Mary Gourdine v. Ellen Crews et al., No. 134, September Term 2007.

DRUG PRODUCT LIABILITY – TORT LAW – DUTY

Ellen Crews, a Type I diabetic, took a combination of insulin medications and while driving, struck an automobile driven by Isaac Gourdine, killing Mr. Gourdine. Petitioner, Mary Gourdine, the wife of Isaac Gourdine, individually, and as Personal Representative of the Estate of Mr. Gourdine, and as Next Friend of Monica J. Gourdine and Lamar T. Gourdine, their two children, filed suit against Respondent, Eli Lilly and Company ("Lilly"), the manufacturer of the insulin medications taken by Ms. Crews, alleging fraud, negligence and strict liability for failure to warn of known concealed defects. The Circuit Court for Prince George's County granted summary judgment in favor of Lilly because Lilly did not owe a duty of care to Mr. Gourdine to warn Ms. Crews of the dangers that were allegedly associated with the specified medications; the Court of Special Appeals affirmed. The Court of Appeals affirmed, concluding that Eli Lilly did not owe a duty of care to Mr. Gourdine, a non-user, to warn Ms. Crews, and therefore, the Circuit Court correctly granted summary judgment in favor of Eli Lilly.

IN THE COURT OF APPEALS OF MARYLAND

No. 134

September Term, 2007

MARY GOURDINE

v.

ELLEN CREWS, et. al.

Bell, C.J.
Harrell
Battaglia
Greene
Eldridge, John C. (Retired, Specially Assigned)
Raker, Irma S. (Retired, Specially Assigned)
Wilner, Alan M. (Retired, Specially Assigned),

JJ.

Opinion by Battaglia, J.
Raker, J., Concurs.

Filed: September 4, 2008

In this products liability case, premised on negligence, strict liability and fraud, Ellen Crews, a Type I diabetic[1] who was taking a combination of insulin medications manufactured by Respondent, Eli Lilly and Company ("Lilly"), while operating her car, suffered a debilitating episode and struck a vehicle driven by Isaac Gourdine, resulting in his death. We are asked to determine whether Lilly owed a duty to Mr. Gourdine, the third-party who did not ingest the drugs. Petitioner, Mary Gourdine, the wife of Mr. Gourdine, argues that it was foreseeable for Lilly that Ms. Crews, allegedly suffering an adverse reaction to the medications, would cause injury and death to third persons while she was operating a motor vehicle, when she had not been adequately warned about the dangers that allegedly were associated with the specified medications, and that such foreseeability, thus, created a duty owed to Mr. Gourdine.[2] The certiorari questions presented are:

> 1. Where the FDCA[3] imposes a duty on a drug manufacturer to refrain from selling a drug with false and misleading advertising and labeling, the violation of which gives rise to criminal liability for misbranding under 21 U.S.C. §§ 331(a), 333(a)(1), and 352, is there any public policy reason for relieving the drug company from liability for injuries to an innocent third-party bystander injured in an actionable motor vehicle accident

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[1] Type I diabetes is "a condition characterized by high blood glucose levels caused by a total lack of insulin;" it is often referred to as "juvenile-onset" diabetes. *Stedman's Medical Dictionary* 530 (28th ed. 2006).

[2] In her opposition to Lilly's Motion for Summary Judgment, Ms. Gourdine conceded that Lilly had no direct duty to warn Mr. Gourdine; "Plaintiffs agree that Lilly had no duty to warn Mr. Gourdine . . . ." Plaintiff's Memorandum of Points and Authorities in Opposition to Defendant's Motion for Summary Judgment (June 1, 2006), at 27.

[3] FDCA refers to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321, *et seq.*

caused by a drug-induced loss-of-consciousness, when the drug manufacturer sold the drugs consumed by the at-fault driver with inadequate warnings, false advertising and made conscious misrepresentations to the medical community as to the true risks associated with the drugs?

2. Did the intermediate appellate court err in a finding as matter of law that Mr. Gourdine's death was not a foreseeable consequence of Defendant Lilly's conduct when Lilly's managing agents admitted that such injuries were foreseeable?

3. Whether a claim for misbranding, false and misleading advertising, a claim for failure to warn, and a claim for negligent misrepresentation and fraud brought against a drug manufacturer is preempted by the FDCA, 21 U.S.C. § 321, *et seq.*?

We respond to the first question by affirming the judgment of the Court of Special Appeals, and thereby the trial court's grant of summary judgment to Lilly, because Lilly did not owe the requisite duty to Mr. Gourdine to sustain the negligence, strict liability and fraud claims asserted in the instant case.[4]

I. Introduction

On the morning of February 25, 2002, Ms. Crews took a combination of Humalog, a quick-acting form of insulin taken with meals, and Humulin N (or "Humulin NPH"),[5] a medication designed to supply a constant source of insulin to the body, both of which were

[4] As a result of our holding, we need not and will not address the second and third questions.

[5] According the affidavit of Dr. James H. Anderson, Jr., an employee of Eli Lilly & Company, Humalog is available only by prescription but Humulin N is available as an over-the-counter medication. This distinction, for our purposes, is irrelevant.

manufactured by Lilly, and prescribed by Ms. Crews' doctor.[6] While driving from Baltimore to College Park, Ms. Crews hit an automobile driven by Isaac J. Gourdine; the force of the collision caused Mr. Gourdine's car to leave the highway and crash into a tractor-trailer, leaving him with a mortal head wound.

On January 7, 2005, Ms. Gourdine, individually, and as Personal Representative of the Estate of Mr. Gourdine, and as Next Friend of Monica J. Gourdine and Lamar T. Gourdine, their two children, filed a Complaint for Wrongful Death and Survival Action and for Compensatory and Punitive Damages for Sale of a Defective Product, Fraud, Conscious Misrepresentation, Negligence and Breach of Warranty, in the Circuit Court for Prince George's County against Lilly, as well as a number of other individuals and companies who are not implicated in the present appeal. In the Complaint, Ms. Gourdine contended that, at the time of the accident, Ms. Crews suffered a hypoglycemic[7] reaction and experienced a "blackout" causing her to lose control of her vehicle.

Against Lilly, several theories of liability were posited, based upon Ms. Gourdine's

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[6] There is disagreement between the parties with respect to whether Ms. Crews's doctor directed Ms. Crews to cease taking her Humalog medication as prescribed. This discrepancy, however, for purposes of the ground upon which we decide this appeal, is immaterial.

[7] "Hypoglycemia" is a condition in which an individual exhibits "symptoms resulting from low blood glucose, which can be either autonomic or neuroglycopenic." *Stedman's Medical Dictionary* at 933. "Autonomic symptoms include sweating, trembling, feelings of warmth, anxiety, and nausea." *Id.* "Neuroglycopenic symptoms include feelings of dizziness, confusion, tiredness, difficulty speaking, headache, and inability to concentrate," *id.*, which can culminate with seizures and coma. *Id.* at 1310.

contention that the combination of Humalog and Humulin N caused increased rates of hypoglycemia, neuroglycopenia and drowsiness between 6 a.m. and noon and that Lilly knowingly failed to include a warning of such possibilities in its labeling and advertising. In Count 1, "strict liability in tort for sale of a misbranded drug with false and misleading advertising and labeling," Ms. Gourdine alleged that the Humalog label at the time it was sold was "false and misleading" because "it boast[ed] on one hand that patients such as Defendant Crews, who had Type I diabetes, had fewer hypoglycemic episodes between midnight and 6 a.m. while on the other hand ignoring the fact that most episodes with both of the constituent insulins contained in the Humalog mixtures tested occurred during mid-day and that a substantial number of the hypoglycemic reactions experienced by type I diabetics occurred without warning at mid-day." Ms. Gourdine alleged that Lilly owed a duty to her husband, as follows:

> 77. At all times relevant hereto, Defendant Lilly had a duty imposed by statute and the common law to warn users of the drug Humalog of the risks to which the drug as compounded and its constituent drugs exposed persons who consumed them.
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> 78. Decedent Isaac J. Gourdine, as a user of the highway, was in the class of persons the statute and regulations of the FDA that Lilly violated intended to protect.
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> 79. Defendant Lilly, therefore, owed a duty to protect users of the highway from drivers suffering from hypoglycemia induced by Defendant Lilly's misbranded drug.
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> 80. It was foreseeable that a Type I diabetic suffering from neuroglycopenia caused by hypoglycemia would cause injury and death to third persons while operating a motor vehicle on a

> highway if the diabetic was not warned of the period of greatest vulnerability for drowsy driving. Such information would enable Type I diabetics to take proper precautions before operating an automobile during this period of maximum vulnerability for drowsiness.

In Count 2, "negligent failure to warn of dangers associated with the use of the drug Humalog as directed," Ms. Gourdine alleged, similarly, that "Lilly breached its duty by failing to warn consumers that a high percentage of Type I diabetics were at greatly increased risk of drug-induced hypoglycemia, neuroglycopenia and drowsiness at mid-day"; with respect to the duty violated by Lilly, Ms. Gourdine repeated:

> 86. At all times relevant hereto, Defendant Lilly had a duty imposed by statute and the common law to warn users of the drug Humalog of the risks to which they were exposed by the drug as compounded and its constituent drugs.
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> 87. Decedent Isaac J. Gourdine, as a user of the highway, was in the class of persons the statute and regulations of the FDA that defendant Lilly violated intended to protect.

