

2001

Jeanne Schaerrer v. Professional Compounding Centers of America, Inc., Stewart's Plaza Pharmacy, Inc., Stewart Koeven, R.PH., Jeffrey W. Johnson, M.D., American Home Products Corp., A.H. Robins Company, Inc., and Wyeth-Ayerst Laboratories Company, Inc. : Reply Brief of Appellant/Cross-Appellee

Utah Supreme Court

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IN THE UTAH SUPREME COURT

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JEANNE SCHAERRER,

Plaintiff and  
Appellant,

v.

PROFESSIONAL COMPOUNDING  
CENTERS OF AMERICA, INC.,  
STEWART'S PLAZA PHARMACY,  
INC., STEWART KOEVEN, R.PH.,  
JEFFREY W. JOHNSON, M.D.,  
AMERICAN HOME PRODUCTS  
CORP., A.H. ROBINS COMPANY,  
INC., AND WYETH-AYERST  
LABORATORIES COMPANY, INC.,

Defendants and  
Appellees.

Utah Supreme Court No. 20010471-SC

**REPLY BRIEF OF THE  
APPELLANT/CROSS-APPELLEE**

Appeal from the Fourth Judicial  
District Court, Utah County,  
Judge James R. Taylor

Utah R. App. P. 29 Priority: 15

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UTAH SUPREME COURT

JUN 14 2002

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CLERK OF THE COURT

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## ARGUMENT

As the trial court stated in denying Stewart's first motion for summary judgment, the Pharmacist in this case wants the best of both worlds: "He wants the economic profit from making a desirable product available for sale but wants to avoid the testing, research and warning responsibility that generally attach to the introduction of a new product." (Record at 1004.) Stewart's created a product not otherwise available to fill what he perceived to be a need in the marketplace, and marketed that product by providing free samples for physicians to try out on their patients. Based on this activity, the trial court correctly found that he stepped from behind the pharmacist's counter and became a pharmaceutical manufacturer by creating and marketing a product not otherwise available. (Id.) Nonetheless, Stewart's maintains that it is subject to none of the legal duties that go with being a pharmaceutical manufacturer, and argues that it should be allowed to take advantage of protections generally afforded to pharmacists. Stewart's cannot have it both ways.

All of Stewart's arguments, both in its Cross-Appeal and in its Response to Schaerrer's Appeal, are based upon two erroneous assertions. First, Stewart's mischaracterizes its role in supplying its product (the combination fen-phen capsule) to Schaerrer. Stewart's arguments are based upon the position that it was merely a passive retailer, an unsuspecting link in the chain of distribution. The evidence is overwhelmingly to the contrary. Second, Stewart's maintains that, in order to prevail on her strict liability claims, Schaerrer is required to prove that some conduct of Stewart's caused her injuries. This is wholly inconsistent with well-settled strict products liability

jurisprudence.

## **CROSS APPEAL**

### **POINT I.     STEWART'S IS NOT IMMUNE FROM PLAINTIFF'S STRICT PRODUCTS LIABILITY CLAIMS**

The issue presented by Stewart's cross-appeal is whether the trial court correctly determined that Stewart's was not entitled to immunity from claims of strict products liability. Stewart's cites several non-Utah decisions holding that pharmacists are immune from strict products liability for injuries caused by defects in drug products they provide to patients. However, apparently recognizing that the circumstances of this case are factually distinct from those in which other courts have granted pharmacist immunity from strict liability, Stewart's urges this Court to adopt a modified version of pharmacist immunity to fit these circumstances. The rule urged by Stewart's is unworkable and is inconsistent with the concepts underlying strict products liability.

#### **A.     The Authorities Cited By Stewart's In Support Of Pharmacist Immunity Are Inapplicable To This Case.**

No Utah court has yet adopted the position advocated by Stewart's, *i.e.* that pharmacists are immune from strict liability for injuries caused by defective drugs. Stewart's cites several decisions from other jurisdictions in urging that this Court adopt such a doctrine. However, all of those decisions involved circumstances which are quite different from this case and which do not support an extension of that doctrine to this case.

Each of the cases cited by Stewart's arose from similar factual circumstances. Those cases are unlike the instant case, however, as those cases involved

pharmaceutical products manufactured, marketed and sold by large drug companies subject to FDA regulations. These finished drug products were supplied to pharmacies, which then dispensed them to plaintiffs pursuant to a doctor's prescription. See Coyle v. Bonnet Lane Pharmacy, 584 A.2d 1383 (Pa. 1991) (case involving prescription drug Bendectin, manufactured by Merrell Dow Pharmaceuticals); Raynor v. Richardson-Merrell, Inc., 643 F.Supp. 238 (D.D.C. 1986) (also involving Bendectin); Murphy v. E.R. Squibb & Sons, Inc., 710 P.2d 247 (Cal. 1985) (case involving prescription drug DES, manufactured by E.R. Squibb & Sons); and Leesley v. West, 518 N.E. 2d 758 (Ill. App. 1988) (case involving drug Feldene, manufactured by Pfizer, Inc.). In Coyle, the Pennsylvania Supreme Court pointed out that,

unlike the marketing system for most other products, the distribution system for prescription drugs is highly restricted. Pharmacists, as suppliers, do not freely choose which 'products' they will make available to consumers in any given instance, and patients, as consumers, do not freely choose which 'product' to buy. Physicians exercising sound medical judgment act as intermediaries in the chain of distribution ...

