WHO SHOULD PAY FOR "EXPERIMENTAL" TREATMENTS? BREAST CANCER PATIENTS v. THEIR INSURERS

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* Editor-in-Chief *The American University Law Review*, Volume 45; J.D., *The American University, Washington College of Law*. B.A., *University of Pennsylvania*. This Comment is dedicated to my mother, Ruth Wolf, who has always inspired me to persevere.

I wish to extend warm thanks to both my father, Howard Wolf, and my sister, Dagny Canard, for their unlimited and unconditional support. I especially want to acknowledge with gratitude Corinne E. Karlin, who has a natural ability to move mountains with her pen, and Andrew Rice and Stephen "Skippy" Weinstein for their assistance. Finally, I am most appreciative to Karen L. Illuzzi Gallinari for her helpful comments on my earlier draft.

> I am involved in a legal battle with Blue Cross and Blue Shield . . . which has denied coverage for my wife's bone marrow transplant for advanced breast cancer. . . . Now, when we need insurance the most, Blue Cross has turned its back on us. Unless the case is settled soon in our favor, I will be forced to sell my house, borrow from friends and relatives, and mortgage my children's future. Blue Cross's position has created a huge financial, emotional and physical burden for my wife, my family and me.

Robert Russo, husband of breast cancer patient, March 1994.[1]

> [Insurers] do not believe that it is appropriate or feasible for them to cover the patient care costs of individuals who are hospitalized for the sole purpose of research . . . .[2]
>
> It is not the role of insurance to finance research.[3]

John Cova, Health Insurance Association of America, 1992 & 1993.

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1. Robert Russo, *I'll Have to Sell the House to Pay for Treatment*, N.Y. TIMES, Apr. 5, 1994, at A26 (letter to editor).

2. John L. Cova, *A Swift Response to a "Modest" Proposal*, 84 J. NAT'L CANCER INST. 744, 744 (1992).

3. Mark Freedman, *When Insurers Refuse to Pay: Experimental Surgical Procedures*, 93 BEST'S REV.—LIFE-HEALTH INS. ED., Apr. 1993, at 38, 39 (quoting John Cova, former director of medical technology assessment for Health Insurance Association of America). Cova asserts that until there is evidence of the safety and clinical effectiveness of therapies, insurers cannot be expected to pay for them. *Id.*

> [T]here is a growing and confusing body of case law that addresses whether [high dose chemotherapy - autologous bone marrow transplants are] experimental procedure[s] for purposes of insurance coverage. The courts that have struggled with the issue have reached different outcomes.

U.S. Circuit Judge Kenneth F. Ripple, writing in *Harris v. Mutual of Omaha Cos.*, 1993.[4]

INTRODUCTION

Every reader of this Comment knows of at least one woman[5] who currently has, or has had, breast cancer.[6] One woman out of nine will develop breast cancer in her lifetime.[7] In 1995, an estimated 46,000 women will die from this devastating disease.[8]

Public awareness of this disease has heightened in recent years, largely due to the relentless efforts of breast cancer patients.[9] Breast cancer support networks[10] and advocacy groups,[11] as well as educa-

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4. 992 F.2d 706, 713 n.4 (7th Cir. 1993).

5. Because breast cancer patients are overwhelmingly female, this Comment will refer to them using feminine gender language. *See* M. MARGARET KEMENY & PAULA DRANOV, REDUCING YOUR HEREDITARY RISK: BREAST CANCER AND OVARIAN CANCER—BEATING THE ODDS 7 (1992) (noting that although about 900 men develop breast cancer annually, vast majority of breast cancer victims are female); U.S. DEP'T OF COMMERCE, STATISTICAL ABSTRACT OF THE UNITED STATES 1994, at 143 tbl. 213 [hereinafter STATISTICAL ABSTRACT] (estimating that 1000 males had breast cancer in 1993).

6. Breast cancer is the most common type of cancer among women in the United States. *See* NATIONAL INSTS. OF HEALTH, NATIONAL CANCER INST., WHAT YOU NEED TO KNOW ABOUT BREAST CANCER, Pub. No. 94-1556, at 1 (1993) [hereinafter WHAT YOU NEED TO KNOW ABOUT BREAST CANCER]. More than 1.6 million women alive in the United States today have been treated for breast cancer. *See* NATIONAL ALLIANCE OF BREAST CANCER ORGS. (NABCO), BREAST CANCER RESOURCE LIST 19 (1994-95 ed.) [hereinafter RESOURCE LIST].

Some well-known women who have publicly acknowledged their breast cancer include Justice Sandra Day O'Connor, Nancy Reagan, Rep. Marilyn Lloyd, Olivia Newton-John, Shirley Temple Black, Julia Child, and Betty Ford. *Id.* "Hardly a person among us has not been touched either directly or indirectly by the occurrence of this virulent disease in themselves, a family member, friend, or loved one." Harris v. Mutual of Omaha Cos., No. 92-1089-C, 1992 WL 421489, at *1 (S.D. Ind. Aug. 26, 1992).

7. *See* Kekis v. Blue Cross & Blue Shield of Utica-Watertown, Inc., 815 F. Supp. 571, 573 n.2 (N.D.N.Y. 1993); KEMENY & DRANOV, *supra* note 5, at 5; *see also* STATISTICAL ABSTRACT, *supra* note 5, at 143 tbl. 213 (estimating 183,000 new cases of breast cancer in 1993); Michael Waldholz, *Feud Brewing Over Breast-Cancer Gene Patent*, WALL ST. J., Oct. 17, 1994, at B1 (mentioning that approximately 185,000 new cases of breast cancer arise each year).

8. AMERICAN CANCER SOC'Y, CANCER FACTS & FIGURES—1995, at 10 (1995); *see also* Melinda Beck et al., *The Politics of Breast Cancer*, NEWSWEEK, Dec. 10, 1990, at 62 (explaining that more than one quarter of 150,000 women diagnosed with breast cancer will die from that disease).

9. *See generally* Beck, *supra* note 8, at 62-65 (describing breast cancer survivors who have spoken out to increase awareness); *see also* Proclamation No. 6739, 59 Fed. Reg. 52,231 (1994) (declaring October 1994 as National Breast Cancer Awareness Month).

10. *See* RESOURCE LIST, *supra* note 6, at 22-39 (listing more than 300 regional breast cancer support groups nationwide). In addition to regional support groups, there are several national groups that provide support, counseling, and information. They are Y-ME National Organization for Breast Cancer Information and Support, American Cancer Society, National

tional and research databases[12] have sprouted throughout the nation. Pressure on lawmakers has led to federal and state funding for research to find new therapies—and improve old therapies—for treating and curing breast cancer.[13]

Breast cancer patients have met with less success, however, when dealing with their insurers.[14] Insurers have in many cases refused to pay for high dose chemotherapy-autologous bone marrow transplants (HDC-ABMT(s)),[15] which are used to treat women with advanced

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Alliance of Breast Cancer Organizations (NABCO), The National Breast Cancer Coalition, Reach to Recovery, and The Komen Alliance. *Id.* at 17-20.

11. *See, e.g.*, THE NATIONAL BREAST CANCER COALITION, THE NATIONAL BREAST CANCER COALITION (1994) (on file with *The American University Law Review*) (describing National Breast Cancer Coalition as group founded in 1991 to effect public policy for breast cancer research).

12. *See* ELEANOR NEALON, WHAT ARE CLINICAL TRIALS ALL ABOUT? A BOOKLET FOR PATIENTS WITH CANCER 22 (National Insts. of Health Pub. No. 92-2706, reprinted June 1992) (describing Cancerfax, which facilitates access, via fax machine, to National Cancer Institute's Physician's Data Query (PDQ) system, which in turn provides prognostic, stage, and treatment information for ongoing clinical trials nationwide). There are also breast cancer patient oriented computer bulletin boards that can be accessed through CompuServe, an on-line service that offers cancer-related public forums. *See* RESOURCE LIST, *supra* note 6, at 16.

13. *See* National Institutes of Health Revitalization Act of 1993, Pub. L. No. 103-43, § 403, 107 Stat. 122, 157 (codified as amended at 42 U.S.C. § 285a-8 (Supp. V 1993)) (appropriating $1 million for fiscal year 1994 and such sums as may be necessary for 1995 and 1996 for research concerning causes, prevention, detection, and treatment of breast cancer); *see also* Keelyn Friesen, *Non-Passage of the Women's Health Equity Act: Inaction May Lead to Cancerous Results*, 14 HAMLINE J. PUB. L. & POL'Y 243, 243 (1993) (advocating increased government funding to foster research for breast cancer via Women's Health Equity Act). *But see Twentieth Anniversary of the National Cancer Act 1991: Hearing Before the Senate Comm. on Labor and Human Resources*, 102d Cong., 1st Sess. 11 (1991) (statement of Hon. Thomas P. O'Neill) (claiming that in decade preceding 1991, funding for cancer research had decreased by 6.2%, while funding on all other medical research programs had increased by 27%).

14. *See* Beck, *supra* note 8, at 65 (discussing some insurers' willingness to approve certain procedures for treatment of leukemia and lymphoma, but not for breast cancer).

15. There are two types of bone marrow transplants. In an allogeneic transplantation, also called a syngeneic transplantation, a patient's bone marrow is replaced with marrow from a donor. *See* NATIONAL CANCER INST., BONE MARROW TRANSPLANTATION: RESEARCH REPORT 16 (National Insts. of Health Pub. No. 92-1178, 1991) [hereinafter BMT RESEARCH REPORT]. In an autologous transplantation, in contrast, the replacement marrow is from the patient herself. *Id.* at 7. The benefit of this procedure is that the patient is less likely to reject her own marrow as opposed to marrow from a donor. *Id.* Autologous bone marrow transplants are used for treating breast cancer. *See* SUSAN STEWART, BONE MARROW TRANSPLANTS: A BOOK OF BASICS FOR PATIENTS 28 (1992).

Another name for HDC-ABMT is high-dose chemotherapy with autologous bone marrow rescue (HDC-ABMR). *See, e.g.*, Harris v. Mutual of Omaha Cos., 992 F.2d 706, 709 (7th Cir. 1993) (using HDC-ABMT and HDC-AMBR interchangeably). Another method used to regenerate bone marrow is high-dose chemotherapy with peripheral blood stem cell transplant (HDC-PBSCT), also called peripheral blood stem cell rescue (HDC-PSCR) or peripheral stem cell transplant (HDC-PSCT). *See* Calhoun v. Complete Health Care, 860 F. Supp. 1494, 1496-97 (S.D. Ala. 1994) (noting that, with ABMT, stem cells are removed from bone marrow while patient is under general anesthesia, whereas with PSCT, stem cells are removed from patient's blood via catheter in neck with no anesthesia); Hasty v. Central States, Southeast & Southwest Areas Health & Welfare Fund, 851 F. Supp. 1250, 1252 (N.D. Ind. 1994) (explaining five stages of HDC-PSCR treatment); Jaecks v. National Ass'n of Letter Carriers Health Benefit Plan, No. 93-C-6855, 1993 WL 498286, at *2 (N.D. Ill. Dec. 1, 1993) (distinguishing HDC-ABMT from HDC-PSCT); Patricia Jassak & Mary Beth Riley, *Autologous Stem Cell Transplant*, 2 CANCER PRAC.

breast cancer, because, according to insurers, this treatment is "experimental," "investigational," "not medically necessary," "not medically accepted," or any combination thereof.[16] Insurers argue that their purposes are to ration health care costs and to protect policyholders from wasteful, and even harmful, treatments,[17] rather than to serve as charities or research institutions.[18] Accordingly, insurers insist that they are not obligated to fund "experimental" medical treatments.[19] Critics, however, accuse insurers of exploiting exclusionary provisions in their policies as a pretext for eliminating expensive treatments.[20] This debate between insurers and their critics centers on the issue of whether a patient's medical treatment, such as HDC-ABMT for breast cancer, is truly "experimental" as defined by her health insurance policy.[21]

As a result of this conflict, women with breast cancer, while trying to fight their disease, are simultaneously embattled with their insurers.[22] Breast cancer patients have become not only angry,[23]

141, 141-44 (1994) (explaining and comparing HDC-ABMT and HDC-PBSCT); *see also* Thomas R. Klumpp, *Autologous Peripheral Blood Stem Cell Transplantation Versus Autologous Bone Marrow Transplantation: Which is Better?*, 2 HEMATOLOGY/ONCOLOGY ANNALS 30, 31 (1994) (comparing advantages and disadvantages of using either HDC-ABMT or HDC-PBSCT). For purposes of this Comment, all of these treatments will be considered together as HDC-ABMT(s).

16. This Comment uses "Experimental Exclusion" to refer to all exclusionary language embodied in health insurance policies.

17. *See* Gary Taylor, *Insurers Deny Coverage; Cancer Treatment Focus of Suits*, 15 NAT'L L.J. 3, 3 (1993) (emphasizing insurance industry's responsibility to all policyholders and to safety of individuals seeking treatment).

18. *See* Freedman, *supra* note 3, at 38.

19. *See* Robert B. Koegel, *Insuring Effective Therapy for Breast Cancer*, N.Y. L.J., Dec. 7, 1992, at 1, 4 (arguing that insurers should not have to pay for treatments that lack solid scientific proof of beneficial results). *But see* Freedman, *supra* note 3, at 40 (mentioning National Insurance Consumer Organization president's belief that insurers should be in forefront of finding cures); Mary McCabe & Michael A. Friedman, *Impact of Third-Party Reimbursement on Cancer Clinical Investigation: A Consensus Statement Coordinated by the National Cancer Institute*, 81 J. NAT'L CANCER INST. 1585, 1585-86 (1989) (reporting that representatives of major oncology organizations recommend third-party coverage of patients' costs in research protocols for cancer treatments).

20. *See* Beck, *supra* note 8, at 65 (asserting that insurers are shying away from treatments, not because of their experimental nature, but because "the universe of potential breast cancer patients is so much larger" than that for other types of cancer for which insurers are willing to pay treatment costs); Michael Friedman & Mary McCabe, *Assigning Care Costs Associated with Therapeutic Oncology Research: A Modest Proposal*, 84 J. NAT'L CANCER INST. 760, 761 (1992) (declaring that insurers deny coverage for treatments under investigation not to protect public health, but for legal and fiscal reasons).

21. *See, e.g.*, Dahl-Eimers v. Mutual of Omaha Life Ins. Co., 986 F.2d 1379, 1382 (11th Cir. 1993) (identifying as major issue definition of phrase "considered experimental" and whether HDC-ABMT fits definition); Holder v. Prudential Ins. Co. of Am., 951 F.2d 89, 91 (5th Cir. 1992) (same).

22. *See* Beck, *supra* note 8, at 65 (discussing increasing number of breast cancer victims spending their "last precious months in court or on picket lines").

23. *See, e.g., Health Care Crisis: Human Impact of Insurance Company Abuse: Hearing of the Senate Comm. on Labor and Human Resources*, 102d Cong., 2d Sess. 8 (1992) [hereinafter *Health Care Crisis*] (statement of breast cancer patient Patricia Geiger). Geiger told the committee:

but also active.[24] This time, they are seeking remedies through the courts.[25] Some breast cancer patients can afford to hire private attorneys,[26] while others rely on pro bono legal assistance.[27]

Increases in breast cancer patient litigation against insurers have forced courts to decide the experimental status of particular medical treatments, ultimately having broad implications on health care policy.[28] Courts, however, are ill-equipped to make these decisions.[29] Even the most well-intentioned judge lacks the knowledge and training necessary to determine whether a new medical treatment is experimental, safe, or superior to conventional treatments.[30] Rather, the legislature is the most appropriate mechanism for

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> [I am] determined to get better. Through will power and love and belief in my physicians, I'll make it happen. But I must tell you that as I sit here today, I feel great anger toward Prudential Insurance Company. I feel as if the insurance company played with my life. Their delay may have cost me the best medical chance I had to cure this disease.

Id.

24. *See, e.g., id.* at 9-11 (describing breast cancer patient Geiger's battle with Prudential Insurance and her effort to persuade Senate to take active role in proscribing congressionally mandated responsibilities for insurance companies).

25. *See* Robert Bazell, *Topic of Cancer*, NEW REPUBLIC, Dec. 31, 1990, at 9 (stating that more and more women with breast cancer are filing suits demanding that their insurance companies pay for HDC-ABMT).

26. *See* Gina Kolata, *Patients' Lawyers Lead Insurers to Pay for Unproven Treatments*, N.Y. TIMES, Mar. 28, 1994, at A1 (stating that average lawyer charges approximately $10,000 for litigation on behalf of breast cancer patients, win or lose). *But see* Karen L. Gallinari, N.Y. TIMES, Apr. 5, 1994, at A26 (letter to editor) (claiming that lawyers who represent breast cancer patients do not collect large profits).

27. *See* Martin Fox, *Women Judges, Lawyers Mobilize on Breast Cancer*, N.Y. L.J., June 29, 1992, at 1 (discussing large number of legal organizations supporting breast cancer education, detection, treatment, and research and assisting in related breast cancer legal matters); Rhea Mandulo, *Lawyers Tapped to Aid Breast Cancer Patients*, N.Y. L.J., Sept. 23, 1992, at 1 (describing Lawyers Breast Cancer Alert and Breast Cancer Legal Advocacy Project, groups formed to assist breast cancer patients who have been denied medical coverage); Lisa Beth Pulitzer, *Legal Aid for Breast Cancer Queries*, N.Y. TIMES, Nov. 8, 1992, at L15 (reporting establishment of lawyer referral service to assist breast cancer patients); Faye A. Silas, *Lawyers Take the Offense in Defense Against Breast Cancer*, BAR LEADER, Nov.-Dec. 1992, at 9 (describing activism for breast cancer issues by bar associations nationwide).

