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New Wave of Tainted Blood Litigation: Hepatitis C Liability Issues

Both individual cases and class actions are raising multiple issues of liability and the bases on which damages may be imposed

By **R. Jo Reser** and
 By **Barbara A. Radnofsky**

A NEW wave of **tainted blood** litigation caused by the hepatitis C virus (HCV) has begun. Thousands of patients in the United States are receiving HCV “look-back” notifications that they may have been exposed to hepatitis C. Plaintiffs’ lawyers are beginning to advertise for people who have contracted hepatitis C through a **blood** transfusion, organ transplant or the use of any **blood** products.

The hepatitis C epidemic in the United States has created international litigation. A group of Canadians, claiming that they were infected by **tainted blood** products collected from prisoners in the United States, have filed a \$ 660 million lawsuit against the Canadian government and several private companies for failing to adequately safeguard the **blood** supply. This class action suit charges Ottawa with neglect for failing to set aside **blood** plasma collected in Arkansas prisons in the early 1980s after U.S. **health** officials already

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ment’s undersecretary for **health**, was quoted in the *Washington Post* as stating that the department’s package, costing \$12,000 to \$15,000 a year per patient, is a harbinger of costly medical treatments to come as new drugs become available to treat chronic ailments in veterans. Kizer said the costs of the HCV initiative—\$250 million to \$300 million this year alone—have provoked questions outside the V.A.

1988 and U.S. health officials already had determined that using the product was “imprudent” because of the high risk of infection. At the time, there was no test to indicate the presence of Hepatitis C. The plasma should not have been collected from inmates who tested positive for hepatitis B.

TREATMENTS FOR HEPATITIS C

While there is no known cure for hepatitis C, in January 1999, the U.S. Department of Veterans Affairs announced plans to offer a costly new drug treatment to former military personnel suffering from hepatitis C. Kenneth W. Kizer, the depart-

about the necessity of this effort.

He said the cost should rise next fiscal year to \$400 million to \$500 million. Even “at government prices,” he maintains the HCV initiative is a cost-effective way to fight a disease that V.A. surveys have found is widespread among veterans. HCV can lead to other costly medical treatments including liver transplants.

Veterans who choose the new treatment face a difficult program. Side effects of the drugs involved—interferons and ribavirin—are said to be serious, and include depression, anemia and flu-like symptoms. Only half of those who take the treatments improve, and those who do are not said to

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have been cured, but only to have eliminated signs of active liver disease.

HCV LOOK BACK

In 1989, Texas enacted Section 162.008 of the Texas **Health** and Safety Code, which enumerates “procedures for notifying **blood** recipients.” This statute provides:

Each hospital, physician, **health** agency and other transfuser of **blood** shall strictly follow the official “Operation Look Back” procedure of the American Association of **Blood** Banks (AABB) or the American Red Cross **Blood** Services in notifying past and future recipients of **blood**. The only exception to notifying a recipient of **blood** is if the recipient is dead or cannot be located.

Physicians and hospitals thus must take seriously the FDA’s recent look back “recommendations.” The FDA recommended that **blood** establishments begin by March

efforts.

Compliance with the FDA’s recommendations is likely to be adopted by the U.S. **Health Care** Financing Administration (HCFA). Development of a compliance plan, as well as the education of physicians, clinical staff, management and directors and/or trustees, is essential for any provider.

While compliance with industry standards has not allowed defendants an out in litigation, the failure to comply with such standards usually proves fatal. Jury research has shown that jurors were not impressed with claims of compliance with government standards. Where industry standards were at issue, compliance was even less of a factor in favorably impressing jurors.

There is strong evidence that a defense based on compliance will elicit no more than a neutral reaction among jurors, ac-

that **blood** establishments begin by March 1999 to look back whenever a donor tests positive for HCV virus. The look back is a retest of samples from all previous donations by such individuals, going back 10 years, followed by notice to hospitals and physicians, who must in turn inform patients who received this reactive **blood** or **blood** products.

The FDA required that this take place as soon as possible and be completed by March of this year. **Blood** consignees, which include hospital and transfusion services, have one year from the date of their notification to attempt to notify recipients of the infected **blood**.

A minimum of three attempts must be made to notify the recipients of HCV-infected **blood**. The notification can be carried out in two ways: (1) by notifying the patient and concurrently the physician who ordered the **blood** or **blood** products, or (2) by notifying the physician who ordered the **blood** products, who is then to notify the patient. If the physician fails to notify the patient, the hospital or transfusion service should notify the patient. The patient's medical record must document all attempts at notification, even unsuccessful

according to Donald Vinson's research in his book *Jury Trials: The Psychology of Winning Strategy*. However, when the defendant is a non-complier, evidence suggests the jurors will be quick to form a negative opinion. In fact, non-compliance has potentially disastrous consequences. On the same approval ratings scale, defendants in non-compliance cases scored very low and were regarded as unbearable by jurors. In fact, if the plaintiffs pursue a strategy of demonstrating that the defendant is in non-compliance with established standards, defense counsel will have a difficult time bringing jurors up to a position of mere neutrality.

