create a new material risk for a treatment. To suggest that the informed consent conversation must change to reflect how that drug's manufacturer is permitted to market the drug, or what the manufacturer is required to print on the drug's label, irrespective of actual characteristics of the drug and the actual state of medical knowledge and medical literature, creates a bewildering and conflicting array of information that a physician must track and share with his patients.

C. Advising a Patient about FDA Regulatory Status Provides Confusing and Misleading Information and Unnecessarily Overburdens the Physician.

Off-label use of FDA approved medications is pervasive in the practice of medicine. In 2006, a study of internists indicated that 21 percent of commonly used drugs were prescribed for off-label use. David C. Radley et al., *Off-Label Prescribing*

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[47] According to the record below, Dr. Shannon discussed the use of Amifostine with Mr. Fusco on March 12, 2003, and the medication was administered to him between April 15, 2003 and May 15, 2003. *Fusco*, 210 Md.App. at 406.

Among Office-Based Physicians, Archives of Internal Medicine 166, no. 9: 1021–26 (May 2006). A 2011 study indicated that 36 percent of all drugs used in intensive-care units are for off-label indications. Ishaq Lat et al., *Off-Label Medication Use in Adult Critical Care Patients*, Journal of Critical Care 26, no. 1: 89–94 (2011). It is estimated that 79 percent of children admitted to pediatric hospitals received one or more off-label drugs. S. S. Shah et al., *Off-Label Drug Use in Hospitalized Children*, Archives of Pediatrics & Adolescent Medicine 161, no. 3: 282–90 (2007). Off-label drug use is particularly common in psychiatric practice, where patients are routinely excluded from clinical trials. G. C. Alexander et al., *Increasing Off-Label Use of Antipsychotic Medications in the United States, 1995–2008,* Pharmacoepidemiol Drug Safety 20, no. 2: 177–84 (2011). Off-label use of medication is also prevalent in oncology and the treatment of cancer, such as that at issue here. The Government Accounting Office has estimated that 25 percent of all anti-cancer drugs are prescribed off-label and that 56 percent of all cancer patients receive at least one drug off-label. *See* United States General Accounting Office, *Off–Label Drugs, Reimbursement Policies Constrain Physicians in Their Choice of Cancer Therapies,* GAO/PEMD 91–14, at 5, 11, 13–14, 40 (Sept.1991). There are medications which are no longer used in the manner approved by the FDA but are used extensively for off-label purposes. For example, tricyclic antidepressants have been largely supplanted by other medications in the treatment of depression, but continue to be used for off-label purposes of treating neuropathic pain associated with strokes, spinal-cord injuries, or cerebral palsy. R. H. Dworkin et al., *Recommendations for the Pharmacological Management of Neuropathic Pain: An Overview and Literature Update*, Mayo Clinic Proceedings 85, no. 3, suppl.: S3–S14 (2010). Aspirin has only been approved for pain management, but is used extensively as a preventive measure for patients at risk of coronary disease. R. S. Stafford, *Regulating Off-Label Drug Use: Rethinking the Role of the FDA*, New England Journal of Medicine 358, no. 14: 1427–29 (2008).

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[48] http://medlibrary.org/lib/rx/meds/amifostine-2/

Every physician using these medications to treat their patients must keep themselves informed of the risks and benefits of their use based on current medical information. Physicians must consistently review medical journals, attend conferences, and engage in continuing medical education in order to keep abreast of these developments in medicine, including the current state of knowledge as to the treatments they use in their field of practice. The risks of cancer treatment, including the use of Amifostine, are what they are, and do not depend upon the particular status of the ever-changing FDA regulation of pharmaceutical manufacturers. Requiring that physicians add to their existing educational obligations the regular review of federal regulations so that they are up-to-date and informed of the current regulatory status of the pharmaceutical companies that manufacture the medications and treatments they use merely adds another layer of complexity to the already complex practice of medicine. This burdensome requirement furthermore has the effect of the FDA regulating the activities of physicians engaged in the practice of medicine, which Congress specifically mandated it was not to do.

A physician is already required to inform a patient as to the material risks and benefits of a proposed treatment based on medical knowledge. Including in that conversation the FDA regulatory status of the manufacturers of the medications used in that treatment adds no additional information regarding the medical risks and benefits of the treatment. Additionally, as the regulatory process lags behind the progress of medical science, the information regarding FDA regulatory status, including the contents of package inserts, may not accurately reflect the current state of medicine and may provide the patient with inaccurate or misleading information. Medical treatments, especially in the field of oncology, may include multiple medications, many of which are being used in an off-label fashion. Because the status of the FDA's regulation of pharmaceutical manufacturers bears no necessary relation to the actual risks of a course of medical treatment, requiring physicians to discuss that topic with their patients will mislead, confuse, and confound patients from a true understanding of the actual risks of a treatment, inhibit a patient's ability to reliably weigh its risks versus its benefits, and thus

encourage patients to choose suboptimal care for themselves. These considerations have been recognized by other jurisdictions in determining that FDA regulatory status was not a necessary element of informed consent. As New Jersey's intermediate appellate court stated:

> [T]here are sound policy reasons why the FDA status need not be disclosed. Requiring disclosure may necessitate a pre-surgery discourse by the physician on the mechanics of the FDA approval process which may dilute the significance of material, medical risks related to the procedure.
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> Patients . . . would be distracted from learning about the nature, risks, and benefits of their treatments by regulatory information of de minimus value. Such information would accentuate the errant notion that all off-label use is by definition inherently risky, novel, or investigational. By implying risk or novelty when there is none, these disclosures could frighten patients away from the very therapies that actually are best for the treatment of their conditions.
>
> Also, disclosure will require the physician to be a student of the cumbersome federal regulatory approval scheme, when the physician's chief concerns are whether the particular device is medically sound considering the specific circumstances of the patient, and that the patient knows of the nature and risks of the operation, the condition intended to be cured, and the availability of other options.

