

Washington Law Review

Volume 66 | Number 3

7-1-1991

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Recommended Citation

Jennifer Belk, Comment, *Undefined Experimental Treatment Exclusions in Health Insurance Contracts: A Proposal for Judicial Response*, 66 Wash. L. Rev. 808 (1991).

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UNDEFINED EXPERIMENTAL TREATMENT EXCLUSIONS IN HEALTH INSURANCE CONTRACTS: A PROPOSAL FOR JUDICIAL RESPONSE

Abstract: Health insurance contracts often exclude coverage for experimental treatments. No accepted definition of experimental treatment exists, however, and insurance contracts rarely define the term. Although experimental treatment exclusions are necessary and desirable, insurers may easily manipulate undefined exclusions to exclude treatments on inappropriate bases such as cost. Thus, courts should construe the term "experimental" narrowly and find treatments non-experimental if there is any demonstrated likelihood of their success.

When standard chemotherapy failed to destroy thirty-five year old Pamela Pirozzi's breast cancer, her doctor recommended a recently developed treatment.¹ Her insurer refused to pay for the treatment, claiming it was experimental and thus excluded under her insurance contract.² Pirozzi sued the insurance company. Because her health plan did not define "experimental,"³ the court had to interpret what the term meant. Pirozzi, who was not expected to survive even a year without the treatment, had to wait three weeks⁴ for the completion of an expedited trial to gain coverage and begin treatment.⁵ Dilemmas such as Pirozzi's are inevitable when insurers exclude experimental treatment but do not define the term.

Most health insurance contracts⁶ exclude experimental treatment.⁷ Health insurers do this to avoid paying for unproven, fraudulent, or worthless treatments and to maintain their ability to offer an affordable product.⁸ Experimental treatment exclusions are useful in achieving these objectives because physicians sometimes recommend new

1. Pirozzi v. Blue Cross-Blue Shield, 741 F. Supp. 586, 588 (E.D. Va. 1990). The recommended treatment was high-dose chemotherapy with autologous bone marrow transplant (HDCT-ABMT).

2. *Id.*

3. *Id.*

4. Washington Post, Apr. 17, 1990, at B1, col. 1, B7, col. 2.

5. 741 F. Supp. at 587.

6. Insurance is a contract where one party, for consideration, promises payment upon the happening of an uncertain event. 1 G. COUCH, CYCLOPEDIA OF INSURANCE LAW § 1.2 (2d ed. 1984). Some health service contracts technically are not insurance contracts because they do not indemnify for medical expenses incurred by the subscriber, but arrange for provision of medical services on a pre-paid basis. For purposes of this Comment, the term "insurance" includes both indemnification contracts as well as arrangements where medical costs are covered on a pre-paid basis.

7. Washington Post, *supra* note 4, at B1, col. 1.

8. See Cline & Rosten, *The Effect of Policy Language in the Containment of Health Care Cost*, 21 TORT INS. L.J. 120, 121, 131-34 (1985).

treatments before they become standard practice.⁹ Physicians may have a particularly strong incentive to prescribe new treatments when patients are terminally ill or in similarly desperate situations.¹⁰ Thus, insureds' expectations that new treatments will be covered competes with insurers' desire to avoid liability for unproven treatments.¹¹

When insurers do not define experimental treatment, they can apply experimental treatment exclusions to inappropriately deny coverage. Litigation may be insureds' only way to obtain coverage. Those without energy, resources, or time to sue may be unfairly denied coverage and vital health care. Occasionally, insureds may gain coverage through either out-of-court settlements or insurer waivers. These tactics, however, allow insurers to avoid changing their standard contract exclusions. Courts reviewing coverage denials under experimental treatment exclusions have an important role in regulating such exclusions.

Courts should require insurers to enunciate in insurance contracts the processes and criteria used to assess and characterize experimental treatments. This will require that insurers consider only those factors disclosed in the contract. It also will facilitate judicial review of insurer decisions. In the absence of such criteria, courts should construe experimental treatment exclusions narrowly and in favor of coverage. Courts should consider any demonstrated likelihood of a treatment's success as strong evidence that it is no longer experimental. A "demonstrated likelihood of success" standard would permit courts to consider evidence such as unpublished study results, physician experience, and expert testimony. This standard is the most appropriate approach to undefined experimental treatment exclusions because it construes health insurance contracts in favor of insureds while addressing the need for some proof of treatment efficacy. Courts should review technology assessment criteria insurers include in experimental treatment exclusions for clarity as well.

I. EXPERIMENTAL TREATMENT EXCLUSIONS AND COURTS

The role and characteristics of health insurance generally, the purposes of the experimental treatment exclusion, and the ways insurers typically administer the exclusion provide the backdrop for a discus-

9. See Banta, Burns & Behney, *Policy Implications of the Diffusion and Control of Medical Technology*, 468 ANNALS 165, 170 (1983).

10. *Id.*

11. Cline & Rosten, *supra* note 8, at 123.

sion of experimental treatment exclusions. In addition, courts consider certain insurance and contract doctrines and public policies in their role of regulating health insurance contracts. They take a variety of approaches in reviewing insurer coverage denials under experimental treatment exclusions.

A. *Health Insurance and Experimental Treatment Exclusions*

Health insurance spreads costs and restricts utilization to those treatments that are safe and effective. Yet, health insurance is vulnerable to manipulation by insurers, insureds and health care providers. For instance, health insurers may control the types of treatments used by limiting coverage to proven treatments through experimental treatment exclusions. Most insurance contracts do not, however, define the term "experimental." Instead, insurers may make technology assessments to determine whether treatments are covered.¹² A technology assessment may consider a variety of factors, including cost.

1. *Health Insurance*

Health insurance serves two public functions. First, it spreads the costs of health care.¹³ Second, health insurance allocates financial resources among different kinds of treatments. For instance, it restricts worthless and untested treatments,¹⁴ the use of which violates public policy.¹⁵ Insurers serve as "gatekeepers," encouraging the use of safe and effective treatments by paying for them and deterring unsafe and ineffective treatments through non-coverage.¹⁶

Despite its benefits, health insurance is vulnerable to manipulation by insureds, insurers, and health care providers.¹⁷ Insureds may overuse coverage, consuming more health care resources than are necessary.¹⁸ For example, insureds may expect or demand access to

12. "Technology assessment" broadly describes a variety of ways to assess the evidence of a new technology's safety and effectiveness. See *infra* notes 43-47 and accompanying text.

13. Riesenfeld, *Health Insurance*, in *ENCYCLOPEDIA OF BIOETHICS* 637, 641 (W. Reich ed. 1978).

14. Monaco & Burke, *Insurer as Gatekeeper: Handling Claims for Unproven Methods of Medical Management*, 18 *FORUM* 591, 591-96 (1983).

15. Cline & Rosten, *supra* note 8, at 131. For example, drugs not meeting Food and Drug Administration (FDA) requirements generally are not permitted to be sold, even to terminally ill patients believed to have no other possibilities for cure. *United States v. Rutherford*, 442 U.S. 544 (1979).