With the U.S. government recommending and offering expensive HCV treatment to thousands of veterans, it would be difficult to explain a failure to follow an FDA or HCFA recommended look back program in the private sector.

Hernandez v. Nueces County Medical Society Community Blood Bank,¹ decided by the Texas Court of Appeals, dealt spe-

1. 779 S.W.2d 867, 871 (Tex.App.—Corpus Christi 1989, no writ).

cifically with hepatitis C infection caused by transfusion after the delivery of a baby by cesarian section. The court examined the new screening procedures being used by other **blood** banks and held that “since, in the instant case, there is evidence that the **blood** bank may have unduly lagged in the adoption of new screening procedures, we hold that evidence of compliance with federal and minimum licensing standard

of human **blood**; and (2) those involving the donation, manufacture and administration of **blood** products.

In most cases involving the donation and administration of human **blood**, the donation is obtained by a **blood** bank or transfusion service from a voluntary donor, who typically (but not always) gives for altruistic reasons. The **blood** is fractionated into two to three separate components

does not conclusively insulate the **blood** bank from liability.”

The court cited Learned Hand’s Second Circuit opinion in *The T.J. Hooper*:

Indeed in most cases reasonable prudence is in fact common prudence; but strictly it is never its measure; a whole calling may have unduly lagged in the adoption of new and available devices. It never may set its own tests, however persuasive be its usages. Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission.²

These are the tasks that risk managers, counsel and physicians are face in dealing with the HCV look-back recommendations of the FDA and other future regulations. To understand the way courts will look at the duties of the physicians, hospitals and their staff, one must examine how the courts in the past have assessed their various responsibilities in similar cases of **tainted blood**.

LEGAL ISSUES

Cases involving **blood** products are personal injury cases, so many of the legal principles to be applies are similar to or the same as those used in cases of general negligence, products liability and medical malpractice.

A. Parties

Blood product cases can be divided generally into two types: (1) those involving the donation, preparation and transfusion

² 60 F.2d 737, 740 (2d Cir. 1983).

(platelets, red **blood** cells, cryoprecipitate, fresh frozen plasma, etc.) and then shipped to a hospital, where the **blood** is transfused under the specific orders of a physician.

In the second category of cases, **blood** is obtained from an altruistic, voluntary donor or from a paid donor. The second category of cases usually involves a process known as “apheresis” (literally—to take away), in which a specific component is removed from the **blood** and the remainder of the **blood** is transfused back into the donor. In most instances, the component withdrawn is plasma, white **blood** cells or platelets. The component is then sold to a manufacturing company, which turns the donated material into a usable end product through specific manufacturing processes. The end product is sold to doctors and hospitals, who prescribe it as needed. These types of cases typically involve factor VIII and factor IX concentrates. Hemophiliacs are usually dependent on factor VIII and factor IX concentrates to clot their **blood**.

Who is a necessary party in a **blood** products case depends on the type of case and the nature of the injury. Physicians have a duty to order a transfusion only when it is medically necessary. Nurses and nurses’ assistants usually are responsible for the actual transfusion. Hospitals are responsible for obtaining and maintaining a supply of safe **blood** and for monitoring its use by physicians who have privileges at the hospital. Hospital laboratories (and pathologists) type and cross-match the **blood** in order to determine whether the **blood** ordered for transfusion is compatible with the patient. **Blood** banks are responsible for the screening of donors, the collection

of **blood** and the testing of **blood** for diseases. The facts of a given case will dictate who are necessary parties.

In the second category of cases, **blood** banks or plasma centers are responsible for the proper selection and screening of donors and the initial testing of the **blood**. The manufacturer of the end product obtains the **blood** product from appropriate and reasonably safe sources, employs good manufacturing processes (which often involve pooling) and manufactures an end product for distribution to doctors and hospitals, with the appropriate (FDA-approved) warnings and instructions.

Rarely will a donor be a proper party to a **blood** case. In fact, in Texas two statutes provide immunity to donors.³

B. Legal Theories

1. Negligence

a. Conduct

In examining the conduct of a “reasonably prudent person,” difficult concepts of risk must be addressed, including current reduced risk of transfusion transmitted disease and recognition that “objective of a zero-risk **blood** supply is virtually unachievable.”⁴

b. Compliance with Standards

Is compliance with custom or recognized standards sufficient? In *Hernandez*, the court held that proof of compliance

with industry custom not sufficient in itself to warrant summary judgment. In *Walls v. Armour Pharmaceuticals Co.*,⁵ a federal district court held that even if the defendant’s practice was consistent with that of the entire pharmaceutical industry with regard to warning of AIDS risk on labeling of factor VIII products, that alone would not provide “evidence” that it acted with “reasonable care.” The court discussed the plaintiff’s evidence that Armour had “reasonable evidence” of AIDS risk prior to its request for FDA permission to issue a factor VIII warning pursuant to federal labeling law. The court concluded: “If Armour violated federal law, then it could not be said that Armour acted with ‘reasonable care,’ whether or not in doing so Armour acted in compliance with contemporaneous industry practice.”⁶

Standards include statutes, such as **blood** bank acts and communicable disease acts; regulations, such as those of the Food and Drug Administration; licensure examination requirements; internal rules, bylaws and regulations of organizations, such as the AABB; professional publications and learned treatises; conduct or standards of like organizations; and expert testimony. While plaintiffs have not met with universal success in establishing that an entire industry was negligent,⁷ a Denver jury once found so.⁸

A majority of courts have held that **blood** banks, as well as physicians and hospitals, are held to a professional stan-

3. See TEX. CIV. PRAC. & REM. CODE § 77.003(a) (one who donates **blood** liable only for negligence or gross negligence or an intentional tort); TEX. HEALTH & SAFETY CODE § 162.012(a) (donor who provides information or **blood** samples pursuant to statute immune from all liability arising from donation of **blood** transfused into recipient).

