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REDEFINING THE “EXPERIMENTAL OR INVESTIGATIONAL” EXCLUSION: A GUIDE FOR ERISA HEALTH PLANS

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INTRODUCTION

As the major provider of health insurance and health plan benefits, employers have seen their medical costs rise at a rate of approximately 18% per year.¹ If this rate continues, analysts project that health care costs will consume 100% of the gross national product by the year 2050.² Faced with this grim financial outlook, employers have turned to cost containment methods to reduce their health care costs. One such method is the inclusion within the health plan of exclusionary clauses, especially those that exclude coverage for experimental or investigational treatments.³

Based on the current state of rapid proliferation and diversity of medical interventions, health care consumers, health care providers, and third-party payers find themselves in disagreement regarding the effectiveness of certain procedures and treatment modalities in the management of injury and disease.⁴ As consumers battle for access to treatments of choice, physicians struggle with balancing research findings from innovative treatments against more generally accepted standards of care and payers attempt to avoid the increased costs for unproven therapies.⁵ While health plans design, draft, and administer

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1. Robert Kuttner, *Sick Joke: The Failings of “Managed” Care*, *Health Insurance*, New Republic, Dec. 2, 1991, at 20.

2. *Id.*

3. Jody C. Collins, *Experimental Medical Treatments: Who Should Decide Coverage?*, 20 Seattle U. L. Rev. 451, 474 (1997).

4. Morreim, *Cost Containment and the Standard of Medical Care*, 75 Calif. L. Rev. 1719 (1987).

5. Eddy, *Comparing Benefits and Harms: The Balance Sheet*, 263 JAMA 2493 (1990).

health benefits, health plan providers are increasingly being called upon to defend their benefit contracts in the face of rapid technological advances, increased consumer demand for these advances, and interventions by the judiciary and legislature. As health plans seek to limit costs, they find themselves in a heated controversy with health care providers and plan participants.

There are many factors that have led to this controversy. First, plan participants expect that their health plans will pay for potentially life-saving treatments, even if these treatments are still under investigation in a research program. When the health plan denies coverage asserting the experimental or investigational exclusion, the plan participant often chooses litigation to obtain the benefits.⁶ Second, health care providers and researchers are desperate to seek third-party reimbursement to support their medical research as a result of decreasing research funds from other sources.⁷ Third, state legislatures often resort to mandating benefits coverage by third-party payers in order to pay for the research.⁸ Finally, state and federal courts have been inconsistent in their interpretations of exclusionary clauses and have increased confusion regarding what is covered.⁹

To escape the judicial uncertainty and state mandated coverage, employers have turned to ERISA for protection. This protection is found in the statute's preemption clause that states that ERISA's provisions "shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan" covered by ERISA.¹⁰ While ERISA exempts state insurance regulations from this preemption, it also provides that ERISA plans shall not be deemed to be an insurance company or other insurer. In effect, this seemingly contradictory language of the statute prevents ERISA plans from being regulated as insurance companies by the states.¹¹ The main goal of preemption is to ensure that ERISA plans are governed by a uniform set of federal regulations, rather than the various state regulations governing insurance companies.¹²

However, employers have not escaped the uncertainty created by the variable interpretations of the federal judiciary. The dilemma facing employers providing ERISA health plans is explained through an analysis of the coverage disputes involving a highly controversial

6. Mary Ader, *Access to Investigational Treatments*, 6 Health Matrix 187 (1996).

7. *Id.*

8. *Id.*

9. *Id.*

10. ERISA, 29 U.S.C. § 1144(a) (1985).

11. *Hewlett-Packard Co. v. Barnes*, 425 F. Supp. 1294 (N.D. Cal. 1977), *aff'd*, 571 F.2d 502 (9th Cir. 1978), *cert. denied*, 439 U.S. 831 (1978).

12. *See Pilot Life Ins. v. Dedeaux*, 481 U.S. 41, 45-46 (1987).

treatment for breast cancer, high dose chemotherapy with autologous bone marrow transplant ("HDC/ABMT"), which was intensely litigated throughout the late 1980's and into the 1990's. This comment will use this case history to illustrate methods that may be used by the ERISA health plan to minimize its exposure to the costs of experimental or investigational treatments. Part I will describe exclusionary clauses and the rationale for their inclusion in health plans. Part II will define clinical research methodology and include a description of the various agencies and organizations that may be involved. Part III will describe the evolution of the judicial interpretations in the HDC/ABMT cases, emphasizing the plan language upon which the courts based their decisions. Part IV will demonstrate the typical plan exclusion clause and offer recommendations to improve it in view of the HDC/ABMT cases.

PART I. EXCLUSIONARY CLAUSES FOR EXPERIMENTAL OR INVESTIGATIONAL TREATMENTS

Health plans pay for medical treatments that have been scientifically proven as safe, effective, and necessary.¹³ However, these plans refuse to pay for procedures and treatments that have no definite scientific value.¹⁴ As a result, health plans protect their participants from unsafe, ineffective, and wasteful treatments while maintaining affordable premiums for all plan participants.¹⁵ With the ever increasing costs of health care, these efforts of health plans are based upon sound policy.¹⁶

Health care costs have risen dramatically in the last decade due in large part to the rapid evolution of new medical technologies.¹⁷ As a direct result, these technologies are a legitimate target for those health plans attempting to curb costs. Courts have recognized that it is both necessary and reasonable for health plans to exclude coverage for "experimental or investigational" treatments. One court noted that "subscriber premiums should not have to pay for procedures which are purely experimental or investigative or subsidize every scientist stirring a magic potion in some laboratory at the top of a mountain with

13. John L. Cova, *A Swift Response to a "Modest" Proposal*, 84 J. Nat'l Cancer Inst. 744 (1992).

14. James Cline & Keith Rosten, *The Effect of Policy Language on the Containment of Health Care Cost*, 21 Tort & Ins. L.J. 120, 131 (1985).

