/*This appeal of Doe v. Miles Laboratories (675 F.Supp. 1466) is reported in 927 F.2d 187 (4th Cir. 1991). */

Jane DOE; John Doe, Plaintiffs-Appellants,

v.

MILES LABORATORIES INC., CUTTER LABORATORIES DIVISION, Defendant-Appellee.

United States Court of Appeals, Fourth Circuit.

Argued May 9, 1990.

Decided March 7, 1991.

EDWARD S. SMITH, Senior Circuit Judge:

INTRODUCTION

Appellants, Jane and John Doe, filed a product liability action against Miles Laboratories, Inc. for manufacturing a blood product which allegedly transmitted the AIDS virus to Jane Doe. Appellants assert that appellee is subject to strict liability in tort and negligence liability. The district court, after certifying the strict liability in tort issue to the Maryland Court of Appeals, granted summary judgment on both counts to the defendant. On appeal, we affirm the conclusion of the district court.

FACTS

In September of 1983, Jane Doe ("Mrs. Doe") began suffering from profuse vaginal bleeding after delivering a baby child. The bleeding could not be controlled initially although Mrs. Doe was treated with substantial amounts of blood components. Mrs. Doe's physician, Dr. Martinez, also gave her a single vial of Koyne which ultimately helped to stop the bleeding. Tragically, Mrs. Doe was subsequently diagnosed as having the HIV virus.

Mrs. Doe possesses no high risk factors for AIDS, other than the fact that she received blood products. Miles Laboratories, Inc., Cutter Laboratories Division ("Miles") manufactured and marketed

the Koyne that Mrs. Doe received. Koyne comprises highly concentrated Factor IX, an essential blood clotting component, which is manufactured from about 12,000 to 14,000 individual plasma donations. The Factor IX is removed from the plasma do nations, freeze dried and distributed as a stable powder that is easily stored and can he reconstituted quickly with water for almost immediate administration. The particular dose of Koyne prescribed for Mrs. Doe was distributed in January of 1983, which was before the date, February of 1983, that Miles began screening plasma donors who had evidence of the AIDS disease. Furthermore, the Koyne was accompanied by a warning that failed to explain of its potential to transmit AIDS.

Factor IX products are generally produced to treat hemophiliacs with hemophilia-B, [footnote 1] a hereditary blood clotting disorder characterized by a Factor IX deficiency, but may also be used to treat rare non-hemophilia bleeding disorders. [footnote 2] In addition to concentrated Factor IX, hemophiliacs can be treated with transfusions of whole human blood or plasma. However, because both contain only low concentrations of the necessary clotting factors, treatment with whole blood or plasma requires infusions of large volumes of fluid. Such treatment creates a significant risk of vascular overload or congestive heart failure. [footnote 3]

The United States Food and Drug Administration ("FDA") regulates and licenses factor concentrates, approves the labels for factor concentrates, approves changes in existing factor concentrates and their labeling, and approves the release of each factor concentrate before it is shipped for distribution. [footnote 4]4 Moreover, the centers which collect plasma donations are subject to federal regulation and must be licensed by the FDA. [footnote 5]

Up through 1983, many hemophiliacs had contracted the AIDS virus, but it was only hypothesized that AIDS was a blood borne virus. [footnote 6] At the time the Koyne was administered to Mrs. Doe, there were only a few cases of AIDS among hemophiliacs and only a single case involving a recipient of Factor IX. There was no consensus that AIDS was transmissible by transfusions of blood until early 1984, with the publication of Curran's analysis of transfusion cases. [footnote 7] In April of 1984, scientists identified the cause of AIDS to be what is now termed the HIV virus. Not until March 2, 1985, did the Secretary of Health and Human Services license the Enzyme Linked Immunosorbent Assay ("ELISA test") as the first test to screen blood and plasma for HIV antibodies.