In Count 3, "conscious misrepresentation and fraud," Ms. Gourdine alleged that "Lilly published, or caused to be published, . . . statements that failed to disclose that Humalog and the Humalog mixtures containing Humulin NPH tested were most likely to be associated with hypoglycemia and drowsiness at mid-day while boasting that Humalog was associated with lower nighttime hypoglycemia," that Lilly knew the statements to be untrue or that Lilly did not have proof that they were true, and that Ms. Crews and her physician "relied on Defendant Lilly's misrepresentations and Defendant Crews drove her automobile at mid-day without taking the proper precautions against undetected hypoglycemia and drowsiness,

resulting in the accident which killed Isaac J. Gourdine."

Lilly subsequently filed a motion for summary judgment, arguing that it was entitled to judgment as a matter of law because "Lilly did not owe a duty to warn Mr. Gourdine, who did not use or consume Lilly's insulin products," "Lilly made no representations to Mr. Gourdine, a non-user, and therefore essential elements of fraud are lacking," and that "without a basis to claim fraud, plaintiff's punitive damages claim fails." Lilly also contended that because the United States Food and Drug Administration ("FDA") approved the warnings for Lilly's insulin products, the "failure to warn claim is preempted as a matter of federal law."

Ms. Gourdine responded and asserted that Lilly owed a duty to Mr. Gourdine to adequately warn Ms. Crews about the risks of the combination of Humalog and Humulin N because it was foreseeable for Lilly that Ms. Crews, allegedly suffering an adverse reaction to the medications, would cause injury and death to third persons while she was operating a motor vehicle, when she had not been adequately warned about the dangers that allegedly were associated with the specified medications, citing *Valk Manufacturing Co. v. Rangaswamy*, 74 Md. App. 304, 537 A.2d 622 (1988), for the proposition that a cause of action in negligence and strict liability may be sustained by a bystander injured as a result of a defective product.

The Honorable Steven I. Platt of the Circuit Court for Prince George's County, after a hearing on the matter, granted Lilly's motion for summary judgment and subsequently filed

a memorandum opinion in which he determined that, "Plaintiffs have not raised any disputes as to material facts, and Defendant Eli Lilly is entitled to judgment as a matter of law, because Eli Lilly did not owe a duty to Mr. Gourdine, and because Plaintiffs' failure to warn claim is pre-empted by federal law." Judge Platt stated that "the issue is what duty is owed the public by a drug manufacturer in a failure to warn case," and concluded that under the "learned intermediary" doctrine,[8] no duty is owed to a non-patient:

> The existence of a legal duty is a question of law, to be decided by the court. *Doe v. Pharmacia & Upjohn Co., Inc.*, 388 Md. 407, 414, 879 A.2d 1088, 1092 (2005).
> In this case, the issue is what duty is owed the public by a drug manufacturer in a failure to warn case. With respect to prescription drugs, Maryland courts have adopted the "Learned Intermediary Rule," which states that a prescription drug manufacturer has a duty to warn **physicians** of potential risks associated with taking a drug, but does not have a duty to warn patients. *Hunt v. Hoffmann-LaRoche, Inc.*, 785 F. Supp. 547, 550 (D.Md. 1992). It follows that if a pharmaceutical manufacturer does not have a duty to give patients using their products warnings, they do not have a duty to warn the people with whom those patients interact.
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> Plaintiffs concede in their Memorandum of Points and Authorities in Opposition to Defendant's Motion for Summary Judgment that Eli Lilly had no duty to warn Mr. Gourdine

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[8] The "learned intermediary" doctrine "imposes on a manufacturer of prescription drugs or devices a duty to give adequate warnings to physicians, dentists, and other licensed health care professionals, including nurses, who may prescribe these products. Under the doctrine, a manufacturer which has adequately warned the physician, in almost every circumstance, has no duty to warn a patient." 2 Frank C. Woodside, III, *Drug Product Liability* Section 14.02[2] (2002).

directly. Instead they argue that it was foreseeable that not warning patients of an increased risk of hypoglycemia between 6 a.m. and 12 p.m. could cause people to suffer from hypoglycemia or neuroglycopenia, and if that occurred while the patient was driving a vehicle, that they could seriously injure other users of the road. Plaintiffs argue that this foreseeability extends a duty to users of the road and so to Mr. Gourdine. This Court declines to extend that duty to Eli Lilly.

Instead this trial court echoes what the Maryland Court of Appeals said in *Doe v. Pharmacia & Upjohn Co., Inc.*, 388 Md. 407, 879 A.2d 1088 (2005), "the imposition of a duty of care in this case would create an indeterminate class of potential plaintiffs." *Id.* at 421, 1096. In *Pharmacia & Upjohn*, the plaintiff was the wife of a laboratory technician who had contracted HIV from his employment in a laboratory. The Court held that the employer did not owe a duty to the wife, because that would create an indeterminate class of potential plaintiffs, including spouses, sexual partners, and then anyone the employee could possibly pass the disease onto. Certainly, if this were an indeterminate class of people, then expanding duty to users of the highway, as Plaintiffs strenuously urge this Court to do in the instant case, would create an equally large and amorphous indeterminate class of Plaintiffs.

Plaintiffs would have us interpret *Valk Mfg. Co. v. Rangaswamy* as authority to impose a liability on Eli Lilly on this case. *Id.*, 74 Md. App. 304, 537 A.2d 622 (1988). In *Rangaswamy*, the Court held that "bystanders . . . are protected under the doctrine of strict liability in tort. *Id.* at 323, 632. However, in the sentence immediately preceding, the *Rangaswamy* Court cited W. Keeton, *Prosser and Keeton on Torts* 704 (5th ed. 1984), to explain that the effect of an expanded duty to bystanders was to put "strict liability on the same footing as negligence, as to all foreseeable injuries." *Rangaswamy*, 74 Md. App. at 323, 537 A.2d 632. It is this Court's opinion in this case, that Eli Lilly did not owe a duty to Plaintiffs even in the negligence claim, and so *Rangaswamy* does not aid Plaintiffs in their strict liability claim.

(Footnote omitted) (emphasis in original).

Ms. Gourdine noted an appeal to the Court of Special Appeals, which affirmed in a reported opinion. *Gourdine v. Crews*, 177 Md. App. 471, 935 A.2d 1146 (2007). The intermediate appellate court concluded that the trial court did not err in granting Lilly's motion for summary judgment because "[Lilly] has no duty to warn a nonuser such as Gourdine" under the "learned intermediary" doctrine:

> With respect to prescription drugs, "Maryland law recognizes the 'learned intermediary' doctrine, which provides that manufacturers need only warn the prescribing physician and not the patient directly." *Ames v. Apothecon, Inc.*, 431 F. Supp. 2d 566, 572 (D.Md. 2006); *see also Nolan v. Dillon*, 261 Md. 516, 523 (1971). Stated alternatively, under the learned intermediary doctrine, the manufacturer of a prescription drug has no duty to directly warn patients. Diane S. Kane, Annotation, CONSTRUCTION AND APPLICATION OF LEARNED-INTERMEDIARY DOCTRINE, 57 A.L.R. 5th 1 (1998). It follows, therefore, that since there is no duty on the part of prescription drug manufacturers to directly warn users of the drug of possible adverse effects, the manufacturer has no duty to warn a nonuser such as Gourdine. *See Kirk v. Michael Reese Hosp. & Med. Ctr.*, 513 N.E.2d 387, 393 (Ill. 1987) (applying the learned intermediary doctrine and holding that drug manufacturers owed no duty to warn a third party who was injured by a patient using their products).

Id. at 478-79, 935 A.2d at 1150 (footnote omitted). The court also opined that even if Lilly's warnings were inadequate, the injuries to Mr. Gourdine were not foreseeable:

> Appellants nonetheless maintain that it was foreseeable that failing to warn patients of an increased risk of hypoglycemia between 6 a.m. and 12 p.m. could cause them to suffer from hypoglycemia, and if that occurred while a patient was driving a vehicle, that the patient could seriously injure other users of the road. According to appellants, the foreseeability of the injuries here at issue extended a duty to warn all users of the

> road and, thus, Gourdine.
>
> Appellants correctly state that "liability for injuries which are foreseeable resulting from a defective product extends to bystanders who are put in peril by the defect." *See e.g. Valk Mfg. Co. v. Rangaswamy*, 74 Md. App. 304, 322-23 (1988), *rev'd on other grounds sub nom. Montgomery County v. Valk Mfg. Co.*, 317 Md. 185 (1989). Even assuming, *arguendo*, that the warnings rendered about the drugs were defective, the injuries sustained by Gourdine were not reasonably foreseeable. It cannot be said that Lilly should have reasonably foreseen that Crews, with her history of hypoglycemia, would ignore her doctor's orders to discontinue her morning insulin, drive a car, suffer a hypoglycemic episode, lose control of her car, strike Gourdine's car, push it into the back of an illegally parked tractor-trailer, and fatally injure Gourdine. Indeed, to impose a duty on Lilly in these circumstances "would create an indeterminate class of potential plaintiffs." *Pharmacia & Upjohn Co.*, *supra*, 388 Md. at 421.