15. Barbara A. Fisfis, *Who Should Rightfully Decide Whether a Medical Treatment Necessarily Incurred Should Be Excluded from Coverage Under a Health Insurance Policy Provision Which Excludes from Coverage "Experimental" Medical Treatment?*, 31 Duq. L. Rev. 777, 779-81 (1993).

16. *Id.*

17. *Id.*

lightning flashing about.”¹⁸ In any rational health care system, there are limitations on coverage and affordability.¹⁹ Despite the rational basis for these exclusions, health plans are in the unenviable position of defining and enforcing these limits. These plans must respond to the demands for new technologies, ensure the safety and efficacy of the treatments, and contain the costs of covered health care.²⁰ As a result, health plans usually include clauses that exclude coverage for “experimental or investigational” treatments. Because ERISA allows employers the freedom of benefit design, almost all ERISA health plans will contain exclusions for “experimental or investigational” treatments.²¹

The issue then becomes how to define “experimental or investigational.” One definition provides that “experimental” procedures are those that are untested or unproved or not related to the patient’s therapy but rather performed solely for the purpose of obtaining scientific data.²² Another definition states that an “experimental or investigational” service is one which:

1. Is under clinical investigation by health professionals and is not generally recognized by the medical profession as tested and accepted medical practice[;]
2. Requires approval by the Federal Drug Administration or other governmental agency, and such approval has not been granted at the time the service or supply is ordered[; or,]
3. Has been classified by the national Blue Cross and Blue Shield Association as experimental or investigational.²³

This definition still leaves a void for it fails to define both “generally recognized” and “accepted medical practice.” This problem of defining these terms is not easily solved as evidenced by the HDC/ABMT cases.

PART II. MEDICAL RESEARCH: HOW DOES IT WORK?

Approval of drugs by the Food and Drug Administration provides health plans with some guidance to determine when a drug or medical device is no longer experimental, but there are no national guidelines or approval processes for procedures and other types of treatments.²⁴

18. *Rollo v. Blue Cross/ Blue Shield*, No. CIV.A.90-597, 1990 WL 312647, at *7 (D.N.J. Mar. 22, 1990).

19. Ader, *supra* note 6.

20. *Id.*

21. *Id.*

22. Jennifer Belk, *Undefined Experimental Treatment Exclusions in Health Insurance Contracts: A Proposal for Judicial Response*, 66 Wash. L. Rev. 809, 809 (1991).

23. *Boland v. King County Med. Blue Shield*, 798 F. Supp. 638, 641 (W.D. Wash. 1992).

24. Letter from Sarah F. Jaggard, Director, Health Financing and Public Health Issues, United States General Accounting office, to the Honorable Ron Wyden, United States Senate

There is no equivalent governmental body that systematically screens medical procedures, including new uses for FDA approved drugs, for safety and efficacy.²⁵ As a result, these procedures and other treatments can be widely used while still being labeled experimental by health plans.²⁶

A. *Approval of Medical Treatments or Procedures*

The American Medical Association has established the Diagnostic and Therapeutic Technology Assessment ("DATTA") program²⁷ while the American College of Physicians ("ACP") similarly reviews procedures through its Clinical Efficacy Assessment Project ("CEAP").²⁸

For example, the DATTA program consists of a five point rating scale where procedures or treatment modalities are ranked between "promising" and "doubtful."²⁹ Those procedures deemed "investigational" appear in the middle of this scale.³⁰

The DATTA program defines an experimental procedure as follows: "There is no consensus on the (a) safety or (b) effectiveness of this technology to date, there is insufficient evidence to determine its appropriateness, or it warrants further study; use of this technology for the given indication in the specified patient population should be confined largely to research protocols."³¹

B. *Clinical Trials*

Clinical trials are conducted to test the effectiveness of new treatments involving new drugs or combinations of existing drugs. Such trials are considered the "gold standard" for judging whether or not these new therapies are better than existing ones.³² The trials are divided into four phases in which each phase is designed to obtain specific types of information.

(Apr. 24, 1996), reprinted in General Accounting Office, *Health Insurance: Coverage of Autologous Bone Marrow Transplantation for Breast Cancer* 1, 12-15 (1996).

25. Cowan, *Innovative Therapy Versus Experimentation*, 21 Tort & Ins. L.J. 619, 626 (1986).

26. *Id.*

27. American Medical Association, *Technology Assessment in Medicine* (visited October 27, 1999) <<http://www.ama-assn.org>>.

28. *White v. Caterpillar, Inc.*, 765 F. Supp. 1418, 1420 (W.D. Mo. 1991).

29. American Medical Association, *Technology Assessment in Medicine* (visited Oct. 27, 1999) <<http://www.ama-assn.org>>.

30. *Id.*

31. *Id.*

32. National Cancer Institute of the National Institutes of Health, *Understanding Trials – An Introduction to Clinical Trials*, (visited Mar. 20, 2000) <<http://cancertrials.nci.nih.gov/understanding/basics/index.html>>.

In Phase I of clinical trials for cancer treatments, a new treatment is given to a small number of patients, usually 20-80.³³ The purpose of a Phase I study is to find the best way to administer a new treatment and how much of it can be given safely.³⁴ Physicians watch patients carefully for any harmful side effects. The research treatment has been well tested in laboratory and animal studies, but the side effects in patients are not completely predictable.³⁵ Phase I studies may involve significant risks such that Phase I cancer trials are offered only to patients whose cancer has spread and who would not be helped by other known treatments.³⁶

Phase II studies determine the effect of a research treatment on various types of diseases, such as cancer.³⁷ Usually groups of 30 to 40 patients with one type of cancer or a particular severity of disease receive Phase II treatment.³⁸ For example, patients with breast cancer that has become resistant to standard therapy may be treated with Phase II treatment. Patients are closely observed for anticancer activity from the beginning of the trial. If their cancer sites shrink appreciably, the patients are said to have “responded” to the treatment. If at least one-fifth of the patients in the Phase II trial respond to treatment, the treatment is judged active against that tumor type.³⁹ In addition to monitoring patients for response, physicians carefully record and access any side effects.⁴⁰ Since larger numbers of patients receive the treatment in Phase II trials than in Phase I trials, there is a greater chance to observe less common side effects.⁴¹