On August 14,1986, the Does sued Miles in the United States District Court for the District of Maryland for producing an unreasonably dangerous product. After the district court denied Miles' motion for summary judgment, the court reconsidered and certified the issue of whether a supplier of blood or blood products is subject to strict liability in tort to the Maryland Court of Appeals. The Maryland Court of Appeals concluded that blood and blood products were not unreasonably dangerous products and therefore not subject to strict liability in tort. [footnote 8] Thereafter, the district court granted summary judgment to Miles on the counts of strict liability in tort and negligence. On appeal, the Does assert that the order granting summary judgment to Miles was in error.

ISSUES

The district court determined that the particular blood product, Koyne, is an unavoidably unsafe product and therefore not unreasonably dangerous under Maryland's interpretation of section 402A comment k. [footnote 9] The district court also determined that the appellee complied with the applicable standards of care. We must decide whether these legal conclusions involve genuine issues of material fact which should be re solved by a trier of fact. If no material issues are presented, and the applicable law supports the district court conclusion, then we must affirm.

Strict Liability in Tort

In Doe v. Miles Laboratories, Inc., [footnote 10] the district court concluded that manufacturers of blood and blood products were subject to the law of strict liability in tort introduced in the Restatement (Second) of Torts 402A and not exempted by comment k. [footnote 11] Shortly after rendering the decision, Judge Ramsey reconsidered and certified this question of law to the Maryland Court of Appeals.

The Maryland Court of Appeals concluded that the "preparation and supplying of Koyne ... constituted a sale" thereby invoking the strict liability in tort principles of section 402A. [footnote 12] Section 402A imposes liability for physical harm caused by "[o]ne who sells any product in a defective condition unreasonably dangerous to the user or consumer...." [footnote 13] However, the court may conclude that a product is not unreasonably dangerous if it is determined to be "unavoidably unsafe"

meaning it is "quite incapable of being made safe for [its] intended and ordinary use." [footnote 14] In concluding that comment k applies to exempt blood and blood products from the operation of section 402A, the court recognized that the fundamental purpose underlying the theory of strict tort liability is to force hazardous products from the market. That rationale plainly has no application to blood or blood products where the manufacturer had no way of knowing that its products-so essential to the life and health of the people- were contaminated by an indetectable virus. [footnote 15]

Although the court concluded that blood and blood products were not unreasonably dangerous products, it left to the district court the responsibility of making the factual determination of whether Koyne, the particular drug in question, was an unreasonably dangerous product. In turn, the district court concluded that Koyne, in particular, was unavoidably unsafe and therefore not unreasonably dangerous. Accordingly, because the manufacturer of Koyne is not subject to strict liability in tort, the district court granted summary judgment to appellee on the relevant count.

We believe that the applicability of strict liability in tort under section 402A to a particular product involves important policy issues that should be considered and weighed by a court of law. [footnote 16] If the relevant determination requires that controverted material factual issues be decided, then the task must be given to the trier of fact. [footnote 17] However, the final balancing of policies based on any factual findings should be made by the court to ensure a legal consistency, which cannot be fostered by several triers of fact. [footnote 18] Therefore, we shall decide whether the applicability of section 402A to Koyne involves any material factual issues that should be decided by a trier of fact. If no material factual issues are involved, summary judgment is in order if the product Koyne is not unreasonably dangerous.

[1] The Maryland Court of Appeals recognized four common threads that are generally considered in most cases which conclude that blood and blood products are not unreasonably dangerous. These four common threads are: (1) the nonexistence of any scientific test capable of detecting the viral agent which contaminated the blood at the time of injury; (2) the great utility of the product; (3) the lack of any substitute for the product; and (4) the relatively small risk of the disease being transmitted by the product. [footnote 19] The district court treated the four common threads as four elements which all must be satisfied to invoke comment k. We see these four common components as the fundamental criteria for balancing the risks associated with the

use of the product against the benefits derived from the product and the inability to avoid the risks inherent in the product. If the balance comes down on the latter side, then comment k is invoked to exempt the manufacturer from strict liability in tort.

