HEADNOTE

Rite Aid Corp. v. Levy-Gray, No. 0133, September Term, 2004

Products Liability - Pharmacy - Federal Preemption - Plaintiff's physician prescribed antibiotic, doxycycline, for treatment of Lyme disease, giving directions only as to dosage. Defendant pharmacy filled prescription and furnished a patient package insert (PPI) representing that "[i]nside is everything you need to know about your prescription." PPI advised to "[t]ake with food or milk if stomach upset occurs[.]" Plaintiff, who suffered stomach upset from the drug and who also intended to resume nursing her newborn upon completing the course of treatment, consumed milk and other dairy products during course of treatment. After active infection eliminated, plaintiff's arthritis-like symptoms continued. Plaintiff's experts diagnosed condition as post-Lyme syndrome and opined that it resulted from reduced effectiveness of drug caused by a decrease in its absorption resulting from interactions with milk and dairy products. Jury found for plaintiff on breach of express warranty theory.

Held: Affirmed. Under U.C.C., PPI contained an affirmation of fact that drug was compatible with milk. Evidence showed plaintiff relied on pharmacy's affirmation of fact. Pre-sale bargaining not required for creation of warranty.

FDA's approval of drug manufacturer's description of product (labeling) does not impliedly preempt state law cause of action. Generally, no preemption as to manufacturer and, *a fortiori*, none for pharmacy.

Expert testimony and requested jury instructions reviewed.

REPORTED

IN THE COURT OF SPECIAL APPEALS
OF MARYLAND

No. 0133

September Term, 2004

RITE AID CORPORATION

v.

ELLEN R. LEVY-GRAY

Murphy, C.J.
Kenney
Rodowsky, Lawrence F.
(retired, specially assigned),

JJ.

Opinion by Rodowsky, J.

Filed: June 3, 2005

The principal issue here is whether, under the circumstances of this case, the appellant and cross-appellee, Rite Aid Corporation (Rite Aid), made an express warranty when it sold the prescription drug, doxycycline, to the appellee and cross-appellant, Ellen R. Levy-Gray (Ms. Levy-Gray or Plaintiff). A jury in the Circuit Court for Baltimore County, finding the elements of an action for breach of express warranty, entered a verdict in favor of Plaintiff for $250,000.[1]

Ms. Levy-Gray awoke on October 6, 2000, experiencing severe pain in her back, and with a fever. When these symptoms persisted for a full week, she sought treatment from her internist, Dr. Christine Bell-Lafferman (Dr. Lafferman). Blood samples taken during the visit were tested, and, on October 25, 2000, Dr. Lafferman contacted Ms. Levy-Gray to inform her that her blood had tested positive for Lyme disease. Dr. Lafferman referred Ms. Levy-Gray to Dr. Ronald W. Geckler (Dr. Geckler), an infectious diseases specialist, who saw Ms. Levy-Gray that day. Dr. Geckler confirmed the Lyme disease diagnosis and prescribed doxycycline, an antibiotic in the tetracyline family. Ms. Levy-Gray was breast feeding her baby at the time, and Dr. Geckler advised her to discontinue breast feeding while she was on the medication.

Dr. Geckler prescribed a 100 mg dosage twice a day, generally to be taken twelve hours apart. He did not provide Ms. Levy-Gray

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[1]The Plaintiff's husband, Scott W. Gray, joined as a plaintiff in a claim for loss of consortium on which the jury found in favor of Rite Aid. That claim is not pressed in this Court.

with any other specific information on how to take doxycycline. At trial he acknowledged that he relied on pharmacies to provide patients with pharmaceutical information "[m]ore so than I used to, I guess because I know that the pharmacies typically give out pretty broad information sheets at the time of the prescriptions. Probably years ago I would have maybe taken more time going through that. But ... I do assume to some extent that the pharmacy will provide that information." Dr. Geckler is not a party to this action.

Plaintiff filled her doxycycline prescription at Rite Aid Pharmacy #4465, located off Padonia Road in Timonium. The doxycycline purchased by her from Rite Aid was purchased by Rite Aid from a non-party to this action, Watson Laboratories, Inc. of Corona, California (Watson), for whom the doxycycline, in turn, was manufactured by Halsey Drug Co., Inc. of Rockford, Illinois, also not a party to this action. Watson shipped the doxycycline in bottles containing 500 capsules, each of 100 mg strength. Included with the package from Watson was an eight-page pamphlet which the manufacturer had submitted to the Food and Drug Administration (FDA) and which had been approved by that agency as "labeling" for that prescription drug.

The labeling contains a chemical description of doxycycline, its "clinical pharmacology," its "indications and usage," "contraindications," "warnings," "precautions," and "adverse

reactions." It further contains sections headed, "overdosage," "dosage and administration," "how supplied," and "animal pharmacology and animal toxicology." This manufacturer's insert was not intended to be, and was not, delivered to Plaintiff. It was intended for prescribing physicians and made available to them by publication in, *inter alia*, the Physicians' Desk Reference.

Along with her prescription, Ms. Levy-Gray received from Rite Aid a "patient package insert" (PPI), *i.e.*, a pamphlet, entitled "Rite ADVICE." The "Rite ADVICE" PPI was prepared and customized for Rite Aid by a non-party to this action, First Databank-The Hearst Corporation. The cover page of the pamphlet informed readers: "Inside is everything you need to know about your prescription. It covers everything in writing from dosage to side effects. If you have any questions, just ask your pharmacist." The inside of the pamphlet stated, in part:

> "IMPORTANT NOTE: THE FOLLOWING INFORMATION IS INTENDED TO SUPPLEMENT, NOT SUBSTITUTE FOR, THE EXPERTISE AND JUDGMENT OF YOUR PHYSICIAN, PHARMACIST OR OTHER HEALTHCARE PROFESSIONAL.
>
> "IT SHOULD NOT BE CONSTRUED TO INDICATE THAT USE OF THE DRUG IS SAFE, APPROPRIATE, OR EFFECTIVE FOR YOU.
>
> "CONSULT YOUR HEALTHCARE PROFESSIONAL BEFORE USING THIS DRUG.
>
> ....
>
> "HOW TO TAKE THIS MEDICATION: Take each dose with a full glass of water ... or more. ... **Take with food or milk if stomach upset occurs unless your doctor directs you otherwise**. Avoid taking antacids, containing magnesium, aluminum or calcium, sucralfate, iron preparations or

> vitamin (zinc) products within 2-3 hours of taking this medication. These products bind with the medicine preventing its absorption. ...
>
> ....
>
> "The information in this leaflet may be used as an educational aid. This information does not cover all possible uses, actions, precautions, side effects, or interactions of this medicine. This information is not intended as medical advice for individual problems."

(Emphasis added).

Ms. Levy-Gray testified that she ate a high volume of dairy products when she initiated her doxycycline treatment because of her desire to breast-feed her younger child and because she was experiencing an upset stomach due to the doxycycline. She said:

> "[B]ecause [her newborn] was nursed, I was eating a very well-balanced diet, high in nutrition, a lot of fruit, a lot of vegetables, a lot of dairy products because it was important that I maintain a high nutritional level of milk products because ... that is very important for ... nursed children. I would eat cheese several times a day, and I would drink between eight and ten glasses of milk ... a day along with water and fruit juices."

Plaintiff experienced stomach irritation as a result of taking doxycycline approximately eight times within a week-long period of fourteen doses. She stated that she would take the medication "with a full glass of water and ... there are also times where I would follow it with a glass of milk." She also described eating dairy-product-containing foods during this period, including macaroni and cheese, grilled cheese sandwiches, yogurt, ice cream, and cottage cheese.

Ms. Levy-Gray ate a snack in the evening before going to bed "because [she] wanted to make sure that [she] went to bed with something in [her] stomach so that [she] wouldn't get a stomach upset[,] as had been described[,] by taking the Doxycycline." She had ice cream three or four nights a week, and then cookies or cereal on the other nights. This snack was eaten within two hours of her evening doxycycline dose. The PPI said to take doxycycline with food or milk if stomach upset occurs, "unless your doctor directs you otherwise." Neither Dr. Geckler nor Dr. Lafferman had directed her otherwise. She "didn't see any reason to [contact her doctor] because the pamphlet itself said what to do. ... I trusted the directions. I didn't see any reason to call the doctor on it."

Rather than improving as a result of the doxycycline treatment, Plaintiff's symptoms worsened. On November 8, 2000, she had a telephone conversation with her brother, Dr. David Levy (Dr. Levy), a urological oncologist living in Seattle, Washington. Dr. Levy informed his sister that the calcium contained in milk products impeded the absorption of doxycycline by the body. Based on her brother's advice, Plaintiff returned to Dr. Lafferman on November 18, informed her of the milk problem, and was given a replacement prescription of doxycycline. According to Dr. Lafferman, Ms. Levy-Gray's condition "began to measurabl[y] improve" within two to three days of discontinuing consumption of milk products with the doxycycline.

