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IX. Evidence

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power over structures that completely span waterways suggests that Congress no longer considers the delegation unconstitutional.⁵⁷ Consequently, the Act currently is more ambiguous than when passed in 1899. The only means of determining the proper interpretation of the sections is for Congress to amend the Act and clarify the meaning of sections 9 and 10.

Amending the Act not only will clarify the meaning of sections 9 and 10 but also will prevent needless litigation over the proper interpretation of the sections.⁵⁸ Repetitive litigation to determine whether the Corps properly issued permits under section 10 is wasteful. Passage of a comprehensive act clarifying sections 9 and 10 would eliminate superfluous litigation by establishing expressly the boundaries of the Corps' structure-approval authority.

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IX. EVIDENCE

Admissibility of Evidence of Subsequent Remedial Measures

Rule 407 of the Federal Rules of Evidence excludes evidence of subsequent repairs by a defendant when offered to prove the negligence or culpable conduct of a defendant in a tort action.¹ Congress enacted

Act of 1920, Congress delegated the authority for licensing the construction of dams to the Federal Power Commission (FPC). The FPC, however, cannot issue a license for a dam unless the Corps approves the plans. 16 U.S.C. § 797(e) (1976). In 1946 Congress enacted the General Bridge Act which delegated Congress' bridge-approval authority to the Corps. Legislative Reorganization Act of 1946, Pub. L. No. 79-601 § 501, 60 Stat. 812 (1946) (codified at 33 U.S.C. § 525 (1976)). In 1966, Congress removed the Corps' bridge-approval authority and gave the authority to the Secretary of Transportation. 49 U.S.C. § 1655(g)(3), (6) (1976). The Corps still must approve the plans, however, before the Secretary of Transportation can issue a bridge permit. *Id.* In addition, with the enactment of the Department of Transportation Act, Congress also vested causeway approval power in the Secretary of Transportation. *Id.* The Secretary of Transportation then delegated his authority to issue permits for bridges and causeways to the United States Coast Guard. 49 C.F.R. § 1.46(c)(9) (1980); see *Sisselman v. Smith*, 432 F.2d 750, 753-54 (3d Cir. 1970) (recognizing Secretary of Transportation's authority to transfer bridge-approval power to Coast Guard).

⁵⁷ See text accompanying notes 43-44 *supra* (reason for Congress' retention of § 9 approval powers).

⁵⁸ Environmentalists recently have focused on the ambiguity of § 9 and § 10. The groups have challenged the Corps' interpretation in an attempt to halt projects they consider undesirable. See notes 25 & 28 (synopsis of cases brought by environmentalists to challenge Corps' interpretation of § 9 and § 10).

¹ FED. R. EVID. 407. Rule provides:

Subsequent Remedial Measures—When, after an event, measures are taken which, if taken previously, would have made the event less likely to occur,

Rule 407 to encourage amelioration of dangerous conditions by preventing plaintiffs from using evidence of subsequent improvements to establish culpability in lawsuits.² The Rule specifically admits repair evidence, however, if the defendant controverts the feasibility of making the repair.³ Negligence or culpable conduct is not an element of the tort of strict liability.⁴ Therefore, Rule 407 does not as clearly limit admissibility of evidence of subsequent remedial measures in strict liability actions as it does in negligence actions.⁵ Under either negligence or strict liability theory, a manufacturer may be liable for damages suffered as a result of an inadequate warning accompanying a prescription drug.⁶ In *Werner v. Upjohn Co.*,⁷ the Fourth Circuit examined whether evidence of subsequent change in a prescription drug warning was admissible under a feasibility or strict liability exception to Rule 407. The Fourth Circuit held that evidence of the modified warning was not admissible under either exception. The *Werner* court found that the defendant had not controverted feasibility at trial,⁸ and due to the strong policy considerations behind the Rule, the court refused to recognize a strict liability exception to Rule 407.⁹

evidence of the subsequent measures is not admissible to prove negligence or culpable conduct in connection with the event. This rule does not require the exclusion of evidence of subsequent measures when offered for another purpose, such as proving ownership, control, or feasibility of precautionary measures, if controverted, or impeachment.

Id. Although Rule 407 applies to criminal as well as civil actions, see FED. R. EVID. 1101, only the applicability of Rule 407 of civil tort actions will be considered in this note.

² See *Werner v. Upjohn Co.*, 628 F.2d 848, 855-56 (4th Cir. 1980), *cert. denied*, 49 U.S.L.W. 3487 (U.S., Jan. 13, 1981); Advisory Committee's Notes, FED. R. EVID. 407.

³ FED. R. EVID. 407. A repair is feasible if it is both economically practical and technologically possible. See *Olson v. Arctic Enterprises, Inc.*, 349 F. Supp. 761, 765 (D.N.D. 1972); Note, *Seller's Liability for Defective Design—The Measure of Responsibility*, 37 WASH. & LEE L. REV. 237, 242 (1980) [hereinafter cited as *Seller's Liability*].

⁴ See W. PROSSER, HANDBOOK OF THE LAW OF TORTS § 75, at 494 (4th ed. 1971) [hereinafter cited as PROSSER].