28. *See infra* Part II.B (discussing cases where policyholder prevails); *infra* Part II.C (discussing cases where insurer prevails).

29. *See* Bechtold v. Physicians Health Plan of N. Ind., 19 F.3d 322, 328 (7th Cir. 1994) (quoting Chesterfield Smith, former American Bar Association president as stating "courts are being asked today to solve problems for which they are not institutionally equipped"); Fuja v. Benefit Trust Life Ins., 18 F.3d 1405, 1412 (7th Cir. 1994) (articulating view that larger social questions raised should be decided by other government branches that benefit from public opinions and hearings); Hasty v. Central States, Southeast & Southwest Areas Health & Welfare Fund, 851 F. Supp. 1250, 1259 (N.D. Ind. 1994) (admitting that insurance coverage for breast cancer treatments raises social reform and public policy issues better suited for other branches of government). *See generally* Richard S. Saver, *Reimbursing New Technologies: Why Are the Courts Judging Experimental Medicine?*, 44 STAN. L. REV. 1095, 1113-16 (1992) (explaining how courts are not equipped to make determinations as to what medical technology is experimental).

30. Saver, *supra* note 29, at 1106-11 (describing approaches followed by judges in determining whether specific treatments should be excluded from coverage, and resulting inconsistent decisions in different jurisdictions).

meaningful resolution of such disputes.[31] The legislature, unlike the judiciary, can benefit from public hearings and lobbying efforts, and can respond, on a large scale, to the needs and concerns of the community.

This Comment recommends that legislation, in order to be most effective, must take into account the competing interests of both breast cancer patients and the insurance industry. On the one hand, a breast cancer patient should reasonably expect that her health insurance will cover a treatment that has been recommended by her physician and that could save her life. On the other hand, health insurers should be permitted to avoid wasteful, fraudulent, and medically unproven treatments so that insurance rates are affordable. Legislation that emphasizes solely the needs of breast cancer patients, and disregards insurers' concerns, is a setback for containing health care costs. At the same time, containing costs must not come at the expense of breast cancer patients' lives.

In the absence of legislation, however, courts must be prepared to resolve disputes over the "experimental" status of new medical treatments. To date, the federal district courts[32] and the various federal circuit courts of appeals are split on whether or not insurers must pay for HDC-ABMT for breast cancer.[33] The Fifth[34] and

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31. *See Health Care Crisis*, *supra* note 23, at 1 (statement of Sen. Kennedy) (discussing necessity for legislative action in patient/insurer disputes); *see also infra* Part III (discussing legislative response to health care crisis).

32. Many federal district court cases have found in favor of insurance companies on this question. *See, e.g.*, Lowery v. Health Chicago, No. 92-C-7657, 1994 WL 194265 (N.D. Ill. May 16, 1994); Jaecks v. National Ass'n of Letter Carriers Health Benefit Plan, No. 93-C-6855, 1993 WL 498286 (N.D. Ill. Dec. 1, 1993); Uhrich v. Caterpillar Inc., No. 93-C-5271, 1993 WL 478990 (N.D. Ill. Nov. 18, 1993); Roseberry v. Blue Cross & Blue Shield of Neb., 821 F. Supp. 1313 (D. Neb. 1992); Dahl-Eimers v. Mutual Omaha Life Ins. Co., 812 F. Supp. 1193 (N.D. Fla. 1992); Lehman v. Mutual of Omaha Ins. Co., 806 F. Supp. 859 (D. Ariz. 1992); Arrington v. Group Hospitalization & Medical Servs., 806 F. Supp. 287 (D.D.C. 1992); Sweeney v. Gerber Prods. Co. Medical Benefits Plan, 728 F. Supp. 594 (D. Neb. 1989); Thomas v. Gulf Health Plan, 688 F. Supp. 590 (S.D. Ala. 1988).

Other federal district courts have ruled in favor of breast cancer patients. *See, e.g.*, Frenderis v. Blue Cross Blue Shield of Mich., No. 94-C-6690, 1995 WL 12662 (N.D. Ill. Jan. 12, 1995); Bailey v. Blue Cross/Blue Shield of Va., 866 F. Supp. 277 (E.D. Va. 1994); Calhoun v. Complete Health Care, 860 F. Supp. 1494 (S.D. Ala. 1994); Scalamandre v. Oxford Health Plans (N.Y.), Inc., 823 F. Supp. 1050 (E.D.N.Y. 1993); Kekis v. Blue Cross & Blue Shield of Utica-Watertown, Inc., 815 F. Supp. 571 (N.D.N.Y. 1993); Nesseim v. Mail Handlers Benefit Plan, 792 F. Supp. 674 (D.S.D. 1992); Wilson v. Group Hospitalization & Medical Servs., 791 F. Supp. 309 (D.D.C. 1992); Kulakowski v. Rochester Hosp. Serv. Corp., 779 F. Supp. 710 (W.D.N.Y. 1991); White v. Caterpillar, 765 F. Supp. 1418 (W.D. Mo. 1991); Bucci v. Blue Cross-Blue Shield of Conn., 764 F. Supp. 728 (D. Conn. 1991); Adams v. Blue Cross/Blue Shield of Md., 757 F. Supp. 661 (D. Md. 1991); Pirozzi v. Blue Cross-Blue Shield of Va., 741 F. Supp. 586 (E.D. Va. 1990).

33. *See generally* Robin E. Margolis, *Tide Turning Against Autologous Bone Marrow Transplantations in Federal Appellate Courts*, 6 HEALTH SPAN 21 (1993) (discussing differing views of federal district and circuit courts regarding experimental status of HDC-ABMT for breast cancer).

Seventh[35] Circuits have characterized the treatment as experimental and have upheld insurers' denial of coverage. In the Third Circuit,[36] a three-judge panel reached the same conclusion, but the decision was later vacated *en banc* based on a wholly unrelated legal technicality.[37] The remaining circuits have not yet ruled on the issue.[38]

A starting point for such litigation is that a health insurance policy is a contract.[39] Courts have traditionally approached litigation between policyholders and insurers as a contract dispute.[40] Because each insurance company's policy is unique, courts must analyze the specific contractual language on a case-by-case basis.[41] Nevertheless, general guidelines can assist the determination of whether or not a new medical treatment is "experimental" under the terms of a given insurance policy.[42] Courts have found the following conditions to be essential components in resolving disputes over insurance coverage for breast cancer treatments:

(1) the policy must contain sufficient, objective criteria for defining "experimental;"[43]

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34. *See* Holder v. Prudential Ins. Co., 951 F.2d 89, 91 (5th Cir. 1992) (holding that at time of plaintiff's illness, HDC-ABMT was experimental under health insurance policy).

35. *See* Fuja v. Benefit Trust Life Ins. Co., 18 F.3d 1405, 1412 (7th Cir. 1994) (upholding insurance company's denial of coverage for HDC-ABMT because policy was not ambiguous).

36. *See* Clark v. K-Mart Corp., No. 91-3723, 1992 WL 106935, at *6 (3d Cir. May 22, 1992) (concluding that HDC-ABMT for breast cancer has not been proven to be beneficial), *vacated on reh'g*, 979 F.2d 965, 969 (3d Cir. 1992) (en banc) (holding that insurance company's challenge to preliminary injunction ordering it to pay for breast cancer patient's HDC-ABMT was moot because insurance company had complied and patient did not receive treatment again).

37. *Clark*, 979 F.2d at 968 (holding that only full hearing by district court could determine whether insurer acted arbitrarily and capriciously).

38. *Cf.* Caudill v. Blue Cross & Blue Shield of N.C., 999 F.2d 74, 80 (4th Cir. 1993) (upholding language of health insurance policy covering only specifically listed ABMTs, which did not include ABMT for breast cancer); Dahl-Eimers v. Mutual of Omaha Life Ins. Co., 986 F.2d 1379, 1383-84 (11th Cir. 1993) (holding that health insurance policy language was ambiguous, but not reaching factual question whether HDC-ABMT for breast cancer was experimental); Farley v. Benefit Trust Life Ins. Co., 979 F.2d 653, 657 (8th Cir. 1992) (holding that HDC-ABMT was medically necessary for advanced cancer, but was not medically necessary for melanomas).

39. *See* 44 C.J.S. *Insurance* § 253 (1993) (stating that insurance policy is written contract and is governed by standard contract principles).

40. *See, e.g.*, Bechtold v. Physicians Health Plan of N. Ind., 19 F.3d 322, 325 (7th Cir. 1994) (explaining that dispute over insurance policy coverage "is a matter of contract interpretation").

41. *See generally* Stuart Bass, *Strict Construction of Health Insurance Contracts*, LAB. L.J., Feb. 1994, at 90, 91-95 (discussing ways courts have interpreted insurance contracts on case-by-case basis). For an explanation of how courts have been reluctant to issue sweeping pronouncements on whether treatments are experimental, see Nina Martin, *Cancer in Court: Wave of Litigation Tests How Much a Life is Worth*, L.A. DAILY J., Jan. 4, 1993, at 1, 8.

42. *See infra* Part IV.

43. *See Bechtold*, 19 F.3d at 326 (holding that because policy was clear and unambiguous as to what was covered, company was entitled to deny coverage).

(2) the insurer must not operate under a conflict of interest;[44] and

(3) the insurer must undertake reasonable efforts in making its coverage determination.[45]

This Comment recommends that courts should not uphold an insurer's refusal to pay for HDC-ABMT in the treatment of breast cancer unless all three of these conditions have been satisfied.

While this Comment focuses on HDC-ABMTs for breast cancer, the issues and suggestions presented are an appropriate model for other emerging medical treatments.[46] Part I discusses the background of HDC-ABMT for breast cancer. It presents the approaches of both the medical community and the insurance industry in defining experimental treatments, both generally and as applied specifically to HDC-ABMT. Part II surveys various courts' approaches to determining insurance coverage for breast cancer treatments. Further, it analyzes appropriate standards of review and relevant case law, including claims based on gender discrimination and breast cancer syndrome. Part III reviews both state legislation and federal policy concerning insurance coverage for HDC-ABMT for breast cancer. Finally, Part IV makes recommendations for legislatures and for courts to follow when resolving health insurance coverage disputes over experimental treatments.

I. BACKGROUND OF HDC-ABMT FOR BREAST CANCER

Medical professionals sometimes disagree over the effectiveness and safety of newly emerging treatments.[47] HDC-ABMTs, which have been used in recent years for treating breast cancer,[48] are no exception. Although HDC-ABMTs have unquestionably proven effective for treating certain types of cancer, such as leukemia[49] and

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44. *Cf.* Firestone Tire & Rubber Co. v. Bruch, 489 U.S. 101, 115 (1989) (explaining that if administrator is acting under conflict of interest, "that conflict must be weighed as a factor in determining whether there is an abuse of discretion").

45. *See* Pitman v. Blue Cross & Blue Shield of Okla., 24 F.3d 118, 122 (10th Cir. 1994) (refusing to grant summary judgment to insurer and implying that reason was lack of any proof of insurer's reasonable efforts to reach fair decision).

46. *See infra* notes 150-61 and accompanying text (citing cases involving insurance companies' denial of coverage for HDC-ABMTs in treatment of cancers and AIDS on ground that they are experimental).

47. Some examples of newly emerging treatments whose effectiveness is contested are genetic therapy, small bowel with liver transplants, and intravascular ultrasound for imaging blood flow. *See* Dave Lenckus, *Venture to Evaluate New Medical Technology*, BUS. INS., Sept. 13, 1993, at 45.

48. *See* STEWART, *supra* note 15, at 28-29.

49. *See* Lynna M. Lesko et al., *Long-Term Psychological Adjustment of Acute Leukemia Survivors: Impact of Bone Marrow Transplantation Versus Conventional Chemotherapy*, 54 PSYCHOSOMATIC MED. 30, 32 (1992) (stating that use of chemotherapy combined with bone marrow transplants affords

lymphoma,[50] their effectiveness for treating breast cancer remains promising, but ultimately unclear.[51] Some physicians recommend the procedure, while others condemn it, thus rendering HDC-ABMT for breast cancer one of the most controversial issues in the medical community today.[52]

Both proponents and opponents of the procedure agree, however, that HDC-ABMT for breast cancer involves high technology, high costs, and high risks.[53] Yet, to a woman with metastasized breast cancer,[54] it offers high hopes,[55] as she knows she will almost certainly die without it.[56] This chance for survival has motivated thousands of women in the United States to undergo HDC-ABMT,[57] while

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leukemia patients greater likelihood of lengthened disease-free survival); *see also* Bechtold v. Physicians Health Plan of N. Ind., 19 F.3d 322, 324 (7th Cir. 1994) (noting that HDC-ABMT has proven effective in treating leukemia).

50. *See* Clark v. K-Mart Corp., No. 91-3723, 1992 WL 106935, at *2 (3d Cir. May 22, 1992) (stating that HDC-ABMT is no longer experimental for treating Hodgkin's disease, lymphoma, and acute leukemia), *vacated on reh'g*, 979 F.2d 965, 969 (3d Cir. 1992).

51. *See* BMT RESEARCH REPORT, *supra* note 15, at 5 (explaining that efficacy of bone marrow transplant is still being evaluated for treatment of breast cancer).

52. *See* William P. Peters & Mark C. Rogers, *Variations in Approval by Insurance Companies of Coverage for Autologous Bone Marrow Transplantation for Breast Cancer*, 330 NEW ENG. J. MED. 473, 473 (1994) (remarking that ABMT for breast cancer has been controversial in medical community due to high costs, frequency of disease, difficulty of procedure, and lack of completed randomized trials); Gary Spitzer, *Autologous Bone Marrow Transplantation in Solid Tumors*, 3 CURRENT OPINION IN ONCOLOGY 238, 238 (1991) (describing bone marrow transplant as most controversial topic in North America in 1991); Marilyn Chase, *Medical Quandary: Breast-Cancer Patients Seeking New Therapy Face Tough Obstacles*, WALL ST. J., Feb. 17, 1993, at A1 (discussing difficulty in coming to rational decision on this controversial topic).

53. *See* Don Colburn, *Bone Marrow Transplants: A Tough Choice*, WASH. POST, Apr. 19, 1994, (Health), at 10.

54. Breast cancer is classified into four stages, according to the extent of the disease. In Stage I, the tumor is less than one inch and is considered small. In Stage II, the tumor is larger, approximately one to two inches, and the cancer has spread to the axillary lymph nodes. In Stage III, the tumor is greater than two inches and is adhering to the chest wall. In the most advanced stage, Stage IV, the cancer has "metastasized," meaning it has spread to other organs or parts of the body, such as the liver, bone marrow, or brain. MERCK MANUAL OF DIAGNOSIS AND THERAPY 2076 (14th ed. 1982); *see also* WHAT YOU NEED TO KNOW ABOUT BREAST CANCER, *supra* note 6, at 18-19.

55. *See generally Transplants Offer Hope to Breast Cancer Patients*, BMT NEWSLETTER, May 1994.

56. *See* Lois Ayash et al., *A Perspective on Dose-Intensive Therapy with Autologous Bone Marrow Transplantation for Solid Tumors*, 5 ONCOLOGY 25, 26-27 (1991) (noting that with conventional chemotherapy breast cancer patients are incurable and have median survival rate of two years).

57. *See* National Alliance of Breast Cancer Orgs. (NABCO), *Bone Marrow Transplantation and Peripheral Stem Cell Transplantation for Breast Cancer* (Feb. 1994) (draft, on file with *The American University Law Review*) [hereinafter NABCO Draft] (citing North American Autologous Bone Marrow Transplant Registry for proposition that 893 HDC-ABMTs were performed on breast cancer patients in 1992, compared to 258 in 1989); *see also Clinical Data for Breast Cancer and Leukemia: American Society of Clinical Oncology Annual Meeting*, CANCER RESEARCHER WKLY., May 23, 1994, at 8 (same).

The Autologous Blood & Marrow Transplant Registry (ABMTR) contains data for 15,277 patients receiving autotransplants. Of these, 4380 (29%) patients received transplants for breast cancer. Fax from ABMTR (Apr. 1995) (on file with *The American University Law Review*). Autotransplants for breast cancer have increased over the past several years: 279 were performed in 1989, 347 in 1990, 681 in 1991, 1024 in 1992, 1062 in 1993 (data incomplete), and

enduring its inherent risks[58] and its severe side effects.[59]

The main purpose of HDC-ABMTs[60] is to enable a breast cancer patient to tolerate much higher doses of chemotherapy[61] than would otherwise be possible.[62] In theory, these higher doses will destroy more cancerous cells, more effectively,[63] thereby increasing a patient's potential for remission or even cure. Complications arise, however, because chemotherapy not only destroys cancerous cells, but also damages and destroys red blood cells, white blood cells, and platelets[64] found in healthy bone marrow.[65] This impairs the body's immune system, subjecting the vulnerable patient to infection.[66] A HDC-ABMT allows a patient to receive far greater doses of chemotherapy than she could tolerate under conventional treatment,[67] without damaging her healthy bone marrow.

HDC-ABMT is a complicated medical procedure. A patient's bone marrow is removed, through a process known as "harvesting," and it is then frozen.[68] While the marrow is being stored, the patient is

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992 in 1994 (data incomplete). *Id.* ABMTR estimates that these figures represent about half of all breast cancer transplants in North America during this time. *Id.* Many hospitals and medical centers do not report transplants performed for breast cancer to ABMTR.

58. *See* Geoffrey Cowley et al., *In Pursuit of a Terrible Killer*, NEWSWEEK, Dec. 10, 1990, at 66, 68 (stating that 5-10% of HDC-ABMT breast cancer recipients die from complications of treatment).