Although Ms. Levy-Gray's condition was somewhat improved, it did not return to baseline, and she was referred by Dr. Lafferman to Dr. Charles A. Haile, the Chief of Medical Staff and Chief of the Division of Infectious Diseases at Greater Baltimore Medical Center. Dr. Haile is board certified in internal medicine and infectious diseases, and he treats roughly thirty to forty Lyme disease patients each year.

Dr. Haile first saw Ms. Levy-Gray on December 28, 2000. At this time, she had been taking doxycycline for over a month, but was not recovering. He saw her four times thereafter, to June 21, 2001. When another six-week course of doxycycline had not alleviated Plaintiff's symptoms, Dr. Haile diagnosed her with post-Lyme syndrome. Post-Lyme syndrome is a chronic autoimmune response, in which patients experience symptoms that can mimic Lyme disease in the absence of an active bacterial infection.

Ms. Levy-Gray sued Rite Aid. At a seven day trial the jury heard considerable expert opinion from witnesses called by each party. The medical theory of Plaintiff's case was that her ingestion of milk and other dairy products, while taking doxycycline, reduced the absorption of that drug and prevented it from operating as efficaciously as it otherwise would have, thereby proximately causing the post-Lyme syndrome. Experts called by Rite Aid opined that absorption of doxycycline is reduced by up to twenty percent when ingested with milk or other dairy products

containing calcium, but that that reduction is clinically insignificant because of the dosage recommended.

From the legal standpoint, the circuit court permitted the case to go to the jury on two theories, negligence and breach of express warranty. There was no expert testimony that there was a general duty of care legally imposed on pharmacists to warn patients of any risks involved in consuming dairy products while taking doxycycline. The court, however, instructed that, by its having furnished the Rite ADVICE pamphlet, Rite Aid could be found to have assumed "a duty" with the concomitant responsibility of performing that duty with reasonable care. The circuit court did not further refine or illustrate the duty. The court also allowed the jury to consider whether the Rite ADVICE pamphlet made an express warranty, as defined by the court. As to both theories of the case, the court left to the argument of counsel how the evidence applied to the instructions. The arguments of counsel are not reproduced in the record.

The jury found in favor of Rite Aid on the negligence claim, and it found in favor of Plaintiff on the breach of express warranty claim. Following the denial of post-judgment motions filed by Rite Aid, this appeal and cross-appeal were timely noted.

Additional facts will be stated in the course of this opinion as necessary to the resolution of the questions presented. Rite Aid presents the following questions:

"1) Whether Rite Aid was entitled to judgment because a) the law does not recognize a cause of action against pharmacists for breach of express warranty, b) the Rite Aid patient brochure made no promise concerning the performance of doxycycline, and c) the brochure was not part of the basis of the bargain between the parties.

"2) Whether Rite Aid was entitled to judgment because [Ms.] Levy-Gray's claim is preempted because it relies on the assertion that Rite Aid should have provided instructions on the taking of doxycycline contrary to those approved by the FDA.

"3) Whether Rite Aid was entitled to judgment because [Ms.] Levy-Gray did not provide reliable expert testimony to establish that Rite Aid caused her injuries.

"4) Whether the trial court's admission of medical opinion evidence that was not rendered to a reasonable degree of medical certainty unduly prejudiced Rite Aid.

"5) Whether the trial court erred in failing to instruct the jury a) on the effect of having alternative potential causes of [Ms.] Levy-Gray's injuries, b) that Rite Aid had no obligation to warn of hazards associated with [Ms.] Levy-Gray's unique susceptibility to injury, and c) that a defendant is liable only for the exacerbation of a pre-existing condition."

Plaintiff, by cross-appeal, raises the following additional issue:

"Whether or not the Trial Court clearly erred and/or abused its discretion by failing to give the jury the product liability failure to warn jury instruction based upon Rite Aid's failure to warn [Ms.] Levy-Gray about the contraindications of Doxycycline and calcium products in light of *Mazda Motor of America Inc. v. Rogowski*, 105 Md. App. 318, 659 A.2d 391, *cert. denied*, 340 Md. 501, 667 A.2d 342 (1995)."

I. Express Warranty

Maryland Code (1975, 2002 Repl. Vol.), § 2-313 of the Commercial Law Article (CL) governs "[e]xpress warranties by affirmation, promise, description, [or] sample." It provides:

> "(1) Express warranties by the seller are created as follows:
>
> "(a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
>
> "(b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
>
> ....
>
> "(2) It is not necessary to the creation of an express warranty that the seller use formal words such as 'warrant' or 'guarantee' or that he have a specific intention to make a warranty, but an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty."

Official Comment 3 to CL § 2-313 furnishes the following elaboration:

> "3. The present section deals with affirmations of fact by the seller, descriptions of the goods or exhibitions of samples, exactly as any other part of a negotiation which ends in a contract is dealt with. No specific intention to make a warranty is necessary if any of these factors is made part of the basis of the bargain. In actual practice affirmations of fact made by the seller about the goods during a bargain are regarded as part of the description of those goods; hence no particular reliance on such statements need be shown in order to weave them into the fabric of the agreement. Rather, any fact which is to take such affirmations, once

> made, out of the agreement requires clear affirmative proof. *The issue normally is one of fact*."

(Emphasis added).

"Bargain" is not a defined term in the Uniform Commercial Code, but it is a term used to define "agreement" in CL § 1-201(3), in relevant part reading:

> "'Agreement' means the bargain of the parties in fact as found in their language or by implication from other circumstances including course of dealing or usage of trade or course of performance as provided in Titles 1 through 10 of this article[.]"

In the UCC, "Agreement," or "bargain of the parties in fact," is to be contrasted with "'Contract' [which] means the total legal obligation which results from the parties' agreement as affected by Titles 1 through 10 of this article and any other applicable rules of law." CL § 1-201(11).

A. Reliance

Understanding Rite Aid's first argument, that there can be no express warranty by a pharmacist dispensing prescription drugs, requires that we review the law applicable to the prescription drug manufacturer-physician-patient relationship. Rite Aid's argument is based on an offshoot of the "learned intermediary" doctrine which governs that relationship. We explain.

"[T]he traditional rules [are] that drug and medical-device manufacturers are liable only when their products contain manufacturing defects or are sold without adequate instructions and warnings to prescribing and other health-care providers."

Restatement (Third) of Torts: Products Liability § 6, "Liability Of Commercial Seller Or Distributor For Harm Caused By Defective Prescription Drugs And Medical Devices," cmt. a. The rationale for the traditional rule is stated in comment b, reading, in relevant part, as follows:

> "The obligation of a manufacturer to warn about risks attendant to the use of drugs and medical devices that may be sold only pursuant to a health-care provider's prescription traditionally has required warnings directed to health-care providers and not to patients. The rationale supporting this 'learned intermediary' rule is that only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy. The duty then devolves on the health-care provider to supply to the patient such information as is deemed appropriate under the circumstances so that the patient can make an informed choice as to therapy. Subsection (d)(1) retains the 'learned intermediary' rule."

Courts have developed a corollary to the learned intermediary rule that extends the defense to pharmacies and pharmacists. Because physicians, possessing knowledge of the range of possible choices among prescription drugs and of the patient's particular condition, have the duty to warn of potential adverse consequences, there are cases that hold that the duty of pharmacists is to dispense the drug in accordance with physicians' prescriptions, generally without injecting themselves into the physician-patient relationship.

The Court of Appeals applied this reasoning in *People's Serv. Drug Stores, Inc. v. Somerville*, 161 Md. 662, 158 A. 12 (1932).

That was a negligence action against a pharmacy that had filled a prescription for capsules, each containing one-fourth grain of strychnine, with other ingredients. The theory of the plaintiff's claim was that the pharmacist should have refused to fill the prescription because the strychnine content was too large. Reversing, without a new trial, a judgment for the plaintiff, the Court reasoned:

> "[I]t does not follow, because a physician in a given case is liable, that the druggist who filled the prescription is also liable. It would be a dangerous principle to establish that a druggist cannot safely fill a prescription merely because it is out of the ordinary. If that were done, many patients might die from being denied unusual remedies in extreme cases. Of course this does not mean that pharmacists can safely fill prescriptions calling for doses that are obviously fatal; or that where the doses prescribed appear to be unusual the prescription can be safely filled without inquiry of the physician to make sure there has been no error. There is no evidence that this precaution was not taken in the present case; but, even if it was not, that would be immaterial here, because the result of such inquiry would have been to confirm the prescription, as the physician who wrote it testified that it was his usual prescription in such cases."