[2] First of all, we agree with the district court that at the time the Koyne was administered in September of 1983, there was no way to determine whether a particular unit of blood was contaminated with the HIV virus. The parties agree that an approved test to identify the presence of the HIV virus was not available until 1985 with the development of the ELISA test. Appellant offers no evidence that the HIV virus was detectable at the time the Koyne was administered. Therefore, it was impossible for appellees to identify and remove contaminated blood samples from its distribution supply when no assay was available to detect the contaminant.

Moreover, we cannot expect appellees to have implemented a blood donor screening program when they did not know that the HIV virus was transmissible through blood or blood products. The facts before us are consistent with the finding of the District Court of the District of Columbia that "[i]t was not until 1984 that the medical community reached a consensus as to the proposition that AIDS was transmissible by blood." [footnote 20] In this particular case which involves such an enigmatic disease, we do not expect a manufacturer of pharmaceutical products to know more than the community of medical experts who could not agree on the transmissibility of AIDS. Because a manufacturer is unable to protect against unknown dangers, we agree with the finding of fact that it is indisputable that appellee was unable to avoid the dangers inherent in the product Koyne.

We also agree with the district court finding that the undisputed material facts indicate that Koyne has great medical utility. Appellants do not dispute this finding. Appellants do dispute the district court finding that Koyne has singular medical utility. The issue of singular medical utility blurs two considerations noted by the Maryland Court of Appeals: that of great medical utility and the absence of adequate substitutes. Because we find that Koyne has great medical utility, we next examine the availability of adequate substitutes.

Koyne is an intense concentration of Factor IX designed to augment the supply of Factor IX which is lacking in a patient's blood without deluging the bloodstream with excessive volumes of unconcentrated Factor IX. Appellant asserts that cryoprecipitate and fresh frozen plasma were both available, adequate substitutes for Koyne. Cryoprecipitate does not contain any Factor IX, but

only contains Factor VIII. Therefore, cryoprecipitate is not an adequate substitute for Koyne.

The only possible alternative source of Factor IX is fresh frozen whole plasma. The advantage of Koyne is that it contains a much greater concentration of Factor IX than does fresh frozen whole plasma.

Thus, a small dosage of Koyne is just as effective as a large dosage of fresh frozen whole plasma. Moreover, a smaller dosage of the drug decreases the risk of volume overload and congestive heart failure which can occur when an excessive volume of fresh frozen whole plasma is introduced into the blood stream. Therefore, we conclude that the district court was correct in finding that no adequate substitute for Koyne was available.

Now with the facts before us that the benefits derived from Koyne are both great and irreplaceable, we must determine if these unavoidable risks inherent in Koyne therapy are small in light of the benefits. The district court concluded that the risk of AIDS transmission with the use of Koyne is relatively small, and we agree. In December of 1982, the National Hemophilia Foundation ("NHF") recommended that available alternatives should be the preferred treatment for those patients not yet exposed to factor concentrates. However, the NHF recognized that overriding medical indications may require the use of factor concentrates even when the patient has not been previously exposed to factor concentrates. "[B]y all means, one should not withhold clotting factor therapy when needed." [footnote 21]

In evaluating the final balance, the pertinent question is should Koyne be removed from the market in order to eliminate its potential risk of transmitting AIDS, thereby depriving patients in dire need of the concentrated blood clotting factor that is essential to their survival. The obvious answer to the question is that this vital product must be made available to patients despite its attendant risks because its unique benefits are paramount The objective of section 402A is to force unreasonably dangerous products out of the market. [footnote 22] This objective clearly does not apply to Koyne which is so valuable to patients who are suffering from uncontrolled bleeding. Accordingly, the district court correctly concluded that Koyne was unavoidably unsafe under comment k and therefore not an unreasonably dangerous product under section 402A relieving Miles of strict liability in tort. [footnote 23]

Negligence

Appellants assert that appellees have committed negligence in two ways: by failing to assure adequately the safety of their product, and by failing to warn adequately those who administer the product of the attendant risk that Koyne might transmit AIDS. We are to examine the evidence presented to the district court and decide if either of these accusations present material issues of fact that should be resolved by a trier of fact, If no issues of material fact are presented and the applicable law sum ports the conclusions of the district court, then summary judgment was proper under Fed.R.Civ.P. 56(c).

