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No Strict Liability for Manufacturer of Unavoidably Unsafe Blood-Clotting Agent Which Gave Woman AIDS

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not an overwhelming burden to the newspaper. Also, because the number of black models used would be entirely discretionary, such requirements would not impose a "quota" on the inclusion of black models. Furthermore, the court held that inclusion of such models would not significantly burden the numerous arbitrary decisions made in every advertisement. Based on the standards above, the court held that the complaint could not be dismissed for failure to state a claim, as the complaint alleged a longstanding pattern in real estate advertisements indicating racial preference.

Constitutional Issues

The Times also argued that section 3604(c) was void for vagueness. The court noted that regardless of whether the vagueness doctrine applied to civil actions, the ordinary reader standard provided constitutionally sufficient notice of the prohibited conduct. Thus, the statute did not fail on the basis of vagueness.

Next, the Times claimed that application of section 3604(c) to newspapers violated the first amendment. The court noted that the first amendment gave less protection to commercial speech than to other constitutionally protected speech. The first amendment did not protect commercial speech relating to illegal activity. The court noted that the Fair Housing Act prohibited advertisements displaying racial preferences. Therefore, the first amendment did not protect advertisements which violated section 3604(c) and promoted illegal activity, discrimination in the sale or rental of real estate.

The court also addressed the supposed unconstitutional burdens imposed on the Times by section 3604(c). First, the court reviewed the Times's argument that application of the Fair Housing Act to newspapers would disrupt the function of the free press. Citing Supreme Court precedent, the court concluded that section 3604(c) would not compromise the unique position of the free press.

The Times also argued that section 3604(c) would unconstitutionally burden newspapers by compelling them to enforce the law under the Fair Housing Act. The appellate court, however, rejected this argument. The court held that the "would-be regulators" were not the publishers, but the offended readers, such as Ragin and Open Housing. These readers bore the burden of proving racial preference in the advertisements. Therefore, the court concluded that section 3604(c) did not place an unconstitutional burden on the publishers.

Lastly, the court dismissed the Times's argument that the publisher was "ill-equipped" to monitor the advertisements. The court noted that advertisements were routinely and extensively reviewed before they were published in the newspaper. Therefore, monitoring the advertisements for racial messages did not impose an unconstitutional burden upon the publisher.

The Second Circuit accordingly affirmed the district court's decision and held that section 3604(c) of the Fair Housing Act applied to human models and that its application to newspapers did not violate the first amendment.

Richard E. Nawracaj

No Strict Liability For Manufacturer of Unavoidably Unsafe Blood-Clotting Agent Which Gave Woman AIDS

In ***Jane Doe and John Doe v. Miles Laboratories, Inc, Cutter Laboratories Div.,*** No. 90-2605 (4th Cir. March 7, 1991)(WESTLAW), the United States Court of Appeals for the Fourth Circuit held that Koyne, a blood-clotting agent manufactured by Miles Laboratories, Inc., Cutter Laboratories Division ("Miles"), was unavoidably unsafe, and therefore, Miles was not subject to strict liability in tort. The court also held that Miles met the applicable standard of care and had no duty to warn of the possible dangers associated with Koyne; therefore, Miles was not negligent.

Background

In September of 1983, after the delivery of her child, Jane Doe ("Mrs. Doe") began suffering from excessive vaginal bleeding. After substantial amounts of blood components failed to control Mrs. Doe's bleeding, her physician administered Koyne, a blood-clotting agent comprised of highly concentrated Factor IX. Factor IX was an essential blood-clotting component derived from thousands of human blood plasma donations and was very effective in stopping uncontrolled bleeding. Mrs. Doe's Koyne was distributed by Miles in January of 1983, which was prior to the availability of an approved test to identify the presence of the human immunodeficiency virus ("HIV"), the virus responsible for the deadly acquired immunodeficiency syndrome ("AIDS"). Mrs. Doe was subsequently diagnosed as having been infected with HIV, and she possessed no AIDS high risk factors that could otherwise account for her infection.

On August 14, 1986, the Does sued Miles in the United States District Court for the District of Maryland based on strict liability and negligence. They asked the court to hold Miles strictly liable based upon a finding that blood and blood products were unreasonably dangerous products. The Does also asserted that Miles was negligent in two ways: (1) by failing to assure adequately the safety of their product, and (2) by failing to warn adequately those who administered the product of the risk that it may transmit AIDS.

The District Court's Decision

In *Doe v. Miles Laboratories, Inc,* 675 F.Supp. 1466 (D. Md. 1987), the district court initially held that Miles was subject to strict liability in tort as a manufacturer of blood or blood products, and denied Miles's motion for summary judgment. However, the district court then reconsidered and certified to the Maryland Court of Appeals the issue of whether a supplier of blood or blood products was subject to strict liability in tort.