Id. at 666-67, 158 A. at 13-14.

Federal courts have applied the rule of *People's Serv. Drug Stores* in negligent failure to warn cases brought against pharmacies that are governed by Maryland law. *See Hofherr v. Dart Indus., Inc.*, 853 F.2d 259, 263-64 (4th Cir. 1988); *Moore v. Wyeth-Ayerst Laboratories*, 236 F. Supp. 2d 509, 512-13 (D. Md. 2002). Other cases holding that the pharmacist-patient relationship ordinarily does not give rise to a duty imposed by law (as

contrasted with an assumed duty) to warn of potential adverse consequences of prescribed drugs include *Ramirez v. Richardson-Merrell, Inc.*, 628 F. Supp. 85 (E.D. Pa. 1986); *Walker v. Jack Eckerd Corp.*, 434 S.E.2d 63 (Ga. App. 1993); *Fakhouri v. Taylor*, 618 N.E.2d 518 (Ill. App.), *cert. denied*, 622 N.E.2d 1204 (Ill. 1993); *Leesley v. West*, 518 N.E.2d 758 (Ill. App. 1988); *Ingram v. Hook's Drugs, Inc.*, 476 N.E.2d 881 (Ind. App. 1985); *Nichols v. Central Merchandise, Inc.*, 817 P.2d 1131 (Kan. App. 1991); *Kinney v. Hutchinson*, 449 So. 2d 696 (La. App.), *cert. denied*, 452 So. 2d 170 (La. 1984); *Adkins v. Mong*, 425 N.W.2d 151 (Mich. App. 1988); *Moore v. Memorial Hosp. of Gulfport*, 825 So. 2d 658 (Miss. 2002); *Batiste v. American Home Prods. Corp.*, 231 S.E.2d 269 (N.C. App.), *cert. denied*, 233 S.E.2d 921 (N.C. 1977); *Griffith v. Blatt*, 973 P.2d 385 (Or. App. 1999), *rev'd*, 51 P.3d 1256 (Or. 2002);[2] *Laws v. Johnson*, 799 S.W.2d 249 (Tenn. App. 1990); *McKee v. American Home Prods. Corp.*, 782 P.2d 1045 (Wash. 1989) (en banc); and *Morgan v. Wal-Mart Stores, Inc.*, 30 S.W.3d 455 (Tex. App. 2000). *Contra Horner v. Spalitto*, 1 S.W.3d 519 (Mo. App. 1999).

Rite Aid's initial argument against any express warranty in the instant matter combines the above-described corollary to the learned intermediary doctrine with Rite Aid's assumption that, in

[2]The reversal was based on Oregon statutes relating to strict liability in tort and not on any change in the common law concerning negligent failure to warn that had been applied by the intermediate appellate court.

Maryland, under CL § 2-313, there must be reliance on the pharmacist in order for the latter's affirmation of fact to be an express warranty. "Whether or not reliance is an essential element of 'basis of the bargain,' [as used in U.C.C. § 2-313(1)(a),] is a question answered differently by the various jurisdictions." 3 *Williston on Sales* § 17-8, at 18 (5th ed. 1996). The Court of Appeals has not had occasion to speak to that issue.[3]

The analysis relied upon by Rite Aid was articulated and applied in *In re Rezulin Prods. Liability Litigation*, 133 F. Supp. 2d 272 (S.D.N.Y. 2001). Rezulin is a prescription diabetes medication, the use of which prompted hundreds of suits against its manufacturer. These suits were consolidated in the Southern District of New York by the Judicial Panel on Multidistrict Litigation. The issue in the reported opinion was whether sixteen cases should be remanded from the consolidation to state courts in Mississippi, Texas, West Virginia, and Louisiana or whether the pharmacies that had dispensed Rezulin to those plaintiffs were

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[3]Reliance was a required element of an express warranty under the Uniform Sales Act. See Maryland Code (1957), Article 83, § 30, which provided:

> "Any affirmation of fact or any promise by the seller relating to the goods is an express warranty if the natural tendency of such affirmation or promise is to induce the buyer to purchase the goods, and if the buyer purchases the goods relying thereon. No affirmation of the value of the goods, nor any statement purporting to be a statement of the seller's opinion only shall be construed as a warranty."

"fraudulently" joined as defendants, thereby preserving federal diversity jurisdiction. The test applied by the court for "fraudulent" joinder was whether the plaintiffs could state a legally sufficient and factually arguable claim against the pharmacies. Among the claims asserted against the pharmacies was breach of express warranty. Under the law of each of the states involved, a pharmacy was not liable to the patient for failure to warn because those states either applied, or were predicted to apply, to pharmacies the above-described corollary to the learned intermediary doctrine. The court concluded that, because patients rely on physicians in purchasing a prescription drug, and not on pharmacists, there could be no express warranty.

This reasoning of the *Rezulin* multidistrict litigation court is most fully set forth in its discussion of the cases from Mississippi. The court said:

> "Patients who purchase prescription drugs from pharmacists do not negotiate or bargain with the pharmacists about the suitability of the product. Even assuming a pharmacist were to make a representation about the safety of a particular drug, the representation would not form 'part of the basis of the bargain' as required by the Mississippi UCC because the patient purchases the drug on the basis of discussions with his or her physician. Unlike the buyer-seller relationship in normal sales transactions, the relationship between the patient and pharmacist is a function of a regulatory system requiring that certain drugs be sold solely by prescription of a physician. It is through the pharmacy that the patient purchases the drug, but in only this sense does the pharmacy function as a 'seller.' The only representations regarding the intrinsic properties of the drug that form the basis of the buyer's purchase are those of the physician. It is precisely for this reason

> that the learned intermediary doctrine focuses on communications between the manufacturer and physicians, rather than patients or pharmacies; it is the physicians who make the ultimate decision on whether to prescribe the drug."

Id. at 291-92. *Accord Salisbury v. Purdue Pharma, L.P.*, 166 F. Supp. 2d 546 (E.D. Ky. 2001); *In re Baycol Prods. Litigation*, 2004 WL 1118642 (D. Minn. 2004).

These cases, utilizing the learned intermediary rule in concluding, as a matter of law, that there can be no reliance on an alleged express warranty by the pharmacy, do not involve PPIs that were prepared, or caused to be prepared, by the pharmacy and distributed in its name.[4]

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[4]One case cited by Rite Aid, *Linnen v. A.H. Robins Co.*, 1999 WL 1441933 (Mass. Super. 1999), did involve a pharmacy-created leaflet, but that case held that the statements in the pamphlet did not constitute an express warranty. Specifically, *Linnen* was a "fen-phen" case. The pamphlet stated that "'most patients experience little or no problems while taking their medication.'" It also stated that "'every medication is capable of producing side effects' and informed the patient about the 'possible side effects' of the particular medication being purchased." *Id.* at *1. The court held this was merely a general statement and not an express promise that the patient would not experience any side effects.

The remaining cases cited by Rite Aid in support of its initial argument against an express warranty are decided on different grounds than the basis of the *Rezulin* decision. In *Tardy v. Eli Lilly & Co.*, 2004 WL 1925536, *3 (Me. Super. 2004), decided on motion to dismiss, the breach of express warranty count was "premised on a failure to warn." *Gressman v. Peoples Serv. Drug Stores, Inc.*, 1988 WL 619115 (Va. Cir. Ct. 1988), holds that a pharmacist renders a health care service under Virginia's Medical Malpractice Act. *Ullman v. Grant*, 450 N.Y.S.2d 955, 956 (N.Y. Sup. Ct. 1982), awarded summary judgment to the pharmacy on the warranty claim because there was no allegation that the defendant offered any warranty to the plaintiff.

In the instant matter, we shall assume, *arguendo*, that, in order to find an express warranty under CL § 2-313, Maryland law requires the buyer's reliance on a statement made by the seller. Nevertheless, under the facts of the instant matter, we cannot hold as a matter of law that Ms. Levy-Gray relied solely on Dr. Geckler to describe for her the characteristics of doxycycline, because he did not advise her of the drug's characteristics or how it should be taken. Rather, Dr. Geckler relied on the dispensing pharmacist to furnish that information to the patient and, perforce, Plaintiff also relied on the dispensing pharmacist.

Indeed, the PPI furnished to Ms. Levy-Gray invited her reliance and evidences Rite Aid's intent that she rely on the affirmations of fact about doxycycline contained in the PPI. Its cover informed her that "[i]nside is everything you need to know about your prescription."

