

/* This case is reported in 866 F.2d 219 (6th Cir. 1989). This case considers contaminated blood products, and finds that the UCC re-definition of blood not to be a "sale" shields the defendants from suit as does the "unavoidably unsafe" doctrine. */

Stella Mae McKEE, individually and as Administratrix of the estate of David Allen McKee, Plaintiff-Appellant,

v.

CUTTER LABORATORIES, INC. and Miles Laboratories, Inc., Defendants-Appellees.

United States Court of Appeals, Sixth Circuit.

Argued Oct. 14, 1988.

Decided Jan. 30, 1989.

RYAN, Circuit Judge.

Plaintiff Stella Mae McKee appeals the district court's grant of summary judgment for defendants Miles Laboratories, Inc., and Cutter Laboratories, Inc., in this product liability action involving strict liability and negligence claims. The action arose from the death of plaintiff's decedent, David McKee, who died after contracting acquired immune deficiency syndrome (AIDS) from a contaminated antihemophilic blood product allegedly manufactured by Cutter. The district court granted summary judgment for defendants on the grounds that (1) the Kentucky blood shield statute, KRS 139.125, barred plaintiff's strict liability claims, and (2) defendants were not negligent because they met the standard of care for production of the blood product. We affirm.

The record on appeal, viewed in a light favorable to plaintiff, establishes the following. Plaintiff's decedent, David McKee, was a type A hemophiliac who used "Koate," an antihemophilic blood product produced by Cutter Laboratories, a division of Miles Laboratories. Koate is used by hemophiliacs to supply Factor VIII, a blood protein necessary for blood coagulation. David McKee used Koate that had been produced from blood contaminated with human immunodeficiency virus (HIV), the retrovirus that is now known to cause AIDS. Mr. McKee was diagnosed with "full blown" AIDS in October 1983, and he died in 1984.

In January 1985, plaintiff, Mr. McKee's wife, brought this product liability action against Cutter Laboratories and Miles Laboratories in federal district court under diversity jurisdiction. Plaintiff claimed that defendants were liable for her husband's death under strict liability and negligence theories.

and she sought compensatory and punitive damages. After discovery, the district court granted defendants' motion for summary judgment on the grounds that (1) KRS 139.125, Kentucky's "blood shield statute," barred plaintiff's strict liability claims, and (2) defendants were not negligent because the standard of care for production of Factor VIII products before the AIDS virus was discovered did not require producers to treat or test the products in ways that have subsequently been discovered to eliminate the risk of AIDS contamination. *McKee v. Miles Laboratories, Inc.*, 675 F.Supp. 1060 (E.D.Ky.1987). This appeal followed. [footnote 1]

I.

This court reviews a district court's grant of summary judgment de novo. *Gutierrez v. Lynch*, 826 F.2d 1534,1536 (6th Cir.1987). Summary judgment is appropriate {w}here the moving party has carried its burden of showing that the pleadings, depositions, answers to interrogatories, admissions and affidavits in the record, construed favorably to the nonmoving party, do not raise a genuine issue of material fact for trial." *Id.* (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986)); see *Fed.R.Civ.P. 56(c)*. "[T]here is no issue for trial unless there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party. If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249-50, 106 S.Ct. 2505, 2510-11, 91 L.Ed.2d 202 (1986) (citations omitted).

A.

Plaintiff first contends that the district court erred in holding that her strict liability claims are barred by the Kentucky blood shield statute, KRS 139.125. This statute, which was enacted in 1968, provides in full:

139.125 Procurement, processing or distribution of blood or human tissue deemed service and not sale.

The procurement, processing, distribution or use of whole blood, plasma, blood products, blood derivatives and other human tissues such as corneas, bones or organs for the purpose of injecting, transfusing or transplanting any of them into the human body is declared to be, for all purposes, the rendition of a service by every person participating therein and, whether or not any remuneration is paid therefor, is declared not to be a sale of such whole blood, plasma, blood products, blood derivatives or other tissues, for any purpose, subsequent to enactment of this section.

In the only reported Kentucky case to discuss KRS 139.125, *McMichael v. American Red Cross*, 532 S.W.2d 7 (Ky.1975), the Kentucky Court of Appeals

(Kentucky's highest court at that time) did not reach the applicability or constitutionality of the statute. In *McMichael*, plaintiff brought strict liability and breach of implied warranty claims against a blood supplier that had allegedly supplied blood contaminated with the serum hepatitis virus. The trial court, at the close of the opening statement, directed a verdict in favor of the defendant-blood supplier on the ground that the action was barred by KRS 139.125. The Kentucky Court of Appeals affirmed the directed verdict for defendant, but on a different ground. It did not reach the applicability or constitutionality of KRS 139.125; instead, it held that defendant was entitled to a directed verdict on the ground that the blood in question was not "unreasonably dangerous" because it was "unavoidably unsafe" under Comment (k) to Section 402A of the Restatement of Torts 2d. "[T]here were no methods available at the time in question by which hepatitis virus could effectively be excluded from blood or the presence of the virus determined." *McMichael*, 532 S.W.2d at 9.