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AIDS

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The Maryland Court of Appeals

The Maryland Court of Appeals, the state's highest court, agreed with the federal district court that the sale and preparation of Koyne invoked the strict liability principles of 402A of the Restatement (Second) of Torts. That section imposed strict liability for harm caused by "[o]ne who sells any product in a defective condition unreasonably dangerous to the consumer...." However, the court also held that the nature of blood and blood products made the exemption contained in comment k to § 402A applicable.

Comment k applied where a product was determined to be "unavoidably unsafe" because it was "quite incapable of being made safe for [its] intended use." In recognizing that blood and blood products were unavoidably unsafe, the Maryland Court of Appeals identified and applied four "common threads," considered in similar cases, that were satisfied by blood and blood products. These were: (1) the non-existence of any test capable of detecting the viral agent which contaminated the blood at the time of the 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. The high court left to the district court the question of whether Koyne was similarly unavoidably unsafe based on its findings of fact.

After receiving the Maryland Court of Appeals' response, the district court held that Koyne was unavoidably unsafe and therefore granted summary judgment to Miles on the strict liability claim. The court also granted summary judgment to Miles on the Does' negligence claims. The Does appealed to the United States Court of Appeals for the Fourth Circuit.

The Fourth Circuit's Decision

The Court of Appeals for the Fourth Circuit agreed with the district court and affirmed the granting of summary judgment to Miles. In doing so, the Fourth Circuit applied the four "common threads" recognized by the Maryland Court of Appeals as the basis for balancing the risks associated with a product against the benefits to be derived from it and the inability to avoid the risks associated with the product.

First, the Fourth Circuit agreed with the district court that at the time the Koyne was administered to Mrs. Doe, there was no way to determine whether the blood plasma was infected with the HIV. The facts presented to the district court demonstrated that until early 1984 there was no consensus that the AIDS virus could be transmitted through blood transfusions or blood products. In April, 1984 scientists finally identified the HIV as the cause of AIDS, and on March 2, 1985 the Secretary of Health and Human Services licensed the first test for screening blood plasma donations for the HIV. Miles distributed Mrs. Doe's Koyne in January, 1983, before Miles began screening plasma donors with obvious signs of the HIV infection in February, 1983. Based on this, the Fourth Circuit concluded that Miles could not have determined if the Koyne was contaminated even if they knew that AIDS was transmitted by blood.

Second, the Fourth Circuit agreed with the district court that Koyne had great medical utility. This finding was demonstrated by the material facts and was undisputed by the Does.

Third, the Fourth Circuit had little difficulty agreeing with the district court that Koyne had no adequate substitute. The Does asserted that two substitutes were available; cryoprecipitate and fresh frozen whole plasma. However, the Fourth Circuit found that cryoprecipitate did not contain Factor IX, an essential and highly effective blood-clotting component, and therefore was not an adequate substitute. In addition, the evidence showed that small amounts of Koyne could replace massive doses of fresh frozen whole plasma. This was important because massive doses of the fresh plasma could have serious, life-threatening side effects. Therefore, the Fourth Circuit concluded that there was no adequate substitute for Koyne.

Finally, the Fourth Circuit was convinced that there existed only a relatively small risk of the transmission of the AIDS virus through the use of Koyne. Compared to this slight risk was evidence that in some cases Koyne was vital to the patient's life.

Based upon a finding that Koyne satisfied the four "common threads," the Fourth Circuit concluded that Koyne, because of its unique benefits and minimal attendant risks, was an unavoidably unsafe product that should not be removed from the market by imposing strict liability on its manufacturers.

The Fourth Circuit also agreed that summary judgment was proper as to the Does' claims that Miles should have screened plasma donors for the AIDS virus and that Miles should have warned them that Koyne may transmit the AIDS virus. In deciding these claims, the Fourth Circuit first found that Miles should be held to the standard of care, skill, and diligence that a reasonable pharmaceutical manufacturer would use under the same or similar circumstances. According to the court, this did not require Miles to screen plasma donors for AIDS at the time the Koyne was administered to Mrs. Doe, as no governmental agency or medical society recommended such screening.

Even assuming that Miles knew of the risk of AIDS in Koyne, the Fourth Circuit concluded that withdrawal of Koyne from the market was not feasible prior to the availability of a test to identify conclusively the presence of AIDS virus. The facts demonstrated that the ELISA test, the first and only HIV test authorized by the federal government, was not available until 1985. Without the test, all Koyne would have to have been withdrawn from the market, thus denying many in dire need of its unique benefits. The court concluded that Miles took all necessary precautions to assure the safety of the Koyne; therefore, Miles was not negligent in that respect.