16. Monaco & Burke, *Insurer as Gatekeeper— Part Two: Policy Obstacles in Unproven Methods Litigation*, 20 *FORUM* 400, 404 (1985).

17. Riesenfeld, *supra* note 13, at 641.

18. *Id.*

highly publicized, new or expensive technologies.¹⁹ On the other hand, insurers may manipulate contracts by leaving gaps in coverage that are not properly understood by insureds.²⁰ The insurer may also create contracts that are unclear as to which procedures are covered and under what circumstances.²¹ Insureds therefore may have to ask courts to determine their contract rights. Insurers also may manipulate contracts by considering inappropriate factors when assessing whether coverage is available under the contract.²² Finally, the likelihood of insurance reimbursement may encourage health care providers to use unnecessary, useless, fraudulent, or overpriced treatments.²³

2. *Experimental Treatment Exclusions*

Most insurers exclude coverage for experimental treatments in their health insurance contracts,²⁴ primarily to limit their financial liability.²⁵ To cover expensive new treatments, insurers may have to charge higher premiums or reduce other benefits.²⁶ They use experimental treatment exclusions to exclude treatments that are so new they cannot be excluded by name.²⁷ Strong physician and patient demand for new treatments necessitates such exclusions.²⁸ Treatments insurers have considered experimental include in vitro fertilization,²⁹ liver

19. Schaffarzick, *Technology Assessment and Health Benefits Determination*, 11 QUALITY REV. BULL. 222, 222 (1985).

20. See Riesenfeld, *supra* note 13, at 641.

21. See Grumet, *Health Care Rationing Through Inconvenience*, 321 NEW ENG. J. MED. 607 (1989).

22. *Reilly v. Blue Cross & Blue Shield*, 846 F.2d. 416 (7th Cir.) (coverage denial predicated on a treatment's success rate of less than 50% may be an unreasonable application of an experimental treatment exclusion), *cert. denied*, 488 U.S. 856 (1988).

23. Riesenfeld, *supra* note 13, at 641; see Daniels, *Why Saying No to Patients in the United States Is So Hard*, 314 NEW ENG. J. MED. 1380, 1382 (1986).

24. Washington Post, *supra* note 4, at B1, col. 1. This Comment uses the phrase "experimental treatment exclusion" to refer to all categorical exclusions of "experimental" treatments, "investigative" treatments, and other similarly worded exclusions because neither courts nor insurers typically differentiate among such terms. *But see Dozsa v. Crum & Forster Ins. Co.*, 716 F. Supp. 131 (D. N.J. 1989) (the insurer abused its discretion in evaluating a treatment with criteria used to assess whether a treatment was investigational when the contract excluded experimental treatment).

25. See Cline & Rosten, *supra* note 8, at 121, 131-34.

26. Schaffarzick, *supra* note 19, at 224.

27. See Cline & Rosten, *supra* note 8, at 131-34 (concluding, however, that exclusions are likely to be ineffective, especially when terminally ill patients are involved).

28. See Schaffarzick, *supra* note 19, at 222.

29. See, e.g., *Reilly v. Blue Cross & Blue Shield*, 846 F.2d 416 (7th Cir.), *cert. denied*, 488 U.S. 856 (1988).

Experimental Treatment Exclusions

transplants,³⁰ sex change operations,³¹ gastric stapling,³² AIDS treatment,³³ and various cancer therapies.³⁴ Many of these treatments are expensive.³⁵

Insurers generally want to limit their liability solely to proven treatments.³⁶ Physicians who are desperate to help their patients, however, may seek to use treatments that look promising before they are proven effective.³⁷ They may feel ethically bound to offer whatever treatment may benefit patients, regardless of cost,³⁸ and in some instances, regardless of the level of clinical studies completed.³⁹

Despite the frequent use of experimental treatment exclusions, no commonly accepted definition of “experimental treatment” exists.⁴⁰ Some scholarly definitions of experimental treatment focus on whether the treatment is intended solely to gather data or whether it is intended to benefit a particular patient.⁴¹ Yet, insurers often do not

30. See, e.g., *Johnson v. District 2 Marine Eng'rs Beneficial Ass'n*, 857 F.2d 514 (9th Cir. 1988), cert. denied, 111 S. Ct. 581 (1990).

31. See, e.g., *Rush v. Parham*, 625 F.2d 1150 (5th Cir. 1980).

32. See, e.g., *Exbom v. Central States Health & Welfare Fund*, 900 F.2d 1138 (7th Cir. 1990).

33. *Bradley v. Empire Blue Cross & Blue Shield*, 149 Misc. 2d 20, 562 N.Y.S. 2d 908 (Sup. Ct. 1990) (HDCT-ABMT followed by intravenous AZT).

34. See, e.g., *Jones v. Laborers Health & Welfare Trust Fund*, 906 F.2d 480 (9th Cir. 1990) (hyperthermia treatment); *Pirozzi v. Blue Cross-Blue Shield*, 741 F. Supp. 586 (E.D. Va. 1990) (HDCT-ABMT); *Zuckerberg v. Blue Cross & Blue Shield*, 119 Misc. 2d 834, 464 N.Y.S.2d 678 (Sup. Ct. 1983) (Gerson's therapy), rev'd on other grounds, 108 A.D.2d 56, 487 N.Y.S.2d. 595 (1985), aff'd, 67 N.Y.2d 688, 490 N.E.2d 839, 499 N.Y.S.2d 920 (1986).

35. See, e.g., *Reilly v. Blue Cross & Blue Shield*, 846 F.2d 416, 421 (7th Cir.) (insurer concerned about high cost of in vitro fertilization), cert. denied, 488 U.S. 856 (1988); *Rollo v. Blue Cross/Blue Shield*, No. 90-597 (D. N.J. Mar. 22, 1990) (LEXIS, Genfed library, Dist file) (HDCT-ABMT to cost \$130,000 to \$140,000); *Pirozzi*, 741 F. Supp. at 588 (HDCT-ABMT to cost \$100,000); *Dozsa v. Crum & Forster Ins. Co.*, 716 F. Supp. 131, 132 (D. N.J. 1989) (HDCT-ABMT to cost \$75,000 to \$125,000).

36. See *Cline & Rosten*, supra note 8, at 131-34.

37. *Cowan, Innovative Therapy Versus Experimentation*, 21 TORT & INS. L.J. 619, 629-32 (1986).

38. *Relman, The Trouble with Rationing*, 323 NEW ENG. J. MED. 911, 912 (1990).

39. *Banta, Burns & Behney*, supra note 9, at 170. Medical ethics limit physicians to providing treatments likely to benefit their patients. Physicians who provide injurious non-standard treatments may be subject to tort liability and negative peer review. *Cowan*, supra note 37, at 629-32.

40. *Cowan*, supra note 37, at 626.