4. Dodd Ry, *The Risk of Transfusion Transmitted Infection*, 327 NEW ENG. J. MED. 419 (1992). See also Donahue et al., *The Declining Risk of Post Transfusion*, 327 NEW ENG. J. MED. 369 (1992).

5. 832 F.Supp. 1505 (M.D. Fla. 1993). See also 832 F.Supp. 1467.

American Association of **Blood** Bank standards).

7. See *Hoemke v. New York Blood Ctr.*, 720 F.Supp. 45 (S.D. N.Y. 1989), *aff’d*, 912 F.2d 550 (2d Cir. 1990).

8. *Quintana v. United Blood Servs.*, No. 86-CV-1750 (U.S. D.C. Colo. Aug 1, 1992).

9. See, e.g., *Kirkendall v. Harbor Ins. Co.*, 698 F.Supp. 768, 778 (W.D. Ark. 1988), *aff’d*, 887 F.2d 857 (8th Cir. 1989); *Shelby v. St. Luke’s Episcopal Hosp.*, 1988 WL 28996 at *3 (U.S.D.C. S.D. Tex.); *Kozup*, 663 F.Supp. at 1051-53, 1055; *United Blood Servs. v. Quintana*, 827 P.2d 509, 524 (Colo. 1992); *Miles Labs. Inc. v. Doe*, 556 A.2d 1107,

6. *Id.* at 1513. See also *Tufaro v. Methodist Hospital Inc.*, 368 So.2d 1219, 1221 (La.App. 1979) (no negligence where screening procedures satisfied

1125 (Md. 1989), *later proceeding*, 927 F.2d 187 (4th Cir. 1991); *Doe v. Am. Red Cross*, 377 S.E.2d 323, 326 (S.C. 1989).

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dard of **care**.⁹ Several jurisdictions apply professional standard of **care** where state statutes equate **blood** banking with the practice of medicine or where **blood** banking is viewed as a distinct specialty within the **health care** profession.¹⁰

c. Liability of Standard-setting Organization

In *Snyder v. American Association of Blood Banks*,¹¹ the New Jersey Supreme Court held that association owed a duty of **care** to a post-August 1984 transfusion AIDS plaintiff who received **blood** from an AABB member **blood** bank. The trial focused on AABB's role in the **blood** banking industry and the reasonableness of its response to increasing evidence that **blood** or **blood** products could transmit AIDS.

After acknowledging the role of FDA, and the state department of **health** in inspecting and licensing, the court the objectives of AABB set out its certificate of incorporation and the AABB's executive director's testimony that the general purpose of the association was "to develop and recommend standards on the practice of **blood** banking, to help promote the public **health** . . . and to conduct numerous programs for communication and education among organization members and the public at large."

The court emphasized the AABB's inspection and accrediting role, quoting from the AABB's annual report that it "leads the

industry, in setting policy and establishing standards of practice for its member **blood** banks in excess of the FDA." It discussed the reliance of **blood** banks on AABB recommendations, citing the testimony of the **blood** bank's part-time medical director that it would have followed any screening or testing recommendations from the AABB.

The court pointed to AABB's role as a member of FDA's **Blood** Products Advisory Council and the criticism of the Committee to Study HIV Transmission Through **Blood** and **Blood** Products that "in the early 1980s, the FDA appeared too reliant upon analyses provided by industry-based members" of the advisory counsel. The court also believed plaintiff's experts' testimony centering on the passiveness of the FDA or state governments in deferring to the AABB.

Relying on the plaintiff's experts, the court recited a lengthy chronology of developments in knowledge of HIV AIDS and the **blood** supply, concluding that, before Snyder received his transfusion, the AABB should have foreseen the "severe risk" of **blood** transmissibility of AIDS and should have recommended surrogate testing and direct questioning of donors. If the AABB had not been "intransigent," the court concluded, the jury could have found that surrogate testing would have been instituted that "could have" led to a rejection of the unit transfused to Snyder. Other than the "could have" commentary, the court

10. *Smith v. Paslode*, 799 F.Supp. 960 (E.D. Mo. 1992); *Seitzinger v. Am. Red Cross*, 1992 U.S. Dist. Lexis 18445 (E.D. Pa.)

11. 676 A.2d 1036 (N.J. 1996).