Id. at 479, 935 A.2d at 1150-51.

Ms. Gourdine filed a petition for certiorari, which we granted. *Gourdine v. Crews*, 403 Md. 612, 943 A.2d 1244 (2008).

II. Standard of Review

The entry of summary judgment is governed by Maryland Rule 2-501, which provides in pertinent part:

> **Entry of judgment.** The court shall enter judgment in favor of or against the moving party if the motion and response show that there is no genuine dispute as to any material fact and that the party in whose favor judgment is entered is entitled to judgment as a matter of law.

Maryland Rule 2-501 (f).

In considering a trial court's grant of a motion for summary judgment, this Court

reviews the record in the light most favorable to the non-moving party. *Anderson v. Council of Unit Owners of Gables on Tuckerman Condominium*, 404 Md. 560, 570-71, 948 A.2d 11, 18 (2008); *Rodriguez v. Clarke*, 400 Md. 39, 926 A.2d 736 (2007); *Rhoads v. Sommer*, 401 Md. 131, 148, 931 A.2d 508, 518 (2007) ("We review the record in the light most favorable to the non-moving party and construe any reasonable inferences that may be drawn from the facts against the moving party."); *Harford County v. Saks*, 399 Md. 73, 82, 923 A.2d 1, 6 (2007) (In reviewing a trial court's decision on a motion for summary judgment, "we seek to determine whether any material facts are in dispute and, if they are, we resolve them in favor of the non-moving party."); *Lovelace v. Anderson*, 366 Md. 690, 695, 785 A.2d 726, 728 (2001) (In reviewing a grant of the defendants' motions for summary judgment, "we must review the facts, and all inferences therefrom, in the light most favorable to the plaintiffs."). If no material facts are in dispute, this Court must determine whether the Circuit Court correctly entered summary judgment as a matter of law. *Anderson*, 404 Md. at 571, 948 A.2d at 18; *Rodriguez*, 400 Md. at 70, 926 A.2d at 754; *Saks*, 399 Md. at 82, 923 A.2d at 6; *Property and Casualty Ins. Guaranty Corp. v. Yanni*, 397 Md. 474, 480-481, 919 A.2d 1, 5 (2007); *Standard Fire Ins. Co. v. Berrett*, 395 Md. 439, 451, 910 A.2d 1072, 1079 (2006). On appeal from an order entering summary judgment, we review "only the grounds upon which the trial court relied in granting summary judgment." *Rodriguez*, 400 Md. at 70, 926 A.2d at 754, quoting *Standard Fire*, 395 Md. at 450, 910 A.2d at 1079; *Eid v. Duke*, 373 Md. 2, 10, 816 A.2d 844, 849 (2003), quoting *Lovelace*, 366 Md. at 695, 785 A.2d at 729.

III. Analysis

Undergirding the grant of summary judgment in this case is the Circuit Court's decision that Lilly did not owe a duty of care to Mr. Gourdine based upon foreseeability that an accident could occur after the ingestion of the specific medications while Ms. Crews was operating a motor vehicle; Ms. Gourdine, of course, disagrees and asserts that the "learned intermediary" doctrine, upon which the trial court and the Court of Special Appeals relied, is inapplicable and that Lilly, in fact, owed a duty to Mr. Gourdine to warn Ms. Crews about the risks of the combination of Humalog and Humulin N because it was foreseeable that inadequate warnings could result in injuries or death to members of the motoring public when Ms. Crews was driving. Ms. Gourdine argues that this duty arises from the common law because the failure to warn Ms. Crews put Mr. Gourdine, a foreseeable victim, in peril. Ms. Gourdine compares this case to those in which liability is imposed on a car manufacturer for injuries caused to third-party bystanders resulting from product defects, relying upon *Valk Manufacturing Co. v. Rangaswamy*, 74 Md. App. 304, 537 A.2d 622 (1988). She also relies on out-of-state cases in which liability was imposed on doctors for injuries sustained by a bystander when the doctor failed to adequately warn the patient about the risks of driving while taking certain medications, citing *Taylor v. Smith*, 892 So.2d 887 (Ala. 2004); *McKenzie v. Hawai'i Permanente Medical Group, Inc.*, 47 P.3d 1209 (Haw. 2002); and *Kaiser v. Suburban Transportation System*, 398 P.2d 14, *modified*, 401 P.2d 350 (Wash. 1965). Ms. Gourdine also argues that the duty is imposed upon Lilly by statute, specifically

the Federal Food, Drug and Cosmetic Act ("FDCA" or "the Act"), which prohibits drug manufacturers from placing a misbranded product into interstate commerce. With respect to her fraud claim, Ms. Gourdine contends that Lilly knowingly published untrue statements about the dangers and risks associated with Humalog and Humulin N, that Ms. Crews and her physician relied on these misrepresentations, and that liability for these statements extends to Mr. Gourdine because his death was foreseeable.

Lilly, conversely, asserts that the Circuit Court and Court of Special Appeals correctly applied the "learned intermediary" doctrine and further argues that no duty was owed to Mr. Gourdine because foreseeability, by itself, is insufficient to create a legally cognizable duty, and because there was no connection between Lilly's allegedly tortious act and Mr. Gourdine's death. Additionally, Lilly contends that this case is different from those involving car manufacturers' liability for injuries directly caused to bystanders because those cases involved manufacturing and design defect claims, rather than failure to warn claims as in the instant case. Likewise, Lilly distinguishes the out-of-state cases that imposed liability on doctors for injuries caused to bystanders because those courts have adopted an interpretation of duty contrary to Maryland law. Lilly also argues that the FDCA does not establish a duty owed by Lilly to Mr. Gourdine because the Act's purpose is to protect the public health generally rather than any specific class of individuals. Lilly contends, with respect to the fraud claim, that the Circuit Court correctly granted summary judgment because there was no duty owed by Lilly to Mr. Gourdine.

A. Failure to Warn Claims – Negligence and Strict Liability

In Counts 1 and 2, negligence and strict liability, Ms. Gourdine alleges that Lilly owed a duty to Mr. Gourdine to warn Ms. Crews about the risks of the combination of Humalog and Humulin N.

"The negligence count of a products liability claim comports with longstanding common law tort principles," *Nissen Corp. v. Miller*, 323 Md. 613, 619, 594 A.2d 564, 567 (1991), and the injured party must allege "(1) that the defendant was under a duty to protect the plaintiff from injury, (2) that the defendant breached that duty, (3) that the plaintiff suffered actual injury or loss, and (4) that the loss or injury proximately resulted from the defendant's breach of the duty." *Doe v. Pharmacia & Upjohn Co., Inc.*, 388 Md. 407, 414, 879 A.2d 1088, 1092 (2005); *Dehn v. Edgecombe*, 384 Md. 606, 619, 865 A.2d 603, 611 (2005); *Horridge v. St. Mary's County Dept. of Soc. Services*, 382 Md. 170, 182, 854 A.2d 1232, 1238 (2004); *Patton v. USA Rugby*, 381 Md. 627, 635-36, 851 A.2d 566, 570 (2004). We acknowledged that duty to warn can undergird a negligence case in *Twombley v. Fuller Brush Co.*, 221 Md. 476, 158 A.2d 110 (1960), a product liability action against a supplier of spot remover, and later refined the concept in *Moran v. Faberge, Inc.*, 273 Md. 538, 543-44, 332 A.2d 11, 15 (1975) (citations omitted), in which we stated,

> that a manufacturer's duty to produce a safe product, with appropriate warnings and instructions when necessary, is no different from the responsibility each of us bears to exercise due care to avoid unreasonable risks of harm to others. Whether any such unreasonable risk exists in a given situation depends on balancing the probability and seriousness of harm, if care is not

> exercised, against the costs of taking appropriate precautions. However, we observe that in cases such as this the cost of giving an adequate warning is usually so minimal, amounting only to the expense of adding some more printing to a label, that this balancing process will almost always weigh in favor of an obligation to warn of latent dangers, if the manufacturer is otherwise required to do so.

We also adopted Section 388 of the Restatement (Second) of Torts (1965), "Chattel Known to be Dangerous for Intended Use," as "a general principle in the duty to warn area":

> One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier
> (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and
> (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and
> (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Moran, 273 Md. at 543-44, 332 A.2d at 15. In *Moran*, a products liability action against a cologne manufacturer alleging negligent failure to warn of concealed dangers, we recognized a framework for analysis in negligent failure to warn cases:

> Based on this negligence law we think that in the products liability domain a duty to warn is imposed on a manufacturer if the item it produces has an inherent and hidden danger about which the producer knows, or should know, could be a substantial factor in bringing injury to an individual or his property when the manufacturer's product comes near to or in contact with the elements which are present normally in the environment where the product can reasonably be expected to be

brought or used.

