[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

Nos. 01-15182 & 02-10332

D. C. Docket No. 99-00250-CV-GET-1

DONNA ELLIS, as guardian for Mary Ruth Brown,

Plaintiff-Appellant,

versus

C. R. BARD, INC. and
BAXTER HEALTHCARE CORPORATION,

Defendants-Appellees,

BAXTER INTERNATIONAL, INC., et. al.,

Defendants.

Appeals from the United States District Court
for the Northern District of Georgia

(November 12, 2002)

Before HULL, FAY and GIBSON[*], Circuit Judges.

PER CURIAM:

In this diversity case under Georgia law, plaintiff Donna Ellis alleges that the defendant manufacturers, C.R. Bard, Inc. ("Bard") and Baxter Healthcare Corporation ("Baxter"), are liable for her mother's brain damage because of their defective labeling and specifically their failure to warn adequately of the danger of having a person other than a doctor or patient activate the morphine pump that was prescribed for her mother. Ellis appeals the district court's order granting the defendants' summary judgment motions and denying her summary judgment motion. Ellis also appeals the district court's subsequent order denying her motion to reduce the costs awarded the defendants as prevailing parties. After review and oral argument, we affirm both of the district court's orders.

I. FACTS

The factual background in this case is largely undisputed. However, where disputes occur, we outline the facts in the light most favorable to the plaintiff.[1]

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[*]Honorable John R. Gibson, Circuit Judge for the Eighth Circuit, sitting by designation.

[1]"We review the district court's grant or denial of a motion for summary judgment de novo, viewing the record and drawing all reasonable inferences in the light most favorable to the non-moving party." Weeks v. Harden Mfg. Corp., 291 F.3d 1307, 1311 (11th Cir. 2002).

A. The Product

The product at issue is the Bard Ambulatory Patient Controlled Analgesia Infusion Pump (the "PCA pump"). The PCA pump is a medical device used to deliver analgesic drugs to patients. The PCA pump is regulated by the Food and Drug Administration and is available only by a doctor's prescription. A doctor typically prescribes the PCA pump for the relief of acute and chronic pain in patients.

The PCA pump is programmed pursuant to a doctor's orders. Those orders control the timing and the amount of the prescribed drug delivered into the patient upon activation. Once programmed, a patient can activate the PCA pump to deliver the prescribed amount of pain medication – here morphine – by pressing either a button on the pump itself or a button on the end of a cord plugged into the pump. When so activated, a dose of the prescribed pain medication is delivered to the patient, either intravenously or via epidural.

The PCA pump is designed so that the doctor can set the amount of drug delivered to the patient upon activation. The PCA pump also can be programmed to have a delay or "lock-out" period between doses. During that period, no drug will be delivered to a patient, even if the activation button is pressed.

It is well known in the medical community that, absent a doctor's specific orders, only the patient should activate the PCA pump.

B. The Incident

In 1997 Mary Ruth Brown, plaintiff's mother, was admitted to the Georgia Baptist Medical Center ("GBMC")[2] for bilateral knee replacement surgery. The day after her surgery, Brown complained of increasing pain. Dr. David Sherbert, the on-call anesthesiologist at GBMC, prescribed to Brown a PCA pump to facilitate the administration of morphine into Brown to help control her post-surgery pain.

A GBMC nurse, Lori Hamilton ("Nurse Hamilton") programmed the PCA pump pursuant to Dr. Sherbert's prescription. That prescription permitted 2 milligrams of morphine upon activation of the PCA pump. There was also a prescribed (1) lock-out period of 8 minutes between patient-activated doses and (2) maximum hourly dosage of 8 milligrams of morphine per hour.

Nurses at GBMC were not authorized to permit a third party to activate the PCA pump unless told to do so by a doctor. Nonetheless, on February 18, 1997, Nurse Hamilton, without a doctor's authorization, instructed one of Brown's

[2]The Georgia Baptist Medical Center is now known as the Atlanta Medical Center.

daughters, Debbie Guest, to press the PCA pump's activation button for Brown while she was sleeping so that she would not wake up in pain. According to Nurse Hamilton, she made this exception to the known general rule that only patients should activate the PCA pump because Brown appeared to be in great pain. Although Nurse Hamilton knew third-party activation could be dangerous, she did not tell Guest that there was any risk in having a third party activate the PCA pump.

That same day, Guest relayed Nurse Hamilton's instruction to Brown's other daughter, plaintiff Ellis. Ellis then pressed the PCA pump button once for Brown. Later that night, Guest also followed Nurse Hamilton's instructions and pressed the activation button. Guest continued to press the button for Brown while she slept through the night of February 18 and the early morning of February 19.

At around 7 a.m. on February 19, Brown's surgeon, Dr. Lee Cross, discovered that Brown was having difficulty breathing. Brown went into cardiac arrest, which led to anoxic brain injury. Brown's injuries, according to plaintiff Ellis, were caused by a morphine overdose due to her and Guest's having pressed the PCA pump's activation button for Brown while she was sleeping.