59. *See* BMT RESEARCH REPORT, *supra* note 15, at 14 (explaining that in addition to side effects of standard chemotherapy, HDC-ABMT creates huge risks of post-procedure infections). Vomiting, nausea, severe skin burn, hair loss, and mouth sores are among the possible side effects of standard chemotherapy. *See generally* SUSAN M. LOVE, DR. SUSAN LOVE'S BREAST BOOK 319-23 (1990).

60. For a detailed discussion of this medical procedure, see generally STEWART, *supra* note 15; BMT RESEARCH REPORT, *supra* note 15.

61. Chemotherapy is a systemic (i.e., throughout the body) chemical treatment in which drugs are injected into the bloodstream to destroy cancer cells. *See* KATHY LATOUR, THE BREAST CANCER COMPANION: FROM DIAGNOSIS THROUGH TREATMENT TO RECOVERY; EVERYTHING YOU NEED TO KNOW FOR EVERY STEP ALONG THE WAY 132 (1993).

62. *See* NABCO Draft, *supra* note 57, ¶ 3 (stating that with increased doses of chemotherapy, amount of drugs administered must be balanced against patient's tolerance of those drugs).

63. *See* Ayash, *supra* note 56, at 25 (stating that most drugs used in chemotherapy exhibit steep dose-responsive curve in laboratory models, meaning that "twofold increase in dose can result in a tenfold increase in tumor cell kill"); Karen Antman & Robert Gale, *Advanced Breast Cancer: High-Dose Chemotherapy and Bone Marrow Autotransplants*, 108 ANNALS INTERNAL MED. 570, 570 (1988) (asserting that response of human breast cancer to drugs is dose-dependent, with higher doses producing disproportionally higher increases in response rates).

64. Platelets and red and white blood cells aid in the body's fight against infection. *See* STEWART, *supra* note 15, at 11. Red blood cells carry oxygen to, and remove waste products from, organs and tissues; white blood cells directly fight infection; and platelets allow blood to clot. *Id.*

65. *See* Adams v. Blue Cross/Blue Shield of Md., 757 F. Supp. 661, 664 (D. Md. 1991); Pirozzi v. Blue Cross-Blue Shield of Va., 741 F. Supp. 586, 588 (E.D. Va. 1990).

66. *See Adams*, 757 F. Supp. at 664.

67. *See* STEWART, *supra* note 15, at 29.

68. *See Adams*, 757 F. Supp. at 664; STEWART, *supra* note 15, at 13-14 (explaining bone marrow harvest procedure and noting that marrow is stored at temperatures between -80 and -196 degrees centigrade until day of transplant).

administered high, almost lethal, doses of chemotherapy.[69] The frozen marrow is then thawed and reinfused into the patient in a process called "rescue," at which point the marrow is expected to begin manufacturing new, healthy blood cells.[70]

Aside from being complicated, a HDC-ABMT is exceptionally expensive.[71] The cost of HDC-ABMT can be over $100,000 per patient,[72] but varies depending on the type and amount of drugs used, medical complications, and the length of the hospital stay.[73] Experts claim, however, that costs will decrease over time as the procedure is refined.[74] Some medical centers are already reducing costs by offering the treatment on an outpatient basis, allowing patients either to return home or to stay at a nearby hotel during treatment, rather than paying the additional expense of inpatient care.[75]

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69. *See Adams*, 757 F. Supp. at 664; *Pirozzi*, 741 F. Supp. at 588 (revealing that some doses administered during HDC-ABMT procedure exceed 1000 times standard low-dose treatment).

70. *See Adams*, 757 F. Supp. at 664.

71. *See* Bruce Hillner et al., *Efficacy and Cost-effectiveness of Autologous Bone Marrow Transplantation in Metastatic Breast Cancer*, 267 JAMA 2055, 2059 (1992) (showing that, compared with standard chemotherapy, HDC-ABMT for breast cancer increases life expectancy by six months, but at cost of $115,800 per year of life gained); Daniel Haney, *Weighing Cost and Pain of Marrow Transplant*, L.A. TIMES, Oct. 13, 1991, at A13 (revealing that cost of HDC-ABMT equals $1 million for each life saved); *see also* Kekis v. Blue Cross & Blue Shield of Utica-Watertown, Inc., 815 F. Supp. 571, 575 (N.D.N.Y. 1993) (noting that standard chemotherapy costs significantly less than HDC-ABMT).

72. *See, e.g.*, Wheeler v. Dynamic Eng'g, 850 F. Supp. 459, 462 (E.D. Va. 1994) (stating that HDC-PSCR costs between $90,000 and $150,000); White v. Caterpillar, Inc., 765 F. Supp. 1418, 1419 (W.D. Mo.) (estimating cost of HDC-ABMT at $195,000), *aff'd*, 985 F.2d 564 (8th Cir. 1991); Taylor v. Blue Cross/Blue Shield of Mich., 517 N.W.2d 864, 867 (Mich. Ct. App. 1994) (estimating costs of plaintiff's HDC-ABMT at between $144,000 to $200,000); *see also* Dave Lenckus, *Cancer Coverage Dispute; Court Says Policy Void if Procedure Is Part of Research*, BUS. INS., Apr. 11, 1994, at 2, 36 (stating that breast cancer patient's medical bill for HDC-ABMT totalled $486,000).

73. *See* NABCO Draft, *supra* note 57, ¶ 10 (claiming that most HDC-ABMT expenses result from lengthy hospitalization in isolated rooms).

74. *See* YASHAR HIRSHAUT & PETER PRESSMAN, BREAST CANCER: THE COMPLETE GUIDE 188 (1992) (noting that costs for bone marrow transplant procedure could be cut by one-third due to drugs called "colony stimulating factors" that hasten recovery); LATOUR, *supra* note 61, at 194-95 (explaining that growth factors are products of recombinant DNA technology that stimulate bone marrow cells to proliferate, enabling faster marrow engraftment after transplant, thereby reducing hospital stay). Companies are now developing stem-cell technology that will allow doctors to isolate cells from the patient's blood, instead of having to invade the bone. NABCO Draft, *supra* note 57, ¶¶ 7-9. This reduces both the length of hospitalization and the likelihood of relapse, and thus saves costs. *Id.* ¶ 6.

75. *See* Jassak & Riley, *supra* note 15, at 143-44 (predicting shift of care from hospitals and medical centers to ambulatory or home settings); Marilyn Chase, *Researchers Seek Ways to Cut Cost of Transplants*, WALL ST. J., Feb. 17, 1993, at A9 (reporting that outpatient treatment and new stem-cell technology further reduce costs of transplant).

A. *Defining Experimental: The Medical Community's Perspective*

The progress of medicine depends on research, experimentation, and data collection.[76] On one level, an experiment is defined as "a procedure done in order to discover or to demonstrate some fact or general truth."[77] On another level, experimentation represents a departure from standard medical practice, and is designed to test a hypothesis with the further goal of developing new knowledge;[78] the experimental treatment has unproven efficacy and is performed for the sole purpose of obtaining scientific data, with no therapeutic intent for the patient.[79]

When and how an experimental procedure becomes standard treatment is often the crux of the debate over insurance coverage for any emerging medical treatment, including HDC-ABMT for breast cancer.[80] Medical research for new drugs and treatments is conducted in four progressive phases of clinical trials,[81] classified according to research objectives and methodology.[82] Progression to the next phase indicates that results from the previous phase were favorable and no serious adverse reactions occurred.[83]

In Phase I studies, the new drug or treatment is adminisered to humans for the first time, usually to healthy males between the ages of eighteen and forty-five.[84] The purpose of Phase I studies is to determine where, if at all, toxicity appears.[85] In Phase II, known as clinical investigation, the drug or treatment is dispensed to actual

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76. *Cf.* Holder v. Prudential Ins. Co. of Am., 951 F.2d 89, 91 (5th Cir. 1992) (remarking that "it is the nature of medical research that what may one day be experimental may the next be state of the art treatment").

77. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 558 (25th ed. 1974).

78. *See* Dale H. Cowan, *Innovative Therapy Versus Experimentation*, 21 TORT & INS. L.J. 619, 622 (1986) (distinguishing experimentation and innovative therapy).

79. *Id.*

80. Chase, *supra* note 52, at A1 (noting that researchers must decide whether experimental treatment becomes standard therapy while facing growing public debate on rising health care costs).

81. Clinical trials are medical experiments conducted with human subjects. *See* Dahl-Eimers v. Mutual of Omaha Life Ins. Co., 812 F. Supp. 1193, 1196 (N.D. Fla. 1992).

82. *See id.* (describing methodology used in conducting clinical trials).

83. *See* Fuja v. Benefit Trust Life Ins. Co., 18 F.3d 1405, 1410 (7th Cir. 1994) (detailing objectives of four phases of clinical cancer trials). Some medical professionals refer to only three phases of medical trials. *See, e.g.*, Reger v. Espy, 836 F. Supp. 869, 872 (N.D. Ga. 1993) (describing "Phase III" as final stage of clinical trial, which compares results of experimental therapy to standard accepted therapy); Lloyd K. Everson, *The Challenge for Clinical Research in Community Oncology Programs*, ONCOLOGY ISSUES, July-Aug. 1994, at 21. *See generally* HIRSHAUT & PRESSMAN, *supra* note 74, at 260-62 (describing phases of clinical trials and offering advice for patients participating in such trials).

84. CHARLES CRAIG & ROBERT STITZEL, MODERN PHARMACOLOGY 131-32 (4th ed. 1994).

85. *Id.*

patients and monitored for its effectiveness, in order to establish an optimal dose rate.[86] Phase III trials evaluate effectiveness with larger numbers of patients, who are closely observed for adverse side effects not apparent in the earlier trial phases.[87] Finally, Phase IV consists of randomized clinical trials,[88] with the goal of determining whether apparently promising treatments are actually superior to conventional treatments.[89] Even after a treatment is accepted into the medical mainstream, however, trials may still be conducted in order to refine and improve it.[90] Conversely, classifying a particular treatment as part of an earlier trial phase does not automatically mean that it is experimental;[91] though a particular treatment has not completed all trial phases, it may still be considered state-of-the-art medical treatment and be used by the finest medical centers and hospitals.[92]

The medical profession's endorsement of HDC-ABMT for breast cancer, although forthcoming, is encountering resistance from some health professionals.[93] In the late 1980s, consistently stagnant and poor results seen in patients receiving conventional chemotherapy[94] drove medical researchers to seek alternative treatments, such as HDC-ABMT.[95] With HDC-ABMT, more promising results began, and have continued, to appear.[96]

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86. *Id.*

87. *Id.* (noting that Phase III studies may involve several hundred to several thousand subjects, depending on drug being tested).

88. *Id.* at 131. Patients who participate in these types of clinical trials are randomly divided into two groups: one half of the participants, called the control group, receives the standard treatment for the disease being studied, while the other half receives the newer treatment being tested. *See* Gina Kolata, *Women Resist Trials to Test Marrow Transplants*, N.Y. TIMES, Feb. 15, 1995, at C3.

89. *See* Everson, *supra* note 83, at 21 (explaining last phase of clinical trials where drug is compared to current therapies).

90. *See* Bucci v. Blue Cross-Blue Shield of Conn., 764 F. Supp. 728, 731 (D. Conn. 1991) (noting that continuous evaluation of medical procedure does not bar its acceptance).

91. Adams v. Blue Cross/Blue Shield of Md., 757 F. Supp. 661, 675 (D. Md. 1991) (finding fact that treatment had not completed Phase III studies did not necessarily mean that treatment was experimental). This demonstrates how use of the term "experimental" differs between the medical community and the insurance industry, and thus leads to litigation.

92. *See* Pirozzi v. Blue Cross-Blue Shield of Va., 741 F. Supp. 586, 591 (E.D. Va. 1990) (listing 15 major medical centers that use HDC-ABMT to treat breast cancer).

93. *See infra* notes 108-10 and accompanying text.

94. *See* Karen Antman et al., *Dose Intensive Therapy in Breast Cancer*, 10 BONE MARROW TRANSPLANTATION 67, 67 (Supp. I 1992) (stating that two-year median survival rate for women with metastatic breast cancer had not changed in five decades).

95. *See* Taylor v. Blue Cross/Blue Shield of Mich., 517 N.W.2d 864, 867 (Mich. Ct. App. 1994) (commenting that medical profession began using HDC-ABMTs for treatment of breast cancer in late 1980s).

96. *See Why Are We Losing the War on Breast Cancer?: Hearing Before the Subcomm. on Aging of the Senate Comm. on Labor and Human Resources*, 102d Cong., 1st Sess. 33, 43 (1991) (prepared statement of Dr. Daniel Ihde, Deputy Director of National Cancer Institute) (stating that for patients with Stage IV breast cancer, trials of high dose chemotherapy followed by ABMT had shown encouraging results); Jacob Bitran, *The Article Reviewed*, 5 ONCOLOGY 33 (1991) (stating

Those promising results have been tempered, however, by other studies that show that breast cancer patients may not need HDC-ABMT to achieve long-term survival.[97] For that reason, the medical debate over HDC-ABMT for breast cancer focuses on whether the treatment is more effective than conventional chemotherapy.[98] Phase IV randomized clinical trials of HDC-ABMT for breast cancer are ongoing[99] and thus far indicate that HDC-ABMTs deliver higher complete response rates[100] than does conventional chemotherapy. Citing these results, proponents argue that HDC-ABMT is superior to

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that after three years of treatment, 15-20% of Stage IV breast cancer patients who received ABMT were alive, disease-free, and did not require therapy); William A. Check, *Bone Marrow Transplantation; Slowly Gaining Favor as a Supportive Measure with Intensive Chemotherapy*, ONCOLOGY TIMES, Dec. 1990, at 16 (discussing fact that oncologists are becoming increasingly convinced of benefits of ABMTs for breast cancer patients); Frank R. Dunphy et al., *Treatment of Estrogen Receptor-Negative or Hormonally Refractory Breast Cancer with Double High-Dose Chemotherapy Intensification and Bone Marrow Support*, 8 J. CLINICAL ONCOLOGY 1207, 1215 (1990) (reporting favorable complete remission rates and proportion of disease-free survivors beyond two years with high-dose chemotherapy and bone marrow support); M. John Kennedy et al., *High-Dose Chemotherapy with Reinfusion of Purged Autologous Bone Marrow Following Dose-Intense Induction as Initial Therapy for Metastatic Breast Cancer*, 83 J. NAT'L CANCER INST. 920, 920 (1991) (indicating that reinfusion of purged autologous bone marrow yields high response rate in women with metastatic breast cancer); John S. MacDonald, *Peripheral Blood Stem Cell Infusions: A Success Story in Applied Technology in Hematology and Oncology*, 2 HEMATOLOGY/ONCOLOGY ANNALS: J. CONTINUING EDUC. HEMATOLOGY & ONCOLOGY 12, 13 (1994) (mentioning that peripheral blood stem cell transplantation shows promise for treating breast cancer); Jacob M. Rowe et al., *Recommended Guidelines for the Management of Autologous and Allogeneic Bone Marrow Transplantation; A Report from the Eastern Cooperative Oncology Group (ECOG)*, 120 ANNALS INTERNAL MED. 143, 143 (1994) (reporting that patients in advanced stages of breast cancer have achieved long-term, disease-free survival through ABMT); Spitzer, *supra* note 52, at 239 (noting that studies of ABMTs for Stage IV breast cancer indicate 10-15% increase in proportion of long-term, disease-free survivors); Stephanie Williams et al., *High Dose Consolidation Therapy with Autologous Stem Cell Rescue in Stage IV Breast Cancer*, 7 J. CLINICAL ONCOLOGY 1824, 1829 (1989) (expressing belief that ABMTs might be curative in women with Stage IV breast cancer).

97. *See, e.g.*, Bruce Cheson, *Clinical Trials*, 5 ONCOLOGY 55, 58 (1991) (cautioning that although HDC-ABMT has frequently been used for treating metastatic breast cancer, in some patients its efficacy is unclear when compared to standard chemotherapy).

98. *See id.* at 55 (explaining that although ABMTs are being conducted more frequently in breast cancer treatment, direct comparison with standard chemotherapy has not yet been conducted). Preliminary data does indicate that high dose chemotherapy alone, requiring neither hospitalization nor ABMT, may be more effective than standard treatments. *Id.*

99. Physician Data Query (PDQ) of the National Cancer Institute (July 5, 1994) (computer database printout on file with *The American University Law Review*). The University of Pennsylvania Cancer Center, the Mayo Clinic, the San Antonio Cancer Institute, and the New England Medical Center are currently performing randomized trials. *Id.* The stated objectives are to:

> I. Compare time to failure and overall survival of patients with metastatic breast cancer ... who are randomly assigned to ... conventional maintenance chemotherapy ... vs. high-dose chemotherapy ... followed by autologous bone marrow and peripheral stem cell rescue.
> II. Compare the toxicity of these 2 regimens.
> III. Compare the financial costs of these 2 regimens.
> IV. Evaluate the quality of life associated with these 2 treatments.

Id.

100. Response rates measure the degree in which a tumor shrinks in size or stops growing altogether.

conventional chemotherapy.[101] To buttress this claim, proponents further argue that rates of morbidity[102] and mortality,[103] as well as medical costs, have been substantially reduced over time,[104] due to improvements in the HDC-ABMT procedure.[105]

Other experts are more skeptical and emphasize that trials have not yet yielded any definitive proof that HDC-ABMT is superior to conventional chemotherapy.[106] Moreover, they argue that the

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101. Karen K. Fields et al., *Ifosfamide, Carboplatin, and Etoposide in Combination for Induction and High-Dose Chemotherapy: Focus on Breast Cancer and Lymphoma*, 10 HEMATOLOGICAL ONCOLOGY 61, 71 (1992) (stating that HDC-ABMT appears to be superior to standard chemotherapy); Edward A. Stadtmauer, *Peripheral Blood Stem Cell Transplantation in Breast Cancer*, 2 HEMATOLOGY/ONCOLOGY ANNALS: J. CONTINUING EDUC. HEMATOLOGY & ONCOLOGY 61, 63 (1994) (noting that 10-20% of HDC-ABMT patients have two-year relapse-free survival, suggesting that HDC-ABMT is superior to conventional dose chemotherapy, for which two-year relapse-free survival is rare); *Bone-Marrow Transplants Increase Survival for Breast Cancer Patients*, CANCER WKLY., May 25, 1992, at 10 ("'It is clear from these studies that high-dose chemotherapy supported by bone-marrow transplantation is superior to current conventional treatments for high-risk breast cancer patients.'" (quoting Dr. Rein Saral, Emory University School of Medicine)); Chase, *supra* note 52, at A1 (reporting National Cancer Institute official's remark that rate of early and complete remissions following HDC-ABMT treatment surpasses that for conventional care).