Phase III trials require entry of large numbers of patients; some trials enroll thousands of patients. One of the groups may receive the standard, or most accepted treatment, so that new treatments can be directly compared to it.⁴² The group that receives the standard treatment is called the “control” group. For example, the control group may receive the standard chemotherapy for breast cancer, while another patient group will receive the new chemotherapeutic agent or combination of existing agents in order to determine if this new drug or combination of drugs improves survival.⁴³ All patients in Phase III

33. *Id.*

34. *Id.*

35. *Id.*

36. *Id.*

37. *Id.*

38. *Id.*

39. *Id.*

40. *Id.*

41. *Id.*

42. *Id.*

43. *Id.*

trials are closely monitored for side effects, and treatment will be discontinued if the side effects are too severe.⁴⁴

After successfully completing Phase III of the clinical trials, the data is reviewed and if appropriate, the drug is approved for use.⁴⁵ During Phase IV, the newly approved drug is evaluated through post-market-ing surveillance to ensure that it continues to be safe and to monitor side effects that may not have been evident during the clinical trials.⁴⁶ If problems become apparent, the drug is recalled.

PART III. HIGH DOSE CHEMOTHERAPY AND AUTOLOGOUS BONE MARROW TRANSPLANT IN PATIENTS WITH METASTATIC BREAST CANCER: A CASE STUDY

The dilemma began in the Eighties when a new procedure was being investigated for use in the treatment of patients with metastatic breast cancer. This treatment was called high dose chemotherapy with autologous bone marrow transplant, or HDC/ABMT. The proposal was to increase the dosage of the regular chemotherapeutic regimen beyond levels that had failed to arrest the previous development of the breast cancer. These levels destroyed the bone marrow within the body and thus, the patients required bone marrow transplants to revive this critical body system. The effectiveness of this procedure was widely debated as discussed below. It was this debate and the intense litigation in the matter that increased the division between providers and third-party payers, while providing many judicial interventions in the exclusion of experimental or investigational procedures.

In the paragraphs that follow, some of the important judicial decisions are discussed in an effort to illustrate some of the many ways in which a health plan can attempt to protect the plan assets and thus, the plan participants from the burden of cost-shifting associated with medical research. This case history focuses on the language of the health plan and the subsequent court's interpretation of that language.

One of the first cases to seek a court's intervention to force payment for HDC/ABMT was *Thomas v. Gulf Health Plan, Inc.*⁴⁷ Thomas sued when the ERISA plan, Gulf Health, denied coverage for HDC/ABMT for the treatment of breast cancer. Gulf Health based its denial upon language in the plan document that stated:

No benefits shall be provided under [sections describing the covered services of this plan] with respect to the following, whether or not recommended or prescribed by a physician.

44. *Id.*

45. *Id.*

46. *Id.*

47. *Thomas v. Gulf Health Plan, Inc.*, 688 F. Supp. 590 (S.D. Ala. 1988).

...
10. Any treatment or procedure, medical or surgical, or any facilities, drugs, drug usage, equipment, or supplies which are Experimental or Investigative.⁴⁸

The plan document also provided that “[t]o be Medically Necessary, the services and supplies furnished must (as determined by the Administrator) . . . not be Experimental or Investigative.”⁴⁹

At trial, Dr. Patrick Earl Ryce, Vice-President and Medical Director of Blue Cross, testified that in February of 1988 the medical review committee of Blue Cross recommended that based upon its study of the matter, HDC/ABMT should no longer be classified as experimental or investigative in connection with certain stages of Hodgkin’s disease, neuroblastoma, acute lymphocytic leukemia, and acute non-lymphocytic leukemia.⁵⁰ When Thomas was admitted to Vanderbilt Medical Center it was disclosed to her that HDC/ABMT for the treatment of breast cancer was still considered “investigatory.”⁵¹ She signed a consent form containing this disclosure.⁵² The treating physician at Vanderbilt noted in a letter to Thomas’ primary physician that he recommended that Thomas proceed with “an experimental treatment” such as HDC/ABMT.⁵³

The court noted that ERISA governed because it involved claims for benefits under the health plan.⁵⁴ The court emphasized that the standard for review of claims denials under ERISA plans was well settled such that the plan administrator’s decision to deny benefits must be upheld unless the decision was arbitrary and capricious.⁵⁵ The court stated that its role was limited to a determination of whether the administrator’s interpretation “was made rationally and in good faith—not whether it was right.”⁵⁶

The court found that the plan’s decision was neither arbitrary nor capricious in light of the evidence offered regarding the experimental nature of the treatment and the plan’s express exclusion of experimental procedures.⁵⁷ Further, it held that the administrator would not be fulfilling his fiduciary duty to expand the terms of coverage pro-

48. *Id.* n.2.

49. *Id.* (alterations in original).

50. *Id.* n.3.

51. *Id.* at 593.

52. *Id.*

53. *Id.* n.4.

54. *Id.* at 595.

55. *Id.*

56. *Id.* (citing *Anderson v. Ciba-Geigy Corp.*, 759 F.2d 1518 (11th Cir.), *cert. denied*, 474 U.S. 995 (1985) (quoting *Griffis v. Delta Family-Care Disability*, 723 F.2d 822, 825 (11th Cir.), *cert. denied*, 467 U.S. 1242 (1984)).