Finally, the Fourth Circuit held that Miles had no duty to warn of the risk of the transmission of the AIDS virus in September of 1983. Although pharmaceutical companies must warn consumers of the reasonably foreseeable risks associated with their products, the court concluded that they cannot be expected to warn of every possible harm associated with those products. The evidence indicated that when the Koyne was administered to Mrs. Doe there was no medical consensus that AIDS was transmissible by blood or blood products. The closest thing Miles had to a warning of the risk was a bulletin issued by the National Hemophilia Foundation in December, 1982 that described an "increased concern" with the "potential risk" of blood or blood product transmission of AIDS. According to the court, the knowledge of the risk at that time was insufficient to require Miles to warn of the possibility of the transmission of AIDS through Koyne. The court refused to force pharmaceutical companies to warn the public about every possible risk associated with the use of drugs, blood or blood products, as that would undermine the effectiveness of the warnings regarding these products. Thus, the Fourth Circuit held that Miles had no duty to warn prospective users about the risks associated with the use of Koyne.

The Fourth Circuit's Disposition of the Case

The Fourth Circuit affirmed the district court's conclusion that there were no issues of material fact necessary to the resolution of any of the Does' claims. According to the court, Koyne was an unavoidably unsafe product, and therefore it was not unreasonably dangerous. Also, the court held that Miles complied with the applicable standard of care both in its duty to ensure the safety of Koyne and in its duty to warn of the product's inherent dangers. Therefore, the Fourth Circuit upheld the summary judgment for the defendant, Miles Laboratories.

Stephen McKenna

Eighth Circuit Holds That Insurer's Duty to Make Certain Coverage Available Was Not Breached by Failure to Explain Such Coverage

In ***Edens v. Shelter Mutual Insurance Company,*** 923 F.2d 79 (8th Cir. 1991), the court held that an insurer made underinsured motorist coverage available to a policyholder when the insurer specifically mentioned, but did not explain such coverage on renewal forms and other correspondence with the policyholder.

Background

Marcus Edens ("Edens") was seriously injured when another vehicle struck the automobile in which he was a passenger. At the time of the accident, Edens was a passenger in a car which belonged to Irwin and Sandra Johnson ("the Johnsons"). The Johnsons were policyholders of Shelter Mutual Insurance Co., Inc. ("Shelter Mutual").

The other driver's insurance company paid Edens $25,000 in settlement of his claim. This amount failed to compensate him fully for the extent of his injuries. The Johnsons had not elected to purchase underinsured motorist coverage which might have entitled them to recover from their own insurer any damages in excess of the amount covered by the policy owned by the driver-at-fault. Edens claimed he was entitled to underinsured motorist coverage under the Johnsons' policy, because Shelter Mutual did not "make available" such coverage as mandated in Ark. Code Ann. § 23-89-209 (Supp. 1989).

The Arkansas underinsured motorist statute provided that every automobile liability insurer must "make available" to its policyholders coverage protecting them against underinsured motorists. Edens argued that Shelter Mutual violated the statute and that the law should therefore impute such coverage to the policyholders, and thus allow him to recover under the statute as a passenger.

Shelter Mutual asserted that it had not deviated from the statutory requirement, and that even if it had, there was no reason to impute coverage. Additionally, Shelter Mutual argued that even if coverage were imputed to the Johnsons, Edens was beyond the sphere of recovery since he was only a passenger in the vehicle.

Edens sued Shelter Mutual in Arkansas state court. The suit was removed on diversity grounds to federal court by Shelter Mutual.

The District Court Proceedings

The United States District Court for the Western District of Arkansas held that Shelter Mutual's practice of offering underinsured motorist coverage to policyholders, by including an obvious reference to it on their application and renewal form, adequately "made available" such coverage, as required by the statute.

Edens contended that Shelter Mutual had the obligation to take affirmative, "commercially reasonable" steps to make available its product, and that simply offering it without explanation put policyholders at a disadvantage. Shelter Mutual counterargued that it met the "make available" standard in the statute by providing a "check-off" box for choosing underinsured motorist coverage, placed three inches above the insured's signature block on the application as well as filing rates with the state insurance commissioner.

The court found the insurer in compliance with the statute and granted summary judgment for the insurer.

The Court of Appeals Affirms

Sitting in diversity to decide this case of first impression under state law, the Court of Appeals expressed its reluctance to expand the meaning of the statute without guidance from the state courts. In making its decision, the court focused on the intent of the Arkansas legislature, and on judicial interpretations from other jurisdictions dealing with similar legislation.

The court gleaned the intent of the Arkansas legislature from Arkansas statutes regulating other

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