12. *Kaiser v. Memorial Blood Ctr. of Minneapolis*, 977 F.2d 1280 (8th Cir. 1992); *Sweeney v. Presbyterian/Columbia Presbyterian Med. Ctr.*, 763 F.Supp. 50 (S.D. N.Y. 1991); *Miles Labs.*, 556 A.2d 1107; *Wadley Research Institute and Blood Bank v. Beeson*, 835 S.W.2d 689 (Tex. App.—Dallas 1992, writ denied); *DiMarco v. Hudson Valley Blood Servs.*, 532 N.Y.S.2d 488 (Sup.Ct. 1988), *rev'd on other grounds*, 542 N.Y.S.2d 521 (App.Div. 1989).

13. 925 S.W.2d 372 (Tex.App.—Corpus Christi 1996), *rev'd on other grounds*, 964 S.W.2d 940 (Tex. 1998).

the court have commented, the court did not analyze causation.

d. Status of Blood Banks

Since **blood** banks are not “**health care** professionals” for purposes of state statutes, the negligence statutes of limitations apply, rather than the usually shorter periods applicable to **health care** professionals.¹²

2. Duty to Warn

The Texas Court of Appeals in *Garcia v. Santa Rosa Health Care Corp.*¹³

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that a hospital that derives information on a patients’ status from “situational conditions”—that is, the use of contaminated **blood** clotting medicines—was not protected from liability for failure to notify the patient and his wife of the probable HIV contraction, despite the Texas Communicable Disease Prevention and Control Act’s prohibition on the release of “test results” to a third party. Since the information was derived from the “situation” and not testing, the court held the act’s prohibitions against disclosure did not apply.

This case is of interest on many levels, particularly the concept of duty to non-patients, consistent with the *Tarasoff* notion of a **health care** provider’s duty to those endangered by a foreseeable patient conduct.¹⁴ On appeal, the Texas Supreme Court reversed the finding of liability on other grounds, because there had been no test to confirm the husband had AIDS.

Garcia is broad in holding that the hos-

be “unavoidably unsafe,” meaning it is “quite incapable of being made safe for [its] intended and ordinary use.” Four factors usually are examined by courts in balancing risks and benefits and inability to avoid risks: (1) the non-existence of any scientific test capable of detecting the viral agent that 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.¹⁶

b. Statutes

The provision of **blood** is viewed as service.¹⁷ State **blood** shield statutes and the Uniform Commercial Code recognize the provision of **blood** as a service, not a product.

For instance, Section 2.316(e) of the Texas Business and Commercial Code, the Texas version of the Uniform Commercial

pital had a duty to notify a future wife of her intended husband's probable infection with HIV. The hospital claimed no duty to warn, citing the decedent's right to confidentiality. In deciding that the Communicable Disease Prevention and Control Act would not bar the suit "for failure to disclose non-confidential information of this nature that may be necessary to protect a third party from exposure to AIDS," the court gave no guidance as to what "environmental and situational factors" would give rise to a duty to warn while still maintaining "test result" confidentiality.

The similarities between hepatitis C virus and HIV may result in similar warning burdens being placed on **health care** providers.

3. Strict Liability and Warranty

a. Restatement

The unavoidably dangerous products theories of Section 402A, Comment k, of the Restatement (Second) of Torts apply. Under that provision, a product is not unreasonably dangerous if it is determined to

Code, provides:

The implied warranties of merchantability and fitness shall not be applicable to the furnishing of human **blood, blood** plasma, or other human tissue or organs from a **blood** bank or reservoir of such other tissues or organs. *Such blood, blood plasma or tissue or organs shall not . . . be considered commodities subject to sale or barter, but shall be considered as medical services.* [Emphasis added.]

And Section 77.003 of the Texas Civil Practice and Remedies Code provides:

14. *Tarasoff v. Regents of the Univ. of California*, 551 P.2d 334 (Cal. 1976).

15. But this should be contrasted with the the Texas Supreme Court's holding in *Bird v. W.C.W.*, 868 S.W.2d 767 (Tex. 1994), rejecting a notion of duty to parents adversely affected by a negligent misdiagnosis of child abuse by a psychologist.

16. *Doe v. Miles Labs. Inc.*, 927 F.2d 187, 191. *See also* *Garvey v. St. Elizabeth Hosp.*, 697 P.2d 248, 249 (Wash. 1985); *Snyder v. Mekhjian*, 582 A.2d 307 (N.J.Super. 1990).

17. *See, e.g., Kozup*, 663 F. Supp. 1048. *Balkowitsch v. Minneapolis War Memorial Blood Bank*, 132 N.W.2d 805, 807 (1965).

(a) A person who donates, obtains, prepares, transplants, injects, transfuses, or transfers a human body part from a living or dead human to another human or a person who assist or participates in that activity is not liable as a result of that activity except for negligence, gross negligence, or an intentional act. . . .

(b) The implied warranties of merchantability and fitness do not apply to the furnishing of human body parts by **blood** banks, tissue banks, or other similar organi-

cited at footnote 5, the plaintiff argued that Armour had "reasonable evidence" of an association of an AIDS risk with its Factor VIII concentrate and failed to apply to the FDA to issue a warning about its product as soon as it was bound to do so. The court held that the FDA approval of Armour's eventual package labeling was irrelevant to a determination of whether Armour applied to the FDA as soon as federal law required it to do so.

zations. For purposes of this chapter, those human body parts are not considered commodities subject to sale or barter.

