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MEDICINE AND LAW: SELECTED RECENT DEVELOPMENTS

Hillary Greene, Michael R. Ragan and M. Stuart Madden

The dynamic interaction of medicine and law continues to raise difficult, cutting-edge challenges for practitioners, scholars, and decision makers in both fields. The process of accommodating new medical problems, techniques, and solutions within the traditional doctrines and processes of the law involved many new or developing issues during the past year. This article will consider the state of the law, as reflected in recent decisions and legislation, in two particularly important medical-legal areas: AIDS and proof of causation.

I. AIDS

The legal community's success in fulfilling its role in the AIDS pandemic will depend upon its ability to deal with AIDS-related issues within the contours of the law and, when necessary, to recontour the law to accommodate those issues. The decision that follows will consider the developing legal reaction to AIDS as reflected in three key areas: tainted blood litigation, civil rights cases, and insurance law.

A. *Tainted Blood and Blood Products*

A tremendous amount of AIDS-related litigation involves tainted blood or blood products. In the seminal case in this area, *Kozup v. Georgetown University*,[1] parents of an infant who contracted AIDS as a result of a blood transfusion unsuccessfully sued the blood bank that collected the blood and the hospital that administered the

1. 663 F. Supp. 1048 (D.D.C. 1987), *aff'd in part, vacated in part, and remanded*, 851 F.2d 437 (D.C. Cir. 1988).

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Part II of this article was authored by M. Stuart Madden, professor of law at the Pace University School of Law. *Professor Madden wishes to acknowledge the assistance provided by David Klein in its preparation.*

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transfusion.[2] In *Kozup* the blood was donated in October 1982 and it was transferred in January 1983. The *Kozup* court predicated its evaluation of the defendants' liability upon the scientific and medical communities' understanding of AIDS in 1982, when the transfusion was administered. Like *Kozup*, nearly all published opinions in this area involve infection arising from blood products collected and utilized prior to 1986. Hospitals, blood banks, and manufacturers have enjoyed a veritable immunity with respect to disease transmissions occurring in this early period.[3]

The plaintiffs in *Kozup* alleged that the American Red Cross (ARC) had been negligent in its failing "(1) to screen donors that were members of high risk groups for AIDS; (2) to implement tests [hepatitis B core antibody test] that would have eliminated blood contaminated with AIDS; and (3) to warn plaintiffs of the dangerous condition of the blood."[4] The plaintiffs also charged Georgetown with negligence in failing to inform them, prior to the transfusion, of "directed donation,"[5] the process whereby family and friends of a patient donate the blood to be used in the event the patient requires a transfusion. The district court, however, based on its medical chronology of research and information about AIDS, concluded that the understanding of AIDS transmissibility in 1982 did not warrant these precautions. The court identified 1984 as the time when the medical community reached a consensus concerning the transmissibility of AIDS through blood and noted that the ELISA test, which screens for antibodies sensitive to HTLV-III, did not become available until May 1985.[6]

The plaintiffs in *Kozup* also sought relief "under the theory of strict liability in tort for an unreasonably dangerous product, under the Restatement (Second) of Torts 402A . . . [and] for breach of the implied warranties of merchantability and fitness . . . under the Uniform Commercial Code."[7] In considering these theories, the district court observed that "the furnishing of blood is more in the nature of a service than of a sale of goods."[8] This characterization led the court to reject the plaintiffs' strict liability and implied warranty claims, which, as the court noted, were "rooted in the implied warranties of blood as a product and the ARC's provision of blood to Georgetown as a sale of a product."[9]

While this analysis could have disposed of the plaintiffs' strict liability and warranty claims, the district court went on to find blood to be an "unavoidably unsafe"—as opposed to unreasonably dangerous—product.[10] Inescapable medical limitations and public policy considerations inspired this conclusion. The court, relying heavily on

2. *Id.*
3. Stevens, *supra* note 1, at 223–24.
4. 663 F. Supp. at 1055–56.
5. *Id.* at 1055.
6. *Id.* at 1052.
7. *Id.* at 1058.
8. *Id.* at 1059. The court rejected plaintiff's claim under the District of Columbia Consumer Products Protection Act on similar grounds. The plaintiff unsuccessfully argued that the blood in question fell below the standard of quality expected, and, therefore, its distribution constituted an unfair trade practice. *Id.* at 1060.
9. *Id.* at 1058–59.
10. *Id.* at 1059

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Fisher v. Sibley Memorial Hospital,[11] noted that strict liability would make suppliers of blood virtual insurers of that blood. Such liability would be particularly problematic given the imperfect ability of blood banks to screen out dangerous viruses.[12] The district court also feared that the reluctance of hospitals and others to risk strict liability would impair the blood supply. To support its position, the court noted that nearly all states had enacted blood shield laws insulating blood suppliers from strict liability.[13]

Predicated upon a lack of informed consent theory, the plaintiffs in *Kozup* also alleged that the transfusion constituted a battery. The district court noted that this theory required the plaintiffs to "show there was a material risk associated with the treatment which, if disclosed, would have caused plaintiff to decline that course of treatment which resulted in plaintiff's injury."[14] In the court's view, however, the AIDS risk was not material when the decedent received his transfusions, as only one possible case of transfusion-related AIDS had been diagnosed at that time.[15] The court considered it unnecessary to address ARC's liability for battery: As the physicians were not obligated to disclose the risk of AIDS to patients, no nondisclosure liability could be imposed on ARC.