⁵ Courts have allowed admissibility of evidence of subsequent repairs in strict liability cases. See, e.g., *Robbins v. Farmers Union Grain Terminal Ass'n*, 552 F.2d 788, 793 (8th Cir. 1977); *Ault v. International Harvester Co.*, 13 Cal. 3d 113, 118, 528 P.2d 1148, 1150-51, 117 Cal. Rptr. 812, 814 (1974). See also PROSSER, *supra* note 4, § 75 at 494.

⁶ See RESTATEMENT (SECOND) OF TORTS § 402A (1965) [hereinafter cited as RESTATEMENT § 402A]. An inadequate warning accompanying a drug is a defect in the drug. *Id.* at comments j and k. The manufacturer may be liable for damages caused by a defect under negligence theory. See *Smyth v. Upjohn Co.*, 529 F.2d 803, 805 (2d Cir. 1975) (*per curiam*); *Chambers v. G.D. Searle & Co.*, 441 F. Supp. 377, 379 (D. Md. 1975), *aff'd per curiam*, 567 F.2d 269 (4th Cir. 1977); *Smith v. E.R. Squibb & Sons, Inc.*, 405 Mich. 79, 88, 273 N.W.2d 476, 479 (1979). A drug manufacturer may also be liable for a defective drug under strict liability theory. See *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 425 (2d Cir. 1969); *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978, 992-93 (8th Cir. 1969); RESTATEMENT § 402A, *supra*.

⁷ 628 F.2d 848 (4th Cir. 1980), *cert. denied*, 49 U.S.L.W. 3487 (U.S., Jan. 13, 1981).

⁸ *Id.* at 851-55.

⁹ *Id.* at 855-58.

Werner brought a diversity action against his physician, Dr. Carbo, and the Upjohn Company (Upjohn) to recover damages for injuries received after taking an antibiotic known as Cleocin.¹⁰ The drug was manufactured by Upjohn and prescribed by Dr. Carbo.¹¹ The Food and Drug Administration (FDA) approved the drug for general use in 1970.¹² As the use of the drug increased, Upjohn began to receive reports of serious side effects from Cleocin use.¹³ Upjohn notified the FDA of the reports, and Upjohn and independent researchers conducted further studies of the drug.¹⁴ Upjohn issued a warning in 1974 of the possibility of pseudomembraneous colitis (PMC) resulting from Cleocin use.¹⁵ The results of the studies prompted Upjohn to revise the warnings again in 1975.¹⁶ The plaintiff first visited Dr. Carbo, however, before Upjohn had released the revised 1975 warning. Dr. Carbo prescribed Cleocin for treatment of a cyst on plaintiff's eyelid.¹⁷ After using the drug for a

¹⁰ *Id.* at 851. The generic name of Cleocin is Clindamycin HCl. *Id.*

¹¹ *Id.*

¹² *Id.* Section 355 of the Federal Food, Drug and Cosmetic Act establishes the requirements for approval of new drugs by the Food and Drug Administration (FDA) before they may be introduced into commerce. 21 U.S.C. § 355 (1976). The manufacturer must submit the following to the Secretary of the FDA: full reports of investigations made of the drug's effectiveness and safety; the components of the drug; the composition of the drug; a full description of the methods, facilities, and controls used in the manufacture, processing, and packing of the drug; samples of the drug and its components; and examples of proposed labeling. *Id.* § 355(b). The Secretary reviews the material and approves the application or gives the applicant an opportunity to present evidence at a hearing. *Id.* at § 355(c). The Secretary may withdraw his approval if he later finds that the drug is unsafe. *Id.* at § 355(e). The statute further requires that the applicant maintain records of reports of clinical experience and other information concerning the drug. *Id.* § 355(j)(1). The Secretary has access to these records upon request. *Id.* § 355(j)(2). FDA regulations are merely minimum standards, however, and do not ensure "foolproof" drugs. See Kessler, *Products Liability*, 76 YALE L.J. 887, 931 (1967).

¹³ 628 F.2d at 851. The side effects of Cleocin include diarrhea and colitis. *Id.* Colitis is inflammation of the colon, or large intestine. See STEDMAN'S MEDICAL DICTIONARY 297 (4th Lawyer's Ed. 1976) [hereinafter cited as STEDMAN'S].

¹⁴ 628 F.2d at 851. Cleocin was reported to cause pseudomembraneous colitis (PMC) in some patients. *Id.* PMC, usually caused by staphylococcus bacteria, occurs most commonly as a postoperative complication due to shock or due to prolonged antibiotic therapy. See STEDMAN'S, *supra* note 13, at 466. Diarrhea and nausea are symptoms of PMC. *Id.* Experts originally thought that the incidence of PMC was low in Cleocin users, but a study published in late 1973 found signs of PMC in 10 percent of a test group that took the drug. Werner did not allege that the PMC found by the study was of the same type which later infected him. *Id.* at 851-52.