Id. at 552, 332 A.2d at 20.[9]

This framework substantially mirrors that of a strict liability action, which was defined by Judge John C. Eldridge, writing for this Court, in *Phipps v. General Motors Corp*., 278 Md. 337, 341, 363 A.2d 955, 957 (1976). In *Phipps*, Judge Eldridge adopted Section 402A of the Restatement (Second) of Torts (1965),

> Special Liability of Seller of Product for Physical Harm to User or Consumer
>
> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
> (a) the seller is engaged in the business of selling such a product, and
> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
> (2) The rule stated in Subsection (1) applies although
> (a) the seller has exercised all possible care in the preparation and sale of his product, and
> (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

and summarized the elements of an action in strict liability:

> The essential elements of an action in strict liability are set forth in § 402A. For recovery, it must be established that (1) the product was in defective condition at the time that it left the

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[9] In *Moran v. Faberge, Inc*., 273 Md. 538, 544-50, 332 A.2d 11, 15-19 (1975), we also addressed the knowledge component in negligent failure to warn cases, which is not an issue before us. *See also Eagle-Picher Industries, Inc. v. Balbos*, 326 Md. 179, 195-204, 604 A.2d 445, 452-57 (1992).

> possession or control of the seller, (2) that it was unreasonably dangerous to the user or consumer, (3) that the defect was a cause of the injuries, and (4) that the product was expected to and did reach the consumer without substantial change in its condition. However, in an action founded on strict liability in tort, as opposed to a traditional negligence action, the plaintiff need not prove any specific act of negligence on the part of the seller. The relevant inquiry in a strict liability action focuses not on the conduct of the manufacturer but rather on the product itself.

Id. at 344, 363 A.2d at 958. Judge Eldridge went on to explain that "the theory of strict liability is not a radical departure from traditional tort concepts" and that:

> Despite the use of the term "strict liability," the seller is not an insurer, as absolute liability is not imposed on the seller for any injury resulting from the use of his product. Proof of a defect in the product at the time it leaves the control of the seller implies fault on the part of the seller sufficient to justify imposing liability for injuries caused by the product.

Id. at 351-52, 363 A.2d at 963. *See also Harig v. Johns-Manville Products Corp.*, 284 Md. 70, 84, 394 A.2d 299, 306-07 (1978) ("[T]he major distinction between an action in strict liability in tort and one founded on traditional negligence theory relates to the proof which must be presented by the plaintiff.").

In *Owens-Illinois, Inc. v. Zenobia*, 325 Md. 420, 601 A.2d 633 (1992), we addressed the issue of whether the seller's knowledge of a defect, or lack thereof, would affect liability. Judge Eldridge, again writing for this Court, noted that most courts addressing the issue require knowledge of defect, as elucidated in Comment j of the Restatement Section 402A:

> Comment j explains that "the seller is required to give warning against [the danger], if he has knowledge, or by the application

> of reasonable, developed human skill and foresight should have knowledge, of the . . . danger." The comment goes on to distinguish a product containing an adequate warning from a defective product, stating: "a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous.
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>
> [T]he majority of courts which have considered a failure to warn case in the context of strict liability have either expressly or implicitly held that a manufacturer of a product, which is defective only because of the lack of an adequate warning, is not liable when the failure to warn resulted from an absence of knowledge of the dangerous quality of that product.
> Moreover, the courts reason, the presence of the required knowledge can be established by evidence that the dangerous quality of the product should have been known by a manufacturer because it was known in the scientific or expert community.
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> * * *
>
> Consequently, in a failure to warn case governed by the Restatement § 402A and Comment j, negligence concepts to some extent have been grafted onto strict liability. In such cases, a majority of courts hold that an element of knowledge or "state of the art" evidence is directly pertinent to a cause of action under § 402A of the Restatement (Second) of Torts, and liability is no longer entirely "strict.

Id. at 433-35, 601 A.2d at 640-41. Judge Eldridge also reflected that our adoption of Section 402A in the *Phipps* case included the knowledge element of its Comment j. *Id.* at 438 n.8, 601 A.2d at 641 n.8.[10]

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[10] In *Owens-Illinois, Inc. v. Zenobia*, 325 Md. 420, 438 n.8, 601 A.2d 633, 641 (continued...)

We have recognized, therefore, that negligence concepts and those of strict liability have "morphed together," as a result, in failure to warn cases. *See ACandS, Inc. v. Asner*, 344 Md. 155, 168, 686 A.2d 250, 256 (1996), quoting *Owens-Illinois, Inc.*, 325 Md. at 435 n.7, 601 A.2d at 640 n.7 (1992) ("Consequently, in a failure to warn case governed by the Restatement § 402A and Comment j, negligence concepts to some extent have been grafted onto strict liability."); *Phipps*, 278 Md. at 351, 363 A.2d at 963 (1976) ("Thus, the theory of

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[10](...continued)
n.8 (1992), we stated:

> Comment j of § 402A is applicable to a strict liability cause of action where the alleged defect is a failure to give adequate warnings. Therefore, the seller is not strictly liable for failure to warn unless the seller has "knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of the presence of the . . . danger." Moreover, we agree with the numerous cases holding that, for purposes of the "should have knowledge" component of comment j, a manufacturer of a product is held to the knowledge of an expert in the field.
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> * * *
>
> we agree . . . that the knowledge or state of the art component is an element to be proven by the plaintiff. In a strict liability failure to warn case, the alleged defect is the failure of the seller to give an adequate warning. The seller, however, need not give any warning if the requisite state of the art or knowledge does not require it. Thus, where a product lacks a warning because of insufficient knowledge on the part of the manufacturer or in the scientific field involved, the product is not defective. As defectiveness is an element to be proven by the plaintiff, the knowledge or state of the art component is not an affirmative defense.

strict liability is not a radical departure from traditional tort concepts."); *Mazda Motor of Am., Inc. v. Rogowski*, 105 Md. App. 318, 325, 659 A.2d 391, 394, *cert. denied*, 340 Md. 501, 667 A.2d 342 (1995) ("Certainly, it is true that a strict liability claim based on failure to warn bears a strong resemblance to a claim of negligence. Concepts of duty, breach, causation, and damages are present in both.").[11] Duty, thus, is an essential element of both negligence and strict liability causes of action for failure to warn.

Seminally, however, we note our divergence from the duty analyses of the trial court and the Court of Special Appeals, because both relied on the "learned intermediary" doctrine, with citation to *Nolan v. Dillon*, 261 Md. 516, 523, 276 A.2d 36, 40 (1971), to determine that Lilly did not owe a duty to Mr. Gourdine. In *Nolan*, a negligence and breach of warranty action, this Court was faced with the question of "whether the warnings which American Home gave regarding the use of Sparine were adequate" to warn of possible venous thrombosis or arteriolar spasm; the package insert contained a warning that use of the drug

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[11] In *Owens-Illinois, Inc.*, 325 Md. at 435 n.7, 601 A.2d at 640 n.7, we noted one difference in the role of contributory negligence:

> We note that despite the overlap of negligence principles in a strict liability failure to warn case, strict liability differs from a negligence cause of action in that contributory negligence is not a defense to a strict liability claim. *Ellsworth v. Sherne Lingerie, Inc.*, 303 Md. 581, 597-598, 495 A.2d 348, 356-357 (1985). In addition, in light of the other comments to § 402A of the Restatement (Second) of Torts, which apply in defective design, defective construction, and failure to warn cases, there are some differences between a negligent failure to warn case and a failure to warn based upon § 402A and Comment j.

"has resulted in localized thrombophlebitis or vascular spasm of digital vessels." In answering the question, we analyzed the reasonableness of the written warnings, without adopting the "learned intermediary" doctrine, *id.* at 523, 276 A.2d at 40; that case clearly lacks the express adoption of the "learned intermediary" doctrine undertaken by other courts. *See e.g. Stone v. Smith, Kline & French Labs.*, 447 So.2d 1301, 1303 (Ala. 1984); *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1200 (Alaska 1992); *West v. Searle & Co.*, 806 S.W.2d 608, 614 (Ark. 1991); *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973); *Vitanza v. Upjohn Co.*, 778 A.2d 829, 835 (Conn. 2001); *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 400 (Del. 1989); *Felix v. Hoffmann-LaRoche, Inc.*, 540 So.2d 102, 104 (Fla. 1989); *McCombs v. Synthes*, 587 S.E.2d 594, 595 (Ga. 2003); *Kirk v. Michael Reese Hosp. & Med. Ctr.*, 513 N.E.2d 387, 393 (Ill. 1987); *Humes v. Clinton*, 792 P.2d 1032 (Kan. 1990); *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 770 (Ky. 2004); *Wyeth Labs., Inc. v. Fortenberry*, 530 So.2d 688, 691 (Miss. 1988); *Hill v. Squibb & Sons, E. R.*, 592 P.2d 1383, 1387-88 (Mont. 1979); *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 842 (Neb. 2000); *Niemiera by Niemiera v. Schneider*, 555 A.2d 1112, 1117 (N.J. 1989); *Martin v. Hacker*, 628 N.E.2d 1308, 1311 (N.Y. 1993); *Seley v. G.D. Searle & Co.*, 423 N.E.2d 831 (Ohio 1981); *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 431 (Tenn. 1994). The "learned intermediary" doctrine, thus, is not an issue that we need to explore in the present case.