The D.C. Circuit affirmed the district court's summary judgment as to both defendants and on all counts, except the battery count against Georgetown.[16] The court of appeals found summary judgment on that count inappropriate, as Georgetown had failed to receive any consent, informed or otherwise, for the blood transfusion. While the appellate court found summary judgment on the claim to be inappropriate, it specifically disavowed any implication that the plaintiffs were entitled to prevail on their battery theory.[17]

Watson v. Medical University[18] represents the second wave of tainted blood litigation—cases in which precautionary measures actually existed but were not followed.[19] *Watson*, which is currently pending, involves a March 1985 transfusion of blood donated in February 1985 to a premature baby who later developed AIDS and died.[20] While the ELISA test was not available in March 1985, it was understood that AIDS is transmissible through blood and that homosexuals constitute a high-

11. 403 A.2d 1130 (D.C. 1979).
12. 663 F. Supp. 1058.
13. *Id.* at 1059 For-profit manufacturers of blood products, such as Factor IX concentrate taken by hemophiliacs, also are exempted from strict liability. Rogers v. Miles Labs., Inc., 802 P.2d 1346 (Wash. 1991); *see also* Snyder v. Mekhjian, 582 A.2d 307, 313 (N.J. Super. Ct. App. Div. 1990).
14. 663 F. Supp. 1053.
15. *Id.* at 1054–55.
16. Kozup v. Georgetown Univ., 851 F.2d 437, 440 (D.C. Cir. 1988).
17. *Id.* at 440.
18. C/A No. 88–2844–18 (D.S.C. Feb. 6, 1991).
19. Stevens, *supra* note 1, at 240–50.
20. *Watson*, C/A No. 88–2844–18, slip op. at 1–2 (D.S.C. Feb. 6, 1991).

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risk group. Watson alleged that the Red Cross negligently screened the donor of the blood in question.[21]

The *Watson* court has indicated that the plaintiff will have to prove that the Red Cross deviated from its procedures and that those procedures were consistent with the then standard of care among blood banks at that time.[22] The nurses do not remember the donor in question, and the donor health history card does not illuminate the alleged negligence. Because information from the donor about the Red Cross procedures will be crucial to the plaintiff's claim, the court has ordered discovery with appropriate protective measures.[23] The *Watson* court concluded that such discovery would not violate the donor's right to privacy or adversely impact the ability of suppliers to maintain a plentiful blood supply. To the extent such negative ramifications might result, the court found them outweighed by the plaintiff's right to the desired information.[24]

As a result of the routine exclusion of high-risk donors and use of the ELISA test, tainted blood cases will become a steadily diminishing proportion of AIDS-related litigation. Nonetheless, *Kozup* and its progeny provide important precedent for future judicial evaluation of both governmental and private-sector responses to AIDS-related issues. The district court in *Kozup*, for example, exculpated the defendants largely because of the absence of any organization in the country that promoted or conducted itself in accordance with the precautions the plaintiffs advanced.[25] The court did not normatively assess whether government or industry regulatory bodies should have recommended such precautions at the time.[26] Individuals have only limited ability to seek relief against governmental agencies and legislatures, due to sovereign immunity and considerable judicial deference, respectively, for their handling of the AIDS crisis.[27] Subsequent judicial decisions, however, have suggested a more stringent evaluation of private institutions than a mere comparison with the relevant community's standard of care: "If a given industry lags behind in adopting procedures that reason-

21. A doctor at the university learned that the donor was an admitted homosexual who was incarcerated. The court, which received this information from the doctor, noted that its order would be the same regardless of whether it considered the information. *Id.* at 4 n.1.

22. *Id.* at 7–8.

23. *Id.* at 4–5.

24. *Id.* at 13. In Rasmussen v. South Fla. Blood Serv., 500 So. 2d 533 (Fla. 1987), the court engaged in a similar evaluation of the competing interests but reached the opposite conclusion. In *Rasmussen*, however, the plaintiff sought names and addresses of blood donors with no restrictions on their use. *Id.* at 537.

25. 663 F. Supp. at 1056.

26. The court reiterated that soon after the first AIDS cases in June 1981, it became clear that the disease was particularly prevalent among homosexual males, intravenous drug users, and recently immigrated Haitians. *Id.* at 1051. The report from the July 1982 meeting of the Centers for Disease Control, National Institute of Health, Food and Drug Administration, American Association of Blood Banks, and National Gay Task Force stated that a "possible mode of transmissions is via blood products." *Id.* However, no recommendations resulted from this meeting. *Id.* Despite growing concern over the safety of the blood supply, when blood bank representatives met in January 1983, they did not recommend screening out homosexuals or the use of any laboratory tests. *Id.* at 1052.

27. *See, e.g.*, New York State Soc'y of Surgeons v. Axelrod, 555 N.Y.S.2d 911 (App. Div. 1990); *see also In re* Complex Blood Bank Litig., No. C 91–0007–MISC–RFP (N.D. Cal., Apr. 8, 1991).

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able prudence would dictate be instituted, then we are free to hold a given defendant to a higher standard of care than that adopted by the industry."[28]

One of the judiciary's most important roles in the medical-legal area is determining when sufficient knowledge of a certain procedure exists for the purpose of finding negligent those who do not perform that procedure. The most straightforward negligence actions will be based upon a failure to comply with established government regulations. Unfortunately, blood bank litigation to date has yielded only limited guidance for the assessment of liability during the transition period between growing appreciation of a particular risk and its formal recognition in government regulations.

B. *Civil Rights*

AIDS-related civil rights issues typically involve questions of privacy rights regarding HIV serostatus and discrimination based on actual or alleged HIV seropositivity. Public health considerations dominate judicial determinations of these issues. The courts recognize that, from a public health standpoint, it is best for HIV-infected individuals to know their status so that they can take appropriate measures to avoid transmitting the disease and to protect their own health. Legal protection of privacy rights and remedies for unlawful discrimination are essential to the promotion of these public health goals.[29] Judicial assessment of the potentially competing interests has been most complicated in cases involving HIV-seropositive health care workers.