¹⁵ 628 F.2d at 852. In the summer of 1974, Upjohn issued the warning in the package insert of Cleocin and in letters to every physician in the United States. *Id.*

¹⁶ *Id.* at 851. The 1974 warning cautioned that "severe and persistent diarrhea" had been reported and that the drug "should be discontinued" when significant diarrhea occurred. *Id.* at 852. The 1975 warning indicated that Cleocin "can cause severe colitis which may end fatally." *Id.* at 853.

¹⁷ *Id.* at 852. The plaintiff also sued Dr. Carbo for malpractice in the district court action. *Id.* at 851. The parties in Werner contested the scope of Dr. Carbo's instructions to the

week, plaintiff developed nausea.¹⁸ Although he stopped using the drug, Werner soon experienced severe dehydration and diarrhea. Eventually, a large portion of his colon had to be removed.¹⁹

At trial, Werner alleged that the 1974 warning inadequately disclosed the information available to Upjohn at the time the warning was released. In light of the defective warning, the plaintiff asserted that Cleocin was unreasonably dangerous and Upjohn was negligent.²⁰ Upjohn argued that the incidence of Cleocin's side effects was quite low and that if the plaintiff had received proper and timely treatment from Dr. Carbo, plaintiff would not have suffered permanent injury.²¹ Upjohn further claimed that all of the plaintiff's reactions were encompassed in the 1974 warning.²²

The plaintiff introduced Upjohn's expanded 1975 caveat into evidence to support his allegation that the 1974 warning inadequately advised prescribing physicians of Cleocin's side effects.²³ Although Upjohn moved to exclude all reference to the 1975 warning, the district court allowed the warning to be admitted. The trial judge instructed the jury that they were not to consider the 1975 warning on the issue of negligence or culpable conduct, but only on the issue of feasibility.²⁴ Never-

plaintiff. Dr. Carbo claimed that he warned the plaintiff that he might experience nausea, vomiting, or diarrhea. Dr. Carbo also claimed that he instructed the plaintiff to decrease the dosage by half if he experienced any adverse reactions. The plaintiff denied that Dr. Carbo had made either of the statements. *Id.* at 852. The jury found Dr. Carbo guilty of negligence in his method of prescribing the drug. *Id.* at 851. Dr. Carbo appealed the decision. *Id.* The Fourth Circuit in *Werner* vacated the judgment against Dr. Carbo and remanded the case for consideration without the admission of the evidence of the warning change. The Fourth Circuit reasoned that although *Werner* focused on the adequacy of Upjohn's warning, Dr. Carbo's duty to instruct his patient was so closely related to Upjohn's warning that the judgment against Dr. Carbo could not stand. *Id.* at 860.

¹⁸ *Id.* at 852.

¹⁹ *Id.* In January of 1975, another doctor examined the plaintiff and discontinued other drugs prescribed by Dr. Carbo that Upjohn discouraged for use with Cleocin in its 1974 warning. *Id.*; see *STEDMAN'S*, *supra* note 13, at 1283. After the removal of his colon, the plaintiff underwent other operations to restore his excretory functions. At the time of his appeal, Werner was under dietary restrictions, had diarrhea, and could not engage in strenuous physical activity. 628 F.2d at 852.

²⁰ *Id.* at 852-53. Plaintiff argued that even if the warning itself were adequate, the warning's adequacy was negated by Upjohn's advertising and the activities of Upjohn's sales representatives. *Id.* See also *Sterling Drug Co. v. Yarrow*, 408 F.2d 978, 991-92 (8th Cir. 1969) (duty of sales representatives to disseminate drug manufacturer's warnings to physicians).

²¹ 628 F.2d at 852. Pharmaceutical manufacturers may be held liable for damages due to a physician's failure to read warnings, if the warnings themselves were not reasonable or if the method chosen to alert physicians to the warnings were inadequate. See *Sterling Drug Co. v. Yarrow*, 408 F.2d 978, 992 (8th Cir. 1969); *Hamilton v. Hardy*, 549 P.2d 1099, 1109 (Colo. App. 1976).

²² 628 F.2d at 852.

²³ *Id.* at 853.

²⁴ *Id.*

theless, the jury found Upjohn negligent in failing to warn physicians properly of Cleocin's side effects,²⁵ and Upjohn appealed.²⁶

On appeal, the Fourth Circuit found that Upjohn did not controvert whether the information in the 1975 caveat feasibly could have been included in the 1974 warning.²⁷ During negotiations with the FDA on the exact language of the 1974 warning, Upjohn had made two statements claiming that language suggested by the FDA for the 1974 warning was misleading.²⁸ In the first statement Upjohn proposed the substitution of "can occur" for "more rarely [occur]," the phrase suggested by the FDA. Upjohn contended to the agency that PMC resulted more often than indicated by the indefinite term "rarely" would indicate.²⁹ The FDA also had requested that Upjohn include a caution that Cleocin not be used for minor infections. In the second statement, Upjohn had contested the necessity of the caution because of the limitations already included in the warning.³⁰ The Fourth Circuit found that Upjohn's suggestions actually strengthened and clarified the warning.³¹ The court determined that Upjohn had not argued that it was infeasible to write a stronger warning, but that the warning adequately conveyed all information