Duty Under Common Law

Ms. Gourdine argues that it was foreseeable for Lilly that Ms. Crews, concededly

suffering an adverse reaction to the medications, would cause injury and death to third persons while she was operating a motor vehicle, when she had not been adequately warned about the dangers that allegedly were associated with the specified medications, and that such foreseeability created a duty to Mr. Gourdine.

With respect to determining whether a duty exists, "we often have recourse to the definition in W. Page Keeton, et al., *Prosser and Keeton on The Law of Torts* § 53 (5th ed. 1984), which characterizes 'duty' as 'an obligation, to which the law will give recognition and effect, to conform to a particular standard of conduct toward another.'" *Patton*, 381 Md. at 636-37, 851 A.2d at 571. *See also Pendleton v. State*, 398 Md. 447, 461, 921 A.2d 196, 204-05 (2007); *Pharmacia & Upjohn*, 388 Md. at 415, 879 A.2d at 1092; *Dehn*, 384 Md. at 619, 865 A.2d at 611; *Horridge*, 382 Md. at 182, 854 A.2d at 1239. At its core, the determination of whether a duty exists represents a policy question of whether the specific plaintiff is entitled to protection from the acts of the defendant. *See Pendleton*, 398 Md. at 461, 921 A.2d at 205; *Rosenblatt v. Exxon*, 335 Md. 58, 77, 642 A.2d 180, 189 (1994) (stating that "ultimately, the determination of whether a duty should be imposed is made by weighing the various policy considerations and reaching a conclusion that the plaintiff's interests are, or are not, entitled to legal protection against the conduct of the defendant"); *Ashburn v. Anne Arundel County*, 306 Md. 617, 627, 510 A.2d 1078, 1083 (1986), quoting Keeton et al., *Prosser and Keeton on the Law of Torts* at Section 53 (commenting that duty "is only an expression of the sum total of those considerations of policy which lead the law

to say that the plaintiff is entitled to protection").

We recently discussed the nature of duty and foreseeability in *Patton*, 381 Md. at 637, 851 A.2d at 571 (citations omitted), in which Judge Glenn T. Harrell, Jr., writing for this Court, stated:

> Where the failure to exercise due care creates risks of personal injury, "the principal determinant of duty becomes foreseeability." The foreseeability test "is simply intended to reflect current societal standards with respect to an acceptable nexus between the negligent act and the ensuing harm." In determining whether a duty exists, "it is important to consider the policy reasons supporting a cause of action in negligence. The purpose is to discourage or encourage specific types of behavior by one party to the benefit of another party." "While foreseeability is often considered among the most important of these factors, its existence alone does not suffice to establish a duty under Maryland law."

See also Remsburg v. Montgomery, 376 Md. 568, 583, 831 A.2d 18, 26 (2003); *Valentine v. On Target, Inc.*, 353 Md. 544, 551, 727 A.2d 947, 950 (1999) (noting that "not all foreseeable harm gives rise to a duty; there are other factors to consider"); *Jacques v. First Nat'l Bank of Maryland*, 307 Md. 527, 535, 515 A.2d 756, 760 (1986). As we clarified in *Ashburn*:

> [t]he fact that a result may be foreseeable does not itself impose a duty in negligence terms. This principle is apparent in the acceptance by most jurisdictions and by this Court of the general rule that there is no duty to control a third person's conduct so as to prevent personal harm to another, unless a "special relationship" exists either between the actor and the third person or between the actor and the person injured.

306 Md. at 628, 510 A.2d at 1083 (citations omitted). *See also Scott v. Watson*, 278 Md.

160, 166, 359 A.2d 548, 552 (1976) ("[A] private person is under no special duty to protect another from criminal acts by a third person, in the absence of statutes, or of a special relationship.").[12]

Duty requires a close or direct effect of the tortfeasor's conduct on the injured party. This close and direct effect has been acknowledged by Prosser and Keeton:

> "The rule that you are to love your neighbor becomes in law, you must not injure your neighbor; and the lawyer's question, Who is my neighbor? receives a restricted reply. You must take reasonable care to avoid acts or omissions which you can reasonably foresee would be likely to injure your neighbor. Who, then, in law is my neighbor? The answer seems to be **persons who are so closely and directly affected by my act** that I ought reasonably to have them in contemplation as being so affected when I am directing my mind to the acts or omissions which are called in question."

Keeton et al., *Prosser and Keeton on the Law of Torts* at Section 53, quoting *Donoghue v. Stevenson*, 1 Q.B. 491 (1893) (emphasis added).

In *Dehn*, 384 Md. at 626, 865 A.2d at 615, we recently had occasion to describe the importance of the close and direct connection between conduct and the injury, again quoting Keeton et al., *Prosser and Keeton on the Law of Torts* at Section 41 (emphasis added):

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[12] We have held that the creation of a "special duty" through a "special relationship" between the parties can be established either by "(1) the inherent nature of the relationship between the parties; or (2) by one party undertaking to protect or assist the other party, and thus often inducing reliance upon the conduct of the acting party." *Doe v. Pharmacia & Upjohn Co., Inc.*, 388 Md. 407, 419 n.3, 879 A.2d 1088, 1095 n.3 (2005); *Remsburg v. Montgomery*, 376 Md. 568, 589-590, 831 A.2d 18, 30 (2003). Special relationship, nevertheless, is not an issue in the present case.

> "As a practical matter, legal responsibility must be limited to those causes which are so closely connected with the result and of such significance that the law is justified in imposing liability. Some boundary must be set to liability for the consequences of any act, upon the basis of some social idea of justice or policy. **This limitation is to some extent associated with the nature and degree of the connection in fact between the defendant's acts and the events of which the plaintiff complains.** Often to greater extent, however, the legal limitation on the scope of liability is associated with policy-with our more or less inadequately expressed ideas of what justice demands. . . ."

In that case, we considered whether a physician owed a duty to a patient's wife, who became pregnant following the patient's failed vasectomy, when the wife was not the doctor's patient and did not have any contact with the doctor. The wife asserted that a duty was owed by the physician to the wife because it was foreseeable that negligence in the execution and post-surgical follow-up of her husband's vasectomy would result in her pregnancy. We stated that foreseeability alone was not sufficient to establish a duty, as well as the fact that the wife could not have relied on the doctor's advice and instructions to her husband because the doctor had not performed the vasectomy or provided post-operative care and the doctor had never met the wife prior to trial. We concluded that under the circumstances of the case, the doctor did not owe a duty of care to the wife:

> A duty of care does not accrue purely by virtue of the marital status of the patient alone; some greater relational nexus between doctor and patient's spouse must be established, if it can be established at all, and here it was not. A duty of care to a non-patient is not one which Maryland law is prepared to recognize under these circumstances. The imposition of a common law duty upon Dr. Edgecombe to the wife under these circumstances could expand traditional tort concepts beyond

> manageable bounds. The rationale for extending the duty would apply to all potential sexual partners and expand the universe of potential plaintiffs. . . . Based on these rationales alone, a family practitioner who ostensibly provides after-care following a sterilization procedure performed by another physician would owe a duty of care not just to the patient who underwent the operation but every sexual partner the patient encounters after the operation – a possibility the law does not countenance.

Id. at 626-27, 865 A.2d at 615.

In *Pharmacia & Upjohn*, 388 Md. at 407, 879 A.2d at 1088, we further confirmed the importance of a close and direct connection between the tortious act and effect. In *Pharmacia & Upjohn*, a husband, who became infected with HIV-2 while handling the virus in the course of his employment in a research laboratory, infected his wife after the two engaged in unprotected marital relations. The husband's employer had conducted tests to detect the existence of HIV-1, but did not inform the husband that a positive initial test result, followed by a subsequent negative, could indicate the existence of HIV-2. The wife argued that because it was foreseeable that she would contract the disease from her husband, the employer owed her a duty to inform her husband of the meaning of laboratory test results for his health and the implications for his future conduct. We concluded that the employer had no duty to the wife because "Ms. Doe had no relationship with Pharmacia. There is no assertion in the complaint that she was ever an employee of Pharmacia, that she had ever been tested for HIV or any other disease by Pharmacia, or that she had ever had any contact with Pharmacia." *Id.* at 420, 879 A.2d at 1095. We also explained that,

> Doe's proposed duty of care to her would create an expansive

> new duty to an indeterminate class of people. This Court has resisted the establishment of duties of care to indeterminate classes of people.
>
> The concern with recognizing a duty that would encompass an indeterminate class of people is that a person ordinarily cannot foresee liability to a boundless category of people. Additionally, we have noted that the imposition of a duty to an indeterminate class would make tort law unmanageable.
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> The imposition of a duty of care in this case would create an indeterminate class of potential plaintiffs. Doe portrays her proposed duty as limited to spouses. She claims that it was foreseeable that she would contract HIV while engaging in unprotected sex with her husband because it is foreseeable that a husband and wife will engage in sexual relations. Doe does not offer any legitimate reason to support a distinction between married plaintiffs and other plaintiffs. The rationale for imposing a duty of care to Ms. Doe could apply to all sexual partners of employees. The potential class to whom Pharmacia would owe a duty under Doe's theory is even greater than all sexual partners of its employees. It includes any person who could have contracted HIV-2 from the employee by any means. The law does not countenance the imposition of such a broad and indeterminate duty of care.