Estate of Behringer v. Medical Center at Princeton[30] involved a board-certified ENT surgeon and staff member at the Princeton Medical Center who learned, while a patient at the medical center, that he had both Pneumocystis Carinni Pneumonia (PCP) and AIDS. The surgeon, Behringer, received a bronchial washing to check for PCP, a conclusive indicator of AIDS, and a blood test screening for the HIV virus during a 1987 visit to the center's emergency room.[31] Both tests yielded positive results. On the day after his release from the center, Behringer received numerous phone calls from hospital colleagues and from friends in the community who indicated knowledge of his diagnosis and expressed concern about his health. Shortly thereafter, Behringer's receptionist began to receive similar calls from patients and doctors, with many of the patients indicating that they no longer desired treatment from Behringer.[32] Upon learning of Behringer's condition, the president of the medical center cancelled his pending surgical cases. Behringer never applied for reinstatement of his surgical privileges.[33] Behringer's estate brought suit against the center and its president, seeking damages for breach of confidentiality of Behringer's diagnosis and test results and for violation of state employment discrimination laws.

The court intensely scrutinized the medical center's efforts to ensure the confidentiality of Behringer's records. Noting that "the privacy right on which the [physician-

28. Hoemke v. New York Blood Ctr., 912 F.2d 550, 552 (2d Cir. 1990).
29. Benjamin R. v. Orkin Exterminating Co., 390 S.E.2d 814, 819 (W. Va. 1990).
30. 592 A.2d 1251 (N.J. Super. Ct. Law Div. 1991).
31. *Id.* at 1255.
32. *Id.* at 1256–57.
33. *Id.* at 1257.

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patient] privilege is based has been held to a level warranting constitutional protection,"[34] the court found that the hospital had breached its duty to keep Behringer's medical records confidential by failing to implement special precautions against employee confidentiality breaches. The court criticized the notation of Behringer's HIV status and PCP diagnosis on his medical charts, which were accessible to nearly all medical center personnel.[35] Given the hospital's practice of charting such results, controversial though it may be, the court suggested that access to HIV-positive patients' charts be restricted on a "bonafide need to know" basis and that hospital personnel be instructed on the importance of maintaining the confidentiality of patient records.[36] The court noted that while all patients, regardless of the nature of their illnesses, are entitled to proper maintenance of the physician-patient privilege, the confidentiality of an AIDS diagnosis is particularly important:

> The sensitive nature of medical information about AIDS makes a compelling argument for keeping this information confidential. Society's moral judgments about the high-risk activities associated with the disease, including sexual relations and drug use, make the information of the most personal kind. . . . The potential for harm in the event of a nonconsensual disclosure is substantial.[37]

The court cited numerous examples of "hysterical public reaction to AIDS" in support of this conclusion.[38] It went on, however, to observe that the confidential nature of Behringer's PCP diagnosis did not prevent disclosure to the New Jersey Department of Health in accordance with the hospital's statutory obligation.[39]

Behringer also sought damages for the revocation of his surgical privileges, which he alleged to violate state antidiscrimination laws.[40] The court held that AIDS is a "handicap" under those laws, noting similar interpretations of legislation in other jurisdictions—both federal and state—prohibiting handicap discrimination.[41] The medical center's admission that it revoked Behringer's privileges based solely on his HIV status, therefore, established a prima facie case of discrimination.[42]

The medical center's board of trustees had adopted a policy providing that "[a] physician or health care provider with known HIV seropositivity *may* continue to treat patients at The Medical Center at Princeton, but *shall not* perform procedures that pose any risk of HIV transmission to the patient."[43] Additionally, the board required patients to sign a supplemental consent form, prior to undergoing operative

34. *Id.* at 1268.
35. *Id.* at 1272.
36. *Id.* at 1273.
37. *Id.* at 1272 (quoting Doe v. Barrington, 729 F. Supp. 376, 384 (D.N.J. 1990)).
38. 591 A.2d at 1272 n.12. Many of the cited incidents involved employment discrimination: "removal of a teacher with AIDS from teaching duties; . . . refusal of co-workers of an AIDS victim to use a truck used by the victim; firing of homosexuals who displayed cold symptoms or rashes." *Id.*
39. *Id.* at 1269.
40. Behringer did not claim a breach of confidentiality for the disclosure of his condition to medical center personnel in change of monitoring surgical practices. *Id.* at 1275 n.15.
41. *Id.* at 1275.
42. *Id.* at 1276.
43. *Id.* at 1260.

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or invasive procedures by an HIV-seropositive health care worker, that acknowledged awareness of their doctor's HIV-positive status and of the possible risk of transmission.[44] The board also had mandated that "[t]he Medical Center at Princeton Medical and Dental Staff *shall* continue to care for patients with AIDS without discrimination."[45]

The court provided an extensive account of the debate among staff members at the medical center as well as the parties' experts concerning the risk of HIV transmission from health care worker to patient. Dr. Selwyn, the plaintiff's expert, argued that the risk of HIV transmission from surgeon to patient was "virtually non-existent statistically."[46] The risk was so "remote," argued Selwyn, that restrictions on plaintiff's privileges and specific pretreatment disclosure of his health status were unwarranted.[47] This position was widely accepted at the time Behringer learned of his HIV status.[48] Dr. Day, the defense expert, disagreed, however, with respect to both the likelihood of HIV transmission and the need for informed consent. Day argued that surgeons and their assistants "incur needle sticks and other cuts in the operating room on a regular basis" and that these occurrences provide opportunities for transmission of the disease.[49] Day accordingly supported the center's policy.

The court sustained the center's policy, concluding that the defense had established "with a reasonable degree of certainty . . . that the employee's handicap presented a materially enhanced risk of substantial harm in the workplace."[50] The court gleaned from the fierce debate over the risk of HIV transmission from health care worker to patient that a "small," though unquantified, risk exists.[51] Giving its extremely risk-averse assessment, the court was not compelled to quantify the risk more precisely[52]: "Where the ultimate harm is death, even the presence of a low risk of transmission justifies the adoption of a policy which precludes invasive procedures when there is 'any' risk of transmission."[53] The court considered the *fear* of transmission, in addition to the actual risk of transmission, to be relevant to its assessment. For example, the patient would have to be informed in the event of an accident that resulted in possible patient exposure to the health care worker's blood.[54] Such a patient would then be subjected to a year of periodic HIV testing and endure tremendous anxiety regardless of whether an infection actually occurred.[55]

44. *Id.*
45. *Id.* at 1259.
46. *Id.* at 1277.
47. *Id.* at 1264.
48. *Id.*
49. *Id.* at 1265.
50. *Id.* at 1276.
51. *Id.* at 1280.
52. The court did not consider dispositive the absence of any recorded cases of such transmission. *Id.* at 1267. CDC investigations have revealed that "a cluster of HIV infections among patients in the practice of one dentist with Acquired Immunodeficiency Syndrome strongly suggests that HIV infection was transmitted to five of the approximately 850 patients evaluated through June 1991." 40 MORBIDITY & MORTALITY WEEKLY Rep. 3 (1991).
53. 592 A.2d at 1283.
54. *Id.* at 1265.
55. *Id.* at 1266.