In the present case, the district court sought certification of the applicability and constitutionality of KRS 139.125, but the Kentucky Supreme Court declined the certification request, referring to *McMichael*. The district court, therefore, was required to decide whether KRS 139.125 barred plaintiffs strict liability claims. It held:

Because [under KRS 139.125] transactions involving blood and blood components are to be considered services, as opposed to sales, they are outside the purview of Kentucky's product liability statute. K.R.S. 411.300; 411.320; 411.340; *McMichael*, supra.

... [B]lood shield statutes in other states uniformly have been interpreted as barring strict liability claims. To permit the plaintiff to circumvent the exemption of blood and blood derivatives by pursuing claims under the product liability statute would defeat the obvious legislative intent of K.R.S. 139.125. Consequently, plaintiff's claims against defendants arising under strict liability should be dismissed.

675 F.Supp. at 1063.

Plaintiff contends that the district court erred in dismissing her strict liability claims on this ground. She argues that although KRS 139.125 makes a transaction in blood products not a sale, Kentucky law does not require a product sale for the doctrine of strict liability to apply. Plaintiff relies on two cases for this proposition: *Taylor v. General Motors, Inc.*, 537 F.Supp. 949 (E.D.Ky.1982), and *Embs v. Pepsi-Cola Bottling Co.*, 528 S.W.2d 703 (Ky.1975).

In *Taylor*, the district court held that under Kentucky strict product liability doctrine a product "seller" may include those responsible for placing a product in the stream of commerce, even if they are not within "the technical category of a 'seller.'" 537 F.Supp. at 952. In *Embs*, the Kentucky Court of Appeals (Kentucky's highest court at that time) held that, in addition to

products consumers and users, bystanders whose injuries were reasonably foreseeable may bring strict product liability actions. 528 S.W.2d at 706. These cases expanded the availability of strict product liability actions under Kentucky law, but neither supports plaintiff's contention that her strict liability claims are actionable notwithstanding KRS 139.125.

[1, 2] KRS 139.125 provides that transactions in blood, blood products, and other human tissues are not to be considered "sales"-they are to be considered "for all purposes, the rendition of a service." Although we are aware of no Kentucky case that holds specifically that a strict product liability action is unavailable against one who renders a service, we have no hesitancy in concluding that this would be the holding of the Kentucky Supreme Court were it faced with the question.[footnote 2] Since *Dealers Transport Co. v. Battery Distributing Co.*, 402 S.W.2d 441 (Ky.1965), Kentucky has followed the view of strict product liability expressed in Section 402A of the Restatement of Torts 2d, which is entitled "Special Liability of Seller of Product for Physical Harm to User or Consumer" (emphasis added). Courts in other jurisdictions have consistently held that "[s]ection 402A does not apply to those who provide a service." *Klein v. Council of Chemical Associations*, 587 F.Supp. 213, 223 (E.D.Pa. 1984); see also Annotation, Application of Rule of Strict Liability in Tort to Person Rendering Services, 29 A.L.R. 3d 1425, 1426 (1970 & 1988 Supp.). Furthermore, Kentucky's Product Liability Act, KRS 411.300 to 411.350, which was enacted in 1978, defines a "product liability action" to include

any action brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formulation, development of standards preparation, processing, assembly, testing, listing, certifying, warning, instructing, marketing, advertising, packaging or labeling of any product.

KRS 411.300 (emphasis added). We hold that KRS 139.125, which defines a blood product transaction as the rendition of a service, bars plaintiff's strict liability claims. We note that this interpretation of Kentucky's blood shield statute is in accord with that given a nearly identical statute in California, *Hyland Therapeutics v. Superior Court*, 175 Cal.App.3d 509, 220 Cal. Rptr. 590 (1985), and the interpretation given blood shield statutes in other states, where they "uniformly have been interpreted as barring strict liability claims, whether or not the statute contains an express bar to such claims." *Coffee v. Cutter Biological*. 809 F.2d 191,194 (2d Cir.1987).

B.