57. *Id.*

vided by the plan.⁵⁸ The court agreed that the decision to enforce the terms of the plan and to deny coverage for the experimental treatment proposed to Thomas was rational and supported by the evidence before him.⁵⁹ As a result, the decision to deny coverage was upheld.⁶⁰

A similar decision was reached in the 1989 case of *Sweeney v. Gerber Products Co. Med. Benefits Plan*.⁶¹ Sweeney's physician proposed HDC/ABMT as a treatment for her breast cancer. In its findings of fact, the court noted that Sweeney's claim was denied based upon the plan provision:

The Medical Expense Benefit Does Not Cover:

...

4. Unnecessary service and supplies, including tests and check-up examinations, that are not needed for medical care of a diagnosed sickness or injury. To be "needed," a service or supply must be (a) ordered by a doctor, (b) commonly and customarily recognized throughout the doctor's profession as appropriate in the treatment or diagnosis of the sickness or injury, (c) neither educational or experimental in nature, (investigational procedures are considered experimental), and (d) neither furnished mainly for the purpose of medical nor other research⁶²

Prudential, as administrator and named fiduciary, denied the claim on the grounds that the proposed treatment was not commonly and customarily recognized throughout the doctor's profession as appropriate and that the treatment was considered educational, experimental, or investigational in nature.⁶³ In its denial, Prudential examined Sweeney's medical history, the specific treatment protocol proposed for her, the status of its viability in the current medical literature, and the opinions of three outside consultants/oncologists.⁶⁴

As a finding of fact, the court noted that HDC/ABMT for breast cancer was in the early stages of development and was at most undergoing efficacy testing in Phase II clinical trials.⁶⁵ The court found that the current medical literature supported the conclusion that the treatment was "investigational" and "experimental" and had not been "commonly and customarily" recognized throughout the medical profession as appropriate in the treatment of metastatic breast cancer.⁶⁶ It emphasized that the physician's own consent forms were replete

58. *Id.* at 596.

59. *Id.*

60. *Id.*

61. *Sweeney v. Gerber Prod. Co. Med. Benefits Plan*, 728 F. Supp. 594 (D. Neb. 1989).

62. *Id.* at 595.

63. *Id.* at 596.

64. *Id.*

65. *Id.*

66. *Id.*

with such terms as “study,” “research,” “investigation,” and “experiment.”⁶⁷

The court concluded that the Gerber Products Co. Medical Benefits Plan was an employee welfare benefit plan as defined by ERISA.⁶⁸ It noted that the Administrative Services Agreement between the plan and Prudential provided that Gerber Products Company retained “all final authority and responsibility for the Plan and its operation” and that Prudential was authorized to act on its behalf.⁶⁹ Further, this agreement specified that Gerber Products Company and Prudential mutually agreed that for purposes of ERISA, “Prudential shall be the ‘appropriate named fiduciary’ of the Plan for the purpose of such review [of claims] and decision thereon” and “Prudential’s decision on any claim shall be final.”⁷⁰ Thus, the court concluded that the decision to deny benefits in the case would be upheld unless it was deemed arbitrary and capricious.⁷¹

The court held that the decision to deny benefits in this case was based upon a reasonable interpretation of the plan provisions.⁷² It also held that this decision was made in good faith following a detailed investigation of the factual background of the claim and the proposed treatment.⁷³ The court concluded that the decision to deny benefits for HDC/ABMT was not arbitrary and capricious and upheld that decision.⁷⁴

The atmosphere began to change in 1991 with the case of *Bucci v. Blue Cross-Blue Shield of Connecticut, Inc.*⁷⁵ Bucci’s physicians recommended that she be given HDC/ABMT because all other forms of treatment had failed. Blue Cross denied the treatment on the policy provision that “[defendant] will not pay for services . . . which are experimental or investigational in nature; meaning any treatment, procedure . . . drugs, drug usage . . . not recognized as accepted medical practice or not recognized by us”⁷⁶ Because of Bucci’s advanced medical condition, the matter was expedited before further deterioration occurred.⁷⁷

67. *Id.*

68. *Id.*

69. *Id.*

70. *Id.*

71. *Id.* (citing *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101 (1989) (the hallmark case for ERISA plans in which the Supreme Court established the standard of review for claims denials)).

72. *Id.*

73. *Id.*

74. *Id.* at 597.

75. *Bucci v. Blue Cross-Blue Shield of Conn., Inc.*, 764 F. Supp. 728 (D. Conn. 1991).

76. *Id.* at 729 (alteration in original).

77. *Id.*

Bucci presented evidence that tended to show that HDC/ABMT was more effective than lower dose chemotherapy.⁷⁸ The evidence varied regarding its effectiveness, but the court noted that conclusive improvement was not controlling, since the question was one of the acceptance of the treatment modality.⁷⁹ Bucci's experts stated that while the advantages of HDC/ABMT were not established by an overwhelming number of cases in which the treatment was tested, there was sufficient experience to support their opinion of the medical efficacy of the treatment.⁸⁰

Blue Cross argued that experience with HDC/ABMT was too limited to permit a meaningful assessment of its efficacy.⁸¹ It noted the care it took to evaluate procedures for payment by highly qualified committees, whose judgments were accepted for payment purposes.⁸² In fact, Blue Cross had applied its five-factor Technical Evaluation Criteria ("TEC") in this case. The criteria were (1) government regulatory approval; (2) evidence which permits conclusions as to the effect on patient health; (3) demonstrated improvement of the patient's health; (4) demonstration of medical benefit at least equal to that offered by established alternative treatment; and, (5) improvement other than in investigational settings.⁸³ Blue Cross had used these criteria to determine that HDC/ABMT was an accepted treatment modality for several other forms of cancer.⁸⁴

Reviewing the case under the arbitrary and capricious standard, the court held that Blue Cross' decision was arbitrary and capricious and that the claim should be paid.⁸⁵ The court stated that Blue Cross was made aware that thirty-eight health insurers had committed to the University of Nebraska, while thirty-two insurers had committed to Duke University to provide coverage for HDC/ABMT.⁸⁶ The court found that while the insuring language and the treatment regimens were not precisely the same as in this case, the issue was sufficiently likely to have been comparable to oblige Blue Cross to inquire of these insurers regarding their determination to provide coverage.⁸⁷ The court stated that Blue Cross' failure to inquire suggests an arbitrary and capricious denial which is made without all reasonably rele-

78. *Id.* at 730.