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The court acknowledged that use of an informed consent form might appear unnecessary in light of the strict prohibition on procedures that pose "any risk" of transmission of the HIV virus from health care worker to patient.[56] In its view, however, the "ultimate arbiter should be a fully informed patient."[57] The court recognized that an informed consent form could effect a de facto prohibition on all invasive procedures by HIV-seropositive health care workers.[58]

The Princeton medical center learned of Behringer's HIV serostatus through chance. If, as the court concluded in *Estate of Behringer*, a health care worker's HIV serostatus is a material consideration for patients, to what extent may hospitals implement mandatory testing procedures? *Leckelt v. Board of Commissioners*[59] involved a licensed practical nurse who was dismissed for refusing to submit HIV test results to the Terrebone General Medical Center (TGMC). Leckelt was homosexual and was the roommate of a patient who eventually died of AIDS-related complications.[60] Upon considering these risk factors, TGMC, which had a preexisting policy requiring employees to report any communicable and infectious diseases, concluded that it needed to know Leckelt's HIV serostatus in order to ensure compliance with CDC guidelines.[61] The Fifth Circuit rejected Leckelt's civil rights challenge to TGMC's requirement that he be tested, however, holding that "a hospital has a right to require such testing [of an employee whom it learns has a high medical risk of such infectious diseases as HIV] in order to fulfill its obligation to its employees and to the public concerning infection control and health and safety in general."[62]

Leckelt's primary claim involved Section 504 of the Rehabilitation Act of 1973. The court found that he had failed to prove any of the elements of a claim under that statute: "(1) that he was regarded as being handicapped; (2) that he was discriminated against solely because of this perceived handicap; and (3) that he is otherwise qualified as a licensed practical nurse."[63] With respect to the first element, the court recognized that Leckelt had to establish only that he was "*regarded* as having . . . an impairment,"[64] but concluded that it was not clear whether AIDS constituted such an impairment or even whether the hospital officials regarded Leckelt as impaired.[65] As to the second element, the court determined that the hospital had fired Leckelt because of his refusal to comply with hospital infection control policies,

56. *Id.* at 1277.
57. *Id.* at 1283.
58. *Id.* at 1280.
59. 909 F.2d 820 (5th Cir. 1990).
60. *Id.* at 823.
61. *Id.* at 826.
62. *Id.* at 824 (quoting Leckelt v. Board of Comm'rs, 714 F. Supp. 1377, 1379 (E.D. La. 1989)).
63. *Id.* at 825.
64. *Id.* (emphasis added).
65. *Id.* In Chalk v. United States Dist. Ct., 840 F.2d 701 (9th Cir. 1988), the Ninth Circuit noted that the lower court had found an HIV-seropositive individual to be "handicapped" within the meaning of Section 504, but did not consider the question, as it was not challenged on appeal. *Id.* at 705 n.6.

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not because of his alleged HIV seropositivity.[66] Lastly, the court found that Leckelt's refusal to submit HIV test results made it impossible to evaluate whether he was "otherwise qualified" for his nursing position.[67]

Leckelt also claimed that TGMC had violated his Fourteenth Amendment guarantee of equal protection. The court held, however, that governmental classifications based on disability are not "quasi-suspect" and, therefore, do not warrant heightened judicial scrutiny.[68] Moreover, TGMC had "a substantial and compelling interest in its infection control policies which applied to any infectious or communicable disease."[69] The court found equally unpersuasive Leckelt's contention that the defendants violated his right to privacy under the Fourth and Fourteenth Amendments, which "prohibit *unreasonable* searches and seizures."[70] The court held that TGMC's interest in infection control "outweighed the limited intrusion on any privacy interest of Leckelt in the results of his HIV antibody test."[71]

Employment practices have proven vulnerable to civil rights abuse based on actual or alleged HIV seropositivity. The Americans with Disabilities Act, which becomes effective in July 1992, will be read to include actual or alleged HIV seropositivity as a handicap.[72] This act censures "hysterical" reactions to HIV-infected coworkers. Unless additional vectors of infection are discovered, health care providers will remain the most heavily regulated segment of the work force with respect to participation of HIV-infected individuals.[73]

C. *Insurance*

The broad provisions of the Americans with Disabilities Act do not apply to insurance or to the actuarially based underwriting of benefits. Nonetheless, Congress has cautioned insurers that they will not be allowed to engage in practices that "evade the purposes" of the act.[74] To what extent, then, may insurers select insureds and

66. *Id.* at 826. Leckelt lost his challenge under the Louisiana Civil Rights for Handicapped Persons Act on the same ground. *Id.* at 831.

67. *Id.* at 827.

68. *Id.* at 831.

69. *Id.* at 832.

70. *Id.*

71. *Id.* at 833.

72. 42 U.S.C.A. § 12112 (West Pamph. 1991); *see also* H.R. REP. NO. 485(II), 101st Cong., 2nd Sess. 51 (1990), *reprinted in* 1990 U.S.C.C.A.N. 303, 333.