Our conclusion that Plaintiff relied on Rite Aid is reinforced by evidence that Ms. Levy-Gray had had prescriptions filled by Rite Aid in the past and, inferentially, had received PPIs from the pharmacy. This evidence tends to show a course of dealing, CL § 1-201(3), under which Plaintiff, who had no instructions regarding the usage of doxycycline from the prescribing physician, relied upon Rite Aid to furnish that information.

B. Is There Sufficient Evidence of a Warranty?

Whether the Rite ADVICE pamphlet contains an express warranty under CL § 2-313 is a much closer question on which there is a dearth of authority. Most of the reported cases dealing with the liability of a pharmacist who is dispensing a prescription drug address a negligence theory of liability. This is consistent with Restatement (Third) of Torts: Products Liability § 6(e), which states the following rule:

> "A retail seller or other distributor of a prescription drug ... is subject to liability for harm caused by the drug ... if:
>
> ....
>
> "(2) at or before the time of sale or other distribution of the drug ... the retail seller or other distributor fails to exercise reasonable care and such failure causes harm to persons."

In the matter before us, the jury exonerated Rite Aid of negligence.

Under CL § 2-313, in order to have an express warranty there must be an affirmative statement of fact by the seller about the goods. A claim that there is a warranty by omission is at odds with the UCC definition of an express warranty. *See Witherspoon v. Philip Morris Inc.*, 964 F. Supp. 455, 465 (D.D.C. 1997). Here, the manufacturer's package insert that accompanied the doxycycline shipped by Watson to Rite Aid contained, *inter alia*, the following statement:

"All patients taking doxycycline should be advised:

....

> "• That the absorption of tetracyclines is reduced when taken with foods, especially those which contain calcium. However, the absorption of doxycycline is not markedly influenced by simultaneous ingestion of food or milk."

The omission of this statement, which was relevant to the negligence claim asserted by Plaintiff, and is of some relevance to the medical causation issues, is not relevant to the creation of an express warranty.

Rite Aid, drawing on cases in which manufacturers were claimed to have made an express warranty, contends that, in order to create an express warranty, there must be a promise concerning the performance or safety of the drug involved. Rite Aid's lead citation is to *Basko v. Sterling Drug, Inc.*, 416 F.2d 417 (2d Cir. 1969). That decision reversed a judgment on verdict for the defendant in a products liability failure to warn case for error in the instructions on causation. The appellate court, however, agreed with the trial court's refusal to submit a breach of express warranty theory to the jury, because the "defendant did not represent either (1) that its drugs were free from all harmful side effects or (2) that its drugs were absolutely harmless." *Id.* at 428. These two alternatives do not exhaust the potential universe of affirmations of fact about a prescription drug for the purpose of CL § 2-313 express warranties. These two alternatives do not

include an affirmative statement as to other substances with which the drug compatibly may be ingested.

Rite Aid also argues that the instructions in the Rite ADVICE pamphlet are analogous to the instruction manual for the snowblower that was involved in *Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378 (D. Md. 2001). There, the plaintiff was injured when he lost his balance and his hand went into the chute of the snowblower. The blades of the machine were still rotating, although the dead man lever had been released, which should have stopped the rotation of the blades. The court entered summary judgment dismissing an express warranty claim because the facts were more consistent with a breach of an implied warranty of merchantability and because the owner's manual, describing the operation of the machine, had not been furnished to the plaintiff until after the sale had been completed. Here, the PPI was delivered simultaneously with the sale, so *Shreve* is not directly on point.[5]

Plaintiff, similarly off point, seeks to expand the express warranty concept. Ms. Levy-Gray emphasizes the cover of the Rite ADVICE pamphlet where it states: "Inside is everything you need to know about your prescription. It covers everything in writing from dosage to side effects. If you have any questions, just ask your

[5]The effect that the timing of affirmations of fact has on whether they comprise part of the bargain under CL § 2-313 is discussed in Part I.C, *infra*.

pharmacist." These statements are not affirmations of fact about doxycycline. They may be descriptive of the information provided as a service by Rite Aid, or of the service provided by any of its pharmacists, but the statements contain no affirmation of fact about doxycycline.

By their nature, express warranties are case specific. Courts may conclude in appropriate cases that a statement by a seller of goods does not create, as a matter of law, an express warranty. Illustrative is *Jones v. Walter Kidde Portable Equip., Inc.*, 183 F.3d 67 (1st Cir. 1999). In that case the plaintiff suffered nerve damage to her arm during surgery caused by undue pressure from a malfunctioning, automatic tourniquet manufactured by the defendant. An expert opined that "the malfunction was due to a foreign particle temporarily holding open the gas supply valve and another blocking the safety relief valve," and that both particles ultimately blew away under pressure. *Id.* at 69. The manufacturer's statements about the product included the following:

> "'IMPORTANT! MONITOR CUFF PRESSURE CONTINUOUSLY DURING USE.
>
> "'Pressure will remain at the selected setting during the entire procedure unless manually changed.
>
> "'[Directions for changing]
>
> "'NOTE: SHOULD A LEAK EVER DEVELOP IN THE TOURNIQUET VALVE DURING USE, THE SET PRESSURE WILL RISE AT LEAST 150 MM HG. BEFORE PRESSURE RELIEF OPERATES.
>
> "'INSTRUCTIONS IN THIS MANUAL FOR MAINTENANCE MUST BE FOLLOWED TO MINIMIZE LEAK POTENTIALS.'

> "In addition, an instruction on the side of the tourniquet's metal shell sa[id], similarly, '[d]uring use monitor pressure gauge continuously for pressure stability.'"

Id. at 70. The plaintiff contended that an express warranty was created by the statement, "Pressure will remain at the selected setting[.]" Affirming a judgment NOV for the defendant, the court said:

> "Where the relied on statement is flanked with another, IMPORTANT advice that something may go wrong and instructions how to guard against it, we hold as a matter of law that the combination cannot be read as warranty that the event will not happen."

Id.

In the case before us, any express warranty rests on the statement: "Take [doxycycline] with food or milk if stomach upset occurs unless your doctor directs you otherwise." This statement is sufficient for a jury reasonably to conclude that Rite Aid represented to Plaintiff that a characteristic or quality of doxycycline was that it was compatible with food or milk. The closest that the Rite ADVICE pamphlet comes to the characteristic of absorption is in the next sentence which reads: "Avoid taking antacids containing magnesium, aluminum or calcium, sucralfate, iron preparations or vitamin (zinc) products within 2-3 hours of taking this medication." Reasonable persons certainly could read this sentence as limited to over-the-counter or prescription antacids, including those containing calcium, that are ingested

within two to three hours of the doxycycline dosage. There is no evidence that Plaintiff was taking antacids.

It is true that the Rite ADVICE pamphlet states, in bold type, that "it should not be construed to indicate that use of the drug is safe, appropriate, or effective for you."[6] This statement must be read in the context of the Rite ADVICE pamphlet as a whole. To hold that that general disclaimer precludes any express warranty in this case requires a judicial finding that no reasonable person could read the Rite ADVICE pamphlet without concluding that the general statement negated the more particular description of doxycycline, *i.e.*, that it could be taken with food or milk. The instant matter, we hold, is one in which comment 3 to § 2-313 is appropriately applied. Whether the disclaimer took the statement of the compatibility characteristic of doxycycline out of the bargain was a question of fact for the jury.

C. Timing of the Affirmation of Fact

Rite Aid's third argument for precluding, as a matter of law, a finding of express warranty rests on the requirement of CL § 2-313(1)(a) that the affirmation of fact become "part of the basis of the bargain." This, Rite Aid submits, means that the affirmation must be a negotiated term of the agreement, or at least there must

[6]We need not decide in this case whether there can ever be an implied warranty of merchantability or of fitness for a particular purpose by a pharmacy dispensing a prescription drug, or whether the quoted language could prevent that result.

be proof that the plaintiff "'read, heard, saw or knew of the advertisement containing the affirmation of fact or promise' before the purchase." *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 752 (W.D. Pa. 2004). *See also Williams v. Dow Chem. Co.*, 255 F. Supp. 2d 219, 230 (S.D.N.Y. 2003); *Boyd v. Johnson & Johnson*, 2002 WL 372959, *3 (Pa. Com. Pl. 2002). These cases involve claims of express warranty based on advertisements. In such cases the requirement that the plaintiff must have seen the advertisement prior to the sale is imposed to prevent fraud, if for no other reason.