Courts uniformly have held **blood** shield statutes constitutional.¹⁸

Actions under state consumer protection acts have not met with success because courts view the provision of **blood** differently from a commercial sales transaction.¹⁹

Blood requires a prescription and is subject to labeling and warning requirements. 21 C.F.R. § 201.57(e) states:

The labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.

In *Walls v. Armour Pharmaceuticals*,

18. *E.g.*, *Shelby*, 1988 WL 28996, at *2; *Doe v. Cutter Labs.*, 703 F.Supp. 573 (N.D. Tex. 1988); *Coffee v. Cutter Biological*, 809 F.2d 191, 193 (2d Cir. 1987); *Hyland Therapeutics v. Superior Court*, 220 Cal.Rptr. 590, 592 (Cal.App. 1985); *Kozup*, 663 F.Supp. 1048; *McKee v. Miles Labs. Inc.*, 675 F.Supp. 1060, 1063 (E.D. Ky. 1987), *aff'd*, 866 F.2d 219 (6th Cir. 1989); *Poole v. Alpha Therapeutic Corp.*, 698 F.Supp. 1367, 1370 (N.D. Ill. 1988); *Samson v. Greenville Hosp. System and Carolina-Georgia Blood Ctr.*, 377 S.E.2d 311, 312 (S.C. 1989); *Zichichi v. Middlesex Memorial Hosp.*, 528 A.2d 805, 1088 (Conn. 1987); *Doe v. Travenol Labs. Inc.*, 698 F.Supp. 780 (D.C. Minn. 1988).

19. *See, e.g.*, *Kozup*, 663 F.Supp. 1048; *Howell v. Spokane and Inland Empire Blood Bank*, 785 P.2d 815 (Wash. 1990).

20. 506 F.2d 841 (5th Cir. 1975).

c. Learned Intermediary

A variant of the learned intermediary doctrine applies. In *Heirs of Fruge v. Blood Services*,²⁰ the Fifth Circuit held that there was sufficient warning of “known risks” by the warning attached to unit and in official package circular distributed to each hospital. In *Walls*, Armour could avail itself of learned intermediary doctrine only by showing both prescribing physician awareness of the information in the “ultimate warning” and by satisfying the burden of showing independent knowledge by the prescribing physician of “reasonable evidence” of an “association” of an AIDS risk with Factor VIII concentrate at the time that Armour should have issued a warning per federal regulations.

The new Restatement (Third) of Torts: Products Liability retains the learned intermediary rule in Section 6(d)(1), but the Comment b goes on to state: “However, in certain limited therapeutic relationships the physician or other **health care** provider has a much diminished role as an evaluator or decision maker. In these instance it may be appropriate to impose on the manufacturer the duty to warn the patient directly.” Those instances are where the manufacturer knew or should have known that no medical provider was in a position to obtain instructions or warnings and reduce risk of harm and, according to commentary, where direct warnings would be feasible and efficacious, where the FDA requires direct warnings, or where the drug or medical device was advertised or promoted directly to consumers.

d. Informed Consent

The concept of informed consent originated with the law of battery. Judicial approaches vary.

Is liability limited to negligence? The trend is toward the “reasonable patient” standard in evaluating content requirements.²¹ The “locality rule” for measuring the standard of **care** for physicians and **health care** providers is being abandoned.

Texas requires disclosure in writing in order to obtain a presumption of compliance with informed consent requirements. The Texas Medical Disclosure Panel adopted transfusion consent wording to be used in order to obtain the presumption. New Jersey and California have adopted statutes requiring specific disclosures to patients who may require **blood** transfusion, including in new Jersey disclosure of options of autologous/designated/homologous and in California of autologous/directed/non-directed.

An AABB policy statement in 1994 reaffirmed informed consent as including the following elements: (1) an understanding of what medical action is recommended; (2) its associated risks and benefits; (3) alternative methods of therapy available and their attendant risks, including the possible consequences of not receiving the recommended therapy; (4) an opportunity to ask questions; and (5) consent to transfusion.

The duty to obtain consent is primarily that of the physician.²³

Autologous **blood** creates a new consent issue, since the **blood** bank sees the patient in the patient’s capacity as donor. The role

of informed consent for donation may be contrasted with informed consent for transfusion. Implied consent may be applicable, particularly in an emergency setting. This may be contrasted with the plaintiff’s burden of proving that the failure to obtain consent was a proximate cause and that a reasonable patient would not have consented. In *Knight v. Department of Army*,²² a federal district court held there was no proof of proximate cause where the patient had no choice but surgery with transfusion, the patient was not a candidate for autologous, and there was adequate evidence of duty to inform regarding directed donations.

e. Market Share, Enterprise and “Non-Identification” Theories

The “concert of action” theory imposes liability on those who pursue a common plan or design to commit a tortious act and actively participate in or lend aid, cooperation or encouragement to the wrongdoer. Concert of action liability may attach only if the defendant’s conduct was independently tortious. A defendant who “innocently, rightfully, and carefully” engages in conduct that effectively cooperates in the tortious design of another cannot be subject to liability based on that act alone.²⁵

Under “enterprise liability”, each manufacturer is held accountable because of its of adherence to an industry-wide standard.²⁶ Enterprise liability applies when it is proved that the defendants were jointly aware of the risks at issue and possessed a

21. *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972), *cert. denied*, 409 U.S. 1064 (1972); *Barner v. Gorman*, 605 So.2d 805 (Miss. 1992); *Korman v. Mallin*, 858 P.2d 1145 (Alaska 1993). *But see* *Culbertson v. Mernitz*, 602 N.E.2d 98 (Ind. 1992) (reasonably prudent physician standard).