73. On the issue of informed consent, Senators Jesse Helms and Strom Thurmond have offered an amendment to a bill in Congress that would impose a maximum $10,000 fine and minimum ten-year prison term, or both, on health care workers who are HIV-seropositive and do not inform their patients. *See* 137 CONG. REC. S9778 (daily ed. July 11, 1991). With respect to prohibitions against performing certain procedures, the CDC now recommends that HIV-seropositive health care workers refrain from "exposure-prone" activities unless they have received counsel from "an expert review panel and [have] been advised under what circumstances, if any, they may continue to perform these procedures." 40 MORBIDITY & MORTALITY WEEKLY Rep. 5 (1991). "Exposure-prone" activities include "digital palpation of the needle tip in a body cavity or the simultaneous presence of the health care worker's fingers and a needle or other sharp instrument or object in a poorly visualized or highly confined anatomic site." *Id.*

74. 42 U.S.C.A. § 12201(c) (West Pamph. 1991); *see also* H.R. REP. NO. 101-485(III), 101st Cong., 2nd Sess. 70-71 (1990), *reprinted in* 1990 U.S.C.C.A.N. 445, 493-94.

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shape benefit plans based on HIV-related considerations? Generally, insurers have continued to make many of the assessments inherent in their business, including those with important ramifications for HIV-seropositive individuals, based on established insurance principles. These include the selection of candidates for health insurance, the voiding of life insurance policies for material misrepresentations, the application of intentional act exclusions, and the determination of worker's compensation benefits.

One of the most important and controversial methods through which the health insurance industry has adjusted to the AIDS crisis is the evaluation of a potential insured's HIV status when determining insurability. In *Health Insurance Association of America v. Corcoran,*[75] for example, the New York superintendent of insurance prohibited insurers selling individual and small group health insurance from considering the HIV serostatus of potential applicants[76] based upon the commissioner of health's determination that such tests were "contrary to the health care needs of the public."[77] Insurers challenged the regulation, which essentially "mandat[ed] coverage for HIV seropositive persons in the general risk pool of applicants for individual and small group health policies."[78] In sustaining the insurers' challenge the court described HIV testing as "nondiscriminatory" and as a "sound underwriting practice" given the link between HIV seropositivity and AIDS.[79] However, the court did not provide a blanket endorsement of HIV testing of health insurance applicants. The court specifically noted that HIV testing of applicants in connection with large group insurance policies is of less-certain validity, as insurers issuing such policies are assessing risks characteristic of a group rather than a particular individual.[80]

Insurers also are particularly concerned with HIV serostatus when issuing life insurance policies. As with any other serious health condition, misrepresentations concerning HIV status generally will render a life insurance policy void. In *William Penn Life Insurance Co. v. Sands,*[81] for example, two men took out life insurance policies naming each other as primary beneficiary. Each denied having either cancer or a blood disorder during the application process. Eight months later one of the men died as a result of AIDS and the other tested HIV-positive. Penn sought to rescind both policies.[82] At trial, a doctor testified that both men were HIV-positive and had inflammatory Kaposi's Sarcoma, a type of cancer, when they applied for the policies. The court noted that misrepresentation will void a life policy "if the insurer in good faith would either not have issued the policy or . . . would not have issued it [or the same terms] if the facts had been known to the insurer as required by the application for the policy or otherwise."[83] Moreover, the court held it unnecessary for the appli-

75. 551 N.Y.S.2d 615 (App. Div.) *aff'd*, 565 N.E.2d 1264 (N.Y. 1990); *see also* Life Ins. Ass'n v. Commissioner of Ins., 530 N.E.2d 168 (Mass. 1988).
76. 551 N.Y.S.2d at 616.
77. *Id.*
78. *Id.* at 618.
79. *Id.* at 619.
80. *Id.*
81. 912 F.2d 1359 (11th Cir. 1990).
82. *Id.* at 1361.
83. *Id.*

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cant to know a statement is inaccurate for policy rescission based on material misrepresentation. In the application at issue, however, the applicants represented that the information given was correct "to the best of my [their] knowledge and belief."[84] In light of this emphasis on the applicants' awareness of their illness rather than the objective facts, the court required Penn to prove that the men had knowingly misrepresented their health in order to deny coverage.[85]

Other insurers focus upon the circumstances under which the HIV virus was transmitted. Determination of coverage for the transmission of the HIV virus during consensual sexual activity likely will parallel that of other sexually transmitted diseases.[86] In *Allstate Insurance Company v. Holt*,[87] Holt infected another person with herpes by engaging in sexual activity at a time when he knew that he had active lesions on his mouth. Holt's homeowner's policy contained an "intentional acts" exclusion, which precluded coverage for damages that "may reasonably be expected to result from the intentional or criminal acts of an insured person."[88] The court found that Holt's sexual activity with active lesions could reasonably have been expected, under an "objective standard of expectation," to result in transmission of the disease.[89] Unpersuaded that Holt's conduct was unintentional because it was the result of "seemingly uncontrollable" lust, the court sustained Allstate's denial of coverage.[90]

Workers' compensation claims by health care workers allegedly infected with the HIV virus in the course of their employment will arise under both accident and occupational disease theories.[91] In *Jackson Township Volunteer Fire Co. v. Workmen's Compensation Appeal Board*,[92] a volunteer fire company was required to pay for the blood tests and shots required for a volunteer who was exposed to the HIV and HBV viruses while responding to an auto accident.[93] Presumably, workers' compensation benefits will cover subsequent bills if the volunteer becomes seropositive and other vectors of infection are excluded.

Application of the "occupational disease" theory to HIV infection is marked by considerable debate. In *Wuesthoff Memorial Hospital v. Hurlbert*,[94] a phlebotomist contracted hepatitis B several months after a dog bite punctured his thumbnail and the skin under it. He could not identify a specific incident exposing his wound to HIV-infected blood.[95] However, because no other potential vectors of infection could

84. *Id.* at 1362.
85. *Id.* at 1365.
86. Dalton, *supra* note 2, at 258.
87. No. 90-1473 (E.D. Mich., Apr. 25, 1991).
88. *Id.*, slip op. at 3.
89. *Id.* at 4.
90. *Id.* at 5. The court noted that Holt, who was married at the time he infected the third person with herpes, had committed the felony of adultery under state law, indicating a potential absence of coverage under the policy's criminal acts exclusion. *Id.* at 3.
91. *See generally* Brennan, *Ensuring Adequate Health Care for the Sick: The Challenge of Acquired Immunodeficiency Syndrome as an Occupational Disease*, in AIDS TWO: AIDS IN THE WORKPLACE 224--7 (J. Vculek ed., 1989).
92. 1991 Pa. Commw. LEXIS 371 (June 28, 1991).
93. *Id.* at *1.
94. 548 So. 2d 771 (Fla. Dist. Ct. App. 1989).
95. *Id.* at 774.