[3] Plaintiff argues that if KRS 139.125 is interpreted to bar her strict liability claims, the statute is unconstitutional under various provisions of the Kentucky Constitution. The district court disposed of this contention by holding, without extended discussion, that "[t]here is nothing within the

provisions of Kentucky's Constitution which would make K.R.S. 139.125 contrary to the framers' intent." 675 F.Supp. at 1062.

Plaintiff's primary constitutional claim is made under the following sections of the Kentucky Constitution:

14. Courts to be open and speedy trial guaranteed

All Courts shall be open and every person, for an injury done him in his lands, goods, person or reputation, shall have remedy by due course of law, and right and justice administered without sale, denial or delay.

26. Bill of Rights to remain inviolate

To guard against transgression of the high powers which we have delegated, we declare that everything in this Bill of Rights is excepted out of the general powers of government, and shall forever remain inviolate; and all laws contrary thereto, or contrary to this Constitution, shall be void.

54. Injuries to person or property; recovery not limited

The General Assembly shall have no power to limit the amount to be recovered for injuries resulting in death, or for injuries to person or property.

241. Recovery for wrongful death

Whenever the death of a person shall result from an injury inflicted by negligence or wrongful act, then, in every such case, damages may be recovered for such death, from the corporations and persons so causing the same. Until otherwise provided by law, the action to recover such damages shall in all cases be prosecuted by the personal representative of the deceased person. The general assembly may provide how the recovery shall go and to whom belong; and until such provision is made, the same shall form part of the personal estate of the deceased person.

Ky. Const. 14, 26, 54, 241. Plaintiff argues that these constitutional provisions preserve a common law right of recovery under strict liability and that therefore if KRS 139.125 were read to bar plaintiff's strict liability claims it would be unconstitutional.

In determining whether a common law right of recovery is preserved inviolate by these provisions of the Kentucky Constitution, the inquiry is initially directed to "whether the right of action affected by a statute 'had become established prior to the adoption of the Constitution [in 1891].'" *Carney v. Moody*, 646 S.W.2d 40, 41 (Ky. 1982) (citations omitted); see also *Fireman's Fund Insurance Co. v. Government Employees Insurance Co.*, 635 S.W. 2d 475, 477 (Ky.1982). Plaintiff argues that under Kentucky law a common law right of recovery under strict liability against providers of products for human consumption existed when the Kentucky Constitution

was adopted in 1891. Plaintiff bases this argument on *Fleet v. Hollenkemp*, 52 Ky. (13 B.Mon.) 219 (1852), which held that druggists were liable for injuries resulting from their sale of a prescription contaminated with poison.

Although it is at least arguable that *Fleet* was decided under a strict liability theory, it cannot be said that this case established a common law right of recovery under strict liability in Kentucky law. The Kentucky Court of Appeals (then Kentucky's highest court) has stated that *Fleet* did not correctly state the law and that a druggist could be liable only for negligence. *Ohio County Drug Co. v. Howard*, 201 Ky. 346, 256 S.W. 705 (1928). It was not until 1965 that Kentucky adopted the doctrine of strict product liability, following a trend begun by the California Supreme Court in *Greenman v. Yuba Power Products, Inc.*, 59 Cal.2d 57, 377 P.2d 897, 27 Cal.Rptr. 697 (1963). *Dealers Transport Co. v. Battery Distributing Co.*, 402 S.W. 2d 441 (Ky.1965); see Prosser, *Handbook of the Law of Torts*, 98 at 657 (4th ed. 1971). As the Kentucky Supreme Court observed in 1985, "in the last twenty years an additional theory of liability labeled 'strict liability in tort' has developed against product manufacturers and suppliers who fall within the class described in Section 402A of the Restatement (Second) Torts." *Tabler v. Wallace*, 704 S.W.2d 179, 186 (Ky.1985) (emphasis added; emphasis omitted), cert. denied, 479 U.S. 822, 107 S.Ct. 89, 93 L.Ed.2d 41(1986). Indeed, the Kentucky Supreme Court has declared, albeit in dicta, that it would be "absurd" to claim that a right of action under strict product liability existed when the Kentucky Constitution was framed:

Today ... we behold the theory of negligence having burgeoned into liability without fault in product liability cases, but it would be absurd to contend that such liability would have been countenanced in 1891.

Fireman's Fund Insurance Co. v. Government Employees Insurance Co., 635 S.W. 2d 475, 477 (Ky.1982) (emphasis added). We hold that an action for strict product liability was not established in Kentucky when its constitution was adopted in 1891 and that such an action is not preserved without limitation by 14, 26, 54, and 241 of the Kentucky Constitution. Therefore, KRS 139.125, which we have interpreted to bar strict liability actions for blood and blood products transactions, does not violate these constitutional provisions.