Id. at 420-21, 879 A.2d at 1095-96 (citations omitted). *See also Valentine*, 353 Md. at 555-56, 727 A.2d at 952 (concluding that a gun dealer owed no duty of care to the public to exercise reasonable care in the display and sale of handguns to prevent the theft and the illegal use of the handguns by others against third parties and noting "that a duty may exist to the public at large without any evidence of a relationship between the parties, is simply too foreign to our well-established jurisprudence to sufficiently advocate a different result than the one we have reached" and that "[t]he class of persons to whom a duty would be owed under these bare facts would encompass an indeterminate class of people"); *Village of Cross*

Keys, Inc. v. United States Gypsum Co., 315 Md. 741, 760, 556 A.2d 1126, 1135 (1989) (stating that no duty was owed between designer of brick veneer and steel-stud curtain wall system and condominium developer when the record revealed that the condominium developer did not follow the design offered; "that duty should extend to those who seek to challenge a system they have used, and not to those who do not").

In the case *sub judice*, there was no direct connection between Lilly's warnings, or the alleged lack thereof, and Mr. Gourdine's injury. In fact, there was no contact between Lilly and Mr. Gourdine whatsoever. To impose the requested duty from Lilly to Mr. Gourdine would expand traditional tort concepts beyond manageable bounds, because such duty could apply to all individuals who could have been affected by Mr. Crews after her ingestion of the drugs. Essentially, Lilly would owe a duty to the world, an indeterminate class of people, for which we have "resisted the establishment of duties of care." *Pharmacia & Upjohn*, 388 Md. at 407, 879 A.2d at 1088. *See also Dehn*, 384 Md. at 627, 865 A.2d at 615 ("The imposition of a common law duty upon Dr. Edgecombe to the wife under these circumstances could expand traditional tort concepts beyond manageable bounds."); *Valentine*, 353 Md. at 553, 727 A.2d at 951 ("One cannot be expected to owe a duty to the world at large to protect it against the actions of third parties, which is why the common law distinguishes different types of relationships when determining if a duty exists. The class of persons to whom a duty would be owed under these bare facts would encompass an indeterminate class of people, known and unknown."); *Village of Cross Keys*, 315 Md. at 744-45, 556 A.2d at 1127 (stating

that the claimed duty "generates the specter of 'liability in an indeterminate amount for an indeterminate time to an indeterminate class,' a liability that . . . continues to concern courts today").

Ms. Gourdine asserts, nevertheless, that Lilly's liability is analogous to a car manufacturer's liability for injuries to an innocent bystander resulting from a product defect, citing *Valk Manufacturing*, 74 Md. App. at 304, 537 A.2d at 622, *rev'd on other grounds sub nom*, *Montgomery County v. Valk Manufacturing Co.*, 317 Md. 185, 562 A.2d 1246 (1989). In *Valk Manufacturing*, Dr. Rangaswamy died as a result of an automobile accident in which he was struck by a dump truck on which a snow plow hitch arm protruded unsafely. The doctor's widow and minor child filed suit against the manufacturer of the snowplow hitch alleging negligence and strict liability for "defective design." A jury awarded the plaintiff's $2,500,000 on the strict liability count, and our intermediate appellate court affirmed the award. Addressing whether the plaintiffs could recover under the theory of strict liability in tort as a "bystander," the Court of Special Appeals noted that "[m]ost jurisdictions, when called upon to do so, have extended the strict liability doctrine to provide relief for bystanders . . . 'to put the strict liability on the same footing as negligence, as to all foreseeable injuries.'" *Id.* at 322, 537 A.2d at 631, quoting Keeton et al., *Prosser and Keeton on the Law of Torts* at Section 100. As a result, the intermediate appellate court was persuaded that "the all-important concept of legal duty" should allow recovery for strict liability to a third-party bystander. *Id.* at 322, 537 A.2d at 631. In *Valk Manufacturing*, however, the defective

product was directly involved in the accident and caused the decedent's injury. *See also Kelley v. R.G. Industries, Inc.*, 304 Md. 124, 158, 497 A.2d 1143, 1160 (1985) ("Saturday Night Special" case; "Finally, once the trier of facts determines that a handgun is a Saturday Night Special, then liability may be imposed against a manufacturer or anyone else in the marketing chain, including the retailer. Liability may only be imposed, however, when the plaintiff or plaintiff's decedent suffers injury or death because he is shot with the Saturday Night Special."). Here, however, there was no direct connection between the drugs and accompanying warnings and the decedent.

Ms. Gourdine, however, also attempts to draw support from cases from other jurisdictions in which she asserts the courts have held that a doctor's duty to warn his or her patient of the risks associated with medication prescribed extends to non-patients who are foreseeably at risk. *E.g., Taylor v. Smith*, 892 So.2d 887 (Ala. 2004) (director of outpatient methadone-treatment center owed duty of due care to a non-patient motorist who was injured in an automobile accident with the director's patient); *McKenzie v. Hawai'i Permanente Medical Group*, 47 P.3d 1209 (Haw. 2002) (physician owed duty to non-patient third party to warn patient that medication may affect patient's driving abilities); *Kaiser v. Suburban Transportation System*, 398 P.2d 14, *modified*, 401 P.2d 350 (Wash. 1965) (doctor owed duty to non-patient bus passenger to warn his patient, a bus driver, of the potential side effect of drowsiness in his medication).

We have not, however, historically embraced the belief that duty should be defined

mainly with regard to foreseeability, without regard to the size of the group to which the duty would be owed, which the Courts in Alabama, Hawai'i and Washington have. *See Havard v. Palmer & Baker Engineers, Inc.*, 302 So.2d 228, 232 (Ala. 1974) (concluding that engineering firm under a contract with the City of Mobile to inspect a tunnel owed a duty to third party "member[s] of the public using" the tunnel to reasonablely apprise the City of Mobile of the "condition of the fire-fighting equipment located in the [t]unnel"; "The ultimate test of the existence of a duty to use due care is found in the foreseeability that harm may result if care is not exercised."), *overruled on other grounds*, *Ex parte Insurance Co. of North America*, 523 So.2d 1064 (Ala. 1988); *Taylor-Rice v. State*, 979 P.2d 1086, 1097 (Haw. 1999) (passenger in car driven by intoxicated individual was injured when car struck guardrail and utility pole; iterating that State owed duty to passenger because the court has "repeatedly recognized a duty owed by all persons to refrain from taking actions that might foreseeably cause harm to others"); *Berglund v. Spokane County*, 103 P.2d 355, 359 (Wash. 1940) (determining that Spokane County owed duty to child who was struck by an automobile while walking on a county bridge; "Inherent in this definition [of duty] is the principle that the care required in a given instance must be commensurate with the risk of harm, or danger, to which others might be exposed by one's conduct.").

Rather, in *Dehn*, 384 Md. at 621-22, 865 A.2d at 612, we emphasized that ordinarily a physician does not owe a duty of care to non-patients and noted that "although the common law does not foreclose the possibility of imposing a duty of care in the absence of a doctor-

patient relationship to a third party who never received treatment from the doctor, it will not do so except under extraordinary circumstances" and that "[t]he imposition of a common law duty upon Dr. Edgecombe to the wife under these circumstances could expand traditional tort concepts beyond manageable bounds." *See also e.g. Gilhuly v. Dockery*, 615 S.E.2d 237, 239 (Ga. Ct. App. 2005) (patient who was involved in a car accident in which sons were injured filed suit on their behalf based on physician's alleged failure to warn patient not to drive after taking certain medications; the Court of Appeals of Georgia rejected the claims on behalf of the sons because "[t]o expand a doctor's duty to his patient to generally include members of the public at large in a case such as this one would be contrary to Georgia public policy"); *Lester ex rel. Mavrogenis v. Hall*, 970 P.2d 590, 597 (N.M. 1998) (holding that physician owed no duty non-patient injured in automobile accident with patient because the "consequences of placing a legal duty on physicians to warn may subject them to substantial liability even though their warnings may not be effective to eliminate the risk in many cases"); *Rebollal v. Payne*, 145 A.D.2d 617, 618 (N.Y. App. Div. 1988) ("There is no duty on the part of the operator of a methadone clinic to control the travel activities of a methadone patient giving rise to liability for accidents to a third party such as plaintiff's decedent."); *Praesel v. Johnson*, 967 S.W.2d 391, 398 (Tex. 1998) (stating that treating physicians do not owe a duty to third parties to warn epileptic patients not to drive, for purposes of negligence claims against physicians for failure to warn if patient has accident and injures third party during seizure; "Balancing both the need for and the effectiveness of

a warning to a patient who already knows that he or she suffers from seizures against the burden of liability to third parties, we conclude that the benefit of warning an epileptic not to drive is incremental but that the consequences of imposing a duty are great.").