C. Source of the PCA Pump

In 1990, a division of defendant Bard, Bard MedSystems, manufactured the PCA pump that was prescribed to Brown. Defendant Bard sold that PCA pump in 1993 to a distributor, Bimeco, Inc, who then supplied it to GBMC.

Defendant Baxter did not manufacture the PCA pump that was prescribed to Brown. In 1993, however, defendant Baxter acquired the assets of Bard MedSystems. Following that asset sale, defendant Baxter continued to manufacture the same model of the PCA pump under the Bard name for about one year. After that and through 1999, defendant Baxter manufactured another model which was substantially similar to the PCA pump.

D. The Warning of Risk

Neither the PCA pump itself nor its user's manual contained a written label warning that third parties should not activate the PCA pump on behalf of the patient to whom it is prescribed. However, through its own sales force and its medical products distributor Bimeco, defendant Bard educated the GBMC staff about the risk of third-party activation and provided patient brochures to the GBMC staff advising that only the patient should press the PCA button.

More specifically, Bimeco sales representatives performed "in service" training to GBMC's doctors and nurses, and representatives from defendant Bard often attended that training. Frank Burdette, a Bimeco employee who performed

training at GBMC since 1994, stated that "[a]s part of this in-service training, it was my routine practice to tell the physicians and nurses in the Pain Service and at GBMC that only the patient should push the pump button, unless otherwise ordered by a physician." To illustrate why family members should not operate the pump, Burdette "would relate an anecdotal report about a family member who oversedated a patient by pushing the patient button."

In 1997 and "prior thereto," Burdette also gave the doctors and nurses at GBMC copies of a patient brochure about the PCA pump, which initially was prepared by defendant Bard in 1988 and later used by defendant Baxter. That brochure, entitled "Controlling your own pain relief – single-handedly," stated, "Important Note: <u>You</u> should be the <u>only</u> person to press your PCA button because <u>only you</u> know if you need it." (emphasis in the original). However, that brochure did not mention or warn what might happen if that directive was ignored. The brochures were provided to GBMC to be used with patients at the doctor's discretion. Nurse Susan Rhodes, who instructed Brown on the use of her PCA pump, confirmed that the patient brochure was used as part of the instruction to patients at GBMC.

Another Bimeco representative, Mark Jungers, also performed in service training at GBMC during the early 1990s. Like Burdette, Jungers routinely told

the staff at GBMC that only the patient should push the PCA pump activation button and shared the story about a family member oversedating a patient. Jungers further testified that he too gave copies of the defendants' patient brochures to the doctors and nurses at GBMC.

E. Actual Knowledge of Risk

Each doctor and nurse involved with Brown's medical care in 1997 was aware that only the patient should activate the PCA pump unless a doctor instructed otherwise. For example, Dr. Sherbert (Brown's prescribing doctor), indicated that he knew prior to 1997 that unauthorized "family member activation" of the PCA pump could result in sedation, which if left untreated "can lead to respiratory depression, respiratory arrest, or cardiac arrest."

The record also indicates that Brown, the patient here, was aware that only she should activate the PCA pump. Specifically, prior to her surgery, Nurse Rhodes instructed Brown on the use of the PCA pump. According to Nurse Rhodes, she routinely advised patients with the PCA pump that only they, and not third parties, should activate the PCA pump. Carol Brisbon, Brown's recovery room nurse, also instructed Brown about the PCA pump. Brisbon testified that it was also her practice to instruct patients that only they should press the activation button, and that family members should not.

As noted, the dangers associated with third-party activation are well known in the medical community. That common knowledge existed before the time of Brown's medical care at GBMC in 1997. Indeed, Dr. David C. Brandon, plaintiff Ellis's medical expert, testified that the medical community which uses PCA pumps has known of the dangers associated with third-party activation since 1987. Defendants' medical expert agreed, testifying that since the late 1980's, it has been widely known in the medical profession that a patient's family members should not activate PCA pumps.

Despite these dangers, the defendants did not place a written label on the PCA pump itself warning of the risk of third-party activation. Medical witnesses, however, explained the importance of the hospital staff's (1) instructing the patients that only they should press the activation button, (2) monitoring regularly the patient to observe vital signs and level of sedation, and (3) watching so that family members or others do not operate the PCA pump. Nurse Hamilton, who authorized the third-party activation at issue here, indicated that she "was keeping an eye on [Brown] making sure she was okay."

II. PROCEDURAL HISTORY

Plaintiff Ellis, as guardian for Brown, filed this action in state court against defendants Bard and Baxter.[3] Ellis alleged that the defendants were liable under Georgia law for Brown's injuries because of their defective labeling and specifically their failure to warn adequately of the danger of having a person other than a doctor or patient activate the PCA pump. The defendants removed this action to federal court based on diversity jurisdiction.

All parties moved for summary judgment. In her summary judgment motion, plaintiff Ellis argued that the defendants had violated certain provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., and regulations promulgated under that Act by not including a written warning label on the PCA pump itself indicating the danger of third-party activation. Ellis contended that the defendants thus were strictly liable under Georgia law for Brown's injuries.