41. Experimental procedures have been described as those “that are untested or unproved . . . or are . . . not related to the [patient's therapy] but rather performed solely for the purpose of obtaining scientific data.” *Id.* at 622. Experimentation has been defined as “an activity designed to test a hypothesis, permit conclusions to be drawn and thereby to develop or contribute to generalizable knowledge . . .” *Id.* Another definition is “any [study] . . . done with the intent of developing new knowledge and which differs in any way from customary medical . . . practice.” *Id.*

define "experimental treatment" in insurance contracts.⁴² When applying the term, some rely on a "technology assessment" to determine whether treatments are experimental. Technology assessment broadly describes a variety of ways of assessing the evidence of a new technology's safety and effectiveness.⁴³ Some insurers consider factors such as published studies, opinions of experts in the treatment area,⁴⁴ and the procedure's cost.⁴⁵ Some insurers use evaluative criteria. For example, the Blue Cross/Blue Shield Association uses five criteria to assess technology.⁴⁶ Procedures that fail to meet all five criteria are considered experimental.⁴⁷

B. Insurance Regulation: Judicial Role and Judicial Doctrine

Courts play an important role in regulating insurance contract terms.⁴⁸ Although most states regulate insurance contracts by statute,⁴⁹ statutory regulation is ineffective in many instances.⁵⁰ Thus, the courts' role in reviewing insurer behavior can counterbalance insurers' broad discretion in administering insurance contracts. Without the possibility of such review, some contract provisions would be unconscionable because of insurers' greater bargaining power.⁵¹

42. See Newcomer, *Defining Experimental Therapy—A Third Party Payer's Dilemma*, 323 NEW ENG. J. MED. 1702 (1990).

43. See Schaffarzick, *supra* note 19, at 222–24.

44. *Id.* at 223.

45. *Id.* at 224 (Blue Shield of California considered cost effectiveness in its technology assessment).

46. See *Pirozzi v. Blue Cross-Blue Shield*, 741 F. Supp. 586, 590 (E.D. Va. 1990). The five technology evaluation criteria are: (1) whether the FDA approved the drug or device for the particular indication or application in question; (2) whether the peer-reviewed medical and scientific literature contains sufficient information to enable the insurer to make conclusions about the safety and efficacy of the drug, device, or procedure; (3) whether the available scientific evidence demonstrates a net beneficial effect on health outcomes; (4) whether the drug, device, or procedure is as safe and efficacious as existing alternatives; and (5) whether the drug, device, or procedure reasonably can be expected to satisfy criteria 3 or 4 when applied outside the research setting. *Id.* at 590–91.

47. *Id.* at 591. Blue Cross also uses the word "investigative." *Id.* at 588.

48. R. KEETON, INSURANCE LAW BASIC TEXT § 6.3(a) (1971).

49. K. ABRAHAM, DISTRIBUTING RISK 126 (1986).

50. See *id.*

51. See *Zuckerberg v. Blue Cross & Blue Shield*, 119 Misc. 2d 834, 464 N.Y.S.2d 678, 681 (Sup. Ct. 1983) (a contract provision that allowed the insurer to judge whether a treatment was necessary, and thus covered, would offend public policy but for the existence of judicial review), *rev'd on other grounds*, 108 A.D.2d 56, 487 N.Y.S.2d 595 (1985), *aff'd*, 67 N.Y.2d 688, 490 N.E.2d 839, 499 N.Y.S.2d 920 (1986). But see *Zweig & Perry, Health Care Goes to Court*, Washington Post, July 17, 1990, at Z6 (Health) (judicial review may be ineffective because testimony on which courts' decisions are based is self-serving and one-sided).

Courts apply general insurance law and contract principles in experimental treatment exclusion cases.⁵² First, they construe contract ambiguities against insurers.⁵³ This approach developed because insurers typically have more control over contract provisions and greater bargaining power than insureds.⁵⁴ Second, to protect insureds from contract ambiguities, courts require informed assent to contract terms.⁵⁵ In other words, contracts must disclose all relevant information and insureds must be able to understand contract terms. Unambiguous disclosure of coverage limitations allows for genuine choices and enhances both freedom of contract and personal autonomy.⁵⁶ Finally, courts construe coverage clauses broadly and exclusion clauses narrowly.⁵⁷ This comports with construing contract ambiguities against the insurer⁵⁸ and achieves the insurance goal of cost-spreading.⁵⁹

Courts have responded to experimental treatment exclusions in a variety of ways. Some courts conclude that such exclusions are ambiguous.⁶⁰ For example, in *Zuckerberg v. Blue Cross & Blue Shield*, the court found an exclusion ambiguous because it limited coverage to treatments “generally recognized” to be effective.⁶¹ The court refused to interpret “generally recognized” to mean recognition by the medi-

52. See 1 G. COUCH, *supra* note 6, § 1.4. Employees with medical insurance through their employer also are protected under a separate statutory scheme, the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. §§ 1001–1467 (1988). The effects of ERISA on experimental treatment exclusion cases are beyond the scope of this Comment.

53. 10A G. COUCH, *supra* note 6, § 41A:2. Note, however, that some health plans are administered through trusts. Trust doctrine differs from contract doctrine in that ambiguities in trust language are resolved in favor of the trustee if the trustee’s interpretation is reasonable. See *Johnson v. District 2 Marine Eng’rs Beneficial Ass’n*, 857 F.2d 514, 516 (9th Cir. 1988), *cert. denied*, 111 S. Ct. 581 (1990).

54. R. KEETON, *supra* note 48, § 6.3(a).

55. K. ABRAHAM, *supra* note 49, at 117.

56. *Id.* (informed assent is “the making of contractual decisions with a complete understanding of the scope of the undertaking”).

57. *McLaughlin v. Connecticut Gen. Life Ins. Co.*, 565 F. Supp. 434, 440 (N.D. Cal. 1983).

58. *Id.*

59. See *supra* note 13 and accompanying text.

60. See, e.g., *Johnson v. District 2 Marine Eng’rs Beneficial Ass’n*, 857 F.2d 514, 516 (9th Cir. 1988) (“In the context of modern medicine, the term ‘experimental’ seems clearly ambiguous on its face.”), *cert. denied*, 111 S. Ct. 581 (1990). But see *Rollo v. Blue Cross/Blue Shield*, No. 90-597 (D. N.J. Mar. 22, 1990) (LEXIS, Genfed library, Dist file) (the court found the exclusion “reasonable,” but granted coverage because the insurer failed to follow its own technology assessment process).