102. The "morbidity rate" refers to the proportion of patients with a particular disease during a given year per given unit of population. STEADMAN'S MEDICAL DICTIONARY 1067 (22d ed. 1972).

103. The "mortality rate" is the ratio of the total number of deaths to the total population of a given community. *Id.*

104. Lois J. Ayash, *High Dose Chemotherapy with Autologous Stem Cell Support for the Treatment of Metastatic Breast Cancer*, 74 CANCER 532 (Supp. I 1994) (reporting findings of prolonged disease-free survival with HDC-ABMT for breast cancer). *But cf.* Trial Brief for Defendant at 8 n.9, Fox v. Health Net (Riverside Super. Ct. of Cal. 1993) (No. 219692) (responding that even though improvements in HDC-ABMT procedure have lowered mortality rate from 10-15% to 5%, it is still substantially higher than that for standard chemotherapy, which is zero).

105. Hematological support, which includes blood stem cells and colony stimulating factors, helps improve the overall effectiveness of the HDC-ABMT procedure. *See* HIRSHAUT & PRESSMAN, *supra* note 74, at 188; *see also* Chase, *supra* note 75 and accompanying text.

106. Karmen Wong & Craig Henderson, *Management of Metastatic Breast Cancer*, 18 WORLD J. SURGERY 98, 105-06 (1994) (finding that data on efficacy of HDC-ABMT is insufficient to conclude that it is better than, or even as good as, conventional chemotherapy in improving survival and quality of life of breast cancer patients).

Some consider Dr. David Eddy of Duke University to be an expert in the use of HDC-ABMT in the treatment of breast cancer. *See* Clark v. K-Mart Corp., No. 91-3723, 1992 WL 106935, at *6 (3d Cir. May 22, 1992) (stating that medical community has relied on Dr. Eddy's work in this area), *vacated on reh'g*, 967 F.2d 841 (3d Cir. 1992). In 1990, the Blue Cross/Blue Shield Association retained Dr. Eddy to study the available literature and studies on HDC-ABMT for treating breast cancer. Dr. Eddy ultimately concluded:

> High-dose chemotherapy with ABMT has a higher treatment mortality and morbidity than conventional dose chemotherapy. The available evidence indicates that high-dose chemotherapy with ABMT delivers higher complete response and overall response rates than does conventional dose chemotherapy. However, there is no evidence that these superior response rates imply longer survival, or a higher probability of a cure.
>
> Not only are there no controlled trials that address this question, but a comparison of clinical series does not indicate that median disease-free survival, median overall survival, or actual survival is superior with high-dose chemotherapy and ABMT versus conventional dose chemotherapy.
>
> The best that can be said with the available evidence is that the effect on survival of high-dose chemotherapy with ABMT, compared with conventional dose chemotherapy is unknown. This is the essential of [sic] criterion for determining if a treatment is

apparently higher response rates for HDC-ABMT may be the result of bias caused by the selection of patients who have previously been medically tested to have particularly responsive cancers.[107] Finally, they argue that it is still too early to know whether these superior response rates imply longer survival or a higher probability of cure.[108] For these reasons, some within the medical community still view HDC-ABMT for breast cancer as experimental.[109]

Yet all parties agree that further randomized control trials are necessary to determine the true value of HDC-ABMT for breast cancer as compared with conventional chemotherapy.[110] The major drawback of formal controlled trials, however, is that women do not want to be randomized into the control group, which receives conventional chemotherapy, a treatment that offers virtually no chance for a cure.[111]

The lack of definitive scientific proof on the overall effectiveness of HDC-ABMT, when measured against the physician's deeply rooted

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"investigational"; the available evidence does not permit conclusions about the effectiveness of the treatment compared with its alternative. Additional research from well controlled clinical trials will be required to determine if high-dose chemotherapy with ABMT is superior to, equal to or worse than conventional dose chemotherapy.

Id. But cf. Clark, 1992 WL 106935, at *9 n.2 (Scirica, J., dissenting) (stating that Dr. Eddy not only relied on dated materials, but also was financed by Blue Cross); Adams v. Blue Cross/Blue Shield of Md., 757 F. Supp. 661, 671 (D. Md. 1991) (noting that Dr. Eddy is a biostatistician, not a practicing physician).

107. *See* Wong & Henderson, *supra* note 106, at 105.

108. *See Insurance Companies and Experimental Cancer Treatments*, NPR, Feb. 16, 1994, *available in* LEXIS, Nexis Library, NPR File (broadcasting Dr. David Eddy's statement that "[a]t present there are no completed randomized control trials that show that [HDC-ABMT for breast cancer] is superior to conventional-dose chemotherapy"); *see also* David M. Eddy, *High-Dose Chemotherapy with Autologous Bone Marrow Transplantation for the Treatment of Metastatic Breast Cancer*, 10 J. CLINICAL ONCOLOGY 657, 666 (1992) (concluding that existing evidence does not demonstrate that ABMT is superior to conventional-dose chemotherapy for treatment of metastatic breast cancer).

109. *See* ROBERT BERKOW ET AL., MERCK MANUAL OF DIAGNOSIS AND THERAPY 363 (16th ed. 1992) (claiming that ABMT should be considered experimental in treatment of breast cancer).

110. *See* David M. Eddy & Bruce E. Hillner, *High Dose Chemotherapy with Autologous Bone Marrow Transplantation for Metastatic Breast Cancer*, 268 JAMA 2055, 2055-56 (1992) (letter to editor) (attempting "to reconcile apparently different conclusions" concerning HDC-ABMT for breast cancer); *see also* Stadtmauer, *supra* note 101, at 63 (noting necessity for randomized trials because HDC-ABMT involves substantial short-term costs and morbidity, while long-term costs and toxicities are unknown); *Cancer Facts, Autologous Bone Marrow Transplantation in the Treatment of Breast Cancer* (National Cancer Inst., Bethesda, Md.), Mar. 1991, at 1 (emphasizing importance of formal, clinical trials to determine effectiveness and toxicity of HDC-ABMT in breast cancer patients).

111. *See* Koegel, *supra* note 19, at 4 (mentioning that national trials are progressing slowly because women do not want to risk being randomized into standard treatment); Ted Wieseman, *Suing Insurers: Litigation Over Autologous Bone Marrow Transplants and Breast Cancer*, 1991 ONCOLOGY ISSUES 7, 11-12 (identifying ethical issue for NCI trials that place patients in low-dose chemotherapy group when there is no chance for cure); Kolata, *supra* note 88, at C8 (mentioning that clinical researchers are concerned that, because breast cancer patients do not want to be randomized, there are no proper studies for determining if treatment is better than standard treatment).

obligation to provide the best treatment for his or her patient,[112] presents difficult challenges for oncologists treating women with breast cancer. A 1991 study reported in the *Journal of Clinical Oncology* found that the majority of oncologists polled would recommend HDC-ABMT for their breast cancer patients.[113] Is widespread use of HDC-ABMT for breast cancer by specialists in the field evidence that it is no longer experimental?[114] Some profess that such evidence does not automatically render it non-experimental. Instead, they argue that institutions and specialists may utilize HDC-ABMT for ulterior motives, namely to gain directly through profits, research, and prestige.[115]

B. Defining Experimental: The Insurance Industry's Perspective

Health insurers will pay for medical treatments that are scientifically proven to be safe, effective, and necessary,[116] but will refuse to pay for procedures that have no definite scientific value.[117] Through

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112. *See* Chase, *supra* note 52, at A1. The notion that physicians cannot ethically allow their patients to receive an inferior treatment is deeply rooted in the tradition of medicine. *See* Reger v. Espy, 836 F. Supp. 869, 872 (N.D. Ga. 1993) (stating that physicians may ethically perform clinical trials only if it is unclear whether experimental or standard treatment is superior); Brief of *Amici Curiae* in Support of Plaintiff-Appellant Mary Dahl-Eimers at 23, Dahl-Eimers v. Mutual of Omaha Life Ins. Co., 986 F.2d 1379 (11th Cir. 1993) (No. 92-1158) (advocating HDC-ABMT as best available treatment for breast cancer and stating that "ethically, doctors do not have the luxury of waiting until a treatment is beyond further study before adopting its use").

In the Oath of Hippocrates, the physician swears to "follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients." BARRY R. FURROW ET AL., BIOETHICS: HEALTH CARE LAW AND ETHICS § 1, at 29-30 (1991). The 1980 Principles of Medical Ethics of the American Medical Association state that a physician should be "dedicated to providing competent medical service" and The Declaration of Geneva of the World Medical Association states that a physician's first consideration must be the health of the patient. *Id.* at 31-33.

113. Daniel Belanger et al., *How American Oncologists Treat Breast Cancer: An Assessment of the Influence of Clinical Trials*, 9 J. CLINICAL ONCOLOGY 7, 15 (1991). The increasing number of oncologists who support HDC-ABMT for breast cancer could mean that an oncologist's failure to recommend or present this procedure to a patient is unethical and represents a departure from medical custom, and therefore is medically negligent.

114. Decisions as to whether HDC-ABMT should be used for treating breast cancer may depend on the patient's wishes, the physician's experience, the physician's age (younger physicians tend to use more aggressive treatments), and the results of published clinical trials. *Id.* at 13, 14.

115. *See, e.g.*, Cova, *supra* note 2, at 745 (accusing medical institutions of offering treatments, such as HDC-ABMT for breast cancer, before they have completed clinical trials, in order to compete for patients). *See generally* Bazell, *supra* note 25, at 9-12 (criticizing doctors for charging exorbitant fees for this procedure).

116. *See* Cova, *supra* note 2, at 744 (arguing that insurer's role is not to fund research).

117. *See* Reger v. Espy, 836 F. Supp. 869, 871 n.2 (N.D. Ga. 1993) (mentioning that insurer excluded HDC-ABMT for breast cancer because of its conclusion that HDC-ABMT is not superior to standard chemotherapy, not for economic reasons). *See generally* MIRIAM MILLS & ROBERT BANK, HEALTH INSURANCE AND PUBLIC POLICY xiii (1992) (arguing that making assumption that everyone has right to unlimited medical care is societally disastrous because of limited resources); James Cline & Keith Rosten, *The Effect of Policy Language on the Containment*

that practice, insurers protect patients from unsafe, ineffective, and wasteful treatments,[118] and curb premium costs for all plan participants.[119] In an age of escalating health costs,[120] legitimate efforts to ration make good policy.[121]

Insurers avoid paying for medically unproven treatments through exclusionary language written into their policies.[122] The exclusions in any particular policy can vary.[123] Among the most frequently

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of Health Care Cost, 21 TORT & INS. L.J. 120, 131 (1985) (noting that medical profession acknowledges health insurers' role in eliminating worthless treatments by refusing to pay for them); Grace Monaco & Rebecca Burke, *Insurer as Gatekeeper—Part Two: Policy Obstacles in Unproven Methods Litigation*, 20 FORUM 400, 404 (1985) (insisting that health insurers have responsibility to separate legitimate claims from illegitimate claims).

118. *See* Zuckerberg v. Blue Cross & Blue Shield of Greater N.Y., 108 A.D.2d 56, 62 (N.Y. App. Div. 1985) (stating that denial of coverage by insurer for cancer treatments with no proven value will "have the desirable effect of affording greater protection to the general public and, in particular, cancer patients who are especially vulnerable to unfounded claims of miraculous cures"), *aff'd*, 499 N.Y.S.2d 920 (1986); 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 Treatments?*, 31 DUQ. L. REV. 777, 779 (1993) (discussing reasons why insurers exclude experimental medical treatments); *cf.* Bazell, *supra* note 25, at 10 (describing Halstad radical mastectomy, a pre-1970s procedure for treating breast cancer that proved to be unnecessarily harmful to patient). The Halstad radical mastectomy is often cited by those who advocate coverage denial for treatments with no scientific proof. *See, e.g., id.* This procedure, which removes not only the breast tissue but all of the chest muscle and lymph nodes, was performed for a period in the earlier part of the 20th century, ending in the mid-1960s. *Id.* Later, it was discovered that removing only the breast tissue and diseased lymph nodes was just as effective. *Id.*; *see also* John Ferguson et al., *Court-Ordered Reimbursement for Unproven Medical Technology*, 269 JAMA 2116, 2121 (1993) (criticizing courts for ordering insurers to pay for medical technologies that had not been adequately assessed or had been found to be unsafe or ineffective, such as laetrile treatments). *But cf.* Friedman & McCabe, *supra* note 20, at 761 (claiming that insurers refuse coverage of treatments not to protect public health but for fiscal reasons).

119. *See* Scalamandre v. Oxford Health Plans (N.Y.), Inc., 823 F. Supp. 1050, 1062 (E.D.N.Y. 1993) (referring to insurer's memorandum that argues that health care plans "were developed expressly to control health care costs by preventing unnecessary and expensive procedures" like HDC-ABMT); Cova, *supra* note 2, at 744 (declaring that coverage of expensive unproven technologies increases health insurance premiums, imposing adverse consequences for lower income individuals).

120. *See* Ellen H. Moskowitz, *Access to Life-Prolonging Care*, TRIAL, Aug. 1994, at 16, 18 (discussing rising costs of health care nationwide).

121. *See generally* Fisfis, *supra* note 118, at 778-79 (suggesting policy reasons for insurers excluding experimental medical treatments from coverage). *But cf.* Malcolm Gladwell, *How Safe Are Your Breasts?*, NEW REPUBLIC, Oct. 24, 1994, at 22, 22-28 (suggesting that National Cancer Institute's decision not to formally recommend mammograms for younger women may be cost-conscious medicine, but is not necessarily good policy).

122. *See* Paul J. Molino, *Reimbursement Disputes Involving Experimental Medical Treatment*, 24 J. HEALTH & HOSP. L. 329, 329 (1991) (discussing reasons for exclusionary language in insurance policies). Some insurers have mistakenly paid for experimental treatments. *See* Grace Powers Monaco, *Moving Ahead in Cancer Research: Who Pays for Patient Supportive Care for Participation in Experimental/Investigational Trials?*, 9 CANCER INVESTIGATION 85, 88-89 (1991) (noting that erroneous payments made for experimental treatments based on misconception that they are standard will not compel insurers to continue to pay).

123. In addition to Experimental Exclusions, policies sometimes contain "not medically necessary" exclusions. Medical necessity exclusions address whether the treatment is appropriate for a given diagnosis. Mary Ader, Managing Emerging Technologies 6 (1993) (unpublished manuscript on file with the *National Health Lawyers Association* (1993)). Experimental Exclusions,

employed options are provisions excluding a particular medical treatment from coverage (Specific Exclusions)[124] and broader provisions that exclude coverage for all medical treatments that are experimental (Experimental Exclusions).[125]

Specific Exclusions tend to be easily defensible in court because they are clearly stated for the policyholder to evaluate upon purchase.[126] There are, however, several disadvantages to Specific

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by contrast, address safety and efficacy. *Id.* at 6-7. *See also* Christine Woolsey, *Medical Care Advances Pose Tough Decisions for Self-Insurers*, BUS. INS., June 22, 1992, at 3, 14 (discussing why insurance companies should separate "not medically necessary" exclusion from "experimental" exclusion).

124. *See* Blue Cross of the Rochester Area & Blue Shield of the Rochester Area, Basic Hospital, Basic Medical and Preferred Blue Million Insurance Contract, at 23 (on file with *The American University Law Review*) [hereinafter Blue Cross of the Rochester Area Contract] (containing specific exclusions for acupuncture, sex hormones related to sex transformation surgery, hypnosis, and marital counseling services). There is a great variety of Specific Exclusions. *E.g.*, Blair v. Metropolitan Life Ins. Co., 974 F.2d 1219, 1220 (10th Cir. 1992) (dental services); Dvorak v. Metropolitan Life Ins. Co., 965 F.2d 606, 606 (9th Cir. 1992) (custodial care); Thomas v. General Am. Life Ins. Co., 568 N.E.2d 937, 940 (Ill. 1991) (cosmetic surgery, unless performed to repair disfigurement caused by accidental injury or birth defect); Dobias v. Service Life Ins. Co. of Omaha, 469 N.W.2d 143, 145 (Neb. 1991) (rehabilitation services).

Many health insurance plans contain Specific Exclusions for HDC-ABMT in the treatment of breast cancer. *See, e.g.*, Hawkins v. Mail Handlers Benefit Plan, No. 1:94CV6, 1994 WL 214262, at *3 (W.D.N.C. Jan. 28, 1994) (noting specific exclusion set forth in health insurance policy, which stated that: "[s]ervices or supplies for or related to surgical transplant procedures for artificial or human organ/tissue transplants not specifically listed as covered, such as autologous bone marrow transplants for breast cancer" were not covered); Jaecks v. National Ass'n of Letter Carriers Health Benefit Plan, No. 93-C-6855, 1993 WL 498286, at *3 (N.D. Ill. Dec. 1, 1993) (quoting insurance policy as specifically excluding "[a]utologous bone marrow transplants for the treatment of solid tumors, such as breast cancer").