In their summary judgment motions, the defendants argued (1) that the FDCA provisions in issue did not require a written label on the PCA pump warning against third-party activation and (2) that all of Ellis's claims were barred

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[3]Prior to filing this lawsuit, Ellis sued GBMC for medical malpractice. Ellis settled that medical malpractice suit with GBMC for structured payments having a present value of approximately $8 million. Ellis then dismissed her suit against GBMC and filed this second lawsuit.

by Georgia's learned intermediary rule. Defendant Baxter further asserted that it could not be liable for the additional reason that it did not manufacture, sell, repair, or service the PCA pump that allegedly injured Brown.

After a hearing, the district court entered an order denying plaintiff Ellis's summary judgment motion and granting the summary judgment motions of each defendant. The district court concluded (1) that Georgia's learned intermediary rule applied to the PCA pump as a prescription medical device and (2) that, under that Georgia rule, the defendants adequately warned of the dangers of third-party activation to the only people they had a duty to warn — the doctors and nurses at GBMC. The district court assumed, without deciding, that a violation of the FDCA could result in negligence per se under Georgia law but also concluded that the defendants had not violated any provision of the FDCA in any event.[4] The district court further determined that the defendant Baxter was entitled to summary judgment because, under Georgia law, it was not a "manufacturer" of the PCA pump that allegedly caused Brown's injuries. After judgment was entered for the defendants, Ellis timely appealed.

III. DISCUSSION

[4]The district court construed Ellis's strict liability claim as one of negligence per se. Ellis does not challenge this characterization on appeal.

The primary issue on appeal is whether the district court properly concluded that Georgia's learned intermediary rule controls this case. Thus, we examine Georgia's rule as well as the provisions of the FDCA at issue here.

A. Learned Intermediary Rule

As the Georgia courts have explained, "the settled 'learned intermediary rule' of Georgia law [is] that the manufacturer of a prescription drug is not normally required to warn the patient of dangers in its use." Presto v. Sandoz Pharms. Corp., 226 Ga. App. 547, 548 (1997) (emphasis in the original); see also McCombs v. Synthes, 250 Ga. App. 543, 545 (2001) (noting that "the duty to warn the patient should rest, not with the manufacturer, designer, or distributor"). Instead, "'in the case of prescription drugs, a warning as to possible danger in its use to the prescribing physician is sufficient.'" Presto, 226 Ga. App. at 548 (quoting Singleton v. Airco, Inc., 169 Ga. App. 662, 664 (1984) and citing Hawkins v. Richardson-Merrell, Inc., 147 Ga. App. 481 (1978) and Parke, Davis, & Co. v. Mayes, 124 Ga. App. 224 (1971)).

In addition, the Georgia courts have decided that "[t]his special standard for prescription drugs is an understandable exception to the . . . general rule that one who markets goods must warn foreseeable ultimate users of dangers inherent in his products." Hawkins, 147 Ga. App. at 483 (internal quotation marks omitted).

Indeed, as reasoned by the Georgia courts, "[a]s 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 . . . [and he] acts as a 'learned intermediary' between manufacturer and consumer." Id. (internal quotation marks omitted).

Although Georgia's learned intermediary rule has its roots in prescription drugs, the Georgia courts repeatedly have applied that rule to prescription medical devices. For example, in Lance v. Am. Edwards Labs., 215 Ga. App. 713 (1994), the plaintiff filed a tort action against, among others, the manufacturer "of a medical device (designed for implantation into the human stomach) known as the Garren-Edwards Gastric Bubble." Id. at 713. In Lance, the Georgia Court of Appeals found that the defendant manufacturer had no duty to warn the plaintiff of any dangers associated with the prescription medical device, noting that the "treating physician had sole responsibility for advising his patient of dangers associated with use of the gastric bubble." Id. at 716. The Georgia court in Lance pointed out that "the gastric bubble is available only upon prescription, application (insertion) and supervision of a physician" and that it was inserted pursuant to a physician's "advice and prescription." Id. The Georgia court further noted that

any information supplied by the defendant manufacturer regarding dangers "may have compromised the doctor-patient relationship and thus impaired the best medical treatment for [plaintiff's] chronic condition." Id.[5]

Recently, the Georgia Court of Appeals adhered to the pronouncements in Lance regarding prescription medical devices, stating, "[i]n Lance, this Court held that when a device can be prescribed and inserted only by a physician, that treating physician has sole responsibility for advising the patient of dangers associated with the use of the device." Williams v. Am. Med. Sys., 248 Ga. App. 682, 685 (2001). And because "[t]he designer, manufacturer, and distributor are under no duty to the patient," Williams, 248 Ga. App. at 685, the Georgia court in Williams affirmed the trial court's grant of summary judgment to a defendant manufacturer of a penile implant on the plaintiff's "claim for failure to warn him of the danger that the tubing could disconnect," Williams, 248 Ga. App. at 685.