22. *Peterson v. Shields*, 652 S.W.2d 929, 931 (Tex. 1983).

23. *Gibson v. Methodist Hosp.*, 822 S.W.2d 95 (Tex.App.—Houston [1st. Dist.] 1991, writ denied); *Ritter v. Delaney*, 790 S.W.2d 29 (Tex.App.—San

See also *Jones v. Philadelphia College of Osteopathic Medicine*, 813 F.Supp. 1125 (E.D. Pa. 1993) (primary treating physician, as opposed to other consulting physicians, could be held liable for failure to obtain informed consent for **blood** transfusion).

24. 757 F.Supp. 790, 791 (W.D.Tex. 1991).

25. *See* R ESTATEMENT (S ECOND) OF T § 876 cmt. b.

26. *Hall v. E.I. DuPont de Nemours & Co.*, 345 F.Supp. 353 (E.D. N.Y. 1972) (exploding blasting

Antonio 1990, writ denied); Howell, 785 P.2d 815.

caps injured numerous children).

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joint capacity to reduce or affect the risks. Enterprise liability has limited application to a highly centralized industry with few manufacturers. Courts decline the theory in large industries because plaintiffs must prove that the defendants collectively controlled conduct or safety standards. In *Gaulding v. Colotex Corp.*,²⁷ the plaintiffs could not meet the criteria for imposing enterprise or industry-wide liability because they could not show that it was more probable than not that the death was caused by exposure to wallboard produced by any of the five defendants.

The “market share” theory of liability requires that a substantial number, but not all, of the manufacturers marketing their products in the relevant geographical area and time period be before the court.²⁸ The plaintiff must prove all elements of the action except which of the defendants manufactured the injury-producing product. Then the burden shifts to each defendant to prove it did not cause the plaintiff’s injuries. When it cannot do that, the defendant is liable for damages in a like percentage to its market share percentage of sales. The *Gaulding* plaintiffs, for instance, could not determine where, when or whether the wallboard was originally marketed in Texas. So they could not identify the relevant market and time span to determine the defendants’ percentage market shares.

In *Mowrer v. Armour Pharmaceutical Co.*,²⁹ a federal district court in Pennsylvania held that strict liability and warranty claims against Factor VIII manufacturers

ing the legislative policy underlying Pennsylvania’s **blood** shield statute precluded reliance on either of these theories. “The Pennsylvania legislative has shown its intention to protect the supply of **blood** and **blood** components by precluding the application of new and expansive theories of recovery,” the court stated.

In *Smith v. Cutter Biological Inc.*,³⁰ Hawaii Supreme Court applied the market share theory in a Factor VII transfusion case. But it rejected alternative liability because the defendant’s actions, even if tortious, occurred at different times; rejected concert of action as excessive and harsh; and rejected enterprise, industry-wide liability because of compliance with FDA standards.

In *Ray v. Cutter Laboratories*, a federal district court in Florida adopted the market share alternative theory for hemophiliacs infected with the AIDS virus during transfusion of Factor VIII, but the plaintiffs were unable to identify which manufacturer’s Factor VIII actually injured them. The court analogized to Florida DES cases that recognized market share but rejected concert of action, alternate and enterprise liability.³¹

In 1996, the Florida Court of Appeals affirmed the dismissal of a market share hemophilia case against four manufacturers, finding that Factor VIII concentrates produced by several manufacturers lacked the same composition, came from different pools of plasma and were derived through different proprietary formulas. The court

were barred by the state's **blood** shield statute, and the court went on to dismiss enterprise and market share liability, not-

27. 772 S.W.2d 66, 70 (Tex. 1989).

28. *Sindell v. Abbott Labs.*, 607 P.2d 924 (Cal. 1980) (DES).

29. 1993 U.S. Lexis 18367 (Pa. E.D. 1993).

30. 823 P.2d 717 (Ha. 1991).

31. 754 F.Supp. 193, 194-95 (M.D. Fla. 1991), *citing* *Conley v. Boyle Drug Co.*, 570 So.2d 275 (Fla. 1990).

32. Supply citation to Florida case

33. 199 P.2d 1 (Cal. 1948).

added that the unrefuted defense testimony differentiated the presence of HIV in the product from the product being infectious, reasoning that there was no valid proof that every unit created a uniform risk of harm.³²

The “non-identification” theory of liability was applied as early as 1948 by the California Supreme Court in *Summers v. Tice*,³³ in which alternate liability was imposed where two hunters negligently fired, but the plaintiff struck by only one shot,

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this theory of liability in Sections 433B(2) and (3) as follows:

[Section 433B(2)] Where the tortious conduct of two or more actors is combined to bring harm to the plaintiff, and one or more actors seek to limit his liability on the ground that the harm is capable of apportionment among them, the burden of proof as to the apportionment is upon each such actor.