61. 119 Misc. 2d 834, 464 N.Y.S.2d 678, 682–83 (Sup. Ct. 1983), *rev’d on other grounds*, 108 A.D.2d 56, 487 N.Y.S.2d 595 (1985) (disagreeing with the trial court’s holding of ambiguity in dicta), *aff’d*, 67 N.Y.2d 688, 490 N.E.2d 839, 499 N.Y.S.2d 920 (1986) (declining to address the ambiguity issue).

cal-scientific community.⁶² The court also found a further provision for payment if a treatment was recognized by an "appropriate" government agency ambiguous.⁶³

Although some courts have established parameters for the term "experimental treatment," none has attempted a simple definition. For example, in *Washington v. Winn Dixie*, the court held that hyperbaric oxygen treatment was experimental, even though no other treatments for spinal cord injuries were available for the patient and the treating physician had experienced success with the treatment.⁶⁴ In *Dozsa v. Crum & Forster Insurance Co.*, however, another court held that a treatment that was the only "appropriate" one remaining for a terminally ill insured after all other treatments had failed was not experimental.⁶⁵

In reviewing insurer denials under experimental treatment exclusions, courts focus on certain factors. These include the treatment's high cost,⁶⁶ testimony from experts in the specialty area,⁶⁷ the patient's condition and the lack of alternative treatments,⁶⁸ the approval and acceptance of the components of the treatment,⁶⁹ the use of research protocols,⁷⁰ consensus in professional medical literature regarding the treatment's effectiveness,⁷¹ how well known a treatment

62. *Zuckerberg*, 464 N.Y.S.2d at 682-83.

63. *Id.* at 682.

64. 736 F. Supp. 1418, 1422 (E.D. La. 1990).

65. 716 F. Supp. 131, 138 (D. N.J. 1989).

66. *Johnson v. District 2 Marine Eng'rs Beneficial Ass'n*, 857 F.2d 514, 517 (9th Cir. 1988) (procedure's high cost considered indicative of its experimental nature), *cert. denied*, 111 S. Ct. 581 (1990).

67. *Dozsa*, 716 F. Supp. at 139 (in assessing whether a treatment is recognized in a doctor's specialty, "[r]ationally, such doctors must be those who would work in the field" of the treatment).

68. *Id.* at 138 (treatment was not experimental because the patient was terminally ill and the treatment was the only available alternative).

69. *Id.* at 139 (treatment was not experimental because both the chemotherapy drugs and bone marrow transplant that constitute the components of HDCT-ABMT are accepted medical treatments).

70. *Sweeney v. Gerber Prods. Co. Med. Benefits Plan*, 728 F. Supp. 594, 596 (D. Neb. 1989) (treatment was experimental because physicians using HDCT-ABMT or breast cancer treatment were experimenting with different protocols). Research protocols sometimes are used to gather data on different treatment regimens to further evaluate treatments. See 3 INTERNATIONAL DICTIONARY OF MEDICINE AND BIOLOGY (E. Becker & S. Landau eds. 1986).

71. *Sweeney*, 728 F. Supp. at 596.

is and its duration of use,⁷² and lack of government approval.⁷³ Other courts have considered some of these factors not indicative that a treatment is experimental. Factors courts have deemed not dispositive or not relevant include the American Medical Association's (AMA's) conclusion that the treatment is non-experimental,⁷⁴ lack of government approval,⁷⁵ coverage by other insurers and Medicare,⁷⁶ lack of support in the literature,⁷⁷ lack of randomized clinical studies,⁷⁸ a death rate as high as fifteen percent,⁷⁹ and a success ratio of less than fifty percent.⁸⁰

C. Pirozzi v. Blue Cross-Blue Shield: A Case Study

*Pirozzi v. Blue Cross-Blue Shield*⁸¹ is a typical experimental exclusion case. Pamela Pirozzi sought coverage for high-dose chemotherapy with autologous bone marrow transplant (HDCT-ABMT), a treatment that was her best chance for survival.⁸² Because the procedure was expensive, the hospital required preauthorization from her

72. *Zuckerberg v. Blue Cross & Blue Shield*, 119 Misc. 2d 834, 464 N.Y.S.2d 678, 682 (Sup. Ct. 1983) (because Gerson's therapy had been used for more than 30 years and was well known, it was not experimental), *rev'd*, 108 A.D.2d 56, 487 N.Y.S.2d 595 (1985), *aff'd*, 67 N.Y.2d 688, 490 N.E.2d 839, 499 N.Y.S.2d 920 (1986).

73. *Jacob v. Blue Cross & Blue Shield*, 92 Or. App. 259, 758 P.2d 382, 383 (1988) (that Gerson's therapy was not approved by "appropriate" government agencies established it as an experimental treatment).

74. *Jones v. Laborers Health & Welfare Trust Fund*, 906 F.2d 480, 482 (9th Cir. 1990) (despite testimony that, according to the AMA, hyperthermia treatment for breast cancer was established medical practice, the insurer's deference to its own medical consultant's claim that the treatment was experimental was not clearly erroneous).

75. *Zuckerberg*, 464 N.Y.S.2d at 682 (although no government body had approved the treatment, the court held it was not excluded under an experimental treatment exclusion).

76. *Jones*, 906 F.2d at 482 (upholding a trustee's determination that a procedure was experimental despite testimony that Medicare and other insurers covered it).

77. *Dozsa v. Crum & Forster Ins. Co.*, 716 F. Supp. 131, 138 (D. N.J. 1989) (although lack of peer-reviewed studies may indicate that a treatment is not recognized, it is not conclusive evidence); *Zuckerberg*, 464 N.Y.S.2d at 683 (if the insurer wanted to exclude coverage because the literature did not support the treatment's use, the contract should have indicated that lack of such support was grounds for exclusion).

78. *Pirozzi v. Blue Cross-Blue Shield*, 741 F. Supp. 586, 593-94 (E.D. Va. 1990) (the lack of such studies is persuasive but not dispositive in light of other evidence that the treatment is not experimental).

79. *Id.* at 593 (a high death rate does not indicate that a treatment is experimental when the treatment is likely to be successful and the patient has poor chance of surviving without the treatment).

80. *Reilly v. Blue Cross & Blue Shield*, 846 F.2d 416, 423 (7th Cir.) (using such a ratio to define experimental could be arbitrary and capricious), *cert. denied*, 488 U.S. 856 (1988).

81. 741 F. Supp. 586 (E.D. Va. 1990).

82. *Id.* at 588. HDCT-ABMT is a procedure in which bone marrow is extracted from the patient and stored while the patient receives large, near lethal doses of chemotherapy. The patient's stored bone marrow is returned after the chemotherapy is complete. *Id.*

insurer.⁸³ Although HDCT-ABMT is covered by most insurers when used for cancers other than breast cancer,⁸⁴ the insurer denied coverage on the grounds that the treatment was experimental and thus excluded under Pirozzi's insurance contract.⁸⁵ Like many health insurance contracts, Pirozzi's contract did not define "experimental treatment."⁸⁶ Pirozzi sued for a declaratory judgment that the contract covered HDCT-ABMT for breast cancer.⁸⁷

The insurer evaluated HDCT-ABMT using five technology evaluation criteria⁸⁸ and found that the procedure failed to meet them.⁸⁹ The court held that the criteria were not binding on the insured because they were not in the contract, nor did the contract state that they would apply.⁹⁰ Furthermore, it considered some of the criteria vague.⁹¹

The court found the experimental treatment exclusion ambiguous because "experimental treatment" was not defined.⁹² The court construed the exclusion by examining each of its provisions.⁹³ In addition to excluding experimental treatment, the exclusion denied coverage to those treatments "of no scientifically proven value," and those "not in accordance with generally accepted standards of medical practice."⁹⁴ Considering the phrases together, the court reasoned that a procedure found in accordance with generally accepted standards of medical practice or of scientifically proven value was not experimental.⁹⁵ The court then considered expert testimony to determine whether the treatment was experimental.⁹⁶

The court held that Pirozzi's experts presented convincing evidence that the treatment had "scientifically proven value" and was "in

83. *Id.* The cost was expected to exceed \$100,000.