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[5]Two special concurrences were filed in Lance. One special concurrence noted that the device was prescribed, surgically implanted, and supervised by a physician, and that "the manufacturer has no practical means to supply a patient with notice of any risks or side effects associated with the use of its product." Lance, 215 Ga. App. at 717. The other special concurrence noted that the defendant manufacturer had no duty to warn "because the device and its application at all times were under the control of the prescribing physician." Id. at 717-18.

Most recently, in McCombs v. Synthes (U.S.A.), 250 Ga. App. 543, 545 (2001), the Georgia Court of Appeals held that the learned intermediary rule barred a failure-to-warn claim against a defendant manufacturer of a spinal plate, as "[i]t is well settled that the 'learned intermediary' rule . . . is applicable to medical devices implanted in patients under the supervision of a physician." Id. at 545. In so holding, the Georgia court pointed out that "[t]he rationale regarding medical devices is the same as that applicable to drugs prescribed by a physician, i.e., that the duty to warn the patient should rest, not with the manufacturer . . ., but solely with the treating physician, in that 'the decision to employ prescription medication involves professional assessment of medical risks in light of the physician's knowledge of a patient's particular needs and susceptibilities.'" Id. (quoting Walker v. Jack Eckerd Corp., 209 Ga. App. 517 (1993) and citing Lance, 215 Ga. App. at 716).

Georgia is not alone in applying the learned intermediary rule to both prescription drugs and prescription medical devices. Instead, the rule is almost universal. As one federal court put it,

> [t]he rule on which the defendant relies, the learned intermediary doctrine, is nearly universal: where drugs or medical devices are only available to the public by prescription from a physician or dentist, the products manufacturer fulfills its duty to warn by advising the professional of the dangers of the product and has no duty to warn the patient.

Pumphrey v. C.R. Bard, Inc., 906 F. Supp. 334, 337 (N.D. W.Va. 1995) (citing to cases applying the state law of South Carolina, Missouri, Louisiana, Texas, and Indiana).[6] See also Vaccariello v. Smith & Nephew Richards, Inc., 763 N.E.2d 160, 164 (Ohio 2002) ("[W]e hold that the learned intermediary doctrine applies to prescription medical devices."); Prohaska v. Sofamor, S.N.C., 138 F. Supp. 2d 422, 444 (W.D. N.Y. 2001) ("As is the case with prescription drugs, '[T]he manufacturer of a medical device does not have a duty to directly warn a patient of risks associated with the device, but instead discharges its duty by providing the physician with sufficient information concerning the risks of the device.'"); Ralston v. Smith & Nephew Richards, Inc., 275 F.3d 965, 974 (10th Cir. 2001) ("Kansas has adopted the 'learned intermediary rule.' Under that rule, the manufacturer's duty to warn its customers is satisfied when the prescribing physician is made aware of the risks and dangers of the product, since the patient cannot obtain the medical product except through the physician."); Phelps v.

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[6]In Pumphrey, discussing the learned intermediary rule generally, the federal court also pointed out that "[o]nly two narrow and specific exceptions have been carved into the 'learned intermediary doctrine.' The first is for polio and other vaccines administered in public, mass clinics, where a physician was not involved in individual vaccinations. The second is for contraceptive medications and devices, where the patient is actively involved in the decision and the products are used for extended periods of time without medical assessment." 906 F. Supp. at 337-38 (internal citations omitted). We do not further discuss these "narrow" exceptions because neither applies here.

Sherwood Med. Indus., 836 F.2d 296, 303 (7th Cir. 1987) ("This 'learned intermediary' exception has equal application to those cases concerning medical devices. Phelps tries here to distinguish the Indiana law regarding prescription drugs from situations involving medical devices. Yet this Court can find no principled basis for such a distinction. . . . it was up to Dr. Rubush, the heart surgeon who, according to the evidence, knew the risks and benefits of this kind of catheter usage, to warn Phelps.").

In light of this background, we conclude that Georgia's learned intermediary rule controls this case, that the defendants adequately warned the doctors and nurses at GBMC of the damages of third-party activation, and that the defendants had no duty to warn about third-party activation to either Brown or third-party family members.[7]

B. Type of Risk

We also reject plaintiff Ellis's claims that Georgia's learned intermediary rule applies only when the risk at issue is "unavoidable." According to Ellis, the PCA pump is safe when a third party does not activate it and thus this is a

[7]Given this conclusion, we need not address whether the district court properly concluded that defendant Baxter was entitled to summary judgment on the additional ground that it was not a "manufacturer" of the PCA pump that allegedly caused Brown's injuries.

"preventable" risk case to which the learned intermediary rule does not apply. More specifically, Ellis argues that the rule applies only to "unavoidable risk warnings" associated with prescription drugs or devices requiring a medical provider (learned intermediary) actually to weigh the potential benefit of the drug or device against an unavoidable side effect. As to "preventable risk warnings," Ellis contends that a learned intermediary need not do any weighing with regard to these preventable risks and thus the duty to warn extends to persons beyond the learned intermediary.

