

COMMONWEALTH OF KENTUCKY
BOONE CIRCUIT COURT
CASE NO. 01-CI-01220

ENTERED
BOONE CIRCUIT/DISTRICT COURT
MAY 17 2005
BY PAT GUTZERT CLERK DC

DAWN MARIE BRANSON, ET AL.

PLAINTIFF

VS.

SHIRE USA, INC.

DEFENDANT

RECEIVED
MAY 23 2005
By

ORDER

This matter is before the Court on Defendant Shire USA, Inc.'s Motion for Summary Judgment on the wrongful death claim of Nathaniel Branson. There are four grounds relied upon by Defendant for Summary Judgment. The grounds are as follows:

- 1 The Release signed by Ken and Dawn Branson in January 2001 in favor of Geico as a matter of law constitutes a release of the Defendant
2. The Plaintiffs' claims are preempted by the Federal Food and Drug and Cosmetic Act.
3. The Plaintiffs' claims are barred by the Learned Intermediary Doctrine.
- 4 The Plaintiffs cannot establish that the inadequacy of the warning was the proximate cause of Nathaniel Branson's death.

I

Dawn Branson and Kim Branson signed a Release with Geico Insurance Company. Dawn Branson signed the Release on January 3,

2001 and Ken Branson signed on January 7, 2001. The pertinent parts of the written document are as follows:

the undersigned, Dawn Branson, parent and heir to Nathaniel Branson (Releasor) hereby release and forever discharges Dawn Branson for the wrongful death claim of Nathaniel Branson, their heirs, personal representatives, successors and assigns, and all other persons, firms or corporations (Releasees), liable or who might be claimed to be liable, none of who admit to any liability, from any and all claims, demands, damages, actions, causes of action or suits of any kind or nature to the person and/or property, which have resulted or may in the future develop from an accident which occurred on or about 3/18/00 at or near Glendale, Arizona.

Releasor hereby declares that the terms of this Release have been completely read and fully understood and voluntarily accepted from the purpose of making a full and final compromise adjustment and settlement of any and all claims, disputed or otherwise, on account of the injuries and damages above mentioned.

Dawn Branson and Ken Branson signed different releases with identical language. At the time of signing the Release the Estate of Nathaniel Branson had not yet been opened.

The individual claims of Dawn Branson and Ken Branson were dismissed by Summary Judgment by this Court on July 6, 2004. The only remaining claim in this case is the wrongful death claim of the estate of Nathaniel Branson.

K.R.S. §441.130 states that a wrongful death action "shall be prosecuted by the personal representative of the estate." As of the date of the execution of the Releases no personal

representative had been appointed. No estate had been opened as of date of the execution of the Releases.

K.R.S. §411.182 states:

A release, covenant not to sue, or similar agreement entered into by a claimant and a person liable, shall discharge that person from all liability or contribution, but it shall not be considered to discharge any other persons liable upon the same claim unless it so provides. However, the claim of the releasing person against other persons shall be reduced by the amount of the released persons' equitable share of the obligation, determined in accordance with the provisions of this section.

In Richardson v. Eastland, Inc., Ky., 660 S.W.2d 7 (1983) the Court held that unless a release shows on its face that others not mentioned in the release are also released or that claimant has been fully compensated for all damages and the release constitutes payment in satisfaction of all claims, a release shall not be interpreted as providing a defense to a third party not expressly covered. The Court reasoned that "A release is nothing more than a contract between the party executing it and the party released. Where the contract is silent we must interpret the intent of the parties."

A review of the Release in this matter does not convince the Court that the Estate of Nathaniel Branson intended to release its claim against Shire USA, Inc. The Motion for Summary Judgment on issue is OVERRULED

II

Defendant maintains as a matter of law the Plaintiffs' claims are barred because they are preempted by the Federal Food Drug and Cosmetics Act. The preemption doctrine arises from the Supremacy Clause of the United States Constitution. In sum, where a state law and federal law conflict, the state law must yield to the federal law. See Gibbons v. Ogden, 22 U.S. 1, 6 L.Ed. 23 (1824) It must be clear, however, the Federal Act was intended by Congress to supersede state law. Preemption occurs in three ways:

1. Congress expresses a clear intent to preempt state law when enacting the federal law.
2. Federal law impliedly preempts state law because Congress revealed an intent to "occupy" the field of regulation
3. Federal law and state law actually conflict.

The Defendant claims that it was unable to change the labeling of its product (and thus the warning) without approval of the FDA. The Defendant maintains that since only the FDA has authority to determine whether the warnings on Adderall labeling complies with the FDA regulations, there is a Congressional intent to provide for national uniformity in the labeling of pharmaceutical products and a state court cannot impose

liability based upon the inadequacy of the warnings on the labeling.