[Section 433B(3)] Where the conduct of two or more actors is tortious and it is proved that harm has been caused to the plaintiff by only one of them, but there is uncertainty as to which one has caused it, the burden is upon each such actor to prove that he has not caused the harm.

Texas has not adopted non-identification liability. *Gaulding* stated: “We are not to be construed as approving or disapproving alternative liability, concert of action, enterprise liability, or market share liability in an appropriate case.”³⁴

f. Pre-emption

which drew concurrence and dissent by Justice O’Connor, joined by Justices Scalia and Thomas and Chief Justice Rehnquist. The Court’s opinion, authored by Justice Stevens and joined by Justices Kennedy, Souter and Ginsberg, held open the possibility of pre-emption where requirements are specific and related and particularized to the device, but it offered little guidance as to any “general” pre-emption.

Justice Breyer’s concurrence, relying in part on the cigarette case, *Cipollone v. Liggett Group Inc.*,³⁶ offers more hope for pre-emption when read with the dissent’s **attack** on a “specificity” requirement not found in the MDA. But the Stevens opinion emphasized the limited nature of the approved pre-emption in *Cipollone*, stating:

The pre-emptive statute in *Cipollone* was targeted at a limited set of state requirements—those “based on smoking and **health**”—and then only at a limited subset of the possible applications of those requirements—those involving the “advertising or

The defense of pre-emption was affected significantly by the U.S. Supreme Court decision in 1996 in *Medtronic Inc. v. Lohr*.³⁵ The Court held that the Medical Device Amendments of 1976, 21 U.S.C. § 360 *et seq.* (MDA), did not preempt a state common law negligence action against the manufacturer of an allegedly defective pacemaker.

The pacemaker had reached the market through the pre-market notification process as a “510(k) device”—that is, one “substantially equivalent” to other products on the market. The lower court had rejected pre-emption as to state design defect claims, since 510(k) devices were not required to satisfy specific design criteria by the MDA. However, the lower court also concluded that the MDA’s good manufacturing practice regulations and labeling requirements were sufficiently specific federal requirements so as to trigger pre-emption of flaw and failure to warn claims.

The Supreme Court reversed as to pre-emption on the flaw and labeling issue,

promotion of any cigarettes the packages of which are labeled in conformity with the provisions of ” the federal statute.³⁷

g. Fear of HCV or AIDS

In **blood** cases, either by transfusion or exposure to a **health care** worker, is there liability for fear of HCV or AIDS?

In *Kerins v. Hartley*,³⁸ the California Court of Appeals had adopted a “reasonable period of anxiety” rule to trigger liability in the case of a patient operated on

34. See also SYSCO Food Servs. v. Trapnell, 890 S.W.2d 796 (Tex. 1994) (refraining from deciding whether Texas law encompasses theory of alternate liability or collective liability, noting that plaintiff would, under such theories, have had to prove exposure to the allegedly harmful product by a preponderance of evidence).

35. 518 U.S. 470 (1996).

36. 505 U.S. 504 (1992).

37. 518 U.S. at 488. See also Quentin F.

Urquhart Jr. & Robert E. Durgin, *Medtronic v. Lohr: Is There a Future for Preemption in Medical Device Cases?* 64 DEF . COUNS . J. 45 (1997).

38. 21 Cal.Rptr.2d 621 (Cal.App. 1993), *superse-*
ded by 33 Cal.Rptr.2d 172 (Cal.App. 1994).

for uterine tumor by a HIV positive surgeon, but this decision was vacated by the California Supreme Court, which ordered reconsideration in light of the supreme court’s decision in *Potter v. Firestone Tire and Rubber Co.*³⁹ *Potter* used a new standard for mental distress damages in toxic exposure cases by permitting recovery for negligent infliction of emotional distress caused by fear of cancer only if exposure to the carcinogen is caused by the defendant’s negligence and the plaintiff’s fear is corroborated by reasonable medical opin-

requirement that the alleged fear be a reasonable one, that it find its origin in actual exposure to a substance or condition capable of causing the feared disease or malady,” the court stated.

HEMOPHILIA CASES

As to class actions in **blood** cases, certification of a class action against the National Hemophilia Foundation and four pharmaceutical companies in the Northern District of Illinois was reported in *Wad-*

corroborated by reasonable medical opinion that, more likely than not, the plaintiff will develop cancer in the future because of the exposure. The case held that future medical monitoring costs may be recovered as long as there is “significant” risk of the disease.

Texas has rejected independent recovery for negligent infliction of emotional distress,⁴⁰ but other states have not.⁴¹

Will fear of HCV be recognized as an injury? “Actual exposure” was required by the Texas Court of Appeals in *Drury v. Baptist Memorial Hospital System*,⁴² a summary judgment case involving failure to honor a request for directed donations of **blood**. Five months after transfusion, the plaintiff tested HIV negative. The court cited the defense experts’ deposition testimony of “absolutely no injury” and then addressed the fear of disease claim, turning to Texas cases on fear of cancer, rabies, or **blood** poisoning. “A common thread running through these cases is reflected in the

39. 863 P.2d 795 (Cal. 1993).