1. Duty to Assure Product Safety

[3] In the manufacture and distribution of blood and blood products, Miles is held to the standard of care, skill and diligence that a reasonable pharmaceutical manufacturer would use under the same or similar circumstances. Appellant asserts that Miles breached this duty by failing to prevent the distribution of contaminated Koyne, thereby allowing AIDS infected Koyne to be administered to Mrs. Doe and causing her to contract AIDS. Appellant contends that Miles should have screened donors that were at high risk for AIDS and implemented a testing procedure which would facilitate the identification and elimination of AIDS contaminated blood from the blood supply.

In delineating the appropriate standard of care required of a reasonable pharmaceutical manufacturer, we must examine the customs practiced by producers of factor concentrates, the regulations imposed by governmental organizations, and those standards recommended by medical associations. [footnote 24] The evidence before the district court shows that at the time Mrs. Doe received the Koyne treatment, no governmental agency, including the United States Food & Drug Administration ("FDA"), or medical association directed that a certain class of blood donors be screened or that procedures for testing plasma be implemented. Moreover, no blood bank or blood concentrate manufacturer in the industry practiced donor screening or implemented procedures for testing plasma at the time Mrs. Doe was treated with Koyne.

These facts do not conclusively establish the standard of care but certainly do compel the conclusion that these screening and testing procedures were not dictated by the applicable standard of care at the time the Koyne was administered to Mrs. Doe. [footnote 25] Hindsight opinions by appellant's experts suggesting that more should have been done to prevent the

transmission of what was then and now remains an enigmatic disease are insufficient to discredit the conclusion that the applicable standard of care did not require Miles to utilize screening and testing procedures at the time of Mrs. Doe's injury. [footnote 26]

[4] Assuming, arguendo, that Miles knew of the risk of AIDS contamination in their Koyne product, withdrawal of Koyne from the market was not feasible without an assay which could identify the presence of the HIV virus in a particular blood unit. Without the means to selectively withdraw only the contaminated Koyne from the distribution channels, all Koyne would have to be withdrawn to effectively reduce the risk of AIDS transmission. The withdrawal of all Koyne from the market would deprive from patients in dire need of concentrated Factor IX, a meaningful chance for surviving an episode of uncontrolled bleeding. Such a measure would be too drastic in light of the disparity between the slight risk of transmitting AIDS during the use of Koyne and the life-essential features of Koyne. Hence, the withdrawal of all Koyne from the market was not a precaution that was compelled by the standard of care. Therefore, we affirm the conclusion of the district court that "Miles' actions bespeak a manufacturer taking all reasonable precautions to assure the safety of its product."

2. Duty to Warn of Risks

[5] A pharmaceutical manufacturer must warn physicians or other medical personnel authorized to prescribe drugs by state law [footnote 27] of risks known or reasonably foreseeable at the time the product is administered. [footnote 28] Therefore, our inquiry is whether Miles knew or should have known that AIDS was transmissible by Koyne at the time it was administered to Mrs. Doe in September of 1983.