The parties have cited cases from other jurisdictions supporting their positions. There is not a Kentucky case on point. However, the Supreme Court of Kentucky held that the historic police powers of our state is not preempted by federal law in absence of a clear and manifest purpose of Congress to do so Niehoff v. Surgidev Corporation, Ky., 950 S.W.2d 816 (1997). The Supreme Court noted that there is a presumption against the preemption of state regulations and the presumption recognizes the historic primacy of state regulation of matters of health and safety. Also see Leslie v. Cincinnati Sub-Zero Products, Inc., Ky.App., 961 S.W.2d 799 (1998). The Supreme Court also noted that a Kentucky common law tort action would assist in enforcing federal regulation under the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act (MDA).

It is the opinion of this Court that this common law state action is not preempted by federal law.

III

The third argument for Summary Judgment is the Plaintiffs' claims are barred by the Learned Intermediary Doctrine. In Larkin v. Pfizer, Inc., Ky., 153 S.W.3d 758 (2004) (a 4-3 decision), our

Supreme Court adopted this rule as set forth in Restatement (Third) of Torts: Products Liability §6(d). The learned intermediary rule is an exception to the general rule that "a manufacturer's duty to warn of any risks or danger inherent in the product runs to the ultimate consumer." at 761

The learned intermediary rule is set forth in §6(d) of the Restatement (Third) of Torts:

Products Liability provides that [a] prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to: (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

Larkin states that this doctrine does not shield a drug manufacturer from liability for inadequate warnings to the physician. If the manufacturer fails to adequately warn the learned intermediary, then it may be liable to the injured patient consumer. An adequate warning is one sufficient to apprise the doctor of the dangerous propensities of the drug. If the doctor is provided an adequate warning, the manufacturer is relieved of its duty to warn the patient regardless of how or if the physician warns the patient.

Kentucky Supreme Court did not decide which, if any, of the recognized exceptions to this rule should be adopted in Kentucky. Even so, the exceptions discussed by the Court are not applicable in this case. The issue therefore is whether the doctors in this case were provided an adequate warning by the Defendant.

Robert Powers saw Dawn Branson one time. He is a general practitioner. He knew Dawn Branson was taking Adderall, but did not initially prescribe it. He had prescribed Adderall before, from time to time. Adderall is prescribed for a month at a time. He had never had a patient claiming they had psychosis with Adderall. He had reviewed the Physician Desk Reference for Adderall before prescribing and familiarized himself with the patented adverse affects and complications. He knew that it could produce, in rare events, a psychotic episode at recommended doses

He recognized psychosis while on Adderall was a possibility and a potential side effect. In this case he did not discuss these issues with Dawn Branson because she had already been prescribed the drug when she saw him and Dr Powers assumed the original prescribing doctor had already done that. He acknowledged the package insert accurately conveyed information to him about Adderall

Robert Castillo was the original prescribing doctor. In his career he has prescribed Adderall thousands of times. He was familiar with Adderall, its package insert and its side effects. He thought Adderall was safe and effective. When he prescribed medication for Dawn Branson in 2000 he understood psychosis could occur at recommended doses even though it was a rare occurrence. He scheduled Dawn Branson for a follow up the next week to evaluate her to determine if she was having side effects such as psychosis.

There were difficulties with Dawn Branson making her appointments and she informed the doctor she found a doctor closer to her home and would not be back.

Plaintiff argues that the Defendant failed to disclose relevant information to the health care provider, as set forth in their brief, so therefore the warnings were not adequate

The learned intermediary doctrine is applicable to this case. The issue, therefore is whether the Defendant adequately warned the doctors in this case of the dangerous propensities of this drug. The Court concludes that the adequacy of the warning to the health care provider is a question of fact to be determined by the jury

Therefore, the Summary Judgment standards must be applied to this issue. Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, stipulations, and

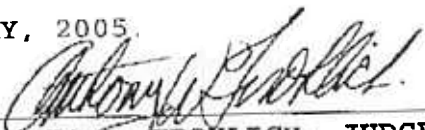
admissions on file, together with the affidavits, if any, show that there is not genuine issues as to any material fact and that the moving party is entitled to a judgment as a matter of law." CR 56.03. Summary Judgment is proper when it appears that it would be impossible for the non-movant to produce evidence at trial warranting a judgment in his favor. Steelvest, Inc. v. Scansteel Service Ctr., Ky., 807 S.W.2d 476 (1991). The movant must show the non-movant could not prevail under any circumstance. Brown Foundation v. St. Paul Ins., Co., Ky., 814 S.W.2d 273 (1991). The Court finds there exists genuine issues of material fact in this case that precludes Summary Judgment.

IV

The Defendant next argues it is entitled to Summary Judgment because the Plaintiff cannot establish any inadequacy of the warning provided by Shire was the proximate cause of Nathaniel Branson's death. To put it simply, there are genuine issues of material fact on this issue and Summary Judgment is inappropriate.

IT IS HEREBY ORDERED AND ADJGDGED that the Defendant's Motions for Summary Judgment are OVERRULED.

DATED this 16th day of MAY, 2005.



ANTHONY W. FROHLICH, JUDGE
BOONE CIRCUIT COURT