Id. at 1386.

Coyle, and the other cases cited by Stewart's, illustrate the body of law which has developed to define the responsibilities of the participants in this "highly restricted distribution system" for prescription drugs. Specifically, these cases govern the duties of: (a) pharmaceutical manufacturers which formulate and test drug products, seek approval from the FDA to market the drug, and prepare warnings, which are also subject to FDA approval, regarding the risks and side effects of their products; (b) physicians who, based upon their evaluations of their patients and information supplied by drug



manufacturers, determine what medications are appropriate for their patients; and (c) pharmacists who receive a prescription from a doctor and simply dispense the drug in the prescribed dosage and quantity to a patient. Legal concepts including limitations on strict products liability for manufacturers of drugs<sup>1</sup>, the learned intermediary doctrine<sup>2</sup>, and pharmacist immunity<sup>3</sup> have developed in this highly restricted distribution system for prescription drugs. These concepts arose from cases such as Coyle, Raynor, etc., in which a pharmaceutical manufacturer goes through the FDA approval process and brings a drug to market, provides information regarding the uses and risks of the drug to prescribing doctors, who can then assess the risks and benefits for a particular patient, and where the pharmacist's role is limited to merely dispensing the correct drug in the dosage and quantity specified by the physician's prescription.

The difference between the circumstances presented by this case and those in the authorities cited by Stewart's is clear. As the trial court correctly held in its September 1, 2000 Order denying summary judgment, Stewart's activities in this case deprived him of the pharmacist immunity which might otherwise attach. (See Record at

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<sup>1</sup> In Grundberg v. The Upjohn Co., 813 P.2d 89 (Utah 1991), this Court adopted comment k to Section 402A of the Restatement (Second) of Torts. This ruling, which limited strict liability claims against pharmaceutical manufacturers, relied heavily on the "elaborate regulatory system" overseen by the FDA as supporting adoption of comment k with respect to manufacturers of prescription drugs. 813 P.2d at 95-97.

<sup>2</sup> "The fact that manufacturers of a prescription drug cannot adequately evaluate the effect of the drug on any particular patient is one of the predominant reasons that courts have adopted the learned intermediary doctrine exempting those manufacturers from the duty to directly warn consumers. [citations omitted]" Leesley v. West, 518 N.E.2d 758, 762 (Ill.App. 1988).

<sup>3</sup> Coyle, supra at 1386.

1003-1008.) Stewart's activities with respect to the development, formulation, marketing and sale of one-a-day fen/phen took him outside of the highly restricted system of prescription drug distribution on which pharmacy immunity is based. The record is clear with respect to the following:

- Stewart Koeven came up with the idea for one-a-day, combination fenfluramine-phentermine capsules, in an effort to address what he saw was a lack of compliance by patients taking these medications. (Record at 680, 687-93.)
- Stewart Koeven created a new product which was not otherwise available and which did not go through the normal FDA-reviewed process of clinical trials to establish safety and efficacy. (Record at 1004, 824-851.)
- Stewart Koeven performed no testing as to the safety or efficacy of his product, and as far as he knew, no one had ever prepared or tested such a product at the time he was developing it. (Record at 680, 687-92; see also Record at 846-51.) Stewart's also failed to provide any warnings regarding potential risks or side effects to the physicians to whom it marketed its products, including Schaerrer's prescribing physician Dr. Jeffrey Johnson. (Record at 848-50, 853-43, 1007.)
- Stewart Koeven created a market for his new product by supplying samples of his drug product to doctors to try out on their patients,

prior to ever receiving a single prescription for the combination fenphen capsule. (Id.; see also Record at 1007.)