It proves too much, however, to apply to written warranties a requirement of pre-sale knowledge by the buyer of the affirmation of fact. We agree with the analysis of the court in *Murphy v. Mallard Coach Co.*, 582 N.Y.S.2d 528 (N.Y. App. Div. 1992), affirming a judgment for the plaintiff on a breach of express written warranty. Rejecting the argument presented here by Rite Aid, the appellate division said:

> "[W]hile the warranty was technically handed over *after* plaintiffs paid the purchase price, the fact that it was given to plaintiffs at the time they took delivery of the motor home renders it sufficiently proximate in time so as to fairly be said to be part of the basis of the bargain (*compare*, UCC [§] 2-313, comment 7; 1 White and Summers, Uniform Commercial Code, § 9-5, at 448-455 [3d ed.]). To accept the manufacturer's argument that in order to be part of the basis of the bargain the warranty must actually be handed over during the negotiation process so as to be said to be an actual procuring cause of the contract, is to ignore the practical realities of consumer transactions wherein the warranty card generally comes with the goods, packed in the box of boxed items or

> handed over after purchase of larger, non-boxed goods and, accordingly, is not available to be read by the consumer until after the item is actually purchased and brought home. Indeed, such interpretation would, in effect, render almost all consumer warranties an absolute nullity."

Id. at 531 (some citations omitted). *See also In re Bridgestone/Firestone, Inc. Tires Prods. Liability Litigation*, 205 F.R.D. 503, 527 (S.D. Ind. 2001), *rev. on other grounds*, 288 F.3d 1012 (7th Cir. 2002) ("Whether the consumer was aware of the terms of the written warranty before the purchase or not, it was certainly part of the bargain, in that the warranty was part of what the seller sold to the buyer").

The Fourth Circuit, applying Virginia law, in *Martin v. American Med. Sys., Inc.*, 116 F.3d 102 (4th Cir. 1997), considered a breach of express warranty claim involving a penile prosthesis, which the plaintiff asserted caused infection. The plaintiff had the product inserted in a hospital, and documents accompanying the delivery of the product stated in part that it was "'delivered to the hospital prefilled and sterile.'" *Id.* at 103. The plaintiff did not learn of this representation until the litigation began. Nevertheless, the court held that "[t]he express warranty inquiry focuses on what it is that the seller agreed to sell, and, absent clear proof that the parties did not intend their bargain to include the seller's description of the goods, that description is an express warranty." *Id.* at 105.

For all the foregoing reasons we hold that Rite Aid expressly warranted that doxycycline could be taken with milk or other dairy products.

II. Preemption

We now address Rite Aid's argument based on the Supremacy Clause of the United States Constitution. The submission contains two steps. Rite Aid first assumes that the Congress of the United States, by enacting the labeling provisions of the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et. seq.*, intended to preempt state law causes of action against prescription drug manufacturers that are based on representations in, or omissions from, the product's "label," as approved by the FDA.[7] From that premise Rite Aid next argues that the immunity from that class of actions under state law should be extended to pharmacies that choose, although not legally compelled to do so, to furnish to their customers information concerning prescription drugs that is substantially the same as in the manufacturer's label.

Rite Aid does not contend that express preemption applies to the prescription drug here. The silence of Congress concerning preemption of state law with respect to prescription drugs may be contrasted with 21 U.S.C. § 379r(a), prohibiting any state or political subdivision thereof from establishing any "requirement"

[7]In this part of the opinion, "label" means a document of the type represented by the eight page description of doxycycline for which Watson obtained FDA approval.

for nonprescription drugs "that is different from or in addition to, or that is otherwise not identical with, a requirement under," *inter alia*, the FDCA. This express preemption provision barred a state law express warranty action involving an over-the-counter product for head lice in *Kanter v. Warner-Lambert Co.*, 99 Cal. App. 4th 780 (2002).

Nor do we deal with preemption by occupation of the field. In *Hillsborough County, Fla. v. Automated Med. Laboratories, Inc.*, 471 U.S. 707, 105 S. Ct. 2371 (1985), the local government regulated blood plasma collection centers by requirements additional to those federally imposed. Sustaining the local regulation, the Court said:

> "To infer pre-emption whenever an agency deals with a problem comprehensively is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive. Such a rule, of course, would be inconsistent with the federal-state balance embodied in our Supremacy Clause jurisprudence."

Id. at 717, 105 S. Ct. at 2377.

Further, this is not a case of direct conflict, as illustrated by *Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1 (Cal. 2004), on which Rite Aid relies. In that case, as a result of a California initiative requiring warnings on products containing chemicals known to the state to cause reproductive toxicity, the California health authorities mandated a warning for products containing nicotine, including nicotine replacement therapies. It read, "'WARNING: This product contains a chemical

known to the State of California to cause birth defects or other reproductive harm.'" *Id.* at 3. The FDA-approved warning, which is set forth in the margin, "serve[d] a nuanced goal--to inform pregnant women of the risks of [nicotine replacement therapy] products, but in a way that will not lead some women, overly concerned about those risks, to continue smoking." *Id.* at 15.[8] No such direct conflict is presented here.

The conflict, as Rite Aid perceives it, is that, in order to avoid the state law warranty liability that the jury found, Rite Aid must depart from the FDA approved language of the Watson label. Such a result, Rite Aid submits, compels preemption; otherwise, Rite Aid would be subjected to criminal penalties for misbranding under 21 U.S.C. § 331(a), (b), and (k). We disagree with the argument both factually and legally.

Under the instructions of the court, the jury's finding of express warranty is based upon the text of the Rite ADVICE pamphlet, not of the Watson label. The variations between the Watson approved label and the Rite ADVICE pamphlet apparently

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[8]The FDA's warning stated:

> "'If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider. Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.'"

Dowhal, 88 P.3d at 4.

result from decisions made by the editors of the PPI at First Databank, and not from a requirement of Maryland law. The Rite ADVICE pamphlet omits precautions concerning which "[a]ll patients taking doxycycline should be advised[.]" The Rite ADVICE pamphlet omits the statement, presented in the label, that "the absorption of tetracyclines is reduced when taken with foods, especially those which contain calcium." The Rite ADVICE pamphlet omits the statement in the label: "However, the absorption of doxycycline is not markedly influenced by simultaneous ingestion of food or milk." Finally, the Rite ADVICE pamphlet juxtaposes its advice to take doxycycline "with food or milk if stomach upset occurs unless your doctor directs you otherwise," with a statement which the jury reasonably could conclude directs the patient's attention to antacids as the potential cause of absorption problems.[9]

Rite Aid's legal theory seems to rest on that form of implied federal preemption that arises when the state law impedes accomplishing a federal purpose. *Michigan Canners & Freezers Ass'n v. Agricultural Marketing & Bargaining Bd.*, 467 U.S. 461, 469, 104 S. Ct. 2518, 2523 (1984). The inapplicability of this form of preemption to state law actions that factually are based on FDA approval of the manufacturer's label is demonstrated by the many

[9]As previously noted, the Rite ADVICE pamphlet states: "Avoid taking antacids containing magnesium, aluminum or calcium, sucralfate, iron preparations or vitamin (zinc) products within 2-3 hours of taking this medication. These products bind with the medicine preventing its absorption."

cases upholding state law products liability claims against pharmaceutical manufacturers whose labels have been FDA approved. Typically, these cases rest liability on failure to warn or defective design of the pharmaceutical, or both.

In *Graham v. Wyeth Laboratories*, 906 F.2d 1399 (10th Cir.), *cert. denied*, 498 U.S. 981, 111 S. Ct. 511 (1990), the court, although reversing a judgment for the plaintiff in a defective design case, adopted the opinion of the District Court on summary judgment, *Graham v. Wyeth Laboratories*, 666 F. Supp. 1483 (D. Kan. 1987), as its rationale for rejecting a preemption argument advanced by the manufacturer defendant. That District Court stated the rule to be: "FDA regulations of prescription drugs are generally viewed as setting *minimum* standards, both as to design and warning." *Id.* at 1491. The court supported the rule by the following citations:

> "*Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652 (1st Cir. 1981) [(design defect)]; *Salmon v. Parke-Davis & Co.*, 520 F.2d 1359 (4th Cir. 1975) [(failure to warn)]; ... *MacGillivray v. Lederle Laboratories*, 667 F. Supp. 743, 746 (D.N. Mex. 1987) [(defective design)]; *Toner v. Lederle Laboratories*, 112 Idaho 328, 732 P.2d 297, 311 n.12 (1987) ('FDA certification represents only the FDA's opinion, albeit an informed one, of the safety and efficacy of the drug. Regrettably, drugs occasionally prove not so safe as the FDA first believed.') [(defective condition)]; *Wooderson v. Ortho Pharmaceutical Corp.*, 235 Kan. 387, 681 P.2d 1038, *cert. denied*, 469 U.S. 965, 105 S. Ct. 365, 83 L. Ed. 2d 301 (1984) [(failure to warn)]; *Feldman v. Lederle Laboratories*, 97 N.J. 429, 479 A.2d 374 (1984) [(failure to warn)]; *Barson v. E.R. Squibb & Sons, Inc.*, 682 P.2d 832, 836 (Utah 1984) [(breach of warranty; failure to

> warn)]; *Ferrigno v. Eli Lilly & Co.*, 175 N.J. Super. 551, 420 A.2d 1305 (1980) [(breach of warranty; failure to warn; design defect)]; *Bristol-Myers v. Gonzales*, 548 S.W.2d 416 (Tex. Civ. App. 1976) [(failure to warn)]; *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. 375, 528 P.2d 522 (1974) [(failure to warn)]; *Stevens v. Parke-Davis & Co.*, 9 Cal. 3d 51, 107 Cal. Rptr. 45, 53, 507 P.2d 653, 661 (1973) [(failure to warn)]."