²⁵ *Id.* at 851. In addition to finding Upjohn negligent, the jury found that Dr. Carbo was negligent in prescribing Cleocin and that his negligence proximately caused or contributed to Werner's injury. The jury also found Upjohn negligent in selling Cleocin and that this negligence proximately caused or contributed to Werner's injuries. *Id.* Upjohn also breached an implied or express warranty in its sale of Cleocin to Dr. Carbo. *Id.* Upjohn was not liable in strict liability for marketing an unreasonably dangerous drug. *Id.* The Fourth Circuit recognized that the verdict for Upjohn on the issue of strict liability was inconsistent with the verdicts against Upjohn on the negligence and breach of warranty issues. *Id.* at 860. The Fourth Circuit held that the admissibility of the evidence of the 1975 warning so influenced the disposition of all of the claims that all judgments must be vacated and remanded. *Id.*

²⁶ *Id.* at 851. Upjohn appealed on the grounds that the 1975 warning was improperly admitted and the Dr. Carbo's admitted failure to read the 1974 warning abrogated Upjohn's liability. *Id.* Dr. Carbo appealed on the grounds that Werner had not established the basic elements of a malpractice case. *Id.* Both Upjohn and Carbo appealed the trial court's refusal to include a jury instruction on contributory negligence and to reduce the \$400,000 damage award to present value. *Id.* Werner cross-appealed that trial court's refusal to allow evidence to support punitive damages. *Id.* Because of the overwhelming impact of the evidence, however, the Fourth Circuit focused only on the admissibility of the subsequent warning in *Werner*. *Id.* at 860.

²⁷ *Id.* at 855. "If controverted" means that the defendant must first deny control, ownership, or feasibility in order for the plaintiff to introduce the evidence. *See* FED. R. EVID. 407; SALTZBURG & REDDEN, FEDERAL RULES OF EVIDENCE MANUAL, 162-63 (2d ed. 1977); text accompanying notes 1-4 *supra*. The Fourth Circuit found that the defendant must actually raise the issue of feasibility in order for the exception to Rule 407 to apply. Mere failure to make a pre-trial concession to the feasibility of the warning does not mean that the issue is controverted. 628 F.2d at 855.

²⁸ 628 F.2d at 855.

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

available in 1974.³² Furthermore, the plaintiff used the 1975 warning at trial not merely in connection with feasibility, but in a direct attempt to prove antecedent negligence.³³ In his closing argument, the plaintiff claimed that Upjohn knew of the dangers of Cleocin and delayed making a change in the warning until March 1975 in order to maximize profits.³⁴ The Fourth Circuit found that the plaintiff's closing arguments clearly violated Rule 407.³⁵

The Fourth Circuit's holding that the evidence of the subsequent warning should be inadmissible to prove Upjohn's negligence is consistent with the wording and policy of Rule 407. The plaintiff clearly failed to show that Upjohn controverted the feasibility of implementing an improved warning. Reversible error occurred when Werner exceeded the judge's allowance of the subsequent warning to show feasibility and used the 1975 warning to show antecedent negligence. On the basis of this error, the Fourth Circuit correctly reversed and remanded for a new trial.³⁶

In addition to the negligence claim, Werner argued that the evidence of the 1975 warning was admissible under strict liability theory.³⁷ Strict liability enables a plaintiff injured by a defective product to recover

³² *Id.* If a defendant does not raise the issue of feasibility, the trial court is entitled to weigh the need for evidence of subsequent repair against the risk that the jury may improperly infer negligence from it. See *Boeing Airplane Co. v. Brown*, 291 F.2d 310, 315 n.3 (9th Cir. 1961). The Fourth Circuit determined that the jury could have improperly inferred negligence, and that this important policy consideration of Rule 407 overshadowed the plaintiff's need for the evidence. 628 F.2d at 856; see C. McCORMICK, *HANDBOOK OF THE LAW OF EVIDENCE* § 275, at 668-69 (2d ed. 1972).

³³ 628 F.2d at 854.

³⁴ *Id.*

³⁵ *Id.* The plaintiff claimed that the limiting instruction given by the district court made any use of the 1975 warning harmless error. *Id.* Rejecting the plaintiff's claim, the Fourth Circuit held that Werner could not offer damaging evidence for a limited purpose, use it for a forbidden purpose over objection, and then insulate reversal by a limiting instruction at the close of the case. *Id.* Alternatively, the plaintiff contended that Upjohn had waived any objection to Werner's use of the 1975 warning because Upjohn failed to state specific grounds for its objection at trial. *Id.* at 853. The Fourth Circuit, however, found that the ground for objection was clear from Upjohn's pretrial motion requesting that all references to the 1975 warning be suppressed. *Id.*; see FED. R. EVID. 103(a)(1) (timely objection to strike must be made unless specific ground of objection is apparent from content). The Fourth Circuit reasoned that if Upjohn had objected during plaintiff's closing arguments, the objection would have only emphasized the impermissible point to the jury. 628 F.2d at 854, citing *Leathers v. General Motors Corp.*, 546 F.2d 1083, 1086 (4th Cir. 1976) (defendant not required to object to damaging argument during plaintiff's closing argument).