Plaintiff also advances various other arguments under the Kentucky Constitution:

KRS 139.125 is (1) impermissible arbitrary legislation under 2, (2) violative of the principle of separation of powers established in 27, 28,109, and (3) impermissible "special legislation" under 59. These arguments do not merit extended discussion. Plaintiff cites no persuasive authority. and this court is aware of none, which would support a holding that KRS 139.~25 is unconstitutional under any of these sections of the Kentucky Constitution.

We affirm the district court's grant of summary judgment for defendants on plaintiff's strict liability claims.

II.

Plaintiff also challenges the district court's grant of summary judgment for defendants on plaintiff's negligence claims. Plaintiff contends that the district court erred by concluding that defendants were not negligent because they had complied with industry custom for production of Factor VIII products. She claims that alternative production methods, now known to inactivate the AIDS virus, were feasible at a time that could have prevented AIDS transmission to plaintiff's decedent. In particular, plaintiff points to heat treatment of Factor VIII, which was used by a German producer of Factor VIII perhaps as early as the late 1970's and has been subsequently adopted by defendants and other Factor VIII producers.

Under Kentucky law, compliance with industry custom is evidence of non-negligence: "[T]he fact that others are making a similar product with a safer design may be important evidence bearing upon the defendant's reasonable care. Likewise the fact that others make use of the same design is evidence for the defendant, although it is not always conclusive." *Jones v. Hutchinson Manufacturing Inc.*, 502 S.W.2d 66, 69 (Ky. 1973) (quoting *Prosser, Handbook of the Law of Torts*, 96 at 645 (4th ed. 1971)).

[4] In this case, industry custom in October 1983, when plaintiff's decedent was diagnosed as having AIDS, [footnote 3] did not require heat treatment or other processes to treat Factor VIII products in order to inactivate the AIDS virus. It is undisputed that it was not until 1984 that the medical community reached a consensus that AIDS could be transmitted by blood and that HIV was identified as the AIDS-causing virus. See *Kozup v. Georgetown University*, 663 F.Supp. 1048,1052 (D.D.C.1987). It is also undisputed that it was not until after this date that it was discovered that heat treatment could inactivate HIV. As the district court noted, plaintiff cannot show that in October 1983 "[a]ny organization, government entity or medical association within the United States ... advocated the use of plaintiff's alternative testing as a means for screening [Factor VIII products] for AIDS." 675 F.Supp. at 1064.

Plaintiff, however, maintains that, based on the testimony of an expert, defendant could have heat treated or otherwise produced Koate to inactivate the AIDS virus, even before the virus was discovered and before production processes were discovered to inactivate it in Factor VIII products. We hold that plaintiff's evidence of alternative feasible production techniques is insufficient for a jury to return a verdict for plaintiff. We are mindful of the tragic consequences of AIDS for plaintiff, and for society, but hindsight opinions as to its possible prevention, before the disease-causing virus and

the efficacy of preventive measures were discovered, are not sufficiently probative to preclude summary judgment. The district court did not err in granting defendants' motion for summary judgment on plaintiffs negligence claims.

For the foregoing reasons, the judgment of the district court is AFFIRMED.

FOOTNOTES:

1. We granted the parties' various motions to file briefs of amici curiae, and we denied defendants' motion to strike a brief of a proposed amicus curiae and to impose sanctions.

2. We are aware of one case in which the Kentucky Supreme Court implicitly recognized that a strict product liability action is unavailable against the renderer of a service. In *Tabler v. Wallace*, 704 S.W.2d 179 (Ky.1985). cert. denied, 479 U.S. 822. 107 S.Ct. 89, 93 L.Ed.2d 41(1986), the Kentucky Supreme Court, in the course of holding that negligence theory does not distinguish between sellers of goods and renderers of services, stated:

In the last twenty years an additional theory of liability labeled "strict liability in tort" has developed against products manufacturers and suppliers who fall within the class described in Section 402A of the Restatement (Second) Torts. But there has never been any distinction under a negligence theory between the treatment of goods and services. *Id.* at 186 (emphasis omitted; emphasis added).

3. Of course, the crucial date is not when plaintiff's decedent was diagnosed as having AIDS. but when he actually contracted the disease from contaminated Koate. a date not clearly established by the record before this court. However, because this distinction is not material to our disposition of the case. we assume, for purposes of this appeal only, that AIDS contraction and diagnosis simultaneously occurred in October 1983.