Id.

Other cases to the same effect are *Tobin v. Astra Pharmaceutical Prods., Inc.*, 993 F.2d 528, 536-38 (6th Cir.) (defective design), *cert. denied*, 510 U.S. 914, 114 S. Ct. 304 (1993); *Hurley v. Lederle Laboratories Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1176-77 (5th Cir. 1989) (failure to warn and defective design); *Abbot v. American Cyanamid Co.*, 844 F.2d 1108, 1110-14 (4th Cir.) (failure to warn and defective design), *cert. denied*, 488 U.S. 908, 109 S. Ct. 260 (1988); *Morris v. Parke, Davis & Co.*, 667 F. Supp. 1332, 1339-40 (C.D. Cal. 1987) (defective design); *Shackil v. Lederle Laboratories*, 561 A.2d 511, 527 (N.J. 1989) (defective design); *McDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65, 70-71 (Mass.) (failure to warn), *cert. denied*, 474 U.S. 920, 106 S. Ct. 250 (1985). Thus, J. Beck & A. Vale, *Drug and Medical Device Product Liability Deskbook* § 5.02[5], at 5.02-13 (2004), states:

> "Decisions addressing implied preemption so far support the following observations:
>
> ....

"• Implied preemption does not broadly preempt traditional warning or design defect claims."

(Footnote omitted).

Rite Aid has referred us to one officially reported decision holding that FDA approval of the labeling of a prescription drug precluded a state law claim, in that case, failure to warn. It is the opinion of a United States Magistrate Judge in the District of North Dakota in 2002, in which the holding is an alternative ground of decision. *See Ehlis v. Shire Richwood, Inc.*, 233 F. Supp. 2d 1189 (D.N.D. 2002). On appeal, the Eighth Circuit did not address that alternative ground of decision, but held that summary judgment was appropriately granted for the manufacturer based upon the learned intermediary doctrine. *Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013 (8th Cir. 2004).[10]

[10]Rite Aid also cites us to two decisions that are not officially reported, *Needleman v. Pfizer, Inc.*, 2004 WL 1773697 (N.D. Tex. 2004), and *Dusek v. Pfizer, Inc.*, 2004 WL 2191804 (S.D. Tex. 2004). The plaintiffs' theory in both cases was that the manufacturer of Zoloft failed to warn that the drug caused suicide in some patients. Both cases hold that the claim against the drug manufacturer was preempted by the FDCA's labeling provisions. Both cases rely on that argument's having been advanced to the Ninth Circuit in a FDA amicus brief on an appeal by the plaintiff in another Zoloft case. *Motus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2004). In *Motus*, the District Court had granted summary judgment in favor of the manufacturer on causation grounds. *Motus v. Pfizer, Inc.*, 196 F. Supp. 2d 984 (C.D. Cal. 2001). The Ninth Circuit affirmed on the ground that the adequacy of the warning was irrelevant because the prescribing doctor did not read Pfizer's warning. Thus, the Ninth Circuit did not reach the preemption issue argued by Pfizer and the FDA.

Whether approval by the Environmental Protection Agency (EPA) of the label of a pesticide preempted a state law claim of breach of express warranty was before the Supreme Court of the United States in *Bates v. Dow Agrosciences LLC*, ___ U.S. ___, 125 S. Ct. 1788, 2005 WL 957193 (2005). The approved label on the product stated: "Use of Strongarm is recommended in all areas where peanuts are grown." Farmers in Texas sued the manufacturer contending that the product stunted the growth of peanuts in soils with pH levels of 7.0 or greater. The statute under which the EPA had approved the label provided that a state, undertaking the regulation of the sale or use of a federally registered pesticide, "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. § 136v(b). The Supreme Court held that the petitioner's express warranty claim was not in conflict with the labeling required under § 136v(b) and was not preempted. The Court said:

> "Rules that require manufacturers to design reasonably safe products, to use due care in conducting appropriate testing of their products, to market products free of manufacturing defects, and to honor their express warranties or other contractual commitments plainly do not qualify as requirements for 'labeling or packaging.' None of these common-law rules requires that manufacturers label or package their products in any particular way. Thus, petitioners' claims for defective design, defective manufacture, negligent testing, and breach of express warranty are not pre-empted.
>
> "To be sure, Dow's express warranty was located on Strongarm's label. But a cause of action on an express

> warranty asks only that a manufacturer make good on the contractual commitment that it voluntarily undertook by placing that warranty on its product. Because this common-law rule does not require the manufacturer to make an express warranty, or in the event that the manufacturer elects to do so, to say anything in particular in that warranty, the rule does not impose a requirement 'for labeling or packaging.'"

____ U.S. at ____, 125 S. Ct. at 1798-99, 2005 WL 957193, at *8 (citations and footnotes omitted).

The above-cited decisions, holding that FDA approval of a prescription drug is not preemptive, are consistent with Maryland law. The Court of Appeals has held that compliance by a manufacturer with federal safety standards permits an inference that the product is not dangerous, but such compliance does not preclude a finding of negligence for failure to take additional precautions. *See Ellsworth v. Sherne Lingerie, Inc.*, 303 Md. 581, 602, 495 A.2d 348, 358 (1985).

Inasmuch as federal approval of a pharmaceutical or pesticide manufacturer's product and its labeling generally does not preempt state law tort or express warranty actions, *a fortiori*, that approval does not preempt state law claims based on a PPI which a pharmacy, unregulated by the FDA, chooses to cause to be produced and to distribute to customers at the point of sale.

An amicus brief in support of Rite Aid has been filed by the National Association of Chain Drug Stores, Inc. and the American Pharmacists Association. It undertakes to explain, or at least to

advance one factor, underlying the decisions by pharmacies to cause production of house label PPIs for prescription drugs.

As we have explained, *supra*, traditionally, under the FDCA framework, labeling information is intended for the prescribing physician, not the patient. *And see* C. Walsh *et al.*, *The Learned Intermediary Doctrine: The Correct Prescription for Drug Labeling*, 48 Rutgers L. Rev. 821, 827-28 (1996). Nevertheless, beginning in the late 1970s, a movement arose to require wider dissemination of pharmaceutical information to patients. In 1979, the FDA issued a proposed rule, requiring PPIs for all prescription drugs. *Prescription Drug Products: Patient Labeling Requirement*, 44 Fed. Reg. 40,016, 40,019-22 (1979). In this proposed rule, the FDA made clear that the PPI requirement was not intended to disturb traditional tort law principles governing the duties of care owed to patients by persons engaged in health care:

> "Patient labeling is not intended to define the duty or set the standard of care manufacturers, physicians, pharmacists, or other dispensers owe to the patient who uses the product. ... Patient labeling will be required solely because of its positive effects, to supplement the information which it is the traditional responsibility of physicians, pharmacists, and other dispensers to provide to patients."

Id. at 40,023.

The final rule, published at 45 Fed. Reg. 60,754 (1980) (codified at 21 C.F.R. § 203 (1981)), required "manufacturers and distributors of prescription drug products to provide [PPIs] for prescription drug products to dispensers. Dispensers are then

required to provide the [PPIs] to patients when a drug product ... is dispensed." *Id.* at 60,756. The final rule mandated that the PPIs be written in "nontechnical language and ... be based primarily on the professional labeling for the product." *Id.*

Although the final rule was scheduled to take effect on October 14, 1980, it never was implemented. Instead, the FDA, after further review of the regulation, formally revoked the rule on September 7, 1982. 47 Fed. Reg. 39,147, 39,147 (1982) (revoking rule codified at 21 C.F.R. § 203 (1981)).