Conversely, some health insurance policies contain specific inclusions of covered medical treatments. When a particular medical treatment is not expressly included in such a list, however, courts may infer that it was purposely excluded. As such, the failure to include an item in a list indirectly has the effect of a Specific Exclusion. For example, in both Caudill v. Blue Cross & Blue Shield of N.C., 999 F.2d 74, 80 (4th Cir. 1993), and Arrington v. Group Hospitalization & Medical Servs., 806 F. Supp. 287, 289 (D.D.C. 1992), the health insurance policies specifically stated that ABMTs were covered for acute lymphocytic or non-lymphocytic leukemia, advanced Hodgkin's lymphoma, advanced non-Hodgkin's lymphoma, advanced neuroblastoma, and testicular, mediastinal retroperitoneal, and ovarian germ cell tumors. Because breast cancer was not expressly included in this list, the courts concluded that HDC-ABMT for breast cancer was not covered and held for the insurer. *Caudill*, 999 F.2d at 80 (stating "language makes it clear that unlisted transplants and related high dose chemotherapy are specifically excluded from the policy"); *Arrington*, 806 F. Supp. at 290.

125. *See infra* notes 135-36 and accompanying text; *see also infra* Part II.

126. *See* Caudill v. Blue Cross & Blue Shield of N.C., No. 92-94-CIV-7-F, 1992 U.S. Dist. LEXIS 21448, at *13 (E.D.N.C. Aug. 24, 1992) (upholding insurers' decision to deny coverage based on exclusion in policy), *aff'd*, 999 F.2d 74 (4th Cir. 1993). *But see* Ponder v. Blue Cross of S. Cal., 193 Cal. Rptr. 632, 643 (Ct. App. 1983) (rejecting insurer's coverage denial because specific exclusion of disease, temporomandibular joint syndrome, was not worded in layperson's terms). *See generally* Frank P. James, *The Experimental Treatment Exclusion Clause*, 12 J. LEGAL MED. 359, 365 (1991) (arguing that insurers' policy of clearly listing specific exclusions in policies is completely defensible under contract law).

Exclusions.[127] First, insurers will face administrative difficulties and costs because they must periodically reevaluate and update their list of Specific Exclusions.[128] Second, state insurance commissions[129] tend to disfavor Specific Exclusions as a matter of policy.[130] Third, growing lists of Specific Exclusions may induce legislative intervention to mandate coverage in certain areas,[131] a prospect that insurers view as undesirable.[132] Finally, insurers risk having to cover all new, unproven treatments claimed by policyholders.[133] A policy that lists Specific Exclusions may give rise to the inference that any treatment not expressly excluded should be covered; in the absence of any Specific Exclusion, a court may presume that the insurer made an affirmative choice not to exclude the treatment at issue.[134]

More prevalent than Specific Exclusions are Experimental Exclusions.[135] A broad Experimental Exclusion clause simply states that any experimental treatment will be excluded from coverage. While some Experimental Exclusions do not define "experimental," those that do are generally more defensible in court.

Insurers have developed various criteria for defining the experimental status of medical treatments and procedures.[136] These criteria

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127. *See* Molino, *supra* note 122, at 329-34 (describing limitations and difficulties for insurers that arise from specific exclusions).

128. *See* Lee N. Newcomer, *Defining Experimental Therapy—A Third-Party Payer's Dilemma*, 323 NEW ENG. J. MED. 1702, 1702-03 (1990) (noting that with continually expanding medical technology, specific exclusions expose insurers to risk for new treatments and procedures created between renewal periods, thus requiring continuous updates); Ader, *supra* note 123, at 22.

129. State insurance commissions regulate insurers doing business within the state. 43 AM. JUR. 2D *Insurance* § 22 (1982). These insurance commissions have the power to approve or disapprove any policy or practice by the insurer in that particular state. *Id.* § 24.

130. Ader, *supra* note 123, at 22.

131. Ader, *supra* note 123, at 22.

132. *See infra* notes 530-31 and accompanying text.

133. *See* Molino, *supra* note 122, at 331-34 (discussing risk that courts will conclude that treatment in question is covered under policy because language on exclusion is not specific enough).

134. *See* Cline & Rosten, *supra* note 117, at 135-36 (stating that "lists of proscribed treatments would be helpful, although it must be recognized that coverage will undoubtedly be extended to any treatment not on the list"); Newcomer, *supra* note 128, at 1702 (recognizing risk, but arguing that this risk may be negligible if renewal period is short enough).

135. *See generally* Jennifer Belk, *Undefined Experimental Treatment Exclusions in Health Insurance Contracts: A Proposal for Judicial Response*, 66 WASH. L. REV. 809, 809 (1991) (stating that most health insurance contracts exclude experimental treatments).

136. The Blue Cross and Blue Shield Association, based in Chicago, developed the Technology Evaluation Criteria (TEC) program in order to assess emerging medical technologies.

According to the TEC, procedures are considered experimental unless they meet the following five criteria:

1. *The technology must have final approval from the appropriate governmental regulatory bodies.* This criteria applies to drugs, biological products, devices and diagnostics. A drug or biological product must have final approval from the Food and Drug Administration.

may relate to one or more of the following categories: scientific criteria, research criteria, and professional criteria. Insurers often consider any medical procedure that fails to meet any one of the criteria set forth in its policy as experimental.[137]

In a scientific category, insurers may require that the proposed treatment reach a certain percent-success ratio,[138] successfully complete various levels of clinical trials,[139] be well-received in peer-reviewed literature,[140] or be superior to all existing procedures.[141]

A device must have final approval from the FDA for those specific indications and methods of use that the Blue Cross and Blue Shield Association is evaluating. Any approval that is granted as an interim step in the FDA regulatory process is not sufficient.

2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.* The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the body of studies and the consistency of the results are considered in evaluating the evidence. The evidence should demonstrate that the technology can measure or alter the physiological changes related to a disease, injury, illness or condition. In addition, there should be evidence or a convincing argument based on established medical facts that such measurement or alteration affects the health outcomes. Opinions and evaluations by national medical associations, consensus panels or other technology evaluation bodies are evaluated according to the scientific quality of the supporting evidence and rationale.

3. *The technology must improve the net health outcome.* The technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.

4. *The technology must be as beneficial as any established alternatives.* The technology should improve the net health outcome as much as, or more than, established alternatives.

5. *The improvement must be attainable outside the investigational settings.* When used under the usual conditions of medical practice, the technology should be reasonably expected to satisfy criteria #3 and #4.

Technology Evaluation Criteria, Blue Cross & Blue Shield Association (on file with *The American University Law Review*); *see also* Adams v. Blue Cross/Blue Shield of Md., 757 F. Supp. 661, 673 (D. Md. 1991) (holding that HDC-ABMT for breast cancer satisfied five scientific criteria developed by Blue Cross' Technology Evaluation Committee). *See generally* Lenckus, *supra* note 47, at 45 (noting that TEC is not influenced by cost-related issues). This program only provides recommendations for insurers, however, which are free to follow the criteria or to develop their own policies. Pirozzi v. Blue Cross-Blue Shield of Va., 741 F. Supp. 586, 590 n.7 (E.D. Va. 1990).

137. *See infra* Part II.

138. *See, e.g.*, Reilly v. Blue Cross & Blue Shield United of Wis., 846 F.2d 416, 423 (7th Cir.) (noting that insurer determined success rate for in vitro fertilization to be less than 50%, and thus considered procedure experimental), *cert. denied*, 488 U.S. 856 (1988).

139. *See, e.g.*, Harris v. Mutual of Omaha Cos., 992 F.2d 706, 708 (7th Cir. 1993) (mentioning that insurer excluded from coverage all medical treatments that are in "on-going phase I, II, or III clinical trials").

140. *See, e.g.*, Dozsa v. Crum & Forster Ins., 716 F. Supp. 131, 135 (D.N.J. 1989) (mentioning that insurance company covers those treatments for which there is clear consensus in peer-reviewed medical literature); Rollo v. Blue Cross/Blue Shield of N.J., No. 90-597, 1990 WL 312647, at *3 (D.N.J. 1990) (noting that insurance company considered peer-reviewed literature in its review process for coverage of medical treatments). Peer-reviewed literature is an "objective forum in which specialists and researchers may relate their data and findings, after being assessed and evaluated for authenticity and accuracy by their peers, to further the progress of science." James, *supra* note 126, at 408.

141. *See, e.g.*, Davis v. Selectcare, Inc., 834 F. Supp. 197, 199 (E.D. Mich. 1993) (noting insurance company's claim that disputed treatment for prostate cancer was not superior to conventional treatments).

The research category focuses on the administration of the treatment, whereby insurers, when making coverage determinations, may consider consent forms,[142] research protocols,[143] or clinical trials as indicia of a treatment's experimental nature.[144] In the professional category, insurers place great emphasis on the consensus of medical professionals.[145] Insurers may insist that the treatment be the standard, accepted practice among medical professionals either nationally or within a designated geographic area.[146] Some insurers further require that the treatment be officially endorsed by a nationally recognized medical organization or a governmental body.[147]

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142. *See Harris*, 992 F.2d at 709 (indicating that insurer, when denying coverage, considered informed consent statement signed by policyholder); *Davis* , 834 F. Supp. at 200 (rejecting insurer's claim that policyholder's signing of informed consent form established that HDC-ABMT is investigational).

143. *See Harris*, 992 F.2d at 708, 710 (indicating that insurer considered written treatment protocol in denying coverage); McLeroy v. Blue Cross/Blue Shield of Or., 825 F. Supp. 1064, 1072 (N.D. Ga. 1993) (noting policy language as excluding all services performed under written research protocol); Sweeney v. Gerber Prods. Co. Medical Benefits Plan, 728 F. Supp. 594, 596 (D. Neb. 1989) (finding use of research protocols for HDC-ABMT for breast cancer to be evidence that treatment was experimental); *cf.* Adams v. Blue Cross/Blue Shield of Md., 757 F. Supp. 661, 675 (D. Md. 1991) (explaining that many accepted medical treatments are administered as part of protocol, and thus existence of protocol does not necessarily mean treatment is experimental).

144. *See* Gripkey v. Mail Handlers Benefit Plan, No. 3:94-378-0, 1994 WL 276265, at *2 (D.S.C. 1994) (noting that insurer cited ongoing clinical trials as evidence that HDC-PSCR is experimental); Leonhardt v. Holden Bus. Forms Co., 828 F. Supp. 657, 668 (D. Minn. 1993) (noting that insurer mentioned clinical trials as reason for denying coverage for HDC-ABMT for multiple myeloma).

145. *But cf.* Reilly v. Blue Cross & Blue Shield United of Wis., 846 F.2d 416, 427 (7th Cir.) (Posner, J., dissenting) (commenting that it is natural for patient's physicians, who are specialists in treatment area, to want to encourage use of exciting and promising treatment), *cert. denied*, 488 U.S. 856 (1988); Ader, *supra* note 123, at 8 (noting that professional consensus standard risks becoming consensus of relevant professionals, and hence consensus of treatment's proponents).

146. *See, e.g., Adams*, 757 F. Supp. at 664 (explaining that provision in health policy specifically excluded services that are not "accepted medical practice by the suitable medical specialty practicing in Maryland").

147. *See, e.g.*, Lowery v. Health Chicago, No. 92-C-7657, 1994 WL 194265, at *1 (N.D. Ill. May 13, 1994) (quoting provision in insurance policy providing that experimental procedures are determined "in conjunction with appropriate medical technology assessment bodies, or the National Institute of Health"); White v. Caterpillar, Inc., 765 F. Supp. 1418, 1420 (W.D. Mo.) (noting that reports from American College of Physicians and American Medical Association should be used as guides to determine which procedures are medically accepted), *aff'd*, 985 F.2d 564 (8th Cir. 1991); Waldrip v. Connecticut Nat'l Life Ins. Co., 556 So. 2d 434, 435 (La. Ct. App.) (noting that insurance company policy defined "experimental" to mean treatment not approved by American Medical Association, U.S. Surgeon General, U.S. Department of Public Health, or National Institutes of Health), *cert. denied*, 571 So. 2d 650 (La. 1990).

There are several problems with this approach: the entity relied upon may not offer an official position on a given medical treatment; its official position may be outdated; or its position may be in conflict with that presented by other similarly situated entities. *See* Karen L. Illuzzi Gallinari, *How Courts View Experimental Treatments*, J. HEALTH CARE BENEFITS, May-June 1994, at 37, 42 (noting that reputable doctors across country often use excellent methods that are not formally approved by National Cancer Institute (NCI), but are consistent with NCI

In recent years, some health insurance companies have designated independent committees, comprised of experts, to assess which treatments are experimental under the policy's criteria.[148] Relying on one or more of the three categories of criteria, health insurers or these independent committees either approve or deny coverage for a policyholder's medical treatment.[149]

Denying coverage for unproven scientific treatments is easily justified in cases involving what are popularly known as "quack therapies."[150] But most newer medical treatments fall within the nebulous area between quack therapies and accepted, mainstream treatments.

Insurers have refused to cover HDC-ABMT for various cancers, including ovarian cancer,[151] testicular cancer,[152] multiple myeloma,[153] cervical cancer,[154] melanoma,[155] lung cancer,[156] brain

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protocols).

148. *See* Cherly Weinstock, *Lawyers Debate the Insurability of Bone-Marrow Transplants*, N.Y. TIMES, Mar. 20, 1994, at 18 (mentioning that insurers such as Aetna, Prudential, and Travelers subscribe to Medical Care Ombudsman Program, which provides fast, authoritative reviews of treatment decisions); *see also* William T. McGivney, N.Y. TIMES, Apr. 5, 1994, at A20 (letter to editor) (stating that Aetna Health Plans cover proposed treatment if one of three independent oncologists believes it is likely to be effective for specific patient).

149. *See infra* Part II.

150. *See, e.g.*, Zuckerberg v. Blue Cross & Blue Shield of Greater N.Y., 108 A.D.2d 56, 61-62 (N.Y. App. Div. 1985) (upholding insurer's denial of coverage because there was no scientific proof that dietary treatment, known as "Gerson therapy," could cure cancer), *aff'd*, 67 N.Y.2d 688 (1986). *Zuckerberg* was a classic "quack therapy" case. The cancer patient, following his doctor's advice, consumed fruits and vegetables at a Mexican medical clinic in an attempt to rid himself of the disease. *Id.*; *see also* Barrie R. Cassileth et al., *Contemporary Unorthodox Treatments in Cancer Medicine*, 101 ANNALS INTERNAL MED. 105, 105-12 (1984) (discussing widespread use of unorthodox therapies by patients who are terminally ill).

151. *See, e.g.*, Mire v. Blue Cross/Blue Shield of Fla., 43 F.3d 567, 568 (11th Cir. 1994) (finding that plain meaning of insurance exclusion eliminated coverage for ovarian cancer); Fenio v. Mutual of Omaha Ins. Co., 868 F. Supp. 318, 319 (S.D. Fla. 1994) (discussing insurers' denials of HDC-ABMT treatment for ovarian cancer); Berry v. Blue Cross of Wash. & Alaska, 815 F. Supp. 359, 360 (W.D. Wash. 1993) (reviewing health plan provider's denial of coverage for bone marrow transplant).

152. *See, e.g.*, Spain v. Aetna Life Ins. Co., 11 F.3d 129, 131 (9th Cir. 1993) (dismissing negligence claim brought against insurer who had denied coverage for HDC-ABMT to patient who subsequently died of testicular cancer), *cert. denied*, 114 S. Ct. 1612 (1994); Cole v. Blue Cross & Blue Shield of Mass., 738 F. Supp. 42, 44 (D. Mass. 1990) (granting preliminary injunction to policyholder seeking coverage for HDC-ABMT to treat refractory testicular cancer).

153. *See, e.g.*, Pitman v. Blue Cross & Blue Shield of Okla., 24 F.3d 118, 120 (10th Cir. 1994) (discussing insurer's refusal to cover ABMT for treatment of multiple myeloma); Doe v. Group Hospitalization & Medical Servs. Inc., 3 F.3d 80, 82 (4th Cir. 1993) (discussing decision by insurer to deny coverage for ABMT for multiple myeloma); Leonhardt v. Holden Bus. Forms Co., 828 F. Supp. 657, 673 (D. Minn. 1993) (ordering insurer to pay for HDC-ABMT in treatment of multiple myeloma); Lehman v. Mutual of Omaha Ins. Co., 806 F. Supp. 859 (D. Ariz. 1992) (considering HDC-ABMT for multiple myeloma experimental); Schnitker v. Blue Cross/Blue Shield of Neb., 787 F. Supp. 903, 906 (D. Neb. 1991) (holding that denial of coverage for HDC-ASCR for multiple myeloma was not arbitrary and capricious); Dozsa v. Crum & Forster Ins. Co., 716 F. Supp. 131, 140 (D.N.J. 1989) (enjoining insurance company from rejecting coverage for bone marrow transplant for patient with multiple myeloma). Multiple myeloma is a blood cancer present in the bone marrow. *Pitman*, 24 F.3d at 119 n.1.

cancer,[157] soft tissue cancer,[158] prostate cancer,[159] and colon cancer,[160] as well as for Acquired Immunodeficiency Syndrome (AIDS).[161] When applying the above-mentioned criteria, insurers have argued that HDC-ABMTs for these particular diseases were experimental.[162] Insurers deny coverage for HDC-ABMT for breast cancer, however, more often than for other cancer therapies.[163]

Some insurers argue that HDC-ABMT is still subject to clinical trials and protocols, and therefore is not yet regularly practiced by the mainstream medical community.[164] Other insurers cover HDC-ABMT only if it is performed in a medical center affiliated with the National Cancer Institute (NCI).[165] Still other insurers, however, do

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154. *See, e.g.*, Evans v. HMO Colo., No. 91-CV-3797 (Colo. Dist. Ct. City & County of Denver, June 14, 1991) (upholding HMO's exclusion of benefits for cervical cancer), *cited in* Ader, *supra* note 123, at I-13.