³⁶ 628 F.2d at 851. The district court in *Werner* abused its discretion by failing to consider whether the plaintiff had not offered the evidence simply to permit the jury to make and improper inference of negligence. See 2 J. WEINSTEIN & M. BERGER, *WEINSTEIN'S EVIDENCE* ¶ 407[03] (1979) [hereinafter cited as WEINSTEIN & BERGER]. Abuse of discretion by a trial court in determining admissibility of evidence can be reversible error. See *Boeing Airplane Co. v. Brown*, 291 F.2d 310, 315 n.3 (9th Cir. 1961).

³⁷ 628 F.2d at 856.

damages from the manufacturer without proof of the negligence or culpable conduct of the manufacturer.³⁸ The plaintiff must prove only that the product was defective in order to recover for his injuries.³⁹

Rule 407 excludes evidence of subsequent remedial measures only if introduced to prove the negligence or culpable conduct of the defendant.⁴⁰ The exceptions listed in Rule 407 which allow evidence proving ownership, control, feasibility, or impeachment are illustrative, but not exhaustive.⁴¹ Courts that admit evidence of subsequent repair hold that strict liability claims constitute another exception to the Rule.⁴² Strict liability requires the manufacturer to bear the costs of damages caused by his products because the manufacturer is acting for his own purpose in seeking a benefit or profit from the sale of his product. The manufacturer is in a better economic position than the victim to bear the cost of injuries by passing the cost to the public in his prices.⁴³

In *Werner*, the Fourth Circuit did not consider the consumer protection policy which underlies strict liability theory.⁴⁴ The Fourth Circuit refused to expand the exceptions to Rule 407 in strict liability claims.⁴⁵ The court found that Congress, in enacting Rule 407, had determined that evidence of subsequent precautions should be excluded in cases in-

³⁸ See *Robbins v. Farmers Union Grain Terminal Ass'n*, 552 F.2d 788, 793 (8th Cir. 1977); *Ault v. International Harvester Co.*, 13 Cal. 3d 113, 118, 528 P.2d 1148, 1150-51, 117 Cal. Rptr. 812, 814 (1974); *Barry v. Manglass*, 55 App. Div. 2d 1, 7, 389 N.Y.S.2d 870, 875 (1976); Note, *Products Liability and Evidence of Subsequent Repairs*, 1972 DUKE L.J. 837, 837-40 (1972) [hereinafter cited as *Subsequent Repairs*]; *Seller's Liability*, *supra* note 3, at 237-38.

³⁹ See *Greenman v. Yuba Power Prods., Inc.*, 59 Cal. 2d 57, _____, 377 P.2d 897, 900-01, 27 Cal. Rptr. 697, 700 (1962); *Barry v. Manglass*, 55 App. Div.2d 1, 7, 389 N.Y.S.2d 870, 875 (1976); RESTATEMENT § 402A, *supra* note 6, comment g; Wade, *On the Nature of Strict Tort Liability for Products*, 44 MISS. L.J. 825, 829 (1972); *Subsequent Repairs*, *supra* note 38, at 837-40; *Seller's Liability*, *supra* note 3, at 237. The strict liability plaintiff must prove that a defect in the product caused the plaintiff physical harm, that the seller is engaged in the business of selling the product, and that the product reached the plaintiff without substantial change in the condition in which the product was sold. See RESTATEMENT § 402A, *supra* note 6. The seller is held to strict liability regardless of his exercise of due care or the absence of any contract between the plaintiff and the seller. *Id.*

⁴⁰ FED. R. EVID. 407, *see* note 1 *supra*.

⁴¹ 628 F.2d at 856; Advisory Committee's Notes, FED. R. EVID. 407. The Advisory Committee's Notes state that the listed exceptions to the exclusionary rule are merely examples. *Id.*

⁴² See *Robbins v. Farmers Union Grain Terminal Ass'n*, 552 F.2d 788, 792-93 (8th Cir. 1977) (subsequent remedial warning admissible against cattle feed manufacturer in strict liability action); *Ault v. International Harvester Co.*, 113 Cal. 3d 113, 118, 528 P.2d 1148, 1153, 117 Cal. Rptr. 812, 814 (1974) (manufacturer's subsequent change of metal used in gear box admissible in strict liability); *Barry v. Manglass*, 55 App. Div. 2d 1, 7, 389 N.Y.S.2d 870, 875 (1976) (General Motor's issuance of recall letters after accident admissible in strict liability claim).

⁴³ See PROSSER, *supra* note 4, at 494-96; *Seller's Liability*, *supra* note 3, at 239-40.

⁴⁴ See text accompanying notes 38-43 *supra*.