84. Washington Post, *supra* note 4, at B7, col 3; N.Y. Times, Nov. 12, 1990, at 1, col. 6, B8, col. 6.

85. Pirozzi, 741 F. Supp. at 588. The contract excluded "[e]xperimental or clinical investigative procedures; services of no scientifically proven medical value; [and] services not in accordance with generally accepted standards of medical practice." *Id.*

86. *Id.* at 589-90.

87. *Id.* at 587. As an employment benefit, the contract was governed by ERISA. *See supra* note 16.

88. *See supra* note 46.

89. Pirozzi, 741 F. Supp. at 591.

90. *Id.*

91. *Id.* The court found that the phrases "sufficient information," "a net beneficial effect on health outcomes," and "safe and efficacious," were "question begging" and undefined. *Id.*

92. *Id.* at 589-90.

93. *Id.* at 590.

94. *Id.*

95. *Id.*

96. *Id.* at 591-94.

accordance with generally accepted standards of medical practice.”⁹⁷ The court identified the following factors as persuasive. First, Pirozzi’s experts testified that the treatment was “far from . . . unusual” and used at most major medical centers.⁹⁸ Second, they testified that HDCT-ABMT was the appropriate treatment for Pirozzi’s condition after other treatments had failed.⁹⁹ The court found the lack of randomized clinical trials unpersuasive evidence that the treatment was experimental.¹⁰⁰ Similarly, evidence that the treatment’s mortality rate was as high as fifteen percent was not dispositive evidence that it was experimental.¹⁰¹ The treatment’s likelihood of success and the near certainty that the patient would die without it outweighed the risk of death.¹⁰² The court granted the declaratory judgment, reasoning that it was not a “quack remed[y]” or “fringe therapy” but “medicine’s state of the art treatment for certain . . . patients.”¹⁰³

II. ANALYZING UNDEFINED EXPERIMENTAL TREATMENT EXCLUSIONS

Courts face competing interests in cases involving experimental treatment exclusions. On one hand, “subscriber premiums should not have to pay for procedures which are purely experimental . . . or subsidize every scientist stirring a magic potion in some laboratory at the top of a mountain with lightening flashing about.”¹⁰⁴ Yet, typical experimental treatment exclusions are undefined and easily manipulated. “In the context of modern medicine, the term ‘experimental’ seems clearly ambiguous on its face.”¹⁰⁵ Courts must protect insureds from such ambiguity.

Courts play an important role in regulating insurance exclusions. Current case law, however, fails to provide a clear statement of what is required of insurers seeking to exclude coverage of experimental treatment or what definition of “experimental” courts should use.¹⁰⁶

97. *Id.* at 591.

98. *Id.*

99. *Id.* at 592.

100. *Id.* at 593–94.

101. *Id.* at 594.

102. *Id.* at 593.

103. *Id.* at 594.

104. *Rollo v. Blue Cross/Blue Shield*, No. 90-597 (D. N.J. Mar. 22, 1990) (LEXIS, Genfed library, Dist file).

105. *Johnson v. District 2 Marine Eng’rs Beneficial Ass’n*, 857 F.2d 514, 516 (9th Cir. 1988), *cert. denied*, 111 S. Ct. 581 (1990).

106. *Cline & Rosten*, *supra* note 8, at 131 (“The only certainty in this area is that one cannot predict the result in any individual case.”).

Courts should consider undefined experimental treatment exclusions ambiguous. They should construe such exclusions narrowly, considering whether a treatment has demonstrated any likelihood of success as indication that it is not experimental. They should not consider certain other factors indicative of non-experimental status, however, to protect the public policy against unproven treatment. Finally, courts should review any technology assessment criteria insurers include in their experimental treatment exclusions for clarity.

A. The Problem with Undefined Experimental Treatment Exclusions

Ambiguous experimental treatment exclusions are undesirable for three reasons. First, insureds' informed assent to contracts is precluded by undefined exclusions. Second, insurers may easily manipulate undefined exclusions to exclude coverage on bases other than a treatment's experimental status. Third, judicial review is hampered when "experimental" is undefined.

1. An Undefined Exclusion Precludes Informed Assent

Health insurance contracts must fully inform insureds of the extent of their coverage if insureds are to make rational purchases. Poorly defined experimental treatment exclusions make such informed assent unlikely. The informed assent doctrine requires conspicuous and plain notice of non-coverage.¹⁰⁷ Thus, if insurers cannot name particular excluded treatments with specificity,¹⁰⁸ contracts should explain how denial decisions are made and what criteria are relevant to those decisions. For example, in *Reilly v. Blue Cross & Blue Shield*,¹⁰⁹ the insurance contract excluded experimental treatment that Blue Cross did not recognize as accepted medical practice.¹¹⁰ The contract did not disclose that the insurer required the treatment to have a success rate greater than fifty percent to be accepted as standard.¹¹¹ The court remanded for consideration of whether a fifty-percent success rate was reasonable.¹¹² Regardless of whether such a requirement was reasonable, the contract should have disclosed it.¹¹³ Without notice of suc-

107. See *supra* notes 55-56 and accompanying text.

108. See *supra* note 27 and accompanying text.

109. 846 F.2d 416 (7th Cir. 1988).

110. *Id.* at 419.

111. *Id.*

112. *Id.* at 423-24.

113. See *supra* notes 55-56 and accompanying text.

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cess-rate criteria or other factors insurers consider relevant to treatments' status, consumers cannot make informed purchases.

2. *Experimental Treatment Exclusions Are Easily Manipulated*

When insurers use undefined exclusions, three opportunities for insurer manipulation arise. First, undefined exclusions create uncertainty about coverage because no agreement on what constitutes experimental treatment exists. Thus, undefined exclusions may discourage legitimate use of health care resources. For instance, uncertainty about insurers' willingness to pay medical bills may influence patients' or physicians' decisions about whether to seek treatment.¹¹⁴ The possibility that insureds may have to go to court to enforce coverage may also deter them from seeking treatment. In cases where treatment is sought but litigation is required, only those with the energy and resources for a court battle will obtain coverage.¹¹⁵ Thus, insurance contracts with poorly defined experimental treatment exclusions may preclude more than truly experimental treatment; they may pose additional barriers to treatment through uncertainty and inconvenience.

Second, given the expense of some new treatments,¹¹⁶ insurers have a financial interest in categorizing them as experimental. Undefined experimental treatment exclusions allow insurers to rely on implicit criteria,¹¹⁷ such as cost, to screen out expensive procedures. By relying on cost as an undisclosed criteria in administering experimental treatment exclusions, insurers can avoid paying for treatments that are not truly experimental, but are just expensive.