155. *See, e.g.*, Farley v. Benefit Trust Life Ins. Co., 979 F.2d 653, 654 (8th Cir. 1992) (holding that HDC-ABMT was not "medically necessary" for policyholder's malignant melanoma); Coryea v. Blue Cross & Blue Shield of S.C., No. 91-377 (D.S.C., Mar. 30, 1992) (upholding insurer's denial of benefits for HDC-ABMT treatment of melanoma on ground it was experimental), *cited in* Ader, *supra* note 123, at I-13.

156. *See, e.g.*, Hendricks v. Central Reserve Life Ins., 39 F.3d 507, 510 (4th Cir. 1994); Snell v. Travelers Ins. Co., No. CIV. A. 93-0001, 1993 WL 274240, at *1 (E.D. Pa. June 30, 1993).

157. *See, e.g.*, McLeroy v. Blue Cross/Blue Shield of Or., 825 F. Supp. 1064, 1074 (N.D. Ga. 1993) (denying preliminary injunction against insurer who refused to pay for ABMT for 13-year-old boy with brain tumor); Hansen v. King County Med. Blue Shield, No. 92-450C (W.D. Wash., Mar. 26, 1993) (involving denial of coverage for HDC-ABMT on experimental grounds for policyholder with brain cancer), *cited in* Ader, *supra* note 123, at IV-1.

158. *See, e.g.*, Helman v. Plumbers & Steamfitters Local 166 Health & Welfare Trust, 803 F. Supp. 1407, 1408-09 (N.D. Ind. 1992) (noting that plaintiff's insurer denied coverage for HDC-ABMT for treating rhabdomyosarcoma, cancer of soft tissue rarely found in adults).

159. *See, e.g.*, Davis v. Selectcare, Inc., 834 F. Supp. 197, 198 (E.D. Mich. 1993) (noting that plaintiff's HMO denied coverage, claiming HDC-ABMT for prostate cancer was "investigational").

160. *See, e.g.*, Thrasher-Meyers v. King County Medical Blue Shield, No. 92-451 (W.D. Wash., Mar. 17, 1993) (involving insurer's denial of benefits for HDC-ABMT for colon cancer on grounds that treatment was experimental), *cited in* Ader, *supra* note 123, at IV-6.

161. *See, e.g.*, Bradley v. Empire Blue Cross & Blue Shield, 562 N.Y.S.2d 908, 910-11 (Sup. Ct. 1990) (holding that chemotherapy and bone marrow transplant were not experimental for treatment of AIDS).

162. *See supra* notes 151-60.

163. *See, e.g.*, Nesseim v. Mail Handlers Benefit Plan, 995 F.2d 804, 805 (8th Cir. 1993) (discussing health plan denial of treatment for plaintiff's breast cancer); Harris v. Mutual of Omaha Co., 992 F.2d 706, 711 (7th Cir. 1993) (discussing letter from Mutual of Omaha stating that HDC-ABMT's "efficaciousness in the treatment of breast cancer has not been established, and that it is still in the experimental/investigative stage"); Dahl-Eimers v. Mutual of Omaha Life Ins. Co., 986 F.2d 1379, 1382-83 (11th Cir. 1993) (reviewing insurer's coverage denial for breast cancer treatment).

164. *See* Holder v. Prudential Ins. Co. of Am., 951 F.2d 89, 89 (5th Cir. 1992) (affirming lower court's decision to deny coverage because treatment was "'experimental in nature' and had not yet been 'recognized throughout the medical profession'").

165. *See* Scalamandre v. Oxford Health Plans (N.Y.), Inc., 823 F. Supp. 1050, 1061 (E.D.N.Y. 1993) (discussing whether cancer center was NCI-approved institution). In return for certain benefits, an NCI-approved institution must provide statistical data to NCI. *Id.* at 1061 n.11.

not view HDC-ABMT for breast cancer as experimental, and therefore provide coverage unconditionally.[166]

Although insurers honor requests for coverage of HDC-ABMT for breast cancer in a large number of cases,[167] nearly one-quarter of such requests are denied, primarily because of the experimental nature of the treatment.[168] In fewer instances, denials have been based on Specific Exclusions.[169] Despite some favorable instances of insurance coverage, commentators charge that insurers' coverage decisions are inconsistent and are made in a medically careless manner.[170] Given the high incidence of breast cancer and the exorbitant costs of HDC-ABMT, many critics believe that denials based on "experimental" grounds are really a pretext for insurers to evade coverage.[171]

II. THE COURTS' APPROACHES: IS HDC-ABMT FOR BREAST CANCER EXPERIMENTAL?

The formulation of health care policy is outside the province of the judiciary.[172] Yet, courts are being asked to determine the experimental status of medical treatments. Ideally, sympathies—either for the insurance company attempting to make rational decisions in a climate of escalating medical costs, or for the policyholder who is fighting against her tragic disease—should play little, if any, role in

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166. *See* Bucci v. Blue-Cross Blue Shield of Conn., 764 F. Supp. 728, 731 (D. Conn. 1991) (noting that 38 health insurers have committed to University of Nebraska and 32 insurers have committed to Duke University to provide coverage for HDC-ABMT to breast cancer patients); *Insurance Update*, BMT NEWSLETTER 4 (Nov. 1992) (quoting, in pertinent part, text of letter from Independent Blue Cross (IBC) of Pennsylvania to policyholder, which read "'[IBC] has reviewed the most recently published literature in peer-reviewed medical journals and has determined that high dose chemotherapy with autologous bone marrow rescue for women with stage IV metastatic breast cancer has therapeutic efficacy. Therefore, IBC no longer considers this treatment experimental and will cover the treatment rendered to your wife.'").

167. *See* Peters & Rogers, *supra* note 52, at 476 (reporting on study that found 77% of all requests to insurance companies for coverage of HDC-ABMT for breast cancer were approved); *see also* Kolata, *supra* note 26, at A1 (noting insurers' willingness to settle claims in order to avoid costs of litigation and large damage awards).

168. Peters & Rogers, *supra* note 52, at 474 (describing results of study concerning effect of insurance approval on receipt of treatment).

169. Peters & Rogers, *supra* note 52, at 474; *see supra* note 124 and accompanying text.

170. Peters & Rogers, *supra* note 52, at 476; *see also* Kolata, *supra* note 26, at A1 (discussing reasons behind insurers' denial of coverage). One critic of insurance companies remarked that insurers use four criteria when deciding whether to deny payments: "'Does this person have a lawyer? Is this person articulate? Have we already tried to say no at least once? Is this a person who can muster sufficient resources to give us a hard time, by getting media attention or starting a letter-writing campaign?'" Kolata, *supra* note 26, at A11 (quoting Dr. Arthur Caplan).

171. *See, e.g.*, Moskowitz, *supra* note 120, at 19 (discussing reasons why health insurers refuse to cover HDC-ABMT).

172. *See* Goepel v. Mail Handlers Benefit Plan, No. CIV.A.93-3711 (JEI), 1993 WL 384498, at *9 (D.N.J. Sept. 24, 1993) (stating that judiciary should defer "pain of health care rationing" to legislature).

judicial review.[173] Rather, courts should adhere strictly to interpreting the language set forth in a particular health insurance policy.[174]

Specifically, courts should approach litigation arising between a breast cancer patient and her health insurer as a contract dispute.[175] The health insurance policy is a contract between two parties—the insurer who designed the contract and the policyholder who purchased it.[176] As such, coverage disputes over terms set forth in the policy are questions of contract interpretation.[177]

Experimental Exclusions that are written into the policy in unambiguous terms should be easily enforceable.[178] Litigation occurs, however, when terms are ambiguous—those that are capable

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173. *See* Comprecare Ins. Co. v. Snow, No. 92-CV-8087, 1993 WL 330929, at *8 (Colo. Dist. Ct. Feb. 16, 1993). In *Comprecare*, Judge Hoffman wrote:

> Of course I have sympathy for [the breast cancer patient]. I also have sympathy for an insurance industry trying to make rational underwriting decisions in an irrational climate of skyrocketing medical costs and rapid technological advancement. But this case is not about sympathies. It is not about the tragedy of cancer or the hard choices that we all face in the public health care debate. It is simply about language in an insurance contract . . . .

Id.; *see also* Arrington v. Group Hospitalization & Medical Servs., 806 F. Supp. 287, 291 (D.D.C. 1992) (stating that court's sympathy for breast cancer patient cannot be material to decision on merits of case); *Cf.* Perry C. Papantonis, *Experimental Exclusions: Are Insurance Companies Really Protected?*, 9 N.Y.L. SCH. J. HUM. RTS. 217, 242 (1991) (stating that court's sympathies in AIDS case created danger for insurance companies, and arguing that court should have adhered to strict contract interpretation (citing Bradley v. Empire Blue Cross Blue Shield, 562 N.Y.S.2d 903 (Sup. Ct. 1990))).

174. *See* Harris v. Mutual of Omaha, No. 92-1089-C, 1992 WL 421489, at *1 (S.D. Ind. Aug. 26, 1992) (discussing difficulties for judges in balancing human compassion with duty to follow law). In *Harris*, U.S. District Judge John D. Tinder wrote:

> Despite rumors to the contrary, those who wear judicial robes are human beings, and as persons, are inspired and motivated by compassion as anyone would be. Consequently, we often must remind ourselves that in our official capacities, we have authority only to issue rulings within the narrow parameters of the law and the facts before us. The temptation to go about, doing good where we see fit, and to make things less difficult for those who come before us, regardless of the law, is strong. But the law, without which judges are nothing, abjures such unlicensed formulation of unauthorized social policy by the judiciary. [The breast cancer patient] well deserves, and in a perfect world would be entitled to, all known medical treatments to control the horrid disease from which she suffers. [In upholding the denial of coverage], no personal satisfaction is taken, but that the law was followed.

Id.

175. *See* AM. JUR. 2D *Insurance* § 1 (1982) ("[I]nsurance is a contract by which one party, for a compensation called the premium, assumes particular risks of the other party . . . .").

176. *See supra* notes 39-40 and accompanying text. A significant number of individuals do not purchase their health insurance policy themselves, however, but obtain it through their employer. As such, a policyholder has less opportunity to select an appropriate health insurance plan.

177. *See, e.g.*, Kekis v. Blue Cross & Blue Shield of Utica-Watertown, Inc., 815 F. Supp. 571, 572 (N.D.N.Y. 1993) (noting that "this litigation presents a question of contract interpretation").

178. *See* Bass, *supra* note 41, at 99 (explaining that if policy language is clear, courts will adhere to its terms).

of two or more reasonable interpretations.[179] Courts determine the reasonable meanings of such terms not according to the view of the insurance company, attorney, or physician, but according to the meaning understood by an average policyholder.[180] Because each health insurer's policy is unique, the outcome in any given case is based on a court's interpretation of the policy's terms.[181] Even so, emerging patterns show how courts are approaching disputes regarding health insurance coverage for HDC-ABMT for breast cancer.[182]

The initial, and perhaps most crucial, consideration is the nature of the insurance policy itself. This determines whether the case could be heard in state or federal court,[183] as well as the appropriate standard of review. Private insurance policies,[184] plans by health maintenance organizations (HMOs),[185] and government plans[186]

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179. *See, e.g.*, Frenderis v. Blue Cross Blue Shield of Mich., 873 F. Supp. 1153, 1156 (N.D. Ill. 1995) (stating that policy language is ambiguous if it is subject to more than one reasonable interpretation); Shanks v. Blue Cross and Blue Shield of Wis., 777 F. Supp. 1444, 1447 (E.D. Wis. 1991) (stating that insurance contract is ambiguous if it is reasonably and fairly susceptible to more than one construction).

180. *See* 43 AM. JUR. 2D *Insurance* § 271 (1982) ("In determining whether ambiguity exists in an insurance policy, the language must be considered from the standpoint of one not trained in the law or insurance business."). *But see* Dahl-Eimers v. Mutual of Omaha Life Ins. Co., 986 F.2d 1379, 1382 (11th Cir. 1993) (declaring that "reasonable interpretation" of what is experimental could be made by medical specialists, standards of medical community, or national association).

181. *See, e.g.*, *Kekis*, 815 F. Supp. at 573 (warning future litigants seeking relief to rely on their own insurance policies, rather than on court's decision); Pirozzi v. Blue Cross-Blue Shield of Va., 741 F. Supp. 586, 594 (E.D. Va. 1990) (warning that court's decision was "not a green light signalling a general expansion of coverage" but was confined specifically to plan and expert medical testimony at bar).

182. *See supra* Part II (analyzing factors that courts use when resolving coverage disputes between insurance companies and breast cancer patients).

183. *See* Koegel, *supra* note 19, at 4 (stating that although interpretation of insurance contract is matter of state law, some contracts are federally regulated and therefore federal courts have jurisdiction).

184. *See generally* STEWART, *supra* note 15, at 124-26 (describing prevalent types of health insurance plans). To obtain a private insurance policy, a policyholder pays a company like Blue Cross/Blue Shield or Prudential an annual premium in exchange for reimbursement of health care expenses. *Id.* at 124. Typically, the policyholder will pay a "deductible" or "copayment" on any claim. *Id.* Under these types of policies, a policyholder may use any physician or hospital of her choice. *Id.* Private insurance policies can be purchased by either an individual or by an employer/association on behalf of its employees/members. *Id.* at 125. The policies are regulated by the individual states' departments of insurance. *Id.*

185. HMOs keep expenses and premiums low by referring participants to only affiliated physicians and hospitals, which are paid a flat fee. An HMO participant pays a fixed monthly fee in exchange for health care services. There is no deductible or copayment requirement. Participants are not reimbursed, however, for services received outside the plan's specified network of physicians and hospitals. HMOs rely more on cost-containment than do private insurance schemes. *See generally* STEWART, *supra* note 15, at 125. For this reason, some doctors may fear that they will be dropped from the network if they recommend that a woman with breast cancer have HDC-ABMT, because they will be viewed as high-cost providers. *See* Marc A. Rodwin, *Conflicts in Managed Care*, 332 NEW ENG. J. MED. 604, 605 (1995) (discussing financial incentives for physicians to reduce spending).

are subject to state law.[187] Self-insured health plans[188] and employee welfare benefit plans[189] are subject to federal law under the Employee Retirement Income Security Act of 1974 (ERISA).[190]

A. Standards of Review

1. Health insurance policies subject to state law

State insurance contract law distinguishes health insurance policies from other types of contracts. The concept of freedom of contract, which holds that equal parties have negotiated, bargained, and voluntarily entered into a lawful agreement, is not presumed to be present in health insurance contracting.[191] Rather, the insurer, who drafts the policy under the guidance of skilled lawyers, offers it to the potential policyholder on a take-it-or-leave-it basis.[192] Because there is no real opportunity for the potential policyholder to bargain, state courts have traditionally viewed health insurance policies as contracts of adhesion, rather than negotiated agreements.[193]

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186. A governmental plan is a health policy provided by a state or municipal employer. *Id.* at 126.

187. *See* Metropolitan Life Ins. Co. v. Massachusetts, 471 U.S. 724, 732 (1985) (asserting that if plan purchases insurance, as opposed to being self-insured, it is "directly affected by state laws that regulate the insurance industry").

188. In a self-insured plan, the employer pays covered health expenses from their own company assets. *See* Wheeler v. Dynamic Eng'g, 850 F. Supp. 459, 462 n.4 (E.D. Va. 1994). Claims can be processed either by a third-party administrator or by the company itself. *Id.*; *see also* Saver, *supra* note 29, at 1103-04 (describing judicial consideration of "experimental medicine" under self-insured plans, in relation to ERISA).

189. An example of an employee welfare benefit plan is the Veterans' Benefits plan, known as CHAMPUS, which is regulated by the Department of Veterans' Affairs.

190. 29 U.S.C. §§ 1001-1461 (1988 & Supp. V 1993). For an excellent discussion of ERISA, see generally MARTIN WALD & DAVID E. KENTY, ERISA: A COMPREHENSIVE GUIDE (1991).

191. *See, e.g.*, Wilson v. Travelers Ins. Co., 605 P.2d 1327, 1329 (Okla. 1980) (stating that insurance contracts are contracts of adhesion and must be interpreted in manner most favorable to policyholder).

192. *See* SAMUEL WILLISTON, WILLISTON ON CONTRACTS § 900, at 19 (3d ed. 1963) (evaluating non-negotiable character of insurance contracts).

193. *See* BLACK'S LAW DICTIONARY 40 (6th ed. 1990) (defining contracts of adhesion as "[s]tandardized contract form[s] offered to consumers of goods and services on essentially 'take it or leave it' basis without affording consumer realistic opportunity to bargain"). *See, e.g.*, Pasteur Health Plan, Inc. v. Salazar, No. 94-738, 1995 WL 254358, at *2 (Fla. App. 3d Dist. May 3, 1995) (finding that HMO contract "bears hallmark of a contract of adhesion"); Ponder v. Blue Cross of S. Cal., 193 Cal. Rptr. 632, 637 (Ct. App. 2d Dist. 1983) (holding that health insurance policy was contract of adhesion because it was prepared entirely by major insurance company, and policyholders could not sit down with insurer and bargain over individual terms). *But see* Jones v. Equitable Life Assurance Soc'y. of United States, 400 N.W.2d 648, 650 (Mich. App. 1986) (holding that restaurant's group health insurance policy was not contract of adhesion because employees had contracted for and knew terms of policy); Robin v. Blue Cross Hosp. Serv. Inc., 637 S.W.2d 695, 697 (Mo. 1982) (holding that group policy was not contract of adhesion because it was product of negotiation between equally strong parties—plaintiff's employer and insurance company).