Blazoski v. Cook, *supra*, 787 A.2d at 920-21, *citing* Beck and Azari, *supra*, 53 Food & Drug L.J. at 101.

D. The Majority of the Courts That Have Considered the Question Have Rejected the Requirement that a Physician Advise a Patient of the FDA Regulatory Status of Treatment.

As the Court of Special Appeals acknowledged, other jurisdictions that have considered the role that regulatory status of a treatment plays upon the physician-patient relationship have held that a physician has no duty to disclose whether a proposed treatment is an off-label use. *Klein*, 673 N.E.2d at 231 ("Off-label use of a medical device is not a material risk inherently involved in a proposed therapy which a physician should disclose to a patient prior to the therapy."); *Southard v. Temple University Hosp.*, 781 A.2d at 108 ("physician need not inform patients of the FDA classification of a

medical device."); *Alvarez v. Smith*, 714 So. 2d 652, 653 (Fla. Dist. Ct. App. 1998) (doctors are not required to disclose the FDA status as it is not a medical risk of surgery); *Blazoski v. Cook*, 787 A.2d at 918 (surgeon not required to disclose regulatory status of medical device). These courts have acknowledged that the labels given to a medical device or treatment "do not speak directly to the medical issues surrounding a particular [treatment]." *Southard*, 781 A.2d at 107. As the *Southard* court noted:

> The category into which the FDA places the device for marketing and labeling purposes simply does not enlighten the patient as to the nature or seriousness of the proposed operation, the organs of the body involved, the disease sought to be cured, or the possible results. The FDA administrative label does not constitute a material fact, risk, complication or alternative to a surgical procedure. It follows that a physician need not disclose a device's FDA classification to the patient in order to ensure that the patient has been fully informed regarding the procedure.

Id.[49]

These courts have indicated, however, that off-label use, which is a matter of medical judgment, does subject a physician to professional liability if that use was not medically indicated. *Univ. of Md Med. Syst. Corp. v. Waldt*, 411 Md. at 236; *Klein*, 673 N.E.2d at 213. Under a medical negligence theory, information about FDA approval and off-label use may be admitted, through the testimony of a properly qualified expert. *Richardson v. Miller*, *supra.* This is a medical negligence analysis however, and does not go to the issue of whether a physician obtained informed consent.

CONCLUSION

A pharmacist such as Dr. Travato lacks the training and experience to testify as to all of the elements in an informed consent claim which this court has identified require expert testimony. Pharmacists have no duty to warn patients about risks associated with

[49] *Compare* with *DeNeui v. Wellman*, 2009 WL 4847086 (D.S.D. Dec. 9, 2009), plaintiff claimed lack of informed consent including failure to inform of off-label use; defendants sought summary judgment as there is no duty to disclose FDA status. Court concluded summary judgment was not appropriate "even if [physician] did not have a duty to disclose the off-label use of BMP, [plaintiff's] claim of lack of informed consent would

medication, they do not practice medicine, and they do not engage in informed consent discussions. Although a pharmacist may be qualified to testify as to some information specific to a drug, such testimony, in isolation, will not serve to educate the jury as to the risks and benefits of a course of treatment in a patient such as the plaintiff below, but rather, will only confuse a jury. Even if the lower court had permitted Dr. Travato to testify as to the limited topic identified by the lower appellate court, the known risks of Amifostine, he was not qualified to provide the testimony on all of the topics identified by the *Sard* court as requiring expert testimony including the risks and benefits of the treatment being offered to Mr. Fusco, of which Amifostine was but a part. The Respondents failed to meet their burden of production, and adding in Dr. Travato's testimony, as suggested by the appellate court below, still would not meet that burden.

The regulatory history of the drug at issue in this case, Amifostine, clearly demonstrates that providing a bright line requirement that a physician inform a patient of the FDA approved labeling of a medication is manifestly unreasonable. A physician has an obligation to be informed about the medical literature regarding the medications he is recommending to his patients and to inform his patients of the material risks demonstrated by that literature. This is the information a patient needs to make an informed decision, irrespective of the precise language that the FDA has stated may or may not be included on the manufacturer's package insert. The new requirement imposed by the Court of Special Appeals will only serve to overburden physicians with the requirement to understand and stay abreast of the regulatory process and to confuse patients with information about a regulatory process that does not accurately reflect medical practices.

Therefore, for the foregoing reasons, Amici Curiae, American Medical Association, Maryland State Medical Society, and Medical Mutual Insurance Society of Maryland, respectfully request that this Court overturn the ruling of the Court of Special Appeals and affirm the ruling of the Circuit Court for Prince George's County.

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survive summary judgment if [physician] failed to disclose other material risk

RULE 8-504(A)(8) STATEMENT

Pursuant to Rule 8-504, Amici Curiae state that this Brief was printed using 13 point, Times New Roman font.

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information."

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that, pursuant to Rule 8-502(c), copies of the foregoing Brief of Amici Curiae, American Medical Association, Maryland State Medical Society, and Medical Mutual Insurance Society of Maryland were mailed this 15th day of October 2013, postage prepaid, to:

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