⁴⁵ 628 F.2d at 856.

volving negligent as well as culpable conduct.⁴⁶ Since a manufacturer's conduct under strict liability is technically less blameworthy than negligent or culpable conduct, by excluding evidence of subsequent repair to prove culpable conduct, Congress must have also intended the exclusions to apply to the less blameworthy strict liability conduct.⁴⁷ The Fourth Circuit further stated that the congressional purpose in enacting Rule 407 would be thwarted if the evidence were admitted under either negligence or strict liability theories because the manufacturer's inclination to make subsequent repairs would be repressed in both cases.⁴⁸

The assumption that admissibility of subsequent remedial measures would discourage defendants from making necessary repairs might be erroneous. Manufacturers of mass-produced products may not be as callous as the exclusionary rule assumes.⁴⁹ Few insured defendants will refrain from making subsequent repairs to avoid future accidents.⁵⁰ A manufacturer with a large number of products on the market has an incentive to effect repairs because the evidence of earlier accidents would be admissible in a subsequent suit to show that the defendant knew of the dangerous condition.⁵¹ Therefore, admissibility of evidence of a subsequent repair will not adversely influence the manufacturer's decision whether to effect subsequent remedial measures. Economic self-interest will prompt most manufacturers to make subsequent repairs, whether or not the manufacturer loses a judgment in the interim.⁵²

⁴⁶ *Id.* at 856-57.

⁴⁷ *Id.* The *Werner* court defined culpable conduct as conduct that is blameworthy and reprehensible, or involves a breach of a legal duty. *Id.*; see BLACK'S LAW DICTIONARY (4th ed. 1968). From this definition, the court determined that culpable conduct is worse than negligence or strict liability conduct. 628 F.2d at 856-58. Nevertheless, the conduct of the seller is not at issue in a strict liability action. See RESTATEMENT § 402A, *supra* note 6. Therefore, even if culpable conduct is worse than strict liability conduct, Rule 407 still does not directly apply in a strict liability action. See text accompanying notes 38-42 *supra*.

⁴⁸ 628 F.2d at 857.

⁴⁹ See *Subsequent Repairs*, *supra* note 38, at 848. Commentators have criticized the use of Rule 407 exclusions in products liability actions. See WEINSTEIN & BERGER, *supra* note 36, ¶ 407[2] (Rule 407 could be eliminated with no great loss to defendants); *Subsequent Repairs*, *supra* note 38, at 849-50 (Rule 407 considered obsolete).

⁵⁰ See WEINSTEIN & BERGER, *supra* note 36, ¶ 407[2]. The insured is motivated to limit future damages due to faulty products in order to minimize his insurance premiums. *Id.*

⁵¹ See FED. R. EVID. 404; WEINSTEIN & BERGER, *supra* note 36, ¶ 407[2]; *Subsequent Repairs*, *supra* note 38, at 848-49. In addition to anxiety over the possibility of future damage judgments, manufacturers' concern for consumer protection is encouraged by the activities of consumer organizations and federal agencies, as well as by mass media exposure of the defects. These factors prompt manufacturers to engage in research and make subsequent repairs. See *Subsequent Repairs*, *supra* note 38, at 848-49.

⁵² The common law codified in Rule 407 was originally developed to protect landowners from liability for injuries on their property. See *Columbia & Puget Sound R.R. v. Hawthorne*, 144 U.S. 202, 208 (1892). The rule which protects owners in cases of a single accident on their land is inappropriate when applied to modern marketplace conditions where an unknowing public buys the products. See Prosser, *The Fall of the Citadel (Strict Liability to the Consumer)*, 50 MINN. L. REV. 791, 799-800 (1966).

Several courts admit evidence of remedial repairs in strict liability actions.⁵³ Other courts, however, accept evidence of subsequent repairs under strict liability theory only for the limited purpose of demonstrating feasibility and then only if the defendant has first disputed the issue.⁵⁴ This use of the feasibility exception to the exclusionary rule, however, ignores the purpose of the Rule.⁵⁵ In negligence, the distinction between evidence offered to prove feasibility and culpability is valid because feasibility evidence focuses on the product while culpability evidence focuses on the defendant's conduct.⁵⁶ In strict liability, however, the evidence is used solely to prove a defect, not culpability. The purpose of the feasibility evidence in both types of cases is to prove the existence of a defect.⁵⁷ Since the evidence is not being used to prove culpability, the requirement that the exception to the exclusionary rule be allowed only if the defendant disputes feasibility is unsound.⁵⁸ The "if controverted" requirement does not protect the defendant because culpability is not at issue and, moreover, harms the plaintiff because exclusion restricts a valuable evidentiary tool.⁵⁹ Therefore, regardless of whether Upjohn controverted feasibility under the negligence claim, the evidence should have been admitted under Werner's strict liability claim.

Evidence of subsequent repairs is relevant⁶⁰ to prove that the product was unreasonably⁶¹ unsafe under negligence and strict liability theories to prove both feasibility and adequacy of the warning.⁶² Rule

⁵³ See *Robbins v. Farmers Union Grain Terminal Ass'n*, 552 F.2d 788, 793 (8th Cir. 1977); *Ault v. International Harvester Co.*, 13 Cal. 3d 113, 118, 528 P.2d 1148, 1150, 117 Cal. Rptr. 812, 814 (1974); *Good v. A.B. Chance Co.*, 193 Colo. App. 211, _____, 565 P.2d 217, 224 (1977); *McCaffrey v. Illinois Cent. Gulf R.R.*, 71 Ill. App. 3d 42, 50, 388 N.E.2d 1062, 1069 (1979); *Barry v. Manglass*, 55 App. Div. 2d 1, 7, 389 N.Y.S.2d 870, 875 (1976).