When interpreting adhesion contracts, the judiciary affords special protection to the weaker party,[194] which in this context is the policyholder. Ambiguous terms are strictly construed against the insurer.[195] The rule of *contra proferentem*[196] broadly construes coverage provisions in favor of the policyholder, and narrowly construes exclusion provisions against the insurer.[197] This pro-policyholder methodology is bolstered by courts' predisposition to ensure that the "reasonable expectations" of the insured are fulfilled.[198]

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194. *See* Bass, *supra* note 41, at 91 (stating courts attempt to protect weaker party from dominant or oppressive party in contractual agreement).

195. *See* 43 AM. JUR. 2D *Insurance* § 283 (1982) (stating general rule that ambiguities in contract are interpreted against party that drafted document); *see also* DiDomenico v. Employers Coop. Indus. Trust, 676 F. Supp. 903, 908 (N.D. Ind. 1987) (holding that if ambiguity exists in medical plans, terms should be interpreted favorably to policyholder); Jury Instruction No. 5, Fox v. Health Net (Cal. Super. Ct. 1993) (No. 219262) (on file with *The American University Law Review*) (instructing that "[a]ny ambiguity or uncertainty in an insurance policy is to be resolved against the insurer").

In an attempt to afford greater protection to policyholders, states have enacted "free look" statutes that permit policyholders to reject a policy within a period of time—usually 10-20 days. Sanford J. Schlesinger et al., *Planning for the Senior Citizen*, C682 ALI-ABA 285, 345 (1991); *see, e.g.*, CAL. INS. CODE § 10233.5 (West 1993) (requiring that insurance policy contain "free look provision" in policy); TENN. CODE ANN. § 56-26-129 (1994) (mandating that every health insurance policy contain provision that purchaser is permitted to return it within 10 days). *But cf.* Falkowitz v. Monarch Life Ins., Life Health & Accid. Ins. Cas. 2d (CCH) ¶ 363 (N.Y. Sup. Ct. 1985) (rejecting argument that adhesion contract should be narrowly construed against insurer when policyholder had 10 days to examine policy, and return for full refund if not satisfied).

196. The court in Heasley v. Belden & Blake Corp. noted that the principle of *contra proferentem* derived from the recognition that

> [i]nsurance policies are almost always drafted by specialists employed by the insurer. In light of the drafters' expertise and experience, the insurer should be expected to set forth any limitations on its liability clearly enough for a common layperson to understand; if it fails to do this, it should not be allowed to take advantage of the very ambiguities that it could have prevented with greater diligence. Moreover, once the policy language has been drafted, it is not usually subject to amendment by the insured, even if he sees an ambiguity; an insurer's practice of forcing the insured to guess and hope regarding the scope of coverage requires that any doubts be resolved in favor of the party who has been placed in such a predicament.

2 F.3d 1249, 1257 (3d Cir. 1993) (quoting Kunin v. Benefit Trust Life Ins. Co., 910 F.2d 534, 540 (9th Cir. 1990)).

197. *See, e.g.*, Phillips v. Lincoln Nat'l Life Ins. Co., 978 F.2d 302, 311-12 (7th Cir. 1992) (favoring practice of narrowly construing vague provisions against insurer); Glocker v. W.R. Grace & Co., 974 F.2d 540, 544 (4th Cir. 1992) (construing plan against its drafter where ambiguities existed); *see also* Jury Instruction No. 2, *Fox* (No. 219262) (instructing that inclusive clauses be read broadly and exclusionary clauses be read narrowly when interpreting health insurance contracts).

198. *See, e.g.*, Wessman v. Massachusetts Mut. Life Ins. Co., 929 F.2d 402, 404 (8th Cir. 1991) (using Minnesota's reasonable expectation doctrine to find in favor of policyholder where ambiguities in policy existed); Anderson v. Country Life Ins. Co., 886 P.2d 1381, 1388 (Ariz. Ct. App. 1994) (stating that "even clear and unambiguous boilerplate language is ineffective if it . . . contravenes the insured's reasonable expectations"); Glarner v. Time Ins. Co., 465 N.W.2d 591, 597 (Minn. Ct. App. 1991) (finding plaintiff had reasonable expectation of coverage). *See* Roger C. Henderson, *The Doctrine of Reasonable Expectations in Insurance Law After Two Decades*, 51 OHIO ST. L.J. 823, 826-27 (1990) (explaining that doctrine of reasonable expectations applies to both ambiguous and unambiguous terms in contract). *But cf.* Meckert v. Transamerica Ins. Co., 701 P.2d 217, 221 (Idaho 1985) (rejecting doctrine of reasonable expectations); Edward Felsenthal,

2. Health insurance policies subject to ERISA

ERISA establishes, among other things, a fiduciary's[199] duties under a health insurance policy. A fiduciary must ensure that the policy is operating solely in the interest of its beneficiaries.[200] In addition, a fiduciary has the duty to act diligently[201] and provide a "full and fair review" of claim requests.[202] From a policy perspective, these standards serve to protect employees from unfair coverage denials.[203] ERISA, through the Supremacy Clause of the U.S. Constitution,[204] exempts self-insured group health plans from state insurance laws, regulations, and coverage mandates.[205]

Rulings Support the Fine Print of Health Plans, WALL ST. J., July 1, 1993, at B1 (reporting tendency of courts to uphold fine print of insurance contracts and deny claims of policyholder on technical grounds).

199. *See* BLACK'S LAW DICTIONARY 625 (6th ed. 1990) (defining fiduciary as person "who must exercise a standard of care in such management activity imposed by law or contract"). Under ERISA, a fiduciary is the health plan administrator who makes benefits determinations. *See* 29 U.S.C. § 1104(a)(1) (1988).

200. A fiduciary's duties and responsibilities are defined by statute as follows:

> (1) [A] fiduciary shall discharge his duties with respect to a plan solely in the interest of the participants and beneficiaries and
>
> (A) for the exclusive purpose of:
>
> (i) providing benefits to participants and beneficiaries; and
>
> (ii) defraying reasonable expenses of administering the plan;
>
> (B) with the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent man acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims; . . .

29 U.S.C. § 1104(a)(1).

201. *Id.*

202. *Id.* § 1133(2).

203. *See* Molino, *supra* note 122, at 330-32 (discussing standards fiduciaries must comply with in determining whether coverage should be offered).

204. U.S. CONST., art. VI.

205. *See* 29 U.S.C. § 1144 (1988) (stating that ERISA "supersede[s] any and all State laws insofar as they may now or hereafter relate to any employee benefit plan"); *see also* Pilot Life Ins. Co. v. Dedeaux, 481 U.S. 41, 47-48 (1987) (finding that common law tort and contract causes of action for improper processing of claim for benefits under ERISA-regulated plan were preempted); Pitman v. Blue Cross & Blue Shield of Okla., 24 F.3d 118, 121 (10th Cir. 1994) (holding that ERISA preempted state law claim of tortious breach of contract); Reilly v. Blue Cross & Blue Shield United of Wis., 846 F.2d 416, 426 (7th Cir. 1988) (dismissing state law claims and demand for punitive damages due to preemption by remedial provisions of ERISA). *See generally* Vicki Gottlich, *ERISA Preemption: A Stumbling Block to State Health Care Reform*, 26 CLEARINGHOUSE REV. 1469, 1470 (1993) (discussing ERISA preemption and its relation to state health care reform). *But cf.* Meadows v. Employers Health Ins., 826 F. Supp. 1225, 1232 (D. Ariz. 1993) (holding that ERISA does not preempt state law misrepresentation claims regarding coverage).

Critics seek to reform ERISA's preemption capabilities. *See Health Care Crisis, Human Impact of Insurance Company Abuse, Hearing of the Senate Comm. on Labor and Human Resources*, 102d Cong., 2d Sess. 31-33 (1992) (statement of Tom Gallagher, Florida Health Insurance Commissioner) (recommending that Congress amend ERISA so that state regulation can protect consumers from fraudulent health benefit providers).

Although ERISA preempts state law, ERISA claims may be heard in either state or federal courts. *See* 29 U.S.C. § 1132(e)(1) (1988) (granting concurrent jurisdiction to federal and state

Two standards of review are used to assess coverage determinations under ERISA-governed plans: (1) "arbitrary and capricious," and (2) "*de novo*."[206] The Supreme Court set out the distinction between the two standards in *Firestone Tire and Rubber Co. v. Bruch*.[207] According to *Firestone*, courts must first decide whether the health insurance plan confers discretionary authority on its plan administrator to determine eligibility for benefits and to construe terms of the plan.[208] If so, the plan administrator's coverage decisions should be reviewed through an arbitrary and capricious standard.[209] Otherwise, the

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courts in benefit claim cases). Insurers, however, typically remove a state court benefit claim action to federal court. *See infra* note 223 and accompanying text.

206. *See* Firestone Tire & Rubber Co. v. Bruch, 489 U.S. 101, 109 (1989) (explaining and distinguishing two standards of review).

207. 489 U.S. 101 (1989).

208. *Id.* at 108. ERISA plans have designated plan administrators who act as fiduciaries for the beneficiaries. *See* 29 U.S.C. §§ 1002(16)(A), 1002(21)(A) (1988).

209. *Firestone*, 489 U.S. at 110. The Supreme Court has never specifically identified the appropriate language necessary in order for a plan to confer discretionary authority. Lower courts, however, have held that the language must demonstrate a clear and unequivocal intent to vest the plan administrator with authority. *See, e.g.*, De Nobel v. Vitro Corp., 885 F.2d 1180, 1187 (4th Cir. 1989) (requiring administrator's authority to clearly appear on face of document). Courts have found that discretionary authority had been clearly granted in the policy and accordingly have applied a deferential standard of review. *See, e.g.*, Doe v. Group Hospitalization & Medical Servs., 3 F.3d 80, 85 (4th Cir. 1993) (quoting insurance contract that grants discretionary authority as follows: "[Blue Cross] shall have the full power and discretionary authority to control and manage the operation and administration of the Contract . . . including, but not limited to . . . [d]etermining the benefits and amounts payable therefor to any Participant or provider of health care services . . . [i]nterpreting, applying, and administering the provisions of the Contract."); Dewitt v. State Farm Ins., 905 F.2d 798, 801 (4th Cir. 1990) (quoting plan language as follows: "[T]he plan administrator shall have the power . . . to make all determinations that the plan requires for its administration. All such rules, regulations, determinations, constructions and interpretations made by the plan administrator shall be binding."); Brown v. Blue Cross & Blue Shield of Ala., 898 F.2d 1556, 1559 (11th Cir. 1990) (quoting plan as follows: "As a condition of precedent to coverage, it is agreed that whenever [insurer] makes reasonable determinations which are not arbitrary and capricious in the administration of the [plan] including . . . determinations whether services, care, treatment or supplies are Medically Necessary . . . such determinations shall be final and conclusive."); Guy v. Southeastern Iron Workers' Welfare Fund, 877 F.2d 37, 39 (11th Cir. 1989) (applying arbitrary and capricious standard because plan conferred "upon trustees 'full and exclusive authority to determine all questions of coverage and eligibility' and 'full power to construe the provisions of [the] Trust'"); Lowry v. Bankers Life & Casualty Retirement Plan, 871 F.2d 522, 524 (5th Cir. 1989) (conferring discretionary authority because plan gave "permissive authority to the [administrators] to 'interpret and construe' the [plan] and the power 'to determine all questions of eligibility and status'").

One commentator proposed the following model provision as sufficient to ensure that the plan grants the administrator sufficient discretionary authority:

> 1. (The company name), as plan administrator, retains all final authority and responsibility for the Health Plan and its operations and (the named fiduciary if different from the company) is empowered to act on behalf of (the company name) in connection with the Health Plan as expressly stated in this agreement or in writing by (the company name) and (the named fiduciary).
> 2. (The company name) and (the named fiduciary) have agreed that for purposes of [ERISA], (the named fiduciary) shall be the "appropriate named fiduciary" of the Health Plan for the purposes of such review of claims and decisions thereon, and the decisions of (the named fiduciary) on any claim shall be final and binding.

court should apply *de novo* review.[210] Although at least one commentator claims that the *de novo* and arbitrary and capricious standards produce similar outcomes,[211] determining the appropriate standard of review is integral to the reasoning in many cases.[212]

Under the first standard, a policyholder who has been denied a benefit must show that the plan administrator's decision was an "abuse of discretion" or "arbitrary and capricious," terms that are used interchangeably by the courts.[213] In such cases, courts are highly deferential to the plan administrator's interpretations of the plan's terms[214] because of the administrator's express authority to control and manage the operation and administration of the plan.[215]

Under the *de novo* standard, on the other hand, courts interpret the plan's provisions without deferring to the administrator's judgment.[216] The court starts anew, interpreting the health insurance

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3. (The company name) empowers (the named fiduciary) with discretionary authority to determine eligibility for benefits and/or to construe the terms of the Health Plan and/or interpret its doubtful or ambiguous provisions to carry out the Health Plan's intent and purpose and to facilitate its administration.

James, *supra* note 126, at 410-11; *cf.* Adams v. Blue Cross/Blue Shield of Md., 757 F. Supp. 661, 666 (D. Md. 1991) (finding that policy language, "as decided by us," was not clear and unequivocal enough to confer discretionary authority to plan administrators). *But see* Bucci v. Blue Cross-Blue Shield of Conn., 764 F. Supp. 728, 729, 731 (D. Conn. 1991) (finding that policy language, "not recognized by us," provided sufficient grant of discretionary authority).

In response to *Firestone*, some insurers have amended their policies "with the explicit goal of clarifying the discretionary authority." Hasty v. Central States, Southeast & Southwest Areas Health & Welfare Fund, 851 F. Supp. 1250, 1258 (N.D. Ind. 1994).

210. *See, e.g.*, Helman v. Plumbers & Steamfitters Local 166 Health & Welfare Trust, 803 F. Supp. 1407, 1413 (N.D. Ind. 1992) (holding that plan administrator's decision that ABMT for cancer of soft tissue was experimental was subject to *de novo* review because discretion to construe and interpret terms was not conferred upon administrator).

211. Julia Field Costich, *Denial of Coverage for "Experimental" Medical Procedures: The Problem of De Novo Review Under ERISA*, 79 KY. L.J. 801, 822 (1990-91). *But see* Papantonis, *supra* note 173, at 221 (asserting that standard of review used is often outcome determinative).

212. *See, e.g.*, Heasley v. Belden & Blake Corp., 2 F.3d 1249, 1254-58 (3d Cir. 1993) (discussing whether *de novo* standard of judicial review would apply to denial of benefits for liver transplant); *Hasty*, 851 F. Supp. at 1254 (mentioning that both parties had discussed at length what standard of review was to be applied because this would greatly affect court's role).

213. *See, e.g.*, Brown v. Blue Cross & Blue Shield of Ala., 898 F.2d 1556, 1562-63 (11th Cir. 1990) (discussing use of "arbitrary and capricious" standard in reviewing administrators' decisions); Guy v. Southeastern Iron Workers' Welfare Fund, 877 F.2d 37, 39 (11th Cir. 1989) (illustrating application of "arbitrary and capricious" standard by court); Bucci v. Blue Cross-Blue Shield of Conn., 764 F. Supp. 728, 731 (D. Conn. 1991) (applying "abuse of discretion" standard to policy where court found sufficient grant of discretionary authority found given to plan administrator).

214. *See* Firestone Tire & Rubber Co. v. Bruch, 489 U.S. 101, 111 (1989) ("'When trustees are in existence, and capable of acting, a court of equity will not interfere to control them in the exercise of a *discretion vested in them by the instrument* under which they act.'" (quoting Nichols v. Eaton, 91 U.S. 716, 724-25 (1875))) (emphasis in original).

215. 29 U.S.C. § 1103(a) (1988).

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

policy as it would any other non-ERISA contract.[217] The court applies rules of contract interpretation, often incorporating analogous state law.[218]

3. Comparing health insurance policies subject to state law with those subject to ERISA

In general, ERISA has been viewed as favorable to insurers, while state law has tended to favor policyholders.[219] One reason for this divergence is that breast cancer patients challenging health insurance policies under state law may have the option of a jury trial,[220] and juries tend to be more sympathetic to the patient than the insurer.[221] ERISA, on the other hand, confers concurrent jurisdiction in either state or federal court.[222] Therefore, insurers often opt to have the case removed to federal court where it will be heard solely by a judge.[223] In addition, state laws allow for tort claims, such as negligence, intentional infliction of emotional distress, mental anguish, and pain and suffering, to be heard in the same action as a coverage dispute.[224] ERISA, however, considers these claims to be extracontractual, and therefore unavailable when recovering benefits that are equitable in nature.[225] Remedies provided by ERISA are

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217. *Id.* at 590 (holding that where do novo standard applied, court has power to make its own interpretation of contract).

218. *See, e.g.*, Kekis v. Blue Cross & Blue Shield of Utica-Watertown, Inc., 815 F. Supp. 571, 583 (N.D.N.Y. 1993) (applying contract principles to ERISA health insurance policy, such that terms susceptible to multiple interpretations should be construed in favor of policyholder).

219. *See generally* J. Edward Neugebauer, *Make Sure Your Plan is an ERISA Plan: A Tale of Two Beneficiaries*, MANAGING EMPLOYEE HEALTH BENEFITS, Summer 1994, at 83-84 (advising employers to choose health plans subject to ERISA); Wieseman, *supra* note 111, at 8 (comparing state and federal courts' treatment of health benefit claims).

220. *See infra* notes 341-45 and accompanying text.

221. Saver, *supra* note 29, at 1104 (discussing reasons insurance companies prefer federal jurisdiction).

222. 29 U.S.C. § 1132(e)(1) (1988).