[6] The evidence before the district court indicates that only one case of AIDS was reported that could possibly have been related to Factor IX treatment. Moreover, only a few AIDS cases were related to the use of any blood factor concentrate. Appellants cite an information bulletin issued by the NHF in December of 1982 which warned that there was "increased concern that AIDS may be transmitted through blood products." [footnote 29] However, the bulletin characterized the risk only as a "potential risk" and qualified the warning by stating that "there are still so many unknowns about this disease ... and how it is spread." [footnote 30]

The evidence shows that at the time the Koyne was administered to Mrs. Doe, the risk that AIDS was transmissible through blood was merely a possibility. In fact, appellants have presented no evidence indicating that there existed in 1983 a medical consensus that AIDS was transmissible by blood. As stated earlier, the finding of the district court comports with the finding of the District Court of the District of Columbia stating that "[i]t was not until 1984 that the medical community reached a consensus as to the proposition that AIDS was transmissible by blood." [footnote 31]

Appellant asserts that her expert witnesses could testify that under the circumstances in 1983, Miles should have warned of the AIDS risk attending the use of Koyne. However, we do not believe that hindsight opinions are sufficiently probative to dispute the absence of a medical consensus that AIDS was borne by blood, thereby presenting a genuine issue of material fact. If pharmaceutical companies were required to warn of every suspected risk that could possibly attend the use of a drug, the consuming public would be so barraged with warnings that it would undermine the effectiveness of these warnings. Hence, we find that the risks then known to be associated with the use of Koyne were not explicit enough to expect Miles to have known or foreseen them in September of 1983. Accordingly, because our finding involves no issue of material fact, we affirm the finding of the district court that no warning was necessary to inform the prospective user of the then-suspected risk attending the use of Koyne. [footnote 32]

CONCLUSION

We find that there were no genuine issues of material fact necessary to the resolution of the legal issues in this case. Consequently, we conclude that Koyne was not an unreasonably dangerous product and therefore does not subject its manufacturer to strict liability in tort. We also conclude that appellees complied with the standard of care as it existed in September of 1983 with regard to their duty to assure adequately the safety of their product and their duty to warn of known or foreseeable risks. Because there are no material issues of fact, and appellees are entitled to a judgment as a matter of law, we affirm the conclusion of the district court.

AFFIRMED.

FOOTNOES:

1. Hemophiliacs are subject to spontaneous hemorrhaging which can be fatal.

2. L. Aledort, Current Concepts in Diagnosis and Management of Hemophilia. Hospital Practice, October 1982, 77-92.

3. Id. Due to the medical advantages and convenience offered by the use of blood factor concentrates, by 1979, the average age of hemophiliacs had risen from 11 to 19 years. Id.

4. 21 C.F.R. 610 (1988).

5. 21 C.F.R. 601, 606, 610 and 640 (1988).

6. M. Hilgartner and L. Aledort, AIDS in Hemophilia, AIDS Conference, November 14, 1983, N.Y. Academy of Sciences, Annals of the N.Y. Academy of Sciences. December 29, 1984, 437: 468-70.

7. J. Curran, et al., New England J. of Medicine, January 12, 1984, 310, No. 2:69-75.

8. Miles Laboratories, Inc., Cutter Laboratories Div. v. Doe, 315 Md. 704. 733, 556 A.2d 1107. 1121(1989).

9. Restatement (Second) of Torts (1965).

10. 675 F.Supp. 1466 (D.Md.1987).

11. The Maryland Court of Appeals adopted the Restatement (Second) of Torts 402A in Phipps v. General Motors Corp., 278 Md. 337, 363 A.2d 955 (1976), thereby implicitly adopting the substance of comment k.

12. Miles Laboratories, Inc., Cutter Laboratories Div. v. Doe, 315 Md. at 725, 556 A.2d at 1117.

13. Restatement (Second) of Torts 402A (emphasis added).

14. Restatement (Second) of Torts 402A comment k.

15. Id. at 733, 556 A.2d at 1121.

16. See Lundgren v. Ferno- Washington Co., 80 Md.App. 522. 565 A.2d 335 (1989) (strict liability for injury caused by design defect should be decided by the courts).

17. A motion for summary judgment shall be granted if all the evidence presented to the court shows "that there is no genuine issue as to any material fact and that the moving party is

entitled to a judgment as a matter of law." Fed.R. Civ.P. 56(c).