40. *Boyles v. Kerr*, 855 S.W.2d 593 (Tex. 1993).

41. *Kaehne v. Schmidt*, 472 N.W.2d 247 (Wis.App. 1991) (via transfusion); *Faya v. Estate of Almaraz*, 1991 WL 317023 (Md.Cir.Ct. 1991), *rev’d*, 620 A.2d 327 (Md. 1993) (via exposure to **health** care worker, reasonable window of anxiety); *Johnson v. West Virginia Univ. Hosp.*, 413 S.E.2d 889 (W.Va. 1991), *overruled*, 437 S.W.2d 436 (W.Va. 1993) (hospital security guard entitled to emotional distress damages for exposure to HIV and fear of AIDS via infected patient).

42. 933 S.W.2d 668 (Tex.App.—San Antonio 1996, writ denied).

43. 157 F.R.D. 410 (N.D. Ill. 1994).

44. *In re Factor VII or IX Concentrate Blood Prods. Litig.*, No. 986 (J.P.M.L.) No. 93-C-7452.

leigh v. Rhone-Poulenc Rorer Inc., and formal certification occurred in November 1995. Class members were given opportunity to opt out as to the NHF, with Judge John Grady stating:

... there may be valid reasons why certain class members would elect not to assert claims against the NHF while still desiring to assert claims against the fractionator defendants. This raises the possibility of class members opting out solely to avoid asserting claims against the NHF. This consideration is sufficient to justify the creation of an opt-out procedure for class members as to the NHF only, while allowing for their continued class membership in the litigation against the fractionator defendants.⁴³

Earlier, prior to certification, two of the four antihemophilic manufacturers announced a tentative settlement of \$140 to \$160 million to fund a settlement if the opt-out level was no more than 150. The suit allege that the defendants had information in the late 1970s and early 1980s that should have prompted heat treatment or other forms of improved processing of **blood** to reduce risk of transmissibility of HCV. Judge Grady, followed by the plaintiffs, rejected the settlement.

The federal Judicial Panel on Multi-district Litigation approved consolidation of 28 suits over HIV-**tainted** anti-hemophilic factor concentrate, rejecting the defendant manufacturers’ claims that the issues were varied and case specific.⁴⁴ TI case were assigned to Judge Grady, and in August 1996, he gave preliminary approval to an agreement paying at least

\$600 million, although the plaintiffs raised the stumbling block of the lien rights of Medicare and Medicaid and the private insurers. No cap on the number of claimants was included in the proposed agreement, reached between the Committee of 10,000 and Baxter Healthcare Corp., Alpha Therapeutic Corp., Armour Pharmaceutical Co., and Bayer.

In late 1996, Judge Grady continued the fairness hearing as to the \$640 million proposed settlement, citing the lack of an agreement to protect the plaintiffs' \$100,000 settlement packages from jeopardizing their eligibility for Medicaid benefits. The settlement ultimately was approved with approximately 300 optouts at this time.

HEPATITIS C

In 1992, the FDA licensed the Ortho HCV 2.0 enzyme immuno assay. The **Blood** Products Advisory Committee called for inventory testing but not for lookback. Regarding information to be conveyed to physicians, donors and patients, questions arise as to whose duty it is and what information to be conveyed. This is complicated by (1) potential confirmatory tests highlighted the role of unlicensed tests and the absence of guidelines for use or non-use; (2) the modes of transmission are unclear, *e.g.*, sexual or perinatal transmission; and (3) there is lack of data on efficacy of treatments, *e.g.*, alfa interferon.

Recommendations from the 1996 Congressional report, *The Need for New National Standards to Meet New Threats*, include that the Department of **Health** and Human Services "take steps to ensure that

the estimated 300,000 living recipients of **blood** and **blood** products who were infected with hepatitis C virus before 1990 are notified of their potential infection so that they might seek diagnosis and treatment."

The American Association of **Blood** Banks, as of November 1996, took no position on HCV look-back, noting that 95 percent of the HCV problem would not be addressed ("less than 3 percent of all HCV infections are transfusion related"); that "lookback has proven to be a highly inefficient means of identifying affected individuals"; and citing recommendations from the Center for Biologics Evaluation and Research.

In regard to products already transfused, FDA is now recommending transfusion recipient/patient tracing and notification at the present time.⁴⁵

CONCLUSION

There are many other considerations in **blood** products cases—for example, damage limitations, charitable immunity, procedural issues relating to discovery and confidentiality, statutes of limitations. Most **blood** cases involve injuries that are latent for at least several years after the patient is exposed to the contaminated **blood** or **blood** product. It would not be unusual for a transfusion recipient infected with Hepatitis C not to show symptoms for several years after the transfusion. But the issues of liability and the possible defenses outlined above are at the core of defending these cases.

45. See Guidance from FDA, Exhibit 1.