Third, technology assessment also is easily manipulated. It is not a precise science. Rather, it necessarily reflects personal bias and expert opinion more than hard data.¹¹⁸ Three problems arise when insurers rely solely on published results of clinical studies in performing technology assessment. First, many new procedures are not rigorously

114. Cf. Grumet, *supra* note 21, at 610.

115. Cf. *Rollo v. Blue Cross/Blue Shield*, No. 90-597 (D. N.J. Mar. 22, 1990) (LEXIS, Genfed library, Dist file); *Newcomer*, *supra* note 42, at 1703 ("The persistent, litigious, or persuasive patient is more likely to receive the possibly experimental treatment with [the current] system."). Insurers may avoid eliminating this coverage obstacle by either settling lawsuits out of court or waiving coverage denials when faced with a lawsuit. See *Woman Wins Coverage for Cancer Treatment*, United Press Int'l, July 24, 1990 (LEXIS, NEXIS library, Wires file). Insurers would then have to pay only those willing to litigate, and not others with possibly legitimate claims.

116. See *supra* note 35.

117. See *Reilly v. Blue Cross & Blue Shield*, 846 F.2d 416, 421, 423 (7th Cir.), *cert. denied*, 488 U.S. 856 (1988); *Newcomer*, *supra* note 42, at 1703.

118. Schaffarzick, *supra* note 19, at 223.

studied.¹¹⁹ Although the Food and Drug Administration analyzes and approves new drugs, no equivalent government body systematically screens medical procedures—including new uses for approved drugs—for their safety and efficacy.¹²⁰ New treatments are not always rigorously studied by private researchers either. The most rigorous studies may be difficult to perform on promising treatments if too few patients are willing to risk being in the group receiving placebos.¹²¹ Second, even if rigorous clinical studies are conducted, a time lag exists between the completion of an encouraging study and its publication in medical journals.¹²² Thus, the availability of evidence used in assessing a treatment's status is delayed.¹²³ Finally, a consensus about a treatment's efficacy is difficult to achieve even from the results of rigorous studies.¹²⁴

The inconsistent study of new technologies, particularly of new combinations of accepted procedures,¹²⁵ may make it easy for insurers to cite a lack of clinical studies when cost or other factors are the true issue.¹²⁶ For instance, in *Dozsa v. Crum & Forster Ins. Co.*, the insured sought coverage for HDCT-ABMT treatment for multiple myeloma.¹²⁷ The treatment was expected to cost between \$75,000 and \$125,000.¹²⁸ The insurer denied coverage, citing a lack of randomized or controlled studies,¹²⁹ even though the company covered HDCT-

119. 3 PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE & BIOMEDICAL & BEHAVIORAL RESEARCH, THE ETHICAL IMPLICATIONS OF DIFFERENCES IN THE AVAILABILITY OF HEALTH SERVICES 232-33 (1983); see Faltermayer, *Medical Care's Next Revolution*, FORTUNE, Oct. 10, 1988, at 126 (quoting Dr. Paul M. Ellwood, Jr., stating that "[h]alf of what the medical profession does is of unverified effectiveness"). Randomized controlled clinical trials (RCTs) are the most rigorous studies of the efficacy of medical technology. Banta, Burns & Behney, *supra* note 9, at 177. They involve administering the new treatment to one group and standard treatment to a control group and comparing their effectiveness. Cowan, *supra* note 37, at 623-24. RCTs, however, are not always performed. Schaffarzick, *supra* note 19, at 223.

120. Cowan, *supra* note 37, at 626.

121. Pirozzi v. Blue Cross-Blue Shield, 741 F. Supp. 586, 594 (E.D. Va. 1990).

122. *Id.* at 592.

123. *Dozsa v. Crum & Forster Ins. Co.*, 716 F. Supp. 131, 139 (D. N.J. 1989).

124. Newcomer, *supra* note 42, at 1703. Little consistency exists in the methods private technology assessment organizations use. Schaffarzick, *supra* note 19, at 223. Thus, their conclusions may be incongruous. *Id.*

125. For an example, see *Dozsa*, 716 F. Supp. at 139 (the components—ABMT and chemotherapy—are accepted treatments; the dose and combination are new).

126. Wehr, *National Health Policy Sought for Organ Transplant Surgery*, 42 CONG. Q. 453, 454-56 (1984) (denial of coverage for liver transplants on the basis that the procedure was experimental was a "convenient way of avoiding facing the enormous cost").

127. 716 F. Supp. at 132.

128. *Id.*

129. *Id.* at 136.

ABMT for a variety of other cancers.¹³⁰ HDCT-ABMT had been successful with those other cancers, thus, in characterizing HDCT-ABMT as experimental for Dozsa's condition, the insurer's consultant had stated that he was aware that he was "splitting hairs [because] once one accepts ABMT as a technique for one indication it is a short way to accepting it for [conditions such as Dozsa's]." ¹³¹ Randomized clinical trials simply had not been completed and published on the use of HDCT-ABMT with the insured's particular condition. Thus, the insurer possibly masked a denial based on cost by claiming a lack of published randomized studies.

3. *Undefined Exclusions Encourage Courts To Rewrite Insurance Contracts*

Meaningful judicial review of experimental treatment exclusions is hampered when technology assessment criteria are not included in the contract. In such cases, courts will construe contracts in ways designed to provide coverage¹³² instead of determining whether insurers' decisions were reasonable in light of the contract terms. This narrow construction may alter the coverage scheme developed by the insurer and purchased by the insured.¹³³ It also may allow courts to mandate coverage of treatments that have not been proven safe and effective.

Such coverage mandates by courts may encourage overly cautious insurer behavior. Although a particular coverage mandate may have minimal effect on an insurer's financial situation, it may lead to uncertainty about which treatments insurers may exclude under experimental treatment exclusions. Insurers may increase or reduce coverage in anticipation of future judicial coverage expansions.¹³⁴ Alternatively, they may respond to coverage mandates by offering more extensive coverage than is desired by most insurance purchasers, driving premiums higher.¹³⁵ For example, some insureds probably would prefer less expensive health insurance over a costly plan that covers any treatment sought, regardless of its safety or effectiveness.¹³⁶

130. *Id.*

131. *Id.*

132. *Cf. McLaughlin v. Connecticut Gen. Life Ins.*, 565 F. Supp. 434, 440 (N.D. Cal. 1983).

133. *Cf. K. ABRAHAM, supra* note 49, at 122-25 (for example, coverage mandates based on insureds' reasonable expectations of coverage involuntarily increase the scope of coverage and premium levels, thus impairing insureds' freedom of choice).

134. *Id.* at 123-25.

135. *Id.*

136. *See id.* at 125.