79. *Id.* at 731.

80. *Id.*

81. *Id.*

82. *Id.*

83. *Id.*

84. *Id.*

85. *Id.*

86. *Id.*

87. *Id.*

vant inquiries.⁸⁸ It stated further that the body of medical acceptance that prompted these insurers to cover the treatment, regardless of the criteria applied, was deemed likely to have been relevant to whether there was substantiation for Bucci's treatment being considered experimental or not experimental.⁸⁹

The court then stated that Blue Cross' reliance on TEC was not valid.⁹⁰ First, government approval was not applicable except as to the drugs, and these drugs had been approved.⁹¹ Second, the court rejected factors two, three, and four stating that they were purely subjective and reflected the essence of Blue Cross' position, that in the absence of a sufficient body of evidence demonstrating the effectiveness of the procedure in providing substantial medical benefit to patients, it was proper to find the procedure not recognized as accepted medical practice.⁹² The court stated that the policy set no standard by which the acceptance was to be measured and thus was invalid.⁹³ It stated that if the standard used was to be regarded as anything other than arbitrary and capricious, then finding that a procedure failed to constitute accepted medical practice could only exist where there was no reasonably substantial, qualified, responsible, relevant segment of the medical community that accepts it as properly within the range of appropriate medical treatment as judged by the standards of the medical community.⁹⁴

The court stated that under Blue Cross' theory any number its experts selected, without any obligation to justify the minimum number required, could result in denial of benefits with impunity.⁹⁵ It emphasized that Blue Cross was attempting to deny the procedure as unacceptable when measured against a standard which was neither defined in the plan nor justified under ERISA.⁹⁶ The court stated that this standard was a "floating standard" that could rise and fall in any fact situation.⁹⁷ The court held that the standard was arbitrary and capricious, and stated that this holding was further substantiated by the fact that the denial avoided a direct expense to Blue Cross rather than an allocation of committed funds and by the "firm, reasonable and logical

88. *Id.* at 732.

89. *Id.*

90. *Id.*

91. *Id.*

92. *Id.*

93. *Id.*

94. *Id.*

95. *Id.* at 733.

96. *Id.*

97. *Id.*

testimony of [Bucci's] two well-qualified oncologists."⁹⁸ As a result, the court ordered that Blue Cross pay for the procedure.

Later that same year, the court in *White v. Caterpillar, Inc.*⁹⁹ reached a similar result. White sued after the self-funded plan denied coverage for ABMT. White was diagnosed with breast cancer. All other forms of treatment failed to arrest the disease. White's physician stated in his affidavit that White had no chance of survival without HDC/ABMT and that with conventional treatment the disease would continue to progress to her death.¹⁰⁰ When White's health plan denied coverage, she filed suit.

White's employer-sponsored health plan qualified as an employee welfare benefit plan under ERISA.¹⁰¹ The Plan provided:

If an Employee or Dependent undergoes a procedure that is not listed in the schedule [of surgical operations] above, the Insurance Carrier or Company shall have the sole and exclusive right to determine whether or not such procedure is a generally accepted surgical operation. The Company or Insurance Carrier will use the reports of the Clinical Efficacy Assessment Project of the American College of Physicians and the Diagnostic and Therapeutic Assessment from the Council on Scientific Affairs of the American Medical Association as a guide to determine whether a surgical procedure is a generally accepted surgical operation.¹⁰²

The Plan contended that based upon this language the denial was proper because the treatment was "investigational" and not a generally accepted surgical operation covered under the Plan.¹⁰³ Since the Plan gave discretion to the administrator to make eligibility determinations, the court applied the arbitrary and capricious standard dictated by *Firestone Tire & Rubber Co. v. Bruch*.¹⁰⁴

Both parties agreed that the Clinical Efficacy Assessment Project ("CEAP") did not address the efficacy of HDC/ABMT in the treatment of breast cancer.¹⁰⁵ Thus, the court turned to the opinion of DATTA on the issue. A 1985 DATTA report concluded that ABMT was a safe and effective means of treating the side effects of HDC, but that it was "still investigational" in the treatment of solid tumors, such as breast cancer.¹⁰⁶ In a 1990 DATTA report that addressed cancer in general rather than solid tumors specifically, the panelists found that

98. *Id.*

99. *White v. Caterpillar, Inc.*, 765 F. Supp. 1418 (W.D. Mo. 1991).

100. *Id.* at 1419.

101. *Id.* at 1419-20.

102. *Id.* at 1420.

103. *Id.* citing *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101 (1989).

104. *Id.*

105. *Id.*

106. *Id.* at 1421.

ABMT was appropriate for the management of post-treatment marrow complications in patients undergoing treatment for cancer.¹⁰⁷ The majority of panelists rated the safety and effectiveness of ABMT as established or promising.¹⁰⁸

The plan argued that this second report did not specifically revise the earlier report with respect to the efficacy of HDC/ABMT on solid tumors. It contended that those earlier findings were still accurate because the second report focused on the efficacy of ABMT as a supportive treatment for the side effects of HDC and did not specifically revise the findings of the 1985 report.¹⁰⁹

White argued that the 1985 report was dated, and her expert witness testified at the hearing that HDC/ABMT was widely recognized and used for the treatment of breast cancer in certain patient populations, including White.¹¹⁰ Her expert also testified that a 1991 study published in the *Journal of Clinical Oncology* reported that eighty percent of the clinical oncologists polled believed that HDC/ABMT was a reasonable therapy.¹¹¹ He added that a physician would be medically negligent not to offer the treatment to an appropriate patient.¹¹²