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be identified, the health services supervisor concluded that "the lab was the most logical place for him to have contracted the virus."[96] In determining the phlebotomist's entitlement to "occupational disease" compensation the court considered whether the disease had "resulted from the nature of the employment . . . and was actually contracted while so engaged."[97] The court determined that the elements of the "occupational disease" theory had been met and, as a result, considered proof of a specific incident of exposure to be unnecessary.[98] The court accordingly held that the injury was compensable under workers' compensation.[99]

In contrast, in *Sperling v. Industrial Commission,*[100] an operating room nurse who contracted hepatitis B was denied workers' compensation benefits. She claimed that she frequently cut herself with bloody operating instruments, but she could not describe any specific incident.[101] The court deferred to the commission's determination that she had failed to establish the requisite connection between her occupation and her hepatitis B infection.[102] Interestingly, the *Sperling* court cited *Sacred Heart Medical Center v. Department of Labor*[103] in support of its deference to the administrative agency's finding of fact. The agencies in *Sperling* and *Sacred Heart*, however, reached different conclusions in evaluating very similar facts.[104] It thus remains unclear to what extent a claimant must show a causal connection between work conditions and contraction of an "occupational disease." Though proof of direct causation is unnecessary, the amount of evidence required seems to vary from agency to agency.

Basic insurance law principles generally reflect public policy considerations. Insurance practices will be challenged when, due to the unique nature of AIDS, an actual or perceived conflict with public health policies arises. In such situations, legislatures may need to intervene and compromise the autonomy of insurers in the interest of other social policies.[105]

II. MEDICAL-LEGAL PROOF OF CAUSATION

Proof of causation in personal injury cases frequently involves vigorous medical-legal disputes over whether the defendant's product or process caused—or even could cause—the plaintiff's injury. These disputes raise difficult legal issues concerning the necessity of expert evidence, the qualification of experts testifying on the issue of proximate cause, the basis for and sufficiency of their opinions, and the quality of expert evidence necessary for a plaintiff to avoid summary disposition.

96. *Id.* at 772.
97. *Id.* at 773.
98. *Id.* at 774–75.
99. *Id.* at 771.
100. 544 N.E.2d 290 (Ill. 1989).
101. *Id.* at 291.
102. *Id.* at 292.
103. 600 P.2d 1015 (Wash. 1979).
104. 544 N.E.2d at 293.
105. *See* Health Ins. Ass'n of Am. v. Corcoran, 551 N.Y.S.2d at 618; *see also* Dalton, *supra* note 2, at 185.

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A. *Burden of Proof and Necessity of Expert Medical Opinion*

When a plaintiff's claimed injury is one of medical harm or disease, his or her proof on the issue of proximate cause may require expert testimony.[106] Such testimony, which "must be stated in terms of reasonable probability,"[107] receives particular scrutiny in toxic tort cases[108] because the issue of causation typically is largely, or even exclusively, the province of expert opinion in such cases.[109]

To raise a triable issue of proximate cause, the toxic tort plaintiff must present "direct or circumstantial evidence of at least one exposure to defendant's products."[110] In asbestos cases, for example, most courts have required proof "that an injured plaintiff was exposed to a particular defendant's asbestos-containing product."[111] A plaintiff will not make a prima facie showing of injurious exposure merely by showing that a toxin was delivered to or present in a workplace or other environment where he or she was present.[112] Plaintiffs in cumulative-impact toxin injury cases generally also are required to show the level and duration of exposure to the toxin through expert medical or scientific testimony.[113] Some courts have concluded that a toxic tort claimant's own testimony that he or she was exposed to the defendant's toxin will not create a triable issue of the level or duration of exposure absent at least some medical or other expert confirmation of exposure.[114]

Proximate cause ordinarily is an issue for jury determination, although a court may grant summary disposition for the defendant when "plaintiff's evidence does not establish a causal connection, leaving causation to the jury's speculation. . . ."[115] When the plaintiff's injury or disease is of a nature that could have been caused by exposure to toxins or conditions not associated with the defendant's product or conduct, he or she must produce expert evidence "isolating other potential causes."[116]

In several cases in which pretrial deposition testimony by an expert fell short of establishing a question of fact on the issue of proximate cause, courts have rejected attempts by parties to avoid summary judgment by presenting an affidavit in which the same expert states his or her conclusions in stronger terms.[117] Most courts have

106. *E.g.*, Rohrbough v. Wyeth Labs., Inc., 916 F.2d 970 (4th Cir. 1990).

107. *E.g.*, *id.*; Niklaus v. Vivadent, Inc., 1991 WL 127182 (M.D. Pa. 1991); Longmore v. Merrell Dow Pharmaceuticals, Inc., 737 F. Supp. 1117 (D. Idaho 1990).

108. *E.g.*, Maddy v. Vulcan Materials Co., 737 F. Supp. 1528 (D. Kan. 1990); Turpin v. Merrell Dow Pharmaceuticals, Inc., 736 F. Supp. 737 (E.D. Ky. 1990).

109. Viterbo v. Dow Chem. Co., 646 F. Supp. 1420 (E.D. Tex. 1986), *aff'd*, 826 F.2d 420 (5th Cir. 1987).

110. Benshoof v. National Gypsum Co., 761 F. Supp. 677 (D. Ariz. 1991).

111. *Id.*

112. *Id.*; *see also* Hyde v. Owens-Corning Fiberglass Corp., 751 F. Supp. 832 (D. Ariz. 1990).