⁵⁴ See *Cunningham v. Yazoo Mfg. Co.*, 39 Ill. App. 3d 498, 500, 350 N.E.2d 514, 516-17 (1976); *LaMonica v. Outboard Marine Corp.*, 48 Ohio App. 2d 43, 45, 355 N.E.2d 533, 535 (1976).

⁵⁵ See Note, *The Case for the Renovated Repair Rule: Admission of Evidence of Subsequent Repairs Against the Mass Producer in Strict Products Liability*, 29 AM. U.L. REV. 135, 157-58 (1979) [hereinafter cited as *Renovated Repair Rule*].

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ See *Hull v. Enger Constr. Co.*, 15 Wash. App. 511, 518-519, 550 P.2d 692, 697 (1976) (either plaintiff or defendant can place feasibility in controversy); *Brown v. Quick Mix Co.*, 75 Wash. 2d 833, _____, 454 P.2d 205, 210 (1969) (evidence of feasibility can be first introduced in either plaintiff's or defendant's case); *Renovated Repair Rule*, *supra* note 55, at 157.

⁵⁹ See *Costello & Weinberger, The Subsequent Repair Doctrine and Products Liability*, 51 N.Y. St. B.J. 463, 499 (1979).

⁶⁰ Any fact tending to make more probable the existence of a material fact is relevant and potentially admissible into evidence. See FED. R. EVID. 401; see generally C. MCCORMICK, HANDBOOK OF THE LAW OF EVIDENCE § 275(g), at 666 (2d ed. 1972).

⁶¹ See RESTATEMENT § 402A, *supra* note 6, at (1). In strict liability, a manufacturer is liable for physical harm caused by a defective product which is unreasonably dangerous. *Id.*

⁶² See *Renovated Repair Rule*, *supra* note 55, at 172-73; *Subsequent Repairs*, *supra* note 38, at 849-50.

407, however, does not allow evidence of subsequent repairs to be admitted to prove the defendant's negligence because of Congress' decision to encourage remedial repair.⁶³ In strict liability, evidence of subsequent repairs is relevant to prove that a manufacturer's warning is inadequate and unreasonable.⁶⁴ The evidence aids the trier-of-fact in defining a standard of reasonable safety against which to compare the injury-causing product.⁶⁵ The trier-of-fact cannot construe the evidence as an admission of the defendant's negligence, since negligence is not an issue under a strict liability claim.⁶⁶ Furthermore, any possibility that the trier-of-fact will misconstrue the evidence is limited since evidence of remedial repair is merely one of several factors which determine the adequacy of the warning.⁶⁷

The Fourth Circuit held evidence of subsequent repairs inadmissible to prove the inadequacy of the 1974 warning under a strict liability theory.⁶⁸ The exclusion of such evidence should not be extended to include strict liability cases because the policy considerations underlying strict liability conflict with those underlying Rule 407.⁶⁹ Not only is the pharmaceutical manufacturer in the best position to spread the cost among the general public,⁷⁰ he is also in the best position to take positive measures to warn physicians about the dangers of his drugs.⁷¹ A patient relies on his doctor for safe health care,⁷² and in turn, the doctor must rely

⁶³ See text accompanying notes 1-2 *supra*.

⁶⁴ See *Subsequent Repairs*, *supra* note 38, at 853-54.

⁶⁵ See *Gasteiger v. Gillenwater*, 57 Tenn. App. 206, 213-14, 417 S.W.2d 568, 572 (1966) (jury allowed to use evidence of subsequent repairs to determine if repairs were required to bring stairs within minimum industry standards as established by expert testimony); WEINSTEIN & BERGER, *supra* note 36, ¶ 407(05); *Renovated Repair Rule*, *supra* note 55, at 173; *Subsequent Repairs*, *supra* note 38, at 850; see also *Rosin v. International Harvester Co.*, 262 Minn. 445, ___, 115 N.W.2d 50, 55 (1962) (plaintiff's expert compared original part to improved part to aid jury to determine adequacy of original part).

⁶⁶ See *Renovated Repair Rule*, *supra* note 55, at 172-73; *Subsequent Repairs*, *supra* note 38, at 850-51.