When insurers use undefined experimental treatment exclusions, courts may more readily mandate coverage of unproven treatments. Courts may be reluctant to uphold coverage denials when orthodox treatments have failed and the insured is desperately ill.¹³⁷ Undefined experimental treatment exclusions may allow courts to construe contracts in favor of coverage regardless of whether a treatment has been proven safe and effective.

When courts overturn reasonable coverage denials, they may interfere with the provision of affordable insurance products and may act contrary to the public policy against the use of unproven medical treatments. Coverage limits provide for affordable insurance products, and allowing insurers to exclude coverage of truly experimental treatments is justifiable and desirable from the "gatekeeper" perspective.¹³⁸ Insurers have a legitimate interest in screening the constant stream of new technologies.¹³⁹ They must do so in order to allocate financial resources prudently.¹⁴⁰ If expensive new treatments are ineffective, their use drains funds unnecessarily from the insurance pool.¹⁴¹

B. A Proposed Judicial Response to Undefined Experimental Treatment Exclusions and to Insurer Criteria

Courts reviewing coverage denials based on undefined experimental treatment exclusions face two distinct tasks. First, they must evaluate the exclusion language for ambiguity. Second, if the exclusion is ambiguous, courts must construe the exclusion in favor of coverage and against the insurer.¹⁴² The analysis that follows recommends that courts consider undefined experimental treatment exclusions ambiguous and accept any demonstrated likelihood of success as evidence that treatments are not experimental. Finally, it recommends an approach for assessing any insurer criteria included in insurance contracts.

137. See Cline & Rosten, *supra* note 8, at 134.

138. See *supra* notes 14–16 and accompanying text.

139. Cf. Schaffarzick, *supra* note 19 (strong public demand for expensive new treatments contributes to rising health care costs, making technology assessment and resource allocation desirable).

140. See *id.*

141. *Free v. Travelers Ins. Co.*, 551 F. Supp. 554, 560 (D. Md. 1982) (requiring "insurers to pay for every remedy, proven or unproven, prescribed by a physician, could invalidate the actuarial basis of current premium rates").

142. 10A G. COUCH, *supra* note 6, § 41A:2.

1. *Courts Should Consider Undefined Experimental Treatment Exclusions Ambiguous and Construe Them Narrowly*

Courts should consider experimental treatment exclusions ambiguous if the contract does not state the criteria the insurer uses to assess whether treatments are experimental. A coverage denial based on undisclosed criteria is a denial based on terms that are not part of the contract.¹⁴³ The *Pirozzi* court applied this reasoning. In *Pirozzi*, the insurer used five criteria to assess new treatments. The court held them non-binding because they were not described in the insurance contract.¹⁴⁴

In construing ambiguous experimental treatment exclusions, courts should define “experimental treatment” narrowly. The important factor should be whether a treatment has demonstrated any likelihood of success and safety. This standard recognizes that not all treatments are rigorously tested, and that consensus is not always achieved after testing.¹⁴⁵ The likelihood-of-success standard allows consideration of evidence from studies not yet published and testimony from providers who have developed expertise with the treatment. At the same time, this approach permits courts to uphold coverage denials in cases where treatments have never been attempted or have shown no likelihood of success.

In applying this standard, courts should consider current evidence and medical opinion, instead of only that existing when the insured first sought coverage. To do otherwise ignores the realities of medical research. It ignores the possibility of rapid technological advancement and that medical journals publish studies long after the research is complete.¹⁴⁶ Courts should not uphold coverage denials when the “proof” materializes only after the claim is submitted.

It is also important that courts not consider the following factors indicative of a treatment’s experimental status. First, a treatment’s high cost does not mean that it is experimental; not all expensive treatments are experimental. For example, HDCT-ABMT may cost as much as \$125,000, but it has been proven safe and effective treatment for some conditions.¹⁴⁷ Allowing insurers to confuse high cost with truly experimental status introduces a new category of excluded treatment that was not part of the contract the insured signed.

143. See, e.g., *Dozza v. Crum & Forster Ins. Co.*, 716 F. Supp. 131, 138 (D. N.J. 1989).

144. *Pirozzi v. Blue Cross-Blue Shield*, 741 F. Supp. 586, 591 (E.D. Va. 1990).

145. See *supra* notes 119–26 and accompanying text.

146. See *supra* note 125 and accompanying text.

147. *Dozza*, 716 F. Supp. at 135.

Second, a treatment that needs further refinement and research is not necessarily experimental. Thus, the use of research protocols should not be considered indicative that a treatment is experimental. Research protocols may be used to refine knowledge about a treatment's applications after it is accepted as standard treatment.¹⁴⁸ For instance, in *Reilly v. Blue Cross & Blue Shield*,¹⁴⁹ expert testimony indicated that in vitro fertilization was "beyond the purely experimental, but that like so much of the rest of medicine, improvements would be made through further experimentation."¹⁵⁰

Third, a physician's treatment recommendation may be persuasive evidence that it is not experimental, but it should not be dispositive.¹⁵¹ Physicians may recommend treatments to seriously ill patients when no other proven approaches are likely to succeed.¹⁵² When physicians recommend treatments as a last resort, their recommendations should not be dispositive evidence that the treatments are non-experimental.

2. Courts Should Review Insurer Criteria for Clarity

By construing undefined experimental treatment exclusions narrowly, courts will encourage insurers to include decisionmaking criteria in their contracts. In reviewing such criteria, courts should consider both the insurers' need for flexibility and the insureds' right to clarity.

Insurers need experimental treatment exclusions flexible enough to respond to the inconsistent testing of new technologies.¹⁵³ Flexibility allows insurers to use a single standard with varying levels of proof of a treatment's safety and efficacy. Consider, for example, the Blue Cross-Blue Shield criteria.¹⁵⁴ The first criterion is unambiguous yet inflexible: "Is the drug or device approved by the [FDA] to market for the particular [condition or use] in question?"¹⁵⁵ The third criterion, however, is less objective but more flexible: "Does the available scientific evidence demonstrate a net beneficial effect on health out-

148. *Pirozzi v. Blue Cross-Blue Shield*, 741 F. Supp. 586, 593 (E.D. Va. 1990).

149. 846 F.2d 416 (7th Cir.), cert. denied, 488 U.S. 856 (1988).

150. *Id.* at 421. But see *Sweeney v. Gerber Prods. Co. Medical Benefits Plan*, 728 F. Supp. 594 (D. Neb. 1989) (that doctors were experimenting with different drugs in different dosages indicated the treatment was experimental).

151. *Cf. Shumake v. Travelers Ins. Co.*, 147 Mich. App. 600, 383 N.W.2d 259, 263-64 (1985) (a doctor's recommendation does not necessarily mean a treatment is necessary, but should be given deference.)

152. See *supra* note 37-39 and accompanying text.

153. See *supra* notes 121-22 and accompanying text.

154. See *supra* note 46.

155. *Pirozzi v. Blue Cross-Blue Shield*, 741 F. Supp. 586, 590 (E.D. Va. 1990).