- With respect to the prescriptions filled for Schaerrer, Stewart's did more than simply "fill a valid prescription." Dr. Johnson initially prescribed to Schaerrer 60 mg of fenfluramine and 20 mg of phentermine. (See, *e.g.*, Record at 617.) Stewart's provided a single capsule with the fenfluramine, phentermine, plus a purported time release agent and a filler, which were not specified in Dr. Johnson's prescription. (Id.; see also Record at 1007.)<sup>4</sup>

Given these facts, this Court should reject Stewart's contention that its role was no different than any other pharmacist filling a prescription. Stewart's activities do not support application of the policies supporting pharmacy immunity, as discussed in Coyle. For example, Stewart's acted like a pharmaceutical manufacturer in that he perceived a need for a specific product in the marketplace (*i.e.*, a one-a-day capsule to address the "compliance" problem), and he developed and marketed that product. Unlike the situation in Coyle, Stewart's did freely choose which products it would make available to consumers. In addition, Dr. Johnson did not act as a learned intermediary in the chain of distribution, as Stewart's failed to make any information about his product available to Dr. Johnson. Finally, the Coyle court pointed out that imposing strict

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<sup>4</sup> The uncontroverted testimony of Schaerrer's expert, Dr. Bruce Woolley, is that this fact alone took Stewart's outside the realm of a compounding pharmacist. Stewart's activities were instead the activities of a pharmaceutical manufacturer conducting a clinical trial of an experimental drug. (Record at 824-30.)

liability on pharmacists would not serve the purpose of preventing the circulation of defective products. Coyle, 584 A.2d at 1386. Here, subjecting Stewart's to strict liability would have the beneficial effect of dissuading pharmacists from concocting new drug products outside the purview of the FDA's regulatory system.

**B. Stewart's Proposed Rule Is Unworkable And Inconsistent With Strict Products Liability.**

Apparently realizing that it is not entitled to pharmacy immunity under the facts of this case, Stewart's urges the Court to adopt a new rule of law whereby a pharmacist engaging in "some manufacturing activity" is not subject to strict liability if the "manufacturing activities are tangential," do not increase the risk of using the drug and the drugs are supplied pursuant to a valid prescription by a doctor. (See Stewart's Brief at 18.) Putting aside the difficulties in determining from case to case whether a particular pharmacist's activities are "tangential," Stewart's proposed rule is simply incompatible with concepts of strict products liability.

The doctrine of strict products liability focuses on the nature of the product at issue, not the conduct of the defendants. To establish strict products liability under Utah law, a plaintiff need only prove that (1) the product is unreasonably dangerous due to a defect or a defective condition; (2) the defect existed at the time the product was sold; and (3) the defective condition was a cause of the plaintiff's injury. Lamb v. B&B Amusements Corp., 869 P.2d 926, 929 (Utah 1993). The conduct of a manufacturer in creating the defect, and whether or not the manufacturer used due care in producing the product, are irrelevant to the strict products liability analysis. As this Court has made

clear, strict liability attaches even if “the seller has exercised all possible care in the preparation and sale of his product.” See Grundberg, *supra*, 602 P.2d at 156, adopting § 402A of Restatement (Second) of Torts. The analysis of whether a seller of a product is subject to strict products liability does not turn on whether the seller’s activities are tangential or central to creation of the defect in the product. The focus is instead on the product itself and whether that product is defective, *i.e.*, it is unreasonably dangerous to the user. Unreasonably dangerous means that the product was dangerous to an extent beyond that which would be contemplated by the ordinary consumer when considering the product’s characteristics, propensities, risks, dangers and uses together with any actual knowledge, training or experience possessed by that particular user. Utah Code Ann. § 78-15-6 (2) (1996). Stewart’s proposed “rule” would require an analysis of the pharmacist’s conduct in causing or contributing to the defect. Such an analysis is at odds with the strict products liability doctrine, and should be rejected.<sup>5</sup>

### **REPLY RE SCHAERRER’S APPEAL**

#### **POINT I. THE FINDINGS OF FACT ARE NOT DISPOSITIVE**

Stewart’s points out that Schaerrer has not challenged the trial court’s findings of fact. However, the findings are not dispositive of the issues presented here and do not compel the result sought by Stewart’s. In addition, Schaerrer does take issue

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<sup>5</sup> Stewart’s would not qualify for pharmacist immunity under the rule it proposes in any event. Stewart’s suggests that this Court limit pharmacy immunity to cases in which “the drugs are supplied pursuant to a valid prescription by physician.” As argued above, Stewart’s went beyond the face of the prescription written by Dr. Johnson for Schaerrer; Stewart’s combination fen-phen product contained ingredients not specified in Dr. Johnson’s written prescription. (See footnote 4, above, and accompanying text.)

with Stewart's characterization of one of the court's findings of fact: Stewart's maintains that "the court found that Stewart's so-called 'manufacturing' activities did not cause Schaerrer's injuries and Schaerrer conceded this point." (Stewart's Brief at 9.) The court did not make this finding and Schaerrer has not conceded this point. What the court actually found was that there was no evidence supporting an inference that the combining of fenfluramine, phentermine and a time-released agent in a single capsule altered or affected the fenfluramine or that the fenfluramine supplied by Stewart's was more dangerous or more likely to cause injury to plaintiff than fenfluramine supplied to plaintiff by defendant American Home Products. (See Record at 1159; see also Appellee's Index, Tab 2.) As argued herein, Schaerrer is not required to prove that Stewart's "activities" caused her injuries.