For this distinction, plaintiff Ellis relies primarily on the Fifth Circuit's decision in Thomas v. Hoffman-LaRoche, Inc., 949 F.2d 806, 813 (5th Cir. 1992), applying Mississippi law to a failure-to-warn claim asserted against the manufacturer of a prescription drug. In Thomas, the Fifth Circuit did "recognize that there are two very different types of warnings that might be associated with a particular product: (1) an unavoidable risk warning; and (2) a preventable risk warning." Id. However, that recognition was not made in connection with the question regarding to whom a manufacturer's duty to warn extends or whether the learned intermediary rule should apply to a given prescription drug or device. Instead, that recognition was made in discussing causation and in response to plaintiff's argument that, for certain types of risks, the independent element of

causation should be presumed given an inadequate warning by a manufacturer to an intermediary. Id. at 812-14. Simply put, Thomas does not suggest, much less hold, that the learned intermediary rule applies only when the risk in question is "unavoidable" as opposed to "preventable."

In any event, plaintiff Ellis cites to no Georgia decision (1) limiting the application of the learned intermediary rule to situations in which the risk is "unavoidable" or (2) otherwise indicating that the applicability of that rule should depend on the type of risk at issue. Ellis does point out correctly that the learned intermediary rule presupposes that the learned intermediary will weigh the benefits of any prescription against its potential dangers. See, e.g., Hawkins, 147 Ga. App. at 483 ("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."). But we disagree with Ellis's suggestion that no "weighing" need be done when the risk at issue is a preventable risk and thus the doctrine should not apply. A learned intermediary does weigh both so-called preventable and unavoidable risks in deciding whether to prescribe a certain medical device or drug. In fact, in making his decision to prescribe the PCA pump to Brown, Dr. Sherbert testified that he knew of the risks associated with third-party activation, but nonetheless chose to

prescribe the PCA pump to Brown instead of some other method of drug administration. That testimony reflects a weighing process on behalf of Dr. Sherbert, the learned intermediary.

In short, we conclude that the Georgia courts have not adopted an approach whereby the applicability of the learned intermediary rule depends on the nature of the risk involved. Indeed, that approach is not hinted at in, much less supported by, the several Georgia decisions that have applied the learned intermediary rule. Nor is it hinted at in any other decision cited by Ellis.

C. Third Parties

Ellis also contends that the learned intermediary rule should not apply in this case because third parties, and not just Brown as a patient, need to be warned of the dangers of third-party activation. This argument also misses the mark for several reasons. Whether Georgia's learned intermediary rule applies in a given case is not based on to whom a warning must be given to make a drug or device safe. Instead, the applicability of that rule depends on the type of drug or device at issue and whether there exists a learned intermediary. Here, the medical device at issue is a prescription one and learned intermediaries exist – the doctors and nurses at GBMC. Thus, the rule applies, and the duty to warn extends only to

the learned intermediary, and to no one else (whether the patient or a third-party family member).

Ellis contends that this conclusion "effectively" means that "no one, except a very literally unconscious patient, has a duty to warn off third parties from well meaning assistance with this pump." Ellis's contention is wrong. We agree that a patient may be too sedated at certain times to warn third parties not to activate the PCA pump. But that patient, nonetheless, can pass the warning on to third parties (including family members) before then. More importantly, Ellis's argument all but ignores the role and duty of the hospital and its staff in these cases. Indeed, as Ellis's settlement with GBMC in this case suggests, the duty to ensure Brown's safety here rested in large part with the hospital and its staff, through, for example, proper supervision and monitoring.

In sum, we are not persuaded that application of Georgia's learned intermediary rule to cases like this one leads to a situation in which no one has a duty to protect the patient. Under the learned intermediary rule, the defendants here had a duty to warn the hospital physicians and nurses. They satisfied that duty. A hospital's or medical staff's failures to perform their duties from that point forward do not operate to create, or to extend, a manufacturer's duty to warn third-party family members, bystanders, or any persons other than the learned

intermediary. See Prohaska, 138 F. Supp. at 444 ("[A] manufacturer [is not] responsible for how a learned intermediary conducts his business.") (internal quotation marks omitted). Moreover, our conclusion in this regard – that the defendants had no duty to warn third-party family members such as Brown's daughters – is consistent with Georgia case law applying the learned intermediary rule. See Presto, 226 Ga. App. at 549 ("Thus, the 'learned intermediary' rule . . . applies here, and [defendant manufacturer] had no duty to directly warn Greg or

the Prestos [the patient's parents] of the potential hazards of the use of Clozaril.").[8]

D. The Carter Five-Part Test

We also address Ellis's argument that her claims should be analyzed under the balancing test set forth in Carter v. E.I. DuPont de Nemours & Co., 217 Ga. App. 139 (1995). Under Georgia law, the balancing test "addresses when a supplier's duty to warn an ultimate consumer can be discharged by a warning