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comes?"¹⁵⁶ This third criterion is broad enough to allow consideration of more than medical journals, permitting consideration of a variety of types of scientific evidence. Further, the net beneficial effect requirement may allow consideration of the impact of the condition on the patient. For instance, when patients are terminally ill a new treatment's possible advantages may easily outweigh its risks.

Although experimental treatment exclusions must be flexible, they should be unambiguous. Courts should consider six factors in reviewing insurer criteria. First, contracts should clearly express the relationship between the criteria and the exclusion. In *Dozza*, the insurance contract excluded "experimental" treatments.¹⁵⁷ Using criteria designed to assess whether a treatment was "investigational," the plan administrator determined that HDCT-ABMT was not covered.¹⁵⁸ The court held that denying coverage on the basis that HDCT-ABMT was "investigational" created a new exclusion because the plan only excluded "experimental" treatment.¹⁵⁹

Second, the decisionmaking criteria should be comprehensive, clear, and specific, including quantifying standards where possible.¹⁶⁰ Thus, an insurer should indicate whether a certain quantity of data or a particular survival rate or cure rate is required for coverage.¹⁶¹ For example, in *Rollo v. Blue Cross/Blue Shield*,¹⁶² the opportunities to study the insured's illness were limited because the insured's condition was rare,¹⁶³ yet the insurer disregarded a group of studies performed in England and denied coverage.¹⁶⁴ At trial, the insurer insisted that too few studies had been performed. When pressed for a number of studies that would be sufficient, the insurer said "there is no specific number," but later said "at least 50," which exceeded the number of cases of the disease worldwide.¹⁶⁵ The insurer's criteria were vague with regard to the amount of evidence required and unresponsive to the problems posed by rare conditions.

156. *Id.*

157. 716 F. Supp. 131, 135 (D. N.J. 1989).

158. *Id.* at 135-36.

159. *Id.* at 138.

160. *But see* Cline & Rosten, *supra* note 8, at 134 (all-inclusive policy language is likely to be unenforceable as a "sea of print," while "simple, direct" language is likely to leave areas of reasonable doubt which courts will resolve in the insureds' favor).

161. *See* Pirozzi v. Blue Cross-Blue Shield, 741 F. Supp. 586, 589-90 (E.D. Va. 1990).

162. No. 90-597 (D. N.J. Mar. 22, 1990) (LEXIS, Genfed library, Dist file).

163. *Id.*

164. *Id.*

165. *Id.*

Third, insurers should incorporate outside technology reviews when assessing treatments. This avoids the appearance and possible influence of insurers' self-interest in the outcome of the assessment process.¹⁶⁶ In *Jones v. Laborers Health & Welfare Trust Fund*, the insurer relied solely on its medical consultant's opinion that hyperthermia treatment was experimental for treating breast cancer.¹⁶⁷ Had the insurer consulted outside organizations, it would have found that the AMA considered the treatment an established medical practice and that Medicare and other insurers covered it.¹⁶⁸ Thus, the insurer's process predetermined the conclusion.

Fourth, insurers should review technologies frequently in specialty areas where developments occur quickly. The insurer in *Pirozzi* denied coverage based on a technology assessment that was more than a year old.¹⁶⁹ Independent expert testimony noted the "substantial time lag" between the conclusion of recent promising experimental studies and publication of their results.¹⁷⁰ Thus, a more recent investigation would have provided the insurer a more positive view of the work being done with HDCT-ABMT. By failing to update its assessment of a rapidly developing treatment, the insurer may have erroneously denied coverage.

Fifth, insurers should consult with experts in the specialty area at issue. For example, in *Dozsa*, the insurer claimed that the medical literature contained insufficient data about the treatment to support its use with the insured's type of cancer, multiple myeloma.¹⁷¹ Experts testified, however, that despite the paucity of medical literature, the treatment was commonly and customarily recognized by oncologists.¹⁷² When an established treatment is used with new conditions, the most up-to-date and accurate information is likely to come from experts in the treatment's specialty area.

Finally, insurers' technology assessment criteria should describe all the factors considered. For instance, if an insurer considers the impact of the condition on the patient, that should be described in the criteria. If a treatment is less likely to be deemed experimental when used to treat someone who will die without it than with someone whose sur-

166. For example, see *Reilly v. Blue Cross & Blue Shield*, 846 F.2d 416, 423 (7th Cir.) ("The fact that Blue Cross . . . relied on the advice of its own advisory groups . . . creates an inherent risk of abuse."), *cert. denied*, 488 U.S. 856 (1988).

167. 906 F.2d 480, 483 (9th Cir. 1990).

168. *Id.* at 482.

169. See *Pirozzi v. Blue Cross-Blue Shield*, 741 F. Supp. 586, 590 (E.D. Va. 1990).

170. *Id.* at 592.

171. 716 F. Supp. 131, 138-39 (D. N.J. 1989).

172. *Id.* at 139.

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vival is not an issue, the criteria should say so. In such a situation, new fertility treatments would be held to stricter standards of proof than treatments for terminally ill patients.¹⁷³

Requiring insurers to enunciate their decisionmaking criteria in health insurance contracts achieves three important goals. First, it promotes informed assent. Public policy requires that consumers are informed about which treatments contracts exclude in order to make informed purchases. A description of criteria relevant to a treatment's status allows insurance consumers to better ascertain the level of coverage offered. Second, including decisionmaking criteria in health insurance contracts minimizes the possibility of insurer manipulation of experimental treatment exclusions. If insurers articulate the factors that will inform their decisions, they will be less likely to consider undisclosed factors such as cost. This approach will likely lead to more meaningful judicial review. When courts review insurers' decisions, insurer consideration of undisclosed factors is more apparent when criteria are enunciated in the contract. Finally, this approach promotes broad coverage, while allowing for reasonable limits on insurer liability. Such limits are possible because a coverage denial predicated on a defined exclusion may withstand judicial review. This approach promotes broad coverage by requiring that insurers consider only disclosed factors in assessing technology.

III. CONCLUSION

General insurance law and contract principles require that insurers fully define coverage exclusions, such as those for experimental treatment, in the contract. Courts construe undefined and ambiguous exclusions against insurers. Under the policy of informed assent, insurers must fully explain exclusions in insurance contracts. Similarly, insurers should enunciate the criteria they use to assess and characterize new treatments both because insurers may easily manipulate undefined experimental treatment exclusions to inappropriately deny coverage and because of the inconsistency with which new technologies are studied and tested.

Courts should consider undefined experimental treatment exclusions ambiguous. In construing such contracts, courts should assess whether treatments have any demonstrated likelihood of success and safety. This standard acknowledges that not all new treatments are studied and that publication of promising studies often is delayed.

173. Cf. *Reilly v. Blue Cross & Blue Shield*, 846 F.2d 416, 423 (7th Cir.), *cert. denied*, 488 U.S. 856 (1988).

Moreover, requiring insurers to enunciate their evaluative criteria will promote informed assent and provide for better insurer decisionmaking and more meaningful judicial review. These requirements will encourage broad coverage while maintaining insurers' ability to place reasonable limits on their liability.

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