The court emphasized that in an environment of rapidly changing medical expertise, the plan steadfastly relied on the results of a study that was over five years old.¹¹³ It noted that prior to the hearing, White provided the plan with copies of four recent articles addressing HDC/ABMT.¹¹⁴ According to the testimony of the medical director for the plan, no one there ever read the articles.¹¹⁵ Instead, the plan relied upon the two sources enumerated in the plan document rather than the other sources provided by White.¹¹⁶

The court disagreed with the plan's reliance stating that the plan's recognition of the two sources was not exhaustive.¹¹⁷ It added that the plan stated that these sources would be used as a "guide" to determine whether a surgical procedure was generally accepted.¹¹⁸ The court stated that nowhere did the plan state that it may use "only" the reports listed in making its coverage decisions.¹¹⁹ It continued that

107. *Id.*

108. *Id.*

109. *Id.*

110. *Id.*

111. *Id.* n.4.

112. *Id.*

113. *Id.* at 1420.

114. *Id.* at 1422.

115. *Id.*

116. *Id.*

117. *Id.*

118. *Id.*

119. *Id.*

this language clearly did not instruct the plan to abdicate all responsibility in the decision process to these reports, especially where one report never addressed the issue while the other report was over five years old.¹²⁰

The court was especially troubled that the plan continued to refuse coverage even after receiving the affidavit of Dr. Elizabeth Brown, the Director of the agency that administered the DATTA studies.¹²¹ In her affidavit, Dr. Brown stated her agency did not “list [ABMT] in conjunction with [HDC] for the treatment of breast cancer as ‘investigational.’”¹²² She also stated that DATTA had not investigated nor published any materials on the efficacy of ABMT in conjunction with HDC for the treatment of breast cancer specifically.¹²³ As a result, the court held that the plan’s decision to deny coverage was arbitrary and capricious and enjoined the plan from denying coverage to White for HDC/ABMT.¹²⁴

In 1992, this trend of coverage for HDC/ABMT was challenged in the case of *Holder v. Prudential Ins. Co.*¹²⁵ Holder’s physicians recommended HDC/ABMT for treatment of her advanced breast cancer. She signed a consent form for treatment and later died of complications.¹²⁶ When Prudential denied coverage for high dose chemotherapy with ABMT, Holder’s estate filed the action.

The consent form signed by Holder stated:

This is an *experimental study* which uses high doses of [chemotherapeutic agents] in the treatment, combined with bone marrow transplantation. The use of higher-than-normal doses of chemotherapy carries with it a greater risk of complications to both the blood-forming cells of the body (the marrow) and other organs. Therefore, the purposes of this *study* are: 1) to find if such a combination is associated with acceptable toxicity to organs other than the bone marrow when used with the infusion of autologous marrow; and 2) to determine if, at these high doses, there is a significant responses rate.¹²⁷

Based upon the terms “experimental” and “study,” the plan denied coverage for the procedure based upon the policy’s exclusion for experimental treatment.¹²⁸ Specifically, the policy for the plan provided that it did not cover:

120. *Id.*

121. *Id.*

122. *Id.*

123. *Id.* at 1423.

124. *Id.*

125. *Holder v. Prudential Ins. Co.*, 951 F.2d 89 (5th Cir. 1992).

126. *Id.* at 90.

127. *Id.* (emphasis added).

128. *Id.*

Non-essentials, check-ups—Anything not ordered by a doctor or not reasonably necessary for medical care of sickness or injury. To be “reasonably necessary,” a service or supply must be ordered by a doctor and be commonly and customarily recognized throughout the doctor’s profession as appropriate in the treatment of the diagnosed sickness or injury. It must neither be educational or experimental in nature, nor provided [sic].¹²⁹

The opinions of the experts were contradictory regarding the experimental nature of this treatment.¹³⁰ Clinical studies showed that the treatment was still being investigated at the time of Holder’s treatment.¹³¹ Most importantly, the court found the testimony of Dr. Fehir, the plan’s expert witness, to be “most compelling” and “most credible.”¹³² Based upon this testimony and the consent form describing the treatment as an “experimental study,” the court upheld the plan’s denial of coverage for the procedure.¹³³

Today, the coverage issues surrounding this procedure are fairly well resolved, but there are still mixed feelings. Most plans have begun to accept liability for the procedure in view of the mixed legal decisions and the lack of “protective” language which can be constructed in the plan.¹³⁴ The effectiveness of the procedure continues to be questioned. A review in 1995 of the medical literature conducted by ECRI, a non-profit technology assessment and health service firm, indicates that high dose chemotherapy and ABMT are no more effective against breast cancer than conventional forms of chemotherapy.¹³⁵ The review also concluded that women with stage IV breast cancer who undergo this costly and difficult experimental procedure have poor outcomes and die sooner than those who receive standard regimens of chemotherapy.¹³⁶ ECRI cautioned that its findings were based solely upon a snapshot of the then current state of medical technology.¹³⁷

129. *Id.* n.3.

130. *Id.* at 90.

131. *Id.*

132. *Id.* at 90-91.

133. *Id.* at 91.

134. William Giese, M.D., *Adjudication of Third Party Payment for High Dose Chemotherapy & Bone Marrow Rescue in the Treatment of Breast Cancer*, 1 DePaul J. Health Care L. 205 (1996).

135. Joan Stephenson, *Medical Technology Watchdog Plays Unique Role in Quality Assessment: ECRI*, 274 JAMA 999, 999 (1995).

136. *Id.*

137. *Id.*

PART IV. REDEFINING THE EXCLUSIONARY CLAUSE IN THE ERISA HEALTH PLAN

What does this mean? How can an ERISA health plan protect itself from the financial, ethical, and emotional struggles that surround “experimental or investigational” treatments such as HDC/ABMT? There are no guarantees, quick fixes, or perfect solutions. This section makes recommendations that are meant to assist ERISA health plan sponsors and plan administrators with the process of research and with the formulation of plan language that may help protect the plan’s assets and thus, the benefits to all plan participants.