Interest in the PPI requirement, however, continued. In the mid-1990s, the FDA issued proposed rulemaking, *Prescription Drug Product Labeling: Medication Guide Requirements*, to promote "private sector initiatives." 60 Fed. Reg. 44,182, 44,182 (1995). Specifically, the FDA set a "goal of distributing useful patient information to 75 percent of individuals receiving new prescriptions by the year 2000 and 95 percent of individuals receiving new prescriptions by the year 2006." The FDA warned, however, that if these goals were not met by private efforts, the agency would intervene.

Approximately one year later, Congress intervened. By § 601 of Public Law 104-180 of August 6, 1996, 110 Stat. 1593, Congress withheld for a limited period of time the authority from the Secretary of the Department of Health and Human Services to implement the proposed rulemaking. Congress directed the Secretary

to request "national organizations representing health care professionals, consumer organizations, voluntary health agencies, the pharmaceutical industry, drug wholesalers, patient drug information database companies, and other relevant parties [to] collaborate to develop a long-range comprehensive action plan to achieve goals consistent with the goals of the proposed rule[.]" The private sector presented an action plan in December 1996 to the Secretary.

At the time Rite Aid dispensed the doxycycline to Ms. Levy-Gray, the legal status of a pharmacy, *viz-a-viz* FDA regulation of pharmacy-originated PPIs, was as described above. Neither amici nor Rite Aid has directed our attention to any subsequent developments. We fail to see how this interesting history has any legally recognized effect in support of Rite Aid's preemption argument.

Accordingly, we hold that there is no federal preemption of the warranty action in this case.

III. and IV. Expert Testimony

Rite Aid presents two arguments related to medical expert testimony. First, it asserts that Plaintiff failed to present "reliable" expert testimony regarding causation. Second, it suggests that the trial court improperly permitted the jury to hear expert opinion that was not rendered to a reasonable degree of medical "certainty." We shall address these issues together.

A. Causation

Rite Aid challenges Plaintiff's medical causation evidence under Maryland Rule 5-702.[11] It asserts that Plaintiff's experts' testimony "lacked the required factual support and analysis through a proper methodology" and "contradicted the undisputed conclusion of every study and authority presented at trial." Appellant faults those experts for not providing "a single study or textbook to support the notion that milk interferes with the absorption of doxycycline to a clinically significant degree." Rite Aid characterizes the link between Plaintiff's post-Lyme syndrome and a decrease in the absorption of doxycycline as "speculative" at best. Plaintiff, in response, correctly points out that conflicts in the evidence were for the jury to resolve and that the testimony of Dr. Lafferman and Dr. Neil A. Crane (Dr. Crane) was sufficient to meet her burden of proving causation.

As a general rule, the qualifications of an expert witness are to be determined by the trial judge in the exercise of sound

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[11]Maryland Rule 5-702 provides:

> "Expert testimony may be admitted, in the form of an opinion or otherwise, if the court determines that the testimony will assist the trier of fact to understand the evidence or to determine a fact in issue. In making that determination, the court shall determine (1) whether the witness is qualified as an expert by knowledge, skill, experience, training, or education, (2) the appropriateness of the expert testimony on the particular subject, and (3) whether a sufficient factual basis exists to support the expert testimony."

discretion. *In re Adoption/Guardianship No. CCJ14746*, 360 Md. 634, 646-47, 759 A.2d 755, 762 (2000). As the Court of Appeals has explained:

> "[T]he admissibility of expert testimony is a matter largely within the discretion of the trial court and its action will seldom constitute a ground for reversal. It is well settled in this State, however, that the trial court's determination is reviewable on appeal and may be reversed if it is founded on an error of law or some serious mistake, or if the trial court clearly abused its discretion."

Radman v. Harold, 279 Md. 167, 173, 367 A.2d 472, 476 (1977) (citations omitted).

It is not the relative appropriateness to the particular subject matter of one type of expert over another that determines qualification to opine. This was made clear in *Deese v. State*, 367 Md. 293, 786 A.2d 751 (2001). There, the Court of Appeals found no abuse of discretion in qualifying a specialist in pediatric emergency care as an expert in a child abuse death case, despite the defendant's argument that an expert in forensic pathology would have been more qualified. In *Deese*, the Court explained:

> "Assuming, *arguendo*, that the most relevant field of expertise was forensic pathology, as distinct from pediatrics and pediatric emergency medicine, previous decisions have affirmed a trial court's admission of expert testimony when the expert, although not a specialist in the field having the most sharply focused relevancy to the issue at hand, nevertheless could assist the jury in light of the witness's 'formal education, professional training, personal observations, and actual experience.' *Massie v. State*, 349 Md. 834, 851, 709 A.2d 1316, 1324 (1998)."

Id. at 303, 786 A.2d at 756.

Rite Aid relies heavily on *Giant Food, Inc. v. Booker*, 152 Md. App. 166, 831 A.2d 481, *cert. denied*, 378 Md. 614, 831 A.2d 481 (2003), a workers' compensation case. At issue was whether the claimant had been exposed to Freon gas and whether that exposure had caused his adult on-set asthma. The Court noted that, "simply because a witness has been tendered and qualified as an expert in a particular occupation or profession, it does not follow that the expert may render an unbridled opinion, which does not otherwise comport with Md. Rule 5-702." *Id.* at 182, 831 A.2d at 490. Rather, an expert's opinion must have a "'sufficient factual basis to support a rational conclusion[.]'" *Id.* (citation omitted). Otherwise, that expert testimony amounts to mere "'conjecture, speculation, or incompetent evidence.'" *Id.* at 182-83, 831 A.2d at 490 (citation omitted); *see also* McLain, *Maryland* Evidence § 702:2, at 731-33 (2001). The *Booker* Court also stressed that expert testimony must "reflect the use of reliable ... methodology in support of the expert's conclusions." *Id.* at 183, 831 A.2d at 490. Applying these principles to the challenged testimony in that case, the *Booker* Court held that the expert's opinion was not admissible because he stated flatly that he was not clear about the substance to which the claimant had been exposed.[12]

[12]Specifically, he stated, "'I'm ... still not clear exactly what happened there. So if it was a clear cut agent that we knew for sure what it was, it would help. But I don't -- I think things are not very clear cut to me.'" *Id.* at 186, 831 A.2d at 492. The (continued...)

We hold that the medical causation element of Plaintiff's case is supported by Dr. Crane's and Dr. Lafferman's testimony. The former, board certified in internal medicine and infectious diseases, treated two or three cases of Lyme disease annually, for which he prescribed doxycycline. He advised his doxycycline patients "to avoid food altogether, take it with water, but especially avoid calcium containing waters such as antacids, items, things like that, and dairy products that contain calcium." He so advised his patients because "[w]e just want optimal absorption."

Based on the records of Dr. Haile and Dr. Lafferman, Dr. Crane reached the conclusion that "milk and dairy products interfered with [Plaintiff's] therapy." He explained: "I think she was basically cured of Lyme disease by the end of December but then she had post infectious complications of the Lyme disease. That usually doesn't happen with proper treatment. So my conclusion is that the interference with absorption le[d] to that." The records indicated that "she wasn't showing any improvement, so she stopped using the milk products and then she started improving." Although he acknowledged that a certain percentage of Lyme disease cases do

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[12](...continued)
expert also stated that his "'research was limited to looking up some textbooks and things like that and I did not see Freon causing asthma in those textbooks.'" *Id.* Nevertheless, the expert stated his opinion that the exposure to the chemical, determined by OSHA investigators to be Freon, had caused the claimant to develop asthma in that case.

not resolve with proper treatment, he stated that this was less likely in Ms. Levy-Gray's case, given her medical history.

Dr. Lafferman, in addition to practicing internal medicine, holds a graduate degree in clinical pharmacology. She sees roughly five Lyme disease patients a month. She agreed that patients taking doxycycline should avoid dairy products. Based on general knowledge regarding the tetracycline family of drugs[13] and on Plaintiff's course of treatment, Dr. Lafferman opined that Plaintiff's post-Lyme disease symptoms resulted from the decrease in absorption of doxycycline that was caused by the concomitant ingestion of milk products. She explained:

> "[Plaintiff] was given a medicine. She was taking it with milk. She stopped taking it with milk, and she started to get better. Before when she was taking it with milk, she did not get better. Temporally that shows me medically that she had a decrease[d] effect of the drug before she stopped taking it with milk. ... *We frequently judge efficacy on those kinds of things.* We also judge side effects. ... I think that is the time span in this that makes a supporting evidence for a drug interaction."

(Emphasis added). Unlike the testimony in *Booker*, the testimony of Plaintiff's experts rested on a sufficiently sound basis to be admissible.