⁶⁷ See *Subsequent Repairs*, *supra* note 38, at 850-51. The plaintiff will usually offer the testimony of experts as the main proof that the product did not meet reasonable industry standards. See *Ault v. International Harvester Co.*, 13 Cal. 3d 113, 118, 528 P.2d 1148, 1150, 117 Cal. Rptr. 812, 814 (1974); *Rosin v. International Harvester Co.*, 262 Minn. 445, 453, 115 N.W.2d 50, 55 (1962); *Gasteiger v. Gillenwater*, 57 Tenn. App. 206, 213-14, 417 S.W.2d 568, 571 (1966). Although the evidence of remedial repair may not prove the inadequacy of the warning by itself, the evidence is still relevant. Evidence having "any tendency" to make "any fact" more or less probable is relevant. See FED. R. EVID. 401; SALTZBURG & REDDEN, FEDERAL RULES OF EVIDENCE MANUAL 102 (2d ed. 1977).

⁶⁸ 628 F.2d at 858.

⁶⁹ See text accompanying notes 42-43 *supra*.

⁷⁰ See PROSSER, *supra* note 4, at 494-95. The manufacturer may recoup costs by raising his price on each of his products. *Id.* But see *Seller's Liability*, *supra* note 3, at 239-40 n.13.

⁷¹ See *Baker v. Saint Agnes Hosp.*, 70 App. Div. 2d 400, 405, 421 N.Y.S.2d 81, 85 (1979).

⁷² See *id.* at 404-05, 421 N.Y.S.2d at 84-85. A patient cannot reasonably expect risk-free health care. Even if a drug is properly manufactured, there is no guarantee that a drug will be both effective and safe. See PROSSER, *supra* note 4, at 991. A drug must be toxic, having

on the pharmaceutical firm for adequate warnings.⁷³ Pharmaceutical firms, like other manufacturers, are subject to market pressures to offer the best products possible.⁷⁴ This market pressure encourages the drug manufacturer to change his warnings to reflect current knowledge regardless of the exclusionary rule.⁷⁵ Therefore, *Werner* implicitly rejects the strict liability policy of placing the economic burden of product defects on the party who can best bear the cost, the seller.⁷⁶ By declining to accept the consumer protection policy of risk-spreading under strict liability and by extending the policy embodied in Rule 407 to strict liability actions, the Fourth Circuit has placed federal procedural law in conflict with state substantive law.⁷⁷ The *Werner* court incorrectly extended Rule 407 to apply to state substantive policy in strict liability cases.⁷⁸

the potential to inflict serious harm, in order to effectively combat diseases. See Note, *The Liability of Pharmaceutical Manufacturers for Unforeseen Adverse Drug Reactions*, 48 *FORDHAM L. REV.* 735, 742 (1980) [hereinafter cited as *Adverse Drug Reactions*]. Certain drugs are so toxic that they are unavoidably unsafe. The manufacturer of unavoidably unsafe drugs escapes liability, however, if the drug is properly prepared and accompanied by an adequate warning because the medicinal value of the drug outweighs its risk. See RESTATEMENT § 402A, *supra* note 6, at comment k.

⁷³ See *Baker v. Saint Agnes Hosp.*, 70 App. Div. 2d 400, 405, 421 N.Y.S.2d 81, 84-85 (1979). The patient's doctor is a "learned intermediary" between the patient and the manufacturer. If properly warned of a side effect, the doctor has an excellent chance of preventing injury to the plaintiff. See *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966).

⁷⁴ See *Subsequent Repairs*, *supra* note 38, at 848-49; note 51 *supra*. But see *Adverse Drug Reactions*, *supra* note 72, at 755 (drug manufacturers may not be able to pass along costs of strict liability because of extensive testing requirements).

⁷⁵ See RESTATEMENT § 402A, *supra* note 6, at comment h. Even though pharmaceutical firms are unable to make a perfectly safe drug, they can warn the public of the dangers and reactions of which the manufacturers have knowledge. *Id.*; see text accompanying notes 49-52 *supra*.

⁷⁶ See RESTATEMENT § 402A, *supra* note 6. The seller is liable for physical injury to any "ultimate user or consumer" caused by the defective product. *Id.* The term "seller" includes manufacturers, wholesale or retail dealers, and distributors. All can be held liable for damages caused by the defect. *Id.* at comment f.

⁷⁷ *Werner* was a diversity action. 628 F.2d at 851. The law of the forum state, Maryland, should have been applied in *Werner*. See *id.* at 848; *Erie R.R. v. Tompkins*, 304 U.S. 64, 78 (1938). Maryland recognized actions for damages in strict liability. See *Phipps v. General Motors Corp.*, 278 Md. 337, 352, 363 A.2d 955, 963 (1976). The Maryland Court of Appeals in *Phipps* recognized that the seller is in a better position than the consumer to take precautions and protect against defects, as well as spread the risks. *Id.* at 352, 363 A.2d at 963.

⁷⁸ When federal and state law conflict in a diversity action, a federal court must follow state substantive law rather than federal procedural law. See *Erie R.R. v. Tompkins*, 304 U.S. 64, 78 (1938). This rule is especially important where the difference between the state and federal laws affects the outcome of the action. See *Guaranty Trust Co. v. York*, 326 U.S. 99, 109 (1945). Outcome, however, is not the only factor to be considered by the court. If the conflict amounts to a mere procedural difference which is not "bound up with the rights and obligations" of the parties, federal procedural law applies. *Byrd v. Blue Ridge Rural Elec.*