A. Generally

First, the best language for the plan will be that which is as specific as possible and excludes any procedures the plan sponsor or plan administrator believes contains “gray” areas.¹³⁸ The plan should include a laundry list of specific exclusions for all services that are deemed to be unsafe, unnecessary, or uninsurable.¹³⁹ However, this list is only a partial solution because of the practical problem of including all materially relevant coverage terms in each summary of the policy.¹⁴⁰ In addition, it may be possible to draft a list that clearly identifies unwarranted procedures or specific applications of useful procedures in unwarranted cases, but such a list cannot be drafted with sufficient detail to cover all the permutations that could possibly occur.¹⁴¹

Second, this language should be stated in both the plan document and the summary plan description (“SPD”) for the ERISA plan. In cases where the SPD incorporated by reference the language in the plan document, courts have rejected outright such incorporation by reference and required that the language must be in the hands of the individual plan participants.¹⁴²

Third, the language should state specific guidelines that will be followed. Blue Cross has been criticized by the courts for failure to incorporate its Technology Evaluation Criteria into its contracts.¹⁴³ While it may not be feasible to specify a threshold after which a treat-

138. See Lee N. Newcomer, *Defining Experimental Therapy – A Third-Party Payer’s Dilemma*, 323 New Eng. J. Med. 1702 (1990).

139. *Id.*

140. *Id.*

141. Grace P. Monaco & Rebecca L. Burke, *Insurer as Gatekeeper-Part Two: Policy Obstacles in Unproven Methods of Litigation*, 20 Forum 400, 402 n.7 (1983).

142. See *Brown v. Blue Cross & Blue Shield, Inc.*, 898 F.2d 1556, 1570 n.16 (11th Cir. 1990); *Van Vactor v. Blue Cross Ass’n*, 365 N.E.2d 638, 644 (Ill. App. Ct. 1977).

143. See *Pirozzi v. Blue Cross-Blue Shield*, 741 F. Supp. 586, 591 (E.D. Va. 1990) (finding Blue Cross’ reliance on its Technology Evaluation Criteria unpersuasive in part because the criteria were not a part of the Plan and because the Plan did not state that the criteria were determinative of a treatment’s experimental status); *Bucci v. Blue Cross-Blue Shield of Conn.*,

ment will be deemed appropriate in all circumstances, the plan can specify the quality of evidence that will be necessary to satisfy the standard for coverage.¹⁴⁴

Fourth, regardless of the precision in which these criteria are drafted, they may ultimately be subjected to judicial interpretation. Therefore, it is imperative that the plan expressly provide that the plan administrator reserves the final right to make decisions regarding coverage. To do so may ensure that where the courts review the decision, they must do so using the arbitrary and capricious standard rather than the *de novo* standard.¹⁴⁵

When courts apply the arbitrary and capricious standard, great deference is given to the plan administrator's decision. This deference is based upon the rationale that the plan trustees are better positioned to apply and to interpret their plans as well as to balance the interests of the plan beneficiaries.¹⁴⁶ The plan administrator's decision will be upheld unless it is determined to have been arbitrary and capricious, which usually results where there is evidence the fiduciary lacked good faith or acted in direct conflict with express language in the plan.¹⁴⁷

Without express language naming the plan administrator, the courts will use the *de novo* standard. First, this removes the deference given by the courts to the plan administrator as a fiduciary and allows the court to determine the interpretation of the plan that most accurately reflects the intentions of all parties to the agreement.¹⁴⁸ More importantly, the court is not limited to the evidence available to the plan administrator at the time of the decision or the information required to make a good faith decision.¹⁴⁹ As a result, this standard of review allows the court much broader freedom and should be avoided.

Fifth, the plan should utilize independent sources to review its decisions to determine whether the treatment should be denied as experimental. While the case law under ERISA does not prohibit a decision on appeal by those with some conflict of interest, the mere existence of a conflict is a factor that is to be considered even under the arbitrary and capricious standard.¹⁵⁰ The courts have employed a variety of methods to deal with this conflict. Some have decreased the defer-

Inc., 764 F. Supp. 728, 733 (D. Conn. 1991) (finding Blue Cross' denial of benefits inappropriate because it was based upon criteria that were not defined in the Plan).

144. Newcomer, *supra* note 138, at 1702.

145. See *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 112 (1989).

146. *Id.* at 102.

147. See *Dennard v. Richards Group, Inc.*, 681 F.2d 306, 314 (5th Cir. 1982).

148. *Firestone*, 489 U.S. at 112.

149. *Id.*

150. *Id.*

ence given the fiduciary in proportion to the seriousness of the conflict.¹⁵¹ Others have refused to forego the deference until serious unfairness is shown.¹⁵²

Finally, the plan should specify the organizations whose medical technology assessment decisions it will follow.¹⁵³ There are various private and governmental agencies that provide various levels of assessment and evaluation.¹⁵⁴ However, the plan administrator should not rely solely on the expressly stated sources and refuse to review additional information if provided by the participant. Such action has been deemed to be arbitrary and capricious.¹⁵⁵

B. *Updating the Typical Plan's Definition*

This section will demonstrate how these recommendations can effectively update the typical "experimental or investigational" exclusion language of an ERISA health plan so that it is consistent with those lessons learned from the HDC/ABMT cases. The typical ERISA health plan will include a definition of medical necessity and/or experimental or investigational that contains the elements:

The term *Medical Necessity* means services or supplies provided by a hospital, physician, or other provider not excluded under this Plan, which are provided to treat or diagnose a sickness or injury, and which as determined by the Plan Administrator, are:

1. Ordered by a physician and consistent with the symptoms or diagnosis and treatment of the sickness or injury.
2. Not primarily for the convenience of the covered person, physician or other provider.
3. Most appropriate standard or level of services which accord with good medical practice and can be safely provided to the covered person.
4. Not of an experimental or educational nature.
5. Not involving unnecessary or repeated tests
6. Commonly and customarily recognized by the medical profession as appropriate in the treatment or diagnosis of the diagnosed condition.