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[13]Although Dr. Lafferman's, and some other experts', understanding of calcium's effect on the absorption of doxycycline came from their knowledge of calcium's effects on the tetracycline class of drugs as a whole, we agree with the circuit court that Rite Aid's suggestion that these experts did not know or ignored the fact that doxycyline was distinguishable from the rest of the tetracycline class of drugs "is not a fair comment, nor is it a correct statement of their testimony."

Rite Aid asserts that the decrease in absorption of doxycycline caused by milk products is not clinically significant, based principally on the statement in the Watson FDA-approved label that the drug's effectiveness is not markedly reduced by ingestion with milk. The operative words in Rite Aid's argument are "significant" and "not markedly." The evidence, with which Rite Aid's expert witnesses generally agreed, was that milk produces about a twenty percent reduction in the absorption of doxycycline. Whether that is clinically significant in the general population under some risk-benefit analysis applied by the FDA, see *Grundberg v. Upjohn Co.*, 813 P.2d 89, 96-97 (Utah 1991) (describing FDA approval process), is not the issue before us. Likewise, whether a lack of clinical significance in the general population would be defensive to a failure to warn claim is not the issue before us. We deal here with breach of an express warranty--that doxycycline was compatible with milk. "If an express warranty exists, the reason it was breached is immaterial. 'The obligation of a warranty is absolute, and is imposed as a matter of law irrespective of whether the seller knew or should have known of the falsity of his representations.'" Beck & Vale, *supra*, § 2.08, at 208-1. Here, there was sufficient evidence that the milk-induced reduction in absorption of the drug was clinically significant to Ms. Levy-Gray.

B. Dr. Levy and Dr. McDonald

Rite Aid also argues that the testimony of two experts called by Plaintiff, Dr. Levy and Dr. Andrea McDonald (Dr. McDonald), was not rendered to a reasonable degree of medical "certainty." Neither the law nor the facts most favorable to Plaintiff support that argument.

Legally, an opinion by a medical expert need not be expressed to a reasonable degree of medical certainty in order to be admissible. An opinion held to a reasonable degree of medical probability is sufficient. *See Mayor & City Council of Baltimore v. Theiss*, 354 Md. 234, 262, 729 A.2d 965, 980 (1999) (Rodowsky, J., concurring); *Davidson v. Miller*, 276 Md. 54, 61-62, 344 A.2d 422, 427-28 (1975); *Samuel v. Ford Motor Co.*, 112 F. Supp. 2d 460, 470-71 (D. Md. 2000).

Dr. Levy, a urological oncologist from Washington State, regularly prescribed doxycycline to patients he diagnosed with prostatitis. He was recognized by the court as an expert in the "proper administration of doxycycline, [and] the way to provide information regarding doxycycline[.]" His statement on deposition that he did not consider himself an "expert" on the absorption of doxycycline went to the weight of his testimony, and not to its admissibility.

Dr. Levy sat on the "forms committee" of the Everett Clinic, where he worked as a physician. The Everett Clinic's 2002 PPI for

doxycycline, distributed by the clinic's pharmacy, advised patients to take doxycycline without food, unless stomach upset occurred. Dr. Levy stated that the information in the flier was consistent with the peer review material in the field. The Everett Clinic pharmacy also placed a sticker on the prescription bottle reading: "Do not take dairy products[,] antacids or iron preparations within 1-hour of this preparation[.]" The short answer to Rite Aid's objection to this testimony is that it was competent and relevant on the failure to warn claim that was viable until the jury verdict. Rite Aid has not directed us to any request on its part that the jury's use of the evidence be limited.

Dr. McDonald, a Doctor of Pharmacy, worked as a clinical pharmacist. The trial court recognized her as an expert in pharmacy and drug interaction. Her knowledge of doxycycline came from her training in pharmacy school and in the residency following that training. Like Dr. Levy, she denied that she was an expert in the absorption of doxycycline, but it was not for her to determine whether she qualified as an expert. In any event, her opinion that the drug's interaction with milk posed a risk of decreased absorption came into evidence without objection.

V. Jury Instructions

Rite Aid's final points relate to the rejection by the circuit court of Rite Aid's requests that its special instruction on

causation,[14] and Maryland Pattern Jury Instructions 26:10(a)[15] and 10:4[16] be given. In order for Rite Aid to have been entitled to these instructions, the legal propositions to be embraced in them must have been generated by the evidence. *See Farley v. Allstate Ins. Co.*, 355 Md. 34, 47, 733 A.2d 1014, 1020 (1999). Further, Maryland Rule 8-504(a)(4) requires that a brief shall contain "[a] clear concise statement of the facts material to a determination of the questions presented" and that "[r]eference shall be made to the pages of the record extract supporting the assertions."

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[14]Rite Aid's special jury instruction No. 11 reads:

> "Where there are several potential causes of Ms. Levy-Gray's injury and Rite Aid is responsible for only one, Ms. Levy-Gray cannot recover if you would be required to speculate as to which of these acts actually caused the injury."

[15]MPJI-Civ 26:10(a), intended for products liability actions, reads:

> "A person cannot recover damages for breach of warranty if the injury or damage resulted from an allergy or physical sensitivity to which normal persons are not subject unless the seller had reason to know that the plaintiff was abnormally vulnerable to injury from the product."

The comment to the Pattern Jury Instruction refers to the "[i]mplied warranty of fitness."

[16]MPJI-Civ 10:4 reads:

> "A person who had a particular condition before the accident may be awarded damages for the aggravation or worsening of that condition."

With respect to its causation instruction, Rite Aid asserts that the harm suffered by Plaintiff "might have been caused by genetic factors[.]" Rite Aid does not refer us to any opinion evidence that the probable cause of the post-Lyme syndrome was a genetic anomaly. Absent any opinion evidence that would permit the jury to consider genetics as an alternative, as opposed to a concurrent, cause, the denied instruction would have invited speculation, even if we assume the validity of Rite Aid's legal premise.

We infer that Rite Aid has in mind, as evidentiary support, the passage quoted below from the direct examination of Dr. Haile.

> "Q. And is the post Lyme syndrome caused at all by when you take Doxycycline or how much Doxycycline you take?
>
> "A. That is a good question. And we believe for the most part that post Lyme syndrome is something that is genetically determined, although we are not absolutely certain of that. But there do seem to be certain genetic differences in people who developed post Lyme syndromes from those who do not.
>
> "There is some information about how early you catch it, how early you get Lyme disease and whether you are more likely or not to develop Lyme syndrome. It is controversial. There is not a lot of literature on it. But it seems in people who go longer than say two months without adequate treatment, there may be a more – it may be more likely in those individuals to develop a post Lyme syndrome. I think that Miss Gray was actually diagnosed quite promptly[.]"

On cross-examination, Dr. Haile acknowledged that he did not know Plaintiff's genetic makeup and had not performed any tests to

determine her genetic markers. Thus, there was no evidence tying the non-responsive portions of Dr. Haile's answer to Plaintiff.

Nor does Rite Aid direct us to any medical opinion that Plaintiff suffered "from an allergy or physical sensitivity to which normal persons are not subject[.]" Consequently, assuming that MPJI-Civ 26:10(a) is a correct statement of the law in an express warranty case, Rite Aid has not demonstrated any prejudicial error in the court's denial of that instruction.

Interestingly, the circuit court instructed the jury on the "eggshell skull rule," D. Dobbs, *The Law of Torts* § 188, at 464-65 (2000), as set forth in the margin.[17] There was no exception taken to this instruction, and no request that it be limited to the tort claim.

As the evidentiary foundation for the granting of MPJI-Civ 10:4, Rite Aid points to the evidence of the symptoms suffered by Plaintiff during the onset of her Lyme disease. Rite Aid, however, does not direct us to any evidence from which the jury could distinguish between the harm resulting from contracting Lyme disease and from post-Lyme syndrome. Moreover, absent a transcript

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[17]The court instructed:

> "The effect that an injury might have upon a particular person depends upon the susceptibility of that injury by that person. In other words, the fact that the injury may have been less serious if inflicted on another person does not mean in any way that damages are to be diminished if to be awarded to the person who sustained injury."

of the jury argument, Rite Aid cannot demonstrate that the denial of the instruction was prejudicial. The theory of Plaintiff's case was that the harm resulting from the breach of warranty was the post-Lyme syndrome, and it is fair to infer that Plaintiff argued the case that way to the jury.

For all of the foregoing reasons, we shall affirm the judgment below. Accordingly, it is unnecessary that we consider Plaintiff's cross-appeal.

JUDGMENT OF THE CIRCUIT COURT FOR BALTIMORE COUNTY AFFIRMED.

COSTS TO BE PAID BY THE APPELLANT.