113. *E.g.*, Rubanick v. Witco Chem. Corp, 543 A.2d 975 (N.J. Super. Ct. Law Div. 1988), *rev'd* 576 A.2d 4 (N.J. Super. Ct. App. Div. 1990).

114. Maddy v. Vulcan Materials Co., 737 F. Supp. 1528 (D. Kan. 1990); *see also* Celotex Corp. v. Catrett, 477 U.S. 317 (1986); Davis v. DuPont, 729 F. Supp. 652 (E.D. Ark. 1989).

115. Benshoof v. National Gypsum Co., 761 F. Supp. 677 (D. Ariz. 1991) (quoting Robertson v. Six Pence Inns of Am., Inc., 789 P.2d 1040 (Ariz. 1990)).

116. *E.g.*, Maddy v. Vulcan Materials Co., 737 F. Supp. 1528 (D. Kan. 1990).

117. Fed. R. Civ. P. 56.

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concluded that the only fact question raised by such tardy initiatives "is to determine which of the two conflicting versions of the . . . . testimony is correct."[118]

B. *Federal Rules of Evidence 702 and 703*

A trial court's assessment of the admissibility of expert testimony requires the application of Federal Rules 702 and 703 or their state-law counterparts. Under Rule 702, a court may reject expert testimony on causation issues if the witness is "unqualified to give expert testimony in the relevant field" or the expert, regardless of qualifications, has relied upon "an unreliable scientific technique."[119] Rule 703 requires that the bases of an expert opinion be of "a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject."[120] The issues raised by challenges to expert testimony under rules 702 and 703 converge when the party opposing admission of an expert's testimony argues both that the "scientific technique" employed is unreliable and that the basis of the opinion is not of a type relied upon by others in that field of expertise. As one court has acknowledged, it may be unclear whether "expert testimony depends on a reliable 'scientific technique,' to be analyzed under Rule 702, or whether the basis for the testimony is 'facts or data . . . of a type reasonably relied upon by experts in the particular field,' to be analyzed under Rule 703."[121]

Rule 702's requirement that expert testimony be "helpful" to the factfinder "turns on whether the expert's 'technique or principle [is] sufficiently reliable so that it will aid the jury in reaching accurate results.' "[122] The court in *In re Paoli Railroad Yard PCB Litigation*,[123] while agreeing that "helpfulness" imports "a quantum of reliability beyond that required to meet a standard of bare logical relevance,"[124] reversed the trial court's Rule 702 "reliability" rejection of the plaintiff's expert "meta-analysis."[125] Unfortunately, the *Paoli* court expressly declined "to define the exact level at which a district court can exclude a technique as insufficiently reliable."

C. *Sufficiency of Expert Testimony*

Even multiple expert opinions supporting a plaintiff's theory of causation will be found inadequate as a matter of law if the experts fail to conclude that there exists a resonable probability that the toxin caused the injury. *Rohrbough v. Wyeth Labo-*

118. Barwick v. Celotex Corp., 736 F.2d 946 (4th Cir. 1984); *accord* Rohrbough v. Wyeth Labs., Inc., 916 F.2d 970 (4th Cir. 1990).

119. *In re* Paoli R.R. Yard PCB Litig., 916 F.2d 829 (3d Cir. 1990). For purposes of Rule 702, a technique is considered "novel"—as opposed to "unreliable"—when its reliability is not so well established as to warrant recognition by judicial notice. *Id.*

120. Fed. R. Evid. 703.

121. *In re* Paoli R.R. Yard PCB Litig.. 916 F.2d 829 (3d Cir. 1990). The *Paoli* court acknowledged that the distinctions between the inquiries required under each rule are "oftimes subtle if not strained." *Id.*

122. DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941 (3d Cir. 1990) (quoting 3 J. WEINSTEIN & M. BERGER, WEINSTEIN'S EVIDENCE ¶ 702[03], at 702–35 (1988).

123. 916 F.2d 829 (3d Cir. 1990).

124. *Id.* at 857.

125. *Id.* at 858.

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ratories, Inc.,[126] a DPT case, illustrates this point. One expert for the plaintiffs in *Rohrbough* testified that he would not rule out the causal contribution of the vaccine; a second stated that the child's seizures could have resulted from the vaccination *or* from an ear infection and fever; and a third established a *temporal* link between administration of the vaccination and reactions, similar to that of the plaintiff's child, in other children. Affirming a summary judgment for the vaccine's manufacturer, the Fourth Circuit concluded that the plaintiffs "ha[d] not met their burden of coming forward with enough evidence that a jury could find that defendant's vaccine probably caused plaintiff's injuries."[127]

D. *Epidemiological Evidence of Causation*

Plaintiffs lacking direct evidence of causation frequently rely upon epidemiological proof. Epidemiology, a hybrid of science and medicine, "uses studies to 'observe the effect of exposure to a single factor upon the incidence of disease in two otherwise identical populations.' "[128] Epidemiological evidence tending to support—or refute—plaintiff's claim of proximate cause has been held admissible in suits claiming injury from products ranging from asbestos to intrauterine devices.[129]

Many courts have permitted nonmedical experts to testify regarding epidemiological evidence of causation.[130] Some authority suggests, however, that a plaintiff who resorts exclusively to epidemiological proof may fail if his or her expert is qualified to address "the incidence of disease over large population groups" but not whether the defendant's product "was the causative agent" in the harm suffered by a particular individual.[131]

In situations in which a majority of epidemiological studies tend to disprove the plaintiff's claim that a particular product more probably than not caused a medical injury, some courts have held that an expert's opinion to the contrary is excludable as having inadequate foundation.[132] Significantly, however, in some cases involving the teratogenicity of a pharmaceutical, expert opinion that the defendant's product more probably than not caused the injury has been held admissible even though most judicial decisions on similar facts and the majority of the expert community have concluded otherwise. For example, in *DeLuca v. Merrell-Dow Pharmaceuticals, Inc.*,[133] the Third Circuit reversed a trial court's refusal to allow the plaintiff's expert to testify that the morning sickness drug Bendectin was the proximate cause of her child's birth defects, even though the expert's opinion and his interpretation of the

126. 916 F.2d 970 (4th Cir. 1990).