NOTE: The fact that a physician may prescribe, recommend, order or approve a service or supply does not, of itself, determine medical necessity.¹⁵⁶

151. Doe v. Group Hospitalization, 3 F.3d 80, 87 (4th Cir. 1993).

152. Atwood v. Newmont Gold Co., 45 F.3d 1317, 1323 (9th Cir. 1994).

153. Monaco & Burke, *supra* note 141, at 409.

154. *Resources Supply Technology Information*, Hospitals, Aug. 5, 1989, at 42.

155. White v. Caterpillar, Inc., 765 F. Supp. 1418, 1422 (W.D. Mo. 1991).

156. 2 Carlton Harker, TPA Guide to the Benefit Administration of Self-Funded Health Care Plans § A (1995).

To update this language according to the recommendations of the preceding section, the following additions would be necessary:¹⁵⁷

The term *Medical Necessity* means services or supplies provided by a hospital, physician, or other provider not excluded under this Plan, which are provided to treat or diagnose a sickness or injury, and which are determined by the Plan Administrator, *[where the Plan Administrator is then expressly named]* to meet the following criteria:

1. Ordered by a physician and consistent with the symptoms or diagnosis and treatment of the sickness or injury.
 2. Not primarily for the convenience of the covered person, physician or other provider.
 3. Most appropriate standard or level of services which accord with good medical practice and can be safely provided to the covered person.
 4. Not of an experimental or educational nature. *Experimental for the purposes of medical necessity, is defined as those treatments, services, or supplies that are:*
 - (1) *A part of a research project, protocol, or study*
 - (2) *A part of any phase of a clinical trial of the FDA, NCI, or other body*
 - (3) *Not supported by current medical literature to be commonly accepted as a routine treatment for the indicated diagnosis*
 5. Not involving unnecessary or repeated tests
 6. Commonly and customarily recognized by the medical profession as appropriate in the treatment or diagnosis of the sickness or injury
- NOTE: *The Plan Administrator, [again expressly named], reserves the full and final discretion regarding determinations of coverage under this Plan.* The fact that a physician may prescribe, recommend, order or approve a service or supply does not, of itself, determine medical necessity.

As further protection, the plan should then incorporate a list of those procedures that are excluded from coverage because they are currently questionable or involved in "heated" medical/legal debate. The plan should also expressly state those agencies or bodies whose technology assessment reports will be used to determine coverage as well as those independent review organizations that will be utilized when denials of coverage are appealed.

CONCLUSION

Managing access to new medical technologies is critical for three reasons.¹⁵⁸ First, it is critical to managing the delivery of quality medical care and ensuring patient safety.¹⁵⁹ Second, it is critical to society's

157. Additions to the model language are presented in italics for emphasis.

158. Ader, *supra* note 6, at 188.

159. *Id.*

ability to deliver a quality health care benefit within the budget of those premiums collected.¹⁶⁰ Finally, it is critical to managing the legal risks of the failure to describe the benefits accurately and to deliver them efficiently.¹⁶¹ ERISA allows employee health plans the freedom of benefit design and the protection from state variances in coverage provisions. This allows employers to curb costs and to reasonably predict their exposure to legal risks because of the limited jurisdiction in which suits may be brought. However, the HDC/ABMT cases illustrate the complexities involved when trying to curb costs at the expense of new technology.

While the HDC/ABMT cases have been basically resolved, the underlying issues are still present. The recommendations presented here are offered to assist ERISA plans in their drafting more precise language to address these issues. While the recommendations are not perfect solutions, they are valuable guides to redefining "experimental or investigational" exclusions.

Why is this so important? Panelists at a Washington, D.C. managed care symposium voiced concerns that ERISA was outdated with the current health care delivery system.¹⁶² One panelist stated that ERISA needs to be "beefed up" in the area of disclosure so that individuals know the criteria used to determine whether a procedure will be excluded as "experimental or investigatory."¹⁶³ The panelist added that ERISA needs a meaningful and fair process for resolving claims and coverage issues.¹⁶⁴ The recommendations made above already reflect these concerns and attempt to increase disclosure as well as inform the plan participants of the processes that will be followed in making such determinations.

More importantly, on July 29, 1999, CNN reported that researchers have successfully developed specialized cells from stem cells and transplanted them into the nervous systems of rats to fight disease.¹⁶⁵ In a report published in *Science* magazine on July 30, 1999, scientists manipulated stem cell into neural cells and injected them into rats whose nervous systems were afflicted with a disease similar to the human disease, Multiple Sclerosis.¹⁶⁶ The cells repaired the damage to the nervous system, but did not cure the disease.¹⁶⁷ With millions

160. *Id.*

161. *Id.*

162. *Managed Care: In Discussion of ERISA, Panelists Mull Federal Versus State Regulation*, BNA Pension & Benefits Daily News, April 7, 1999, at 3.

163. *Id.*

164. *Id.*

165. *Stem Cells Show Promise in Treating Neurological Diseases* (visited October 26, 1999) <<http://www.cnn.com/HEALTH/9907/29/stem.cell.advance/index.html>>.

166. *Id.*

167. *Id.*

of Americans suffering from nervous tissue disorders, this procedure could bring hope to all of them. In another report by CNN, the United States government has announced that it will begin partially financing this research.¹⁶⁸ The question then becomes who will pay for that part not financed by the government? As in the case of HDC/ABMT, ERISA health plans will certainly be asked to pay for these procedures. This debate is not over, and ERISA health plans must take action now to update their plan documents.

168. *U.S. Government to Fund Controversial Stem Cell Research* (visited Oct. 26, 1999) <<http://www.cnn.com/HEALTH/9901/19/stem.cell.research/index.html>>.