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[8]Ellis also suggests that, even if the learned intermediary rule applies, there was a jury issue regarding the sufficiency of the warnings given by the defendants to the learned intermediaries in this case. We disagree. As the district court noted, defendants presented evidence that, through Bimeco, it warned the physicians and nurses at GBMC that only the patient should press the activation button unless a doctor ordered otherwise. In any event, the record shows that the risks associated with third-party activation were well known to the medical community at the time of Brown's injuries, and the doctors and nurses at GBMC had actual knowledge of those risks. See Wheat v. Sofamor, S.N.C., 46 F. Supp. 2d 1351, 1363 (N.D. Ga. 1999) (applying Georgia law and concluding that "[r]egardless of the sufficiency or insufficiency of the warnings at issue here, Plaintiff still cannot recover. Where a learned intermediary has actual knowledge of the substance of the alleged warning and would have taken the same course of action even with the information the plaintiff contends should have been provided, courts typically conclude that the learned intermediary doctrine applies or that the causal link is broken and the plaintiff cannot recover."); Harden v. Danek Med. Inc., 985 S.W.2d 449, 451 (Tenn. Ct. App. 1998) ("[I]t is generally held that the learned intermediary doctrine may shield a manufacturer from liability when the physician was independently aware of the risks involved."); Zachary v. Dow Corning Corp., 884 F. Supp. 1061 (M.D. La. 1995) (applying Louisiana law and stating that "the duty to warn in the learned intermediary context requires an adequate warning of inherent dangers not within the knowledge of or obvious to the average learned intermediary").

given to an intermediary party." Id. at 143. In that regard, a court must balance several factors: "the burden of requiring a warning; the likelihood that the intermediary will provide a warning; the likely efficacy of such a warning; the degree of danger posed by the absence of such a warning; and the nature of the potential harm." Id. (internal quotation marks omitted).

We agree with the district court that the Georgia decision in Presto, discussed ante, forecloses Ellis's argument about Carter. In Presto, the Georgia Court of Appeals applied the learned intermediary rule to a failure-to-warn claim involving a prescription drug and explained that Carter had no applicability, as follows:

> Carter involved plaintiffs who purchased clothing available to the general public without warnings regarding the fabric's flammability. Carter is not applicable to this case, which involves a prescription drug, available only through a licensed, skilled physician.

Presto, 226 Ga. App. at 548 (emphasis in the original). Here, the PCA pump is a prescription medical device available only through a licensed, skilled physician. Thus, under Presto, the balancing test used in Carter does not apply.

E. The FDCA

Finally, Ellis argues that the defendants' violations of the FDCA constitute negligence per se,[9] and that the FDCA conflicts with, and thus preempts, application of Georgia's learned intermediary rule. Specifically, Ellis claims that the defendants violated the FDCA's labeling requirements in 21 U.S.C. § 352(f) and in certain FDCA regulations. As outlined below, we conclude that the district court properly concluded that the defendants did not violate the FDCA provisions or its regulations at issue in this case and that Georgia's learned intermediary rule is not preempted by them either.

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[9]For purposes of this opinion we assume but do not decide that Georgia law permits a claim for negligence per se for violation of the FDCA. There is a split of authority among the states as to whether a violation of the FDCA or its regulations can serve as a predicate for a negligence per se claim under state law. Compare Blinn v. Smith & Nephew Richards, Inc., 55 F. Supp.2d 1353, 1361 (M.D. Fla. 1999) (no negligence per se claim under Florida law for violation of the FDCA), with Prohaska v. Sofamor, S.N.C., 138 F.Supp. 2d 422, 448 (W.D.N.Y. 2001) ("[U]nder New York law, a cause of action exists under negligence per se when the underlying claim is for misbranding or otherwise illegally omitting product warnings required by the FDCA.").

No Georgia court has weighed in on the issue. However, we note the defendants' arguments that the FDCA provisions to which Ellis cites are too general to form the predicate for a negligence per se cause of action. See, e.g., Chadbourne v. Kappaz, 779 A.2d 293, 297 (D.C. 2001) (concluding that a D.C. Code section was "too general a statute to be the subject of a negligence per se [jury] instruction"); Shanks v. Upjohn Co., 835 P.2d 1189, 1201 (Alaska 1992) (noting that a trial court can decline to give a negligence per se instruction if "a statute is too vague or arcane to be used as a reasonable standard of care").

Ellis first focuses on the "labeling" provisions of 21 U.S.C. § 352(f) which provide as follows:[10]

> A drug or device shall be deemed to be misbranded . . . . [u]nless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

21 U.S.C. § 352(f).[11] Ellis contends that the defendants failed to comply with both subsections (1) and (2) of § 352(f).

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[10]The PCA pump is a prescription medical device that is regulated by the FDCA. See 21 C.F.R. § 880.5725. However, no private right of action exists for a violation of the FDCA. See 21 U.S.C. § 337(a) (reserving to the United States enforcement actions for violation of the FDCA); see also Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 n.4 (2001); Medtronic, Inc. v. Lohr, 518 U.S. 470, 487 (1996). Thus, plaintiff Ellis alleges violations of the FDCA constitute negligence per se, or at least ordinary negligence, under Georgia law. Specifically, plaintiff Ellis contends that Georgia law imposes duties to warn in adequate labels that parallel her interpretation of the FDCA requirements.