Our conclusion that Lilly did not owe a duty to Mr. Gourdine also is buttressed by persuasive authority utilizing a duty analysis similar to ours, that of *Kirk v. Michael Reese Hospital & Medical Center*, 513 N.E.2d 387 (Ill. 1987). In *Kirk*, a driver, apparently because of undisclosed side effects of certain prescription drugs, lost control of his vehicle and collided with a tree, injuring a passenger. The passenger brought an action against the drug manufacturers, and others, alleging failure to warn based in negligence and strict liability. Before the Supreme Court of Illinois, the passenger asserted that his injuries were foreseeable and that "while the class of persons to whom the warning is required to be given may be very limited, the class of persons to whom the duty is owed includes the public generally." *Kirk*, 513, N.E.2d at 392. The court rejected this argument, determining that "foreseeability . . . is not intended to bring within the scope of the defendant's liability every injury that might possibly occur" and that the manufacturer of the prescription drug owed no duty to a "nonuser." *Id.* at 392-93. We agree.

Therefore, although there may be circumstances where foreseeability alone may give rise to liability to a third party because of policy reasons, this is not the case. We conclude that Lilly did not owe a duty to Mr. Gourdine.

Duty Under Statute

Ms. Gourdine, alternatively, argues that the duty between Lilly and Mr. Gourdine is prescribed by statute and refers us to the Federal Food, Drug and Cosmetic Act ("FDCA" or "the Act"), 21 U.S.C. Section 321, *et seq.*, which prohibits drug manufacturers from placing a misbranded product into interstate commerce.

A duty may be established by statute "'when the plaintiff is a member of the class of persons the statute was designed to protect and the injury was of the type the statute was designed to prevent.'" *Pendleton*, 398 Md. at 466, 921 A.2d at 207, quoting *Remsburg*, 376 Md. at 584, 831 A.2d at 27; *Erie Ins. Co. v. Chops*, 322 Md. 79, 84, 585 A.2d 232, 234 (1991). Furthermore, the statute must "set forth mandatory acts clearly for the protection of a *particular class* of persons rather than the public as a whole." *Id.*, quoting *Remsburg*, 376 Md. at 584, 831 A.2d at 27; *Ashburn*, 306 Md. at 635, 510 A.2d at 1087. *See also Polakoff v. Turner*, 385 Md. 467, 483, 869 A.2d 837, 847 (2005) ("To make out a prima facie case in a negligence action based on the breach of a statutory duty, a plaintiff must show "(a) the violation of a statute or ordinance designed to protect a specific class of persons which includes the plaintiff, and (b) that the violation proximately caused the injury complained of."); *Brooks v. Lewin Realty III, Inc.*, 378 Md. 70, 78, 835 A.2d 616, 620-21 (2003) ("Moreover, where there is an applicable statutory scheme designed to protect a class of persons which includes the plaintiff, another well-settled Maryland common law rule has long been applied by this Court in negligence actions. That rule states that the defendant's duty ordinarily 'is prescribed by the statute' or ordinance and that the violation of the statute

or ordinance is itself evidence of negligence.").

In *Horridge*, 382 Md. at 170, 854 A.2d at 1232, we considered whether the Department of Social Services ("DSS") statute created a duty to a child who had been the subject of many reported child abuse incidents; the statute at issue, Section 5-706 of the Family Law Article, Maryland Code (2003), required DSS, promptly after receiving a report of child abuse, to make a "thorough investigation" in order to protect the health, safety, and welfare of the child. DSS contended that the governing statute imposed upon it a duty to the public at large, and not to a particular class of individuals. We rejected this argument, recognizing that the statutory duties imposed "are far more specific and focused," and that "the statute makes clear in several places that the sole and specific objective of the requirement is the protection of a specific class of children – those identified in or identifiable from specific reports made to DSS and those also found in the home or in the care or custody of the alleged abuser. This is not an obligation that runs to everyone in general and no one in particular. It runs to an identified or identifiable child or discrete group of children." *Id.* at 189-90, 854 A.2d at 1243.

In contrast, in *Muthukumarana v. Montgomery County*, 370 Md. 447, 499-500, 805 A.2d 372, 403 (2002), we determined that the statutory duty imposed on 911 operators and supervisors to protect "the safety and well-being of the citizens of Maryland" was owed to the public at large rather than to an individual citizen, and in *Ashburn*, 306 Md. at 631, 510 A.2d at 1085, we noted that a police officer's statutory duty to follow certain procedures

when stopping or detaining a driver under suspicion of intoxication did not create a duty to a pedestrian injured by the drunk driver where the officer detected the driver's condition before the accident but failed to stop and detain him because the underlying concern of the statute was the safety of the public and not a particular class of persons. Also, in *Remsburg*, 376 Md. at 585, 831 A.2d at 28, we held that statutes regulating hunting licenses, hunting seasons, endangered species and the number and type of wildlife and game that may be hunted did not create a duty on the part of the leader of a hunting party to protect third parties from being shot by members of his hunting party because "[a]bsent from these statutes . . . is any mention of a duty placed upon a leader of a hunting party, by virtue of his or her position as such, to protect all other hunters or landowners from the negligent acts of members of his or her hunting party." Moreover, in *Lamb v. Hopkins*, 303 Md. 236, 253, 492 A.2d 1297, 1306 (1985), we concluded that probation officers who failed to seek the revocation of probation of an individual, although aware that the individual had committed a number of drunk driving offenses during the probationary period, owed no duty to the parents of a child severely injured by the probationer, because the officers' statutory duty to report violations to the court only was owed to the court.

Ms. Gourdine, nevertheless, alludes to the Act's prohibition of the placement of misbranded products into interstate commerce by drug manufacturers. *See* 21 U.S.C. Section 331 (a)-(b) ("The following acts and the causing thereof are prohibited: (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic

that is adulterated or misbranded. (b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce."); 21 U.S.C. Section 352 (a) (stating that a "drug or device shall be deemed to be misbranded . . . [i]f its labeling is false or misleading in any particular"). She also refers to several federal regulations prohibiting misleading advertising and requiring certain information to be disclosed. *See* 21 C.F.R. Section 201.56 (b) ("The labeling shall be informative and accurate and neither promotional in tone nor false or misleading in any particular."); *Id.* at Section 201.57 (f)(2) ("[T]he labeling shall contain the following subsections as appropriate for the drug: . . . (2) Information for patients. This subsection of the label shall contain information to be given to patients for safe and effective use of the drug, e.g., precautions concerning driving or the concomitant use of other substances that may have harmful additive effects."); *Id.* at Section 202.1 (e)(5)(ii)-(iii) ("An advertisement does not satisfy the requirement that it present a 'true statement' of information in brief summary relating to side effects, contradictions, and effectiveness if: (i) It is false or misleading with respect to side effects, contradictions, or effectiveness; or (ii) It fails to present a fair balance between information relating to side effects and contradictions and information relating to effectiveness of the drug . . . .").

These statutes and regulations, however, are framed to protect the public in general, *see United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798, 89 S.Ct. 1410, 1418, 22 L.Ed.2d 726 (1969) (noting that "the Act's overriding purpose [is] to protect the public health"), and, as we have heretofore stated, a statutory obligation which "runs to

everyone in general and no one in particular" cannot impose a duty between two parties. *Horridge*, 382 Md. at 190, 854 A.2d at 1243. Therefore, we decline to find that a statutory basis supports the imposition on duty on Lilly to Mr. Gourdine.

B. Fraud

Ms. Gourdine, in Count 3, asserts a claim based in fraud, alleging that Lilly knowingly published untrue statements about the dangers and risks associated with Humalog and Humulin N, that Ms. Crews and her physician relied on these misrepresentations, resulting in the accident that killed Mr. Gourdine. This claim was also resolved on the grant of summary judgment in favor of Lilly. Ms. Gourdine argues that because Lilly owed a duty to Mr. Gourdine, her fraud claim is viable, while Lilly, conversely, contends that the Circuit Court's decision was correct because there was no duty owed by Lilly to Mr. Gourdine, and regardless, there were no misrepresentations made to Mr. Gourdine.

To prevail on a claim for fraud, a plaintiff must show:

> (1) that the defendant made a false representation to the plaintiff, (2) that its falsity was either known to the defendant or that the representation was made with reckless indifference as to its truth, (3) that the misrepresentation was made for the purpose of defrauding the plaintiff, (4) that the plaintiff relied on the misrepresentation and had the right to rely on it, and (5) that the plaintiff suffered compensable injury resulting from the misrepresentation.