127. *Id.* at 976.

128. DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941 (3d Cir. 1990) (quoting Black & Lilienfeld, *Epidemiological Proof in Toxic Tort Litigation*, 52 FORDHAM L. REV. 732 (1984)). *See generally* Callahan, *Establishment of Causation in Tort Litigation*, 23 ARIZ. ST. L.J. 604 (1991).

129. Marder v. G.D. Searle & Co., 630 F. Supp. 1087 (D. Md. 1986) (intrauterine device); In re Agent Orange Litig., 597 F. Supp. 740 (E.D.N.Y. 1984) (Agent Orange), *aff'd*, 818 F.2d 145 (2d Cir. 1987); Landrigen v. Celotex Corp., 579 A.2d 1268 (N.J. Super. Ct. App. Div. 1990) (asbestos).

130. *In re* Paoli R.R. Yard PCB Litig., 916 F.2d 829 (3d Cir. 1990).

131. *Id.*

132. *E.g.*, Ealy v. Richardson-Merrell, Inc., 897 F.2d 1159 (D.C. Cir. 1990).

133. 911 F.2d 941 (3d Cir. 1990).

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epidemiological basis for it were controverted by the weight of scientific opinion and rejected by most courts considering similar claims.[134]

There is agreement that tort claimants need not establish the scientific standard of proximate cause—the existence of a 95 percent level of confidence "that the observed relationship is not related to random chance"[135] or, stated otherwise, a "statistically significant" relationship between the alleged cause and result.[136] In general, courts have held that a plaintiff need not present epidemiological evidence conveying a statistically significant confidence level that the defendant's product caused the injury.[137] A growing body of authority suggests instead that a plaintiff makes a prima facie showing that exposure to a defendant's product or process more probably than not caused the injury in question by introducing epidemiological evidence that a person so exposed is twice as likely to be afflicted with the disease or medical injury than a person not so exposed.[138]

Even if the defendant's product or process is conceded to produce elevated risk factors in exposed populations, a plaintiff relying on epidemiological evidence may have difficulty proving that the defendant more likely than not caused his or her own injury. This dilemma is aptly described in Judge Weinstein's observation in *In re "Agent Orange" Product Liability Litigation*[139] that "even if plaintiffs as a class could prove that they were injured by Agent Orange," for any individual claimant "[t]he probability of specific cause would necessarily be less than 50%."[140]

Most courts still hold that plaintiffs who are unable to demonstrate a risk elevation equal to or exceeding 2.0 fail to establish proximate cause absent specific proof of individual causation. Some courts, however, have held that the absence of a demonstrated risk factor of 2.0 or more does not preclude plaintiff's expert testimony on the issue of proximate cause, even if the expert relies substantially on epidemiological studies, at least when the studies themselves are offered only as a basis for the expert's opinion and not as direct evidence of causation.[141]

E. In Vitro, In Vivo, *and Other Studies*

While epidemiological studies have gained measured acceptance in court as bases for expert opinions, the court in *In re Bendectin Products Liability Litigation*[142] cautioned that "division in the scientific community over whether epidemiological studies should be relied upon exclusively necessitates the inescapable conclusion that experts may reasonably rely upon other types of data when forming an opinion as to . . . teratogenicity."[143]

134. *Id.* at 953.
135. Longmore v. Merrell Dow Pharmaceuticals, Inc., 737 F. Supp. 1117 (D. Idaho 1990).
136. *See* DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941 (3d Cir. 1990).
137. Longmore v. Merrell Dow Pharmaceuticals, Inc., 737 F. Supp. 1117 (D. Idaho 1990).
138. *E.g., In re* Joint E. & S. Dist. Asbestos Litig., 758 F. Supp. 199 (S.D.N.Y. 1991); *see also* Cook v. United States, 545 F. Supp. 306 (N.D. Cal. 1982).
139. 597 F. Supp. 740 (E.D.N.Y. 1984).
140. *Id.* at 833–34.
141. Grassis v. Johns-Manville Corp., 591 A.2d 671 (N.J. Super. Ct. App. Div. 1991).
142. 732 F. Supp. 744 (E.D. Mich. 1990).
143. *Id.* at 749.

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Courts remain divided as to the foundational value of nonepidemiological studies, such as *in vivo, in vitro*, or structure activity analysis. The court in one Bendectin case found that plaintiff's proposal to prove the teratogencity of Bendectin "through the presentation of . . . studies using *in vitro* testing, structure activity analysis, sales chart analysis, and animal studies" sufficient to defeat the defendant's motion for summary judgment.[144] In other cases, however, courts have found extrapolations from *in vivo* and *in vitro* animal studies to be inadequate as an expert's basis for an opinion on causation.[145]

F. *Significance of Publication and Peer Review*

When an expert's testimony is based on his or her own writing or other analysis, trial courts continue to ascribe weight to the presence or absence of prior publication of the findings.[146] Expert affidavits will be disregarded if unsupported by internal reference to or extrinsic support in any "medical literature, scientific publications, or personal experience" of the affiant.[147] An expert's inability to identify medical literature supporting his or her conclusion as to casuation not only may reflect an inadequate basis for the opinion under Rule 703, but also may indicate that the expert is not qualified to render it.[148]

144. *Id.* at 748.

145. Richardson v. Richardson-Merrell, Inc., 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S. Ct. 218 (1989); Lynch v. Merrell-Nat'l Labs., 830 F.2d 1190 (1st Cir. 1987).

146. *E.g.*, Richardson v. Merrell Dow Pharmaceuticals, Inc., 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S. Ct. 218 (1989).

147. Maddy v. Vulcan Materials Co., 737 F. Supp. 1528 (D. Kan. 1990).

148. *E.g.*, *id.*

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