[11]Several parts of the FDCA were amended on October 26, 2002, by the Medical Device User Fee and Modernization Act of 2002, Pub. L. No. 107-250, 116 Stat. 1588 (Oct. 26, 2002). The amendments do not affect the outcome of this case and thus we do not discuss them. Instead, we quote from and apply the FDCA provisions in the form prior to the amendments.

Section 352(f)(1) provides that a prescription device is misbranded unless its labeling bears "adequate directions for use." However, 21 C.F.R. § 801.109 expressly exempts a prescription device from § 352(f)(1) so long as the device complies with the conditions in 21 C.F.R. § 801.109. As outlined below, the record shows that the defendants' device satisfied the conditions of 21 C.F.R. § 801.109, thus triggering the exemption from § 352(f)(1).

The parties do not appear to dispute that the conditions in § 801.109(a) were satisfied here because the defendants' device was sold to the patient on the prescription of the physician in the course of his professional practice. Instead, Ellis contends that the defendants did not satisfy the conditions in § 801.109(b) and (c) which address labeling as follows:

> (b) The label of the device, other than surgical instruments, bears:
> (1) The statement "Caution: Federal law restricts this device to sale by or on the order of a -------", the blank to be filled with the word "physician", "dentist", "veterinarian", or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and
> (2) The method of its application or use.
>
> (c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for

> which it is advertised or represented: Provided, however, That such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device. Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a proposal to omit such information from the dispensing package under this proviso.

21 C.F.R. § 801.109. After review, we conclude that the defendants also met the conditions in § 801.109(b) and (c). As to § 801.109(b)(1), the PCA pump bore this label: "CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician." Thus, the defendants affixed the cautionary statement required by § 801.109(b)(1) to the pump.

As to § 801.109(b)(2), this condition does not relate to warnings; rather it requires that the label describe how the device should be used. Defendants complied with § 801.109(b)(2) by including the following directions on the back of the pump: "Read Operator's Manual before use. Ensure tubing is properly installed. Prime tubing to remove all air bubbles. Refer to Operator's Manual or physician's instructions if alarm sounds."

As to § 801.109(c), this condition requires that the labeling bear information for use, including "any relevant hazards" and "precautions"; however, § 801.109(c) does not require the manufacturer to include these hazards and precautions <u>on the device itself</u>. Instead, this information must be included "on or within the package

from which the device is to be dispensed." 21 C.F.R. § 801.109(c). In addition, § 801.109(c) is not directed toward providing information to bystanders, but by its own terms to "practitioners licensed by law to administer" the device so that they "can use the device safely and for the purpose for which it is intended." 21 C.F.R. § 801.109(c). As the Second Circuit has concluded, "pursuant to 21 C.F.R. § 801.109, information is [to be] disseminated to physicians and the medical community rather than to the patient directly." Fane v. Zimmer, Inc., 927 F.2d 124, 129 (2d Cir. 1991).

Thus, contrary to Ellis's contentions, § 801.109 did not require defendants to include a written, on-pump label warning family members against the danger of third parties activating the pump. Instead, the defendants provided the necessary information both in writing and orally to GBMC, its doctors and nurses, and thereby complied with the conditions in § 801.109. Thus, the defendants' prescription device, the PCA pump, was exempt from the requirements in § 352(f)(1). As the district court recognized, §801.109 is actually consistent with the learned intermediary rule. See Pumphrey, 906 F. Supp. at 338 ("[T]he learned intermediary doctrine is consistent with federal regulations [§ 801.109] for prescription devices."). Indeed, § 801.109(c) goes further and provides that the labeling information may even be omitted from the dispensing package when the

hazard is "commonly known to practitioners licensed by law to use the device." Id. This is also precisely the case here.

Plaintiff Ellis also argues that the defendants violated the labeling requirements in § 352(f)(2), which provides as follows:

> A drug or device shall be deemed to be misbranded . . . . [u]nless its labeling bears . . . such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users . . . .

21 U.S.C. § 352(f)(2) (emphasis added). Although the prescription device here is exempt from § 352(f)(1), the defendants do not dispute that the PCA pump is subject to this general labeling requirement in the FDCA. The defendants, however, point out that 21 U.S.C. § 321(m) of the FDCA defines "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m) (emphasis added). Thus, as defendants argue, § 352(f)(2) likewise does not require an "on-pump" or "point-of-use" warning to family members because this section mandates that warnings be included on the device's "labeling," which includes either labels "upon any article" or "accompanying such article." Id. Therefore, defendants' labeling satisfied § 352(f)(2), as well as their alleged duties under

Georgia law, by including the warning in the materials "accompanying" the pump, and distributing them to GBMC and its physicians and nurses.