Maryland Env't Trust v. Gaynor, 370 Md. 89, 97, 803 A.2d 512 (2002); *VF Corp. v. Wrexham Aviation*, 350 Md. 693, 703, 715 A.2d 188, 192-93 (1998); *Nails v. S & R*, 334 Md.

398, 415, 639 A.2d 660, 668 (1994).[13] Each of these elements must be proven by clear and convincing evidence. *Gaynor*, 370 Md. at 97, 803 A.2d at 512; *VF Corp.*, 350 Md. at 703, 715 A.2d at 192-93; *Nails*, 334 Md. at 415, 639 A.2d at 668.

Clearly, in order to sustain a cause of action based on fraud or deceit, the defendant must have made a false representation **to the person defrauded**. *Hoffman v. Stamper*, 385 Md. 1, 867 A.2d 276 (2005); *Gaynor*, 370 Md. at 97, 803 A.2d at 512; *VF Corp.*, 350 Md. at 703, 715 A.2d at 192-93; *Nails*, 334 Md. at 415, 639 A.2d at 668. *In Bachrach v. Washington United Cooperative, Inc.*, 181 Md. 315, 29 A.2d 822 (1943), a corporation filed suit to set aside a foreclosure sale on the ground of fraud, alleging that the mortgagee's assignee acted with malice to harm the corporation. We rejected the corporation's arguments and dismissed the complaint, stating that "[w]here the loss to the complaining party was not caused by any breach of legal or equitable duty, it is damnum absque injuria," *id.* at 323, 29 A.2d at 826, or "[l]oss or harm that is incurred from something other than a wrongful act and occasions no legal remedy." Black's Law Dictionary (8th ed. 2004). In the case *sub judice*,

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[13] It has long been clear that "[f]raud may consist in a suppression of the truth as well as in the assertion of a falsehood." *Schnader v. Brooks*, 150 Md. 52, 57, 132 A. 381, 383 (1926). We described the elements of an action based on fraudulent concealment of material facts in *Green v. H & R Block, Inc.*, 355 Md. 488, 525, 735 A.2d 1039, 1059 (1999):

> (1) the defendant owed a duty to the plaintiff to disclose a material fact; (2) the defendant failed to disclose that fact; (3) the defendant intended to defraud or deceive the plaintiff; (4) the plaintiff took action in justifiable reliance on the concealment; and (5) the plaintiff suffered damages as a result of the defendant's concealment.

Lilly did not owe a duty to Mr. Gourdine;[14] moreover, Mr. Gourdine was not a party to the alleged misrepresentations made by Lilly to Ms. Crews. As a result, the Circuit Court did not err in entering summary judgment in Lilly's favor on the fraud claim.

IV. Conclusion

Therefore, we conclude that Lilly did not owe the requisite duty to Mr. Gourdine to sustain the negligence, strict liability and fraud claims asserted in the instant case, and thus, that the Circuit Court did not err in granting summary judgment in favor of Lilly.

JUDGMENT OF THE COURT OF SPECIAL APPEALS AFFIRMED. COSTS IN THIS COURT TO BE PAID BY PETITIONER.

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[14] Ms. Gourdine cites *Village of Cross Keys, Inc. v. United States Gypsum Co.*, 315 Md. 741, 566 A.2d 1126 (1989), and asserts that because Sections 310 and 311 of the Restatement (Second) of Torts, involving negligent misrepresentation threatening physical harm, impose liability for a misrepresentation to the benefit of a third-party, her fraud claim should survive summary judgment. This argument, however, fails to recognize that duty is a requisite element of the cause of action as we explained in *Village of Cross Keys, Inc.*, "'[l]iability in such cases arises only where there is a duty.'" *Id.* at 757, 566 A.2d at 1133, quoting *Int'l Prods. Co. v. Erie R. Co.*, 244 N.Y. 331, 155 N.E. 662, 664 (N.Y. 1927).

In the Circuit Court for Prince George's County
Case No. CAL 05-00480

IN THE COURT OF APPEALS
OF MARYLAND

No. 134

September Term, 2007

Mary Gourdine

v.

Ellen Crews, et. al.

Bell, C.J.
Harrell
Battaglia
Greene
Eldridge, John, C.
(Retired, specially assigned)
Raker, Irma, S.
(Retired, specially assigned)
Wilner, Alan, M.
(Retired, specially assigned),

JJ.

Concurring Opinion by Raker, J.

Filed: September 4, 2008

Raker, J., concurring:

I join the majority opinion hold that there is no duty of care owed to Mr. Gourdine by respondent, insulin manufacturer Eli Lilly and Company. I write separately to state that, in addition to the majority's reasoning, I would adopt the "learned intermediary" doctrine in Maryland.

The trial court based its hold, in part, on the learned intermediary doctrine. The Court of Special Appeals affirmed the trial court's grant of summary judgment, stating in relevant part as follows:

> "With respect to prescription drugs, 'Maryland law recognizes the 'learned intermediary' doctrine, which provides that manufacturers need only warn the prescribing physician and not the patient directly.' *Ames v. Apothecon, Inc.*, 431 F.Supp.2d 566, 572 (D. Md. 2006); *see also Nolan v. Dillon*, 261 Md. 516, 523, 276 A.2d 36 (1971). Stated alternatively, under the learned intermediary doctrine, the manufacturer of a prescription drug has no duty to directly warn patients. Diane S. Kane, Annotation, CONSTRUCTION AND APPLICATION OF LEARNED-INTERMEDIARY DOCTRINE, 57 A.L.R. 5th 1 (1998). It follows, therefore, that since there is no duty on the part of prescription drug manufacturers to directly warn users of the drug of possible adverse effects, the manufacturer has no duty to warn a nonuser such as Gourdine. *See Kirk v. Michael Reese Hosp. & Med. Ctr.*, 513 N.E.2d 387, 393 (1987) (applying the learned intermediary doctrine and holding that drug manufacturers owed no duty to warn a third party who was injured by a patient using their products)."

Gourdine v. Crews, 177 Md. App. 471, 478-79, 935 A.2d 1146, 1150 (2007) (footnote omitted).

In my view, the learned intermediary doctrine squarely addresses the issue of duty in this case and should be adopted as Maryland law. As described by the majority opinion in this case,

> "[t]he 'learned intermediary' doctrine 'imposes on a manufacturer of prescription drugs or devices a duty to give adequate warnings to physicians, dentists, and other licensed health care professionals, including nurses, who may prescribe these products. Under the doctrine, a manufacturer which has adequately warned the physician, in almost every circumstance, has no duty to warn a patient.' 2 Frank C. Woodside, III, *Drug Product Liability* Section 14.02[2] (2002)."

Gourdine v. Crews, __ Md. __, __, __ A.2d __, __ [slip. op. at 7 n.8] (2008). The United States Court of Appeals for Fifth Circuit explained the reasoning behind the learned intermediary doctrine as follows:

> We cannot quarrel with the general proposition that where *prescription* drugs are concerned, the manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use. This special standard for prescription drugs is an understandable exception to the Restatement's general rule that one who markets goods must warn forseeable ultimate users of dangers inherent in his products. *See Restatement (Second) of Torts*, Section 388 (1965). Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only

> the prescribing physician, who acts as a 'learned intermediary' between manufacturer and consumer."

Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1276 (5th Cir. 1974) (emphasis in original) (footnotes omitted).

As the majority notes, *id.* at __, __ A.2d at __ [slip op. at 20-21], most states addressing the issue of drug manufacturers' duty to warn have adopted the "learned intermediary" doctrine. *See, e.g., Stone v. Smith, Kline & French Labs.*, 447 So.2d 1301, 1304-05 (Ala. 1984); *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1200 (Alaska 1992); *West v. Searle & Co.*, 806 S.W.2d 608, 614 (Ark. 1991); *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973); *Vitanza v. Upjohn Co.*, 778 A.2d 829, 835 (Conn. 2001); *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 400 (Del. 1989); *Felix v. Hoffmann-LaRoche, Inc.*, 540 So.2d 102, 104 (Fla. 1989); *McCombs v. Synthes*, 587 S.E.2d 594, 595 (Ga. 2003); *Kirk v. Michael Reese Hosp. & Med. Ctr.*, 513 N.E.2d 387, 392 (Ill. 1987); *Humes v. Clinton*, 792 P.2d 1032, 1039 (Kan. 1990); *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 770 (Ky. 2004); *Wyeth Labs., Inc. v. Fortenberry*, 530 So.2d 688, 691 (Miss. 1988); *Hill v. Squibb & Sons, E. R.*, 592 P.2d 1383, 1387-88 (Mont. 1979); *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 842 (Neb. 2000); *Niemiera by Niemiera v. Schneider*, 555 A.2d 1112, 1117 (N.J. 1989); *Martin v. Hacker*, 628 N.E.2d 1308, 1311 (N.Y. 1993); *Seley v. G.D. Searle & Co.*, 423 N.E.2d 831 (Ohio 1981); *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 431 (Tenn.1994).

The learned intermediary doctrine is well established and provides a clear, straightforward and sensible resolution to the case *sub judice*. We should adopt it in Maryland.