18. See Lundgren, 80 Md.App. 522, 565 A.2d 335.

19. Miles Laboratories, 315 Md. at 72~26, 556 A.2d at 1118.

20. Kozup v. Georgetown University, 663 F.Supp. 1048, 1052 (D.D.C.1987) (citing Curran, Lawrence, et al., Acquired Immune Deficiency Syndrome (AIDS) Associated with Transfusions, 310 New Eng.J.Med. 69, 70 (1984); AIDS Transmission via Transfusion Therapy, 8368 The Lancet 102 (Jan. 14, 1984), cited in Hospital and Blood Bank Liability to Patients Who Contract AIDS Through Blood Transfusions, 23 San Diego L.Rev. 875, 878 & n. 10)), aff'd in relevant part and vacated in part, 851 F.2d 437 (D.C.Cir.1988).

21. National Hemophilia Foundation Medical Bulletin No. 4, AIDS Implications Regarding Blood Product Use (December 21, 1983).

22. Miles Laboratories, 315 Md. at 733, 556 A.2d at 1121.

23. Appellant asserts that comment k is inapplicable because Koyne is sold without an accompanying warning. Therefore, Koyne must be unreasonably dangerous because comment k cannot be invoked to render Koyne unavoidably unsafe. Comment k does contemplate that "[s]uch a product [be] accompanied by proper directions and warning," but this rule is qualified later in the comment. Restatement (Second) of Torts 402A comment k. Comment k further states that the product must be accompanied by a "proper warning ... where the situation calls for it ... " id. This qualification indicates that a warning is only required in appropriate situations. An inappropriate situation was presented here because the risk of AIDS transmission through blood was just a hypothesis. There was no consensus in the medical community that AIDS is transmitted through blood. Therefore, we conclude that no warning was required to invoke comment k in this particular situation.

24. See Wright v. BF Huntley Furniture Co., 299 F.2d 904, 907 (4th Cir.1962); Jones v. Miles Laboratories, Inc., 887 F.2d 1576, 1580 (11th Cir. 1989).

25. See Jones, 887 F.2d at 1580.

26. See Mckee v. Miles Laboratories, Inc., 675 F.Supp. 1060 (E.D.Ky.1987), aff'd, 866 F.2d 219 (6th Cir.1989).

27. Stanback v. Parke, Davis & Co., 657 F.2d 642 (4th Cir.1981).

28. Chambers v. G.D. Searle & Co., 441 F.Supp. 377. 381 (D.Md.1975), aff'd, 567 F.2d 269 (4th Cir. 1977).

29. National Hemophilia Foundation Medical Bulletin No. 4, supra, note 21.

30. Id.

31. Kozup, 663 F.Supp. at 1052.

32. The district court concluded that causation was absent because Dr. Martinez testified that she would have administered the Koyne even if she had read an accompanying warning of the AIDS risk. Although the causation issue is not necessary to the disposition of this case in light of our conclusion that Miles breached no duty, we do believe that the district court conclusion was erroneous because its reliance on Stanback, 657 F.2d 642, was misplaced.

Stanback involved a situation where no warning accompanied the influenza vaccine administered to the plaintiff which caused her to contract Guillain-Barre Syndrome. The court concluded that the drug manufacturer was not negligent, because the failure to warn was not the cause-in-fact of the plaintiff's injury. Id. at 645. The administering doctor's deposition indicated that even if a warning had been provided with the drug, he would not have advised the patient of its inherent risks. Because the administering physician was already fully aware of the risks which would have been listed in a proper warning, the lack of warning on the drug did not have any effect on the doctor's decision to use the drug. Id.

This fact situation is distinct from the fact situation at bar because Dr. Martinez did not know of the AIDS risk that attended Koyne. Although Dr. Martinez testified that she would have administered the drug regardless of the AIDS risk, her hindsight opinion is not conclusive of what she would have done had she been invested with all pertinent facts regarding Koyne. Thus, the causation issue, which is irrelevant to the disposition of this case, presents a genuine issue of material fact.