Georgia's learned intermediary rule also does not conflict with § 352(f). The language in § 352(f)(2) does not require that the warning in the labeling be provided on the pump device itself or be given directly to third parties. This also is not a case where the patient user was not warned adequately. Moreover, contrary to Ellis's assertions, the learned intermediary rule does not compel a defendant manufacturer to avoid labeling its devices in accordance with federal law, such as § 352(f). Instead, the learned intermediary rule operates only to insulate defendant manufacturers from certain tort liability under state law when they warn a learned intermediary of certain risks associated with a prescription medical device or drug. This is not a situation in which federal law requires one thing, and state law requires another thing. If anything, the learned intermediary doctrine is consistent with the federal law that warnings regarding prescription-only medical devices are to be disseminated to the medical community, which acts as the learned intermediary between the manufacturer and patient. Thus, plaintiff Ellis in this case cannot evade application of Georgia's learned intermediary rule by relying on the FDCA.

We also note that Ellis cites to no Georgia or Eleventh Circuit decisions indicating that Georgia's learned intermediary rule somehow is preempted by certain provisions in the FDCA. Instead, Ellis relies on the Tenth Circuit's decision in Edwards v. Basel Pharmaceuticals, 116 F.3d 1341 (10th Cir. 1997), which dealt with the learned intermediary rule under Oklahoma law. Aside from the fact that Edwards dealt with Oklahoma law, Ellis's reliance on that case also is misplaced. Edwards did not conclude that a provision of the FDCA preempted the application of the learned intermediary rule. We recognize that Edwards discusses an exception to the learned intermediary rule, carved out by the Oklahoma Supreme Court, providing that "when the FDA requires warnings be given directly to the patient with a prescribed drug, an exception to the learned intermediary doctrine has occurred, and the manufacturer is not automatically shielded from liability by properly warning the prescribing physician." Edwards, 116 F.3d at 1343 (internal quotation marks omitted). But the Oklahoma Supreme Court carved out that exception in the context of a specific mandate by the FDA requiring a patient insert warning regarding particular risks associated with a particular product.[12]

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[12]The Tenth Circuit had certified to the Oklahoma Supreme Court the following question: "Under Oklahoma law, what determines the scope or extent of the prescription drug manufacturer's duty to warn the consumer when FDA

Several federal regulations promulgated under the FDCA require specific labeling for certain specific drugs, products, or devices. See 21 C.F.R. § 801.405 ("Labeling of articles intended for lay use in the repairing and/or refitting of dentures"); § 801.420 ("Hearing aid devices; professional and patient labeling"); § 801.430 ("User labeling for menstrual tampons"); § 801.433 ("Warning statements for prescription and restricted device products containing or manufactured with chlorofluorocarbons or other ozone-depleting substances"); § 801.437 ("User labeling for devices that contain natural rubber"). However, Ellis cites to, nor are we aware of, any specific mandate with regard to the PCA pump or the types of infusion pumps at issue in this case. Section 352(f)(2) is only a general provision. Without a specific FDA mandate in this case requiring a certain warning on a PCA pump, and in light of Georgia's well-established learned intermediary rule, we need not address whether an exception to Georgia's learned intermediary rule is warranted.

F. Motion to Reduce Costs

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recognition of the need for direct warnings has undercut application of the learned intermediary rule? More specifically, what is the effect of the manufacturer's compliance with the very FDA requirements invoking this exception to the rule?" Edwards, 116 F.3d at 1343. The Tenth Circuit in Edwards pointed out that "the FDA mandate for direct patient warnings" was admitted and uncontroverted, even though the "operative administrative regulation, directive, or stipulation was never produced." Id. at 1343 n.1 (internal quotation marks omitted).

Ellis also appeals the district court's order denying her motion to reconsider the costs awarded to the defendants after entry of judgment in their favor.[13] In that motion, Ellis claimed that, due to insufficient funds in Brown's guardianship estate, she lacked the financial means to pay the costs awards. The district court denied Ellis's motion, concluding that Ellis failed to present sufficient evidence that she, as guardian for Brown, suffered from dire financial circumstances.[14]

"We review a district court's decision about costs only for abuse of discretion." Chapman v. AI Transp., 229 F.3d 1012, 1039 (11th Cir. 2000). We find no abuse of discretion in the district court's denial of Ellis's motion as to costs. Even assuming arguendo that Ellis presented evidence of dire financial circumstances, this Court has held that a district court may, but need not, consider financial status in making a costs award to a prevailing party. Id. ("We hold that a non-prevailing party's financial status is a factor that a district court may, but need not, consider in its award of costs pursuant to Rule 54(d).").[15]

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[13]As prevailing parties under Federal Rule of Civil Procedure 54(d), defendant Baxter was awarded $28,548.98 and defendant Bard was awarded $20,318.47.

[14]This Court granted Ellis's motion to consolidate her appeal of this order with her appeal of the order granting defendants' summary judgment motion and denying her summary judgment motion.

[15]We also question, but do not decide, whether Ellis, as guardian for Brown, truly faces dire financial circumstances. As defendants point out, the proceeds

IV. CONCLUSION

For all of these reasons, we affirm the district court's orders granting summary judgment to the defendants, denying summary judgment to the plaintiff, and awarding costs in favor of the defendants.

AFFIRMED.

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from the eight million dollar structured settlement with GBMC are in a trust account for Brown, and Ellis is a co-trustee of that account.