**POINT II. STEWART'S HAS NOT DEMONSTRATED THAT IT IS ENTITLED TO INDEMNIFICATION FROM PCCA**

Stewart's argues that it is entitled to indemnification from PCCA as a matter of law. (Stewart's Brief at 10-12). Stewart's argument is based upon two fallacies: First, Stewart's maintains that the only basis on which it may be strictly liable is as a mere link in the chain of distribution of fenfluramine. (*Id.*) Second, Stewart's argues that Schaerrer is required to submit evidence that some conduct of Stewart's caused Schaerrer's injuries.

**A. Stewart's Is More Than A Passive Link In The Distribution Chain.**

As argued at length in Schaerrer's opening brief, Stewart's role in providing diet drugs to Schaerrer went far beyond simply passing along a product

manufactured by somebody else. The product that injured Schaerrer (Stewart's combination fen-phen capsule) did not even exist until Stewart's came up with the idea of combining fenfluramine and phentermine in a single capsule with a purported time release agent, marketing it through word of mouth by supplying free samples to doctors to try out on their patients and making it available to patients who requested that their doctors prescribe its product to them.<sup>6</sup> These activities distinguish Stewart's from a mere passive retailer, and make him the manufacturer of the product which caused injury to Schaerrer. This point has been conceded by Stewart's and adopted by the trial court. (See Record at 1007.) Having conceded that it is a manufacturer, Stewart's is forced to argue that the specific activities which made it a manufacturer did not cause Schaerrer's injuries. However, in order to prevail on her strict liability claims, Schaerrer is not required to prove that she was injured by this conduct. She can prevail on her strict liability claims by proving that a defect in Stewart's product caused her injury.

**B. Evidence That Stewart's Conduct Caused Schaerrer's Injuries Is Not An Element of the Strict Products Liability Claim.**

The sufficiency of Schaerrer's evidence that Stewart's combination fen-phen capsule caused or contributed to her valvular heart disease is not at issue in these appeals. (See, e.g., Statement of Issues Presented For Review, Stewart's Brief at 2.) However, there is ample expert testimony in this case, not all of which is before the

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<sup>6</sup> Stewart's will likely argue that the "product" at issue is the raw fenfluramine powder which he obtained from PCCA to incorporate into his combination capsule. However, Schaerrer did not simply ingest raw fenfluramine powder passed on to her by Stewart's. She purchased and ingested combination fen-phen capsules created, manufactured, marketed and sold by Stewart's.

Court, from which a jury could find that the product supplied to Schaerrer by Stewart's, the combination fen-phen capsule, was unreasonably dangerous and defective and caused or contributed to Schaerrer's heart valve injury. As argued above at pages 7-8, the relevant analysis is whether the defective condition of the product caused Schaerrer's injury, not whether Stewart's conduct caused the injury.

**C. Comparative Fault Principles Apply to Strict Products Liability Claims.**

Stewart's also makes the argument, echoing the trial court's statements at the hearing on the underlying summary judgment motion, that the trier of fact would be unable to apportion fault among several defendants in this strict liability action.

(Stewart's Brief at 15.) As argued in Schaerrer's opening brief, this is simply wrong.

(See Brief of Appellant, at 18-20.) The Utah Liability Reform Act expressly applies to strict liability claims, including strict products liability. Utah Code Ann. § 78-27-37 (2).

This Court has previously held that comparative fault principles apply in strict products liability actions. Mulherin v. Ingersoll-Rand Co., 628 P.2d 1301 (Utah 1981). Strict liability is a method of determining who is liable for a particular injury; it is not a method of allocating damages among various tortfeasors.

**CONCLUSION**


For the foregoing reasons, plaintiff and appellant Jeanne Schaerrer respectfully requests that this Court (1) reverse the trial court's April 30, 2001 Order and Judgment granting Stewart's motion for summary judgment and dismissing Schaerrer's complaint against Stewart's; (2) affirm the trial court's September 1, 2000 Order denying



summary judgment; and (3) remand this matter to the trial court for further proceedings, including trial.

Dated: June 11, 2002

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Appellees.

Utah Supreme Court No. 20010471-SC

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I am readily familiar with Lieff, Cabraser, Heimann & Bernstein, LLP's practice for collection and processing of documents for mailing with the United States Postal Service, and that practice is that the documents are deposited with the United States Postal Service with postage fully prepaid the same day as the day of collection in the ordinary course of business.

On June 11, 2002, I served the following document(s):

1. **REPLY BRIEF OF THE APPELLANT/CROSS APPELLEE;**  
*and*
2. **PROOF OF SERVICE BY U.S. MAIL**

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I declare under penalty of perjury that the foregoing is true and correct. Executed at San Francisco, California on June 11, 2002.

  
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