223. Saver, *supra* note 29, at 1104. Although the right to a trial by jury is not specifically addressed in ERISA, the circuit courts, in applying common law of trusts, have uniformly concluded that jury trials are unavailable under ERISA. *See, e.g.*, Blake v. Unionmutual Stock Life Ins. Co., 906 F.2d 1525, 1526 (11th Cir. 1990) (holding that under de novo standard of review, traditional equitable relief does not come under domain of Seventh Amendment right to jury trial); Chilton v. Savannah Food & Indus., 814 F.2d 620, 623 (11th Cir. 1987) (stating that beneficiaries under ERISA are not entitled to jury trial); Calamia v. Spivey, 632 F.2d 1235, 1237 (5th Cir. 1980) (concluding that there is no right to jury trial for strictly equitable determinations under ERISA).

224. *See, e.g.*, 37 Ins. L. Rep. (CCH) 178 (June 1994) (noting that plaintiff in *Fox v. Health Net* asserted intentional infliction of emotional distress claim based on HMO's coercion of treating oncologist to withdraw his support for plaintiff's ABMT for breast cancer). *But cf.* Taylor v. Blue Cross/Blue Shield of Mich., 517 N.W.2d 864, 871 (Mich. Ct. App. 1994) (stating that insurer's failure to pay contractual obligation does not amount to outrageous conduct necessary to sustain intentional infliction of emotional distress claim).

225. *See* Massachusetts Mut. Life Ins. Co. v. Russell, 473 U.S. 134, 148 (1985) (holding that "Congress did not provide, and did not intend the judiciary to imply" recovery for

limited to accrued benefits, a declaratory judgment of entitlement to benefits under the plan, or an injunction against refusal to pay for a treatment.[226]

B. Case Law Analysis—Policyholder Prevails

Both state and federal courts have ruled in favor of policyholders challenging insurers' denial of coverage of HDC-ABMT for breast cancer.[227] These courts generally approach such disputes in two ways. In some cases, courts focus on both the terms of the health insurance contract and the medical controversy surrounding the treatment; they have inquired whether HDC-ABMT for breast cancer falls within the Experimental Exclusion and whether it satisfies the objective coverage criteria set forth in the health insurance policy.[228]

In other cases, courts have looked beyond the contract and focused on the process by which insurers have arrived at their coverage determination.[229] These courts have asked whether the insurer undertook every reasonable effort on which to base its coverage determinations, and whether the insurer had operated under a conflict of interest while making its coverage determination.[230] This Comment maintains that if insurers operate under a conflict of interest or do not exercise reasonable efforts, then the coverage denial should not be upheld, even if the plan decisionmaking process is entitled to deference under ERISA.[231]

1. Absence of defining criteria in policy

While most health insurance policies expressly exclude coverage for experimental treatments,[232] not all policies clearly define what that

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extracontractual damages under ERISA); *but cf.* Robert Kamp, *The Argument for "Extra-Contractual" Damages Under ERISA*, 82 ILL. B.J. 70 (1994) (discussing alternative legal theories under which policyholders can offset ERISA's shortcomings).

226. 29 U.S.C. § 1132(a)(1)(B) (1988).

227. *See, e.g.*, Kekis v. Blue Cross & Blue Shield of Utica-Watertown, Inc., 815 F. Supp. 571, 583-84 (N.D.N.Y. 1993); Bucci v. Blue Cross-Blue Shield of Conn., 764 F. Supp. 728, 730 (D. Conn. 1991); Adams v. Blue Cross/Blue Shield of Md., 757 F. Supp. 661, 669 (D. Md. 1991); Pirozzi v. Blue Cross-Blue Shield of Va., 741 F. Supp. 586, 589 (E.D. Va. 1990); Taylor v. Blue Cross/Blue Shield of Mich., 517 N.W.2d 864, 867 (Mich. Ct. App. 1994).

228. *See infra* Part II.B.1.

229. *See infra* Part II.B.2-3.

230. *See infra* Part II.B.2-3.

231. *See infra* Part IV.B-C. *But see* Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (stating that Court cannot substitute its judgment for that of administrator under arbitrary and capricious standard of review); Jett v. Blue Cross & Blue Shield of Ala., 890 F.2d 1137, 1140 (11th Cir. 1989) (insisting that plan administrator's decisions must not be disturbed under arbitrary and capricious standard of review, even if evidence supports contrary decision).

232. *See supra* notes 107-38 and accompanying text.

entails.[233] Specifically, Experimental Exclusions often do not set out objective standards for determining whether a proposed treatment is experimental.[234] Courts consider such undefined Experimental Exclusions to be inherently ambiguous.[235]

Health insurance policies subject to state laws are governed by

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233. *See* Angela R. Holder, *Funding Innovative Medical Treatment*, 57 ALB. L. REV. 795, 800-03 (1994) (discussing experimental exclusions in health insurance contracts); *see also* Blue Cross of the Rochester Area Contract, *supra* note 124, at TR-64 (describing criteria for Blue Cross/Blue Shield of Rochester experimental exclusion). A policy clearly defines what constitutes an experimental treatment through use of objective criteria. For example, the Blue Cross/Blue Shield of Rochester policy uses four criteria to define its experimental exclusion:

> 1. Any medical device, drug or biological product must have received final approval to market by the [FDA] for the particular diagnosis or condition . . . .
> 2. Conclusive evidence from . . . published peer-reviewed medical literature must exist that the technology has a definite positive effect on health outcomes; such evidence must include well-designed investigations that have been reproduced by nonaffiliated authoritative sources with measurable results, backed up by the positive endorsements of national medical bodies or panels regarding scientific efficacy and rationale.
> 3. Demonstrated evidence as reflected in the published peer-reviewed medical literature must exist that the technology is at least as effective in improving health outcomes as established technology, or is usable in appropriate clinical contexts in which established technology is not employable.
> 4. Proof as reflected in the published peer-reviewed medical literature must exist that improvement in health outcomes, as defined in paragraph 3, is possible in standard conditions or medical practice, outside clinical investigatory settings.

Id.

234. For an example of a health insurance policy where the Experimental Exclusion adequately lists objective criteria, see the policy discussed in Bechtold v. Physicians Health Plan of N. Ind., 19 F.3d 322, 325-26 (7th Cir. 1994). That policy read, in part:

> "Experimental or Unproven Procedures" means any procedures, devices, drugs or medicines or the use thereof which falls within any of the following categories:
> 1. Which is considered by any government agency or subdivision, including but not limited to the [FDA], the Office of the Health Technology Assessment, or [Health Care Financing Administration] Medicare Coverage Issues Manual to be:
> a. experimental or investigational;
> b. not considered reasonable and necessary; or
> c. any similar finding;
> 2. Which is not covered under Medicare reimbursement laws, regulations or interpretations; or
> 3. Which is not commonly and customarily recognized by the medical profession in the state of Indiana as appropriate for the condition being treated.

Id.

235. *See, e.g.*, Dahl-Eimers v. Mutual of Omaha Life Ins. Co., 986 F.2d 1379, 1380 (11th Cir. 1993) (concluding that phrase "considered experimental" is ambiguous as matter of law); 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."); Brief of *Amici Curiae* for Plaintiff-Appellant at 8 n.4, *Dahl-Eimers* (No. 92-1158) (arguing that term experimental is "inherently ambiguous"); *see also* Belk, *supra* note 135, at 810 (advocating that courts construe undefined experimental exclusions against insurer). *See* Fisfis, *supra* note 118, at 795 (arguing that any undefined exclusionary clause in policy is "per se ambiguous"); *but see, e.g.*, Fuja v. Benefit Trust Life Ins. Co., 18 F.3d 1405, 1409 (7th Cir. 1994) (rejecting trial court's finding that phrase "in connection with medical or other research" is ambiguous); Farley v. Benefit Trust Life Ins. Co., 979 F.2d 653, 661 (8th Cir. 1992) (refusing to "consider the language of any of the criteria so vague as to be ambiguous or unenforceable").

contract principles, which construe ambiguities against insurers.[236] That rule of construction, however, does not necessarily apply to ambiguities in an ERISA-governed policy that sufficiently confers discretionary authority in its plan administrator;[237] in such instances, courts resolve the ambiguity,[238] without automatically construing it against the insurer, by relying predominately on medical expert testimony.[239] Because an ERISA plan administrator's determination is entitled to deferential review, courts have resolved ambiguities in favor of the administrator's interpretation so long as it is reasonable and not arbitrary and capricious.[240]

This Comment, however, recommends that courts resolve ambiguities about the experimental status of a treatment by making an independent determination through *de novo* review, without deferring to an ERISA plan administrator.[241] Specifically, in conducting *de novo* review, courts should apply a "primary purpose to benefit the patient" standard.[242] In short, if the proposed treatment's primary purpose is to benefit the patient, and research is merely a secondary purpose, courts should not regard it as experimental. Only when the primary purpose is research related, should courts deem the treatment experimental.

A "primary purpose to benefit the patient" standard serves the competing interests of both policyholders and insurers. It guarantees policyholders coverage for worthwhile and potentially life-saving medical treatments that are still under investigation. At the same time, it requires some level of proven medical value so that insurers avoid paying for quack therapies.

Even though the medical community is divided as to the overall, long-term efficacy of HDC-ABMT for breast cancer, it has reached a

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236. *See supra* notes 191-98 and accompanying text; *see, e.g.*, Waldrip v. Connecticut Nat'l Life Ins. Co., 566 So. 2d 434, 437 (La. App. 1990) (maintaining that experimental exclusion was ambiguous and therefore had to be construed against insurer, and in favor of coverage for liver transplant).

237. *See* Gottlich, *supra* note 205, at 1473 (explaining ERISA's preemptive effect on state laws, including common constructional rules used by state courts).

238. Gottlich, *supra* note 205, at 1473.

239. *See generally* Fisfis, *supra* note 118, at 797-98.

240. *See, e.g.*, Johnson v. District 2 Marine Eng'rs Beneficial Ass'n, 857 F.2d 514, 516 (9th Cir. 1988) (stating that ambiguities must be resolved in favor of trustees' interpretation under ERISA).

241. *But see* Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (stating that lower court should not substitute its judgment for that of ERISA fiduciary); Reilly v. Blue Cross & Blue Shield United of Wis., 846 F.2d 416, 420 (7th Cir. 1988) (refusing to undertake *de novo* review when reviewing insurance company's coverage denial because ERISA governed health plan).

242. *Accord* BELK, *supra* note 135, at 825 (proposing that courts should use demonstrated likelihood of success standard when defining what constitutes experimental medical treatment).

consensus that the short-term effects are favorable.[243] For that reason, most health professionals will agree that HDC-ABMT has some proven medical value in the treatment of breast cancer.[244] Therefore, in applying a "primary purpose to benefit the patient" standard to an undefined Experimental Exclusion, courts should conclude that HDC-ABMT is not experimental for the treatment of breast cancer.[245]

In resolving coverage disputes, courts rely on expert testimony to establish the value of HDC-ABMT for breast cancer. The following four cases, *Taylor v. Blue Cross/Blue Shield of Michigan*,[246] *Pirozzi v. Blue Cross-Blue Shield of Virginia*,[247] *Bucci v. Blue Cross-Blue Shield of Connecticut*,[248] and *Adams v. Blue Cross & Blue Shield of Maryland*,[249] illustrate how some courts have reached decisions favorable to the breast cancer patient by employing the equivalent of a "primary purpose to benefit the patient" standard when weighing expert medical testimony.

In *Taylor v. Blue Cross/Blue Shield of Michigan*,[250] Debra Taylor's health insurer, Blue Cross/Blue Shield of Michigan, refused to cover HDC-ABMT treatment for her breast cancer, which had spread to areas of her spine, based on an Experimental Exclusion.[251] The policy did not, however, define experimental. The Michigan Court of Appeals accepted a lower court's determination that the term

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243. *See supra* notes 96-110 and accompanying text (reporting that clinical trials comparing HDC-ABMT and conventional chemotherapy show that HDC-ABMT delivers higher complete response rates, but noting that it is too early to know long-term survival rates).

244. *See supra* note 113 and accompanying text (reporting that majority of oncologists polled would recommend HDC-ABMT to breast cancer patients).

245. Earlier cases concluded, however, that HDC-ABMT for the treatment of breast cancer was experimental. These cases addressed treatments undergone before 1989. *See* Sweeney v. Gerber Prods. Co. Medical Benefits Plan, 728 F. Supp. 594, 596 (D. Neb. 1989) (declaring that "[t]here is no question that [HDC-ABMT] as a treatment for breast cancer, remains today a treatment which is in an experimental and investigational stage"); Thomas v. Gulf Health Plan, 688 F. Supp. 590, 595 (S.D. Ala. 1988) (concluding that "[i]t is undisputed that, as it relates to the treatment of breast cancer, [HDC-ABMT] is experimental").

These early cases involved health insurance policies that did not expressly incorporate defining criteria with their Experimental Exclusions. Even had the courts applied a "primary purpose to benefit patient standard," it is most likely that they would have reached the same conclusion given the expert testimony at that time. In other words, in *Thomas*, not only did all the experts believe that HDC-ABMT was experimental, but also both parties conceded this point. 688 F. Supp. at 592. In *Sweeney*, the court did not consider expert testimony, but deferred to coverage decisionmakers. 728 F. Supp. at 596.

246. 517 N.W.2d 864 (Mich. Ct. App. 1994).

247. 741 F. Supp. 586 (E.D. Va. 1990).

248. 764 F. Supp. 728 (D. Conn. 1991).

249. 757 F. Supp. 661 (D. Md. 1991).

250. 517 N.W.2d 864 (Mich. Ct. App. 1994).

251. Taylor v. Blue Cross/Blue Shield of Mich., 517 N.W.2d 864, 867 (Mich. Ct. App. 1994). The health insurance policy did not cover "[b]enefits for care, services, supplies or devices which are experimental or research in nature." *Id.*

"experimental" was ambiguous because it could be understood in different ways if not accompanied by defining criteria.[252] A reasonable policyholder could interpret the term to mean either a medical procedure designed "solely for testing a hypothesis without contemplation that any benefit whatsoever would be gained by the patient" or "primarily for providing a benefit for the patient, but which would have the side effect of testing a hypothesis."[253]

The appellate court found persuasive the expert testimony of Taylor's treating oncologists,[254] who testified that with conventional chemotherapy, her life expectancy would be measured in months, whereas with HDC-ABMT she could be cancer-free for at least two to three years with no need for additional treatment.[255] Applying what resembled a "primary purpose to benefit the patient" standard,[256] the appellate court in *Taylor* affirmed the lower court's finding that HDC-ABMT for the treatment of breast cancer was not experimental.[257] In doing so, the court went so far as to explicitly recognize the superiority of HDC-ABMT over conventional treatments for breast cancer.[258]

A federal district court reached a similar result in *Pirozzi v. Blue Cross-Blue Shield of Virginia*.[259] The health insurance policy in question contained an Experimental Exclusion,[260] but did not define experimental.[261] Pamela Pirozzi, a Blue Cross-Blue Shield policyholder, was a thirty-three-year-old mother of three children when she was diagnosed with advanced breast cancer.[262] After conventional chemotherapy[263] and radiation treatments failed to stop the spread of her breast cancer through her rib cage, Pirozzi's

252. *Id.* at 868-69.
253. *Id.* at 869.
254. *Id.*
255. *See id.* The insurer's expert testified that with conventional chemotherapy, a cancer-free outlook was zero percent. *Id.*
256. *Id.* The court stated that, "[a]lthough . . . research was an underlying purpose of the procedure, . . . the primary purpose of the procedure was to provide [the breast cancer patient] her only opportunity to become free of cancer for a substantial period." *Id.*
257. *Id.* at 869-70 (recognizing HDC-ABMT as effective form of therapy for breast cancer, and requiring insurer to cover costs of treatment).
258. *Id.* at 869 (stating that breast cancer patients who are given HDC-ABMT experience better prognoses than those who choose conventional treatments).
259. 741 F. Supp. 586 (E.D. Va. 1990).
260. Pirozzi v. Blue Cross-Blue Shield of Va., 741 F. Supp. 586, 588 (E.D. Va. 1990). The Experimental Exclusion clause excluded "[e]xperimental or clinical investigative procedures; services of no scientifically proven medical value; also services not in accordance with generally accepted standards of medical practice." *Id.*
261. *Id.* at 589-90 (explaining that plan did not even require certain success rate from medical treatment to determine whether or not it was experimental).
262. *See id.* at 587-88.
263. The Blue Cross plan covered Pirozzi's conventional chemotherapy. *See id.* at 588 n.4.

treating physicians prescribed HDC-ABMT, concluding that it was her "best chance for any type of meaningful survival."[264] The HDC-ABMT procedure included a ten-day hospital stay, chemotherapy, a bone marrow transplant, and follow-up medical care, at an approximate cost of $100,000.[265] Blue Cross, claiming that the procedure was still experimental and had not been conclusively proven to increase survival rates, denied Pirozzi coverage.[266]

The federal district court, applying *de novo* review under ERISA,[267] relied heavily on expert testimony, first to resolve the meaning of the term experimental and then to determine whether HDC-ABMT for breast cancer was in fact experimental.[268] Blue Cross' expert testified, not as an oncologist but as an administrator, with respect to plan coverage and technology assessment.[269] The expert, who was responsible for rejecting Pirozzi's pre-authorization for HDC-ABMT based his coverage denial on three factors: (1) the Blue Cross-Blue Shield Association's December 1988 Uniform Medical Policy Memorandum, which concluded that HDC-ABMT was experimental;[270] (2) his readings of published, peer-reviewed literature, which indicated that there was no data demonstrating increased survival in breast cancer patients who had undergone HDC-ABMT;[271] and (3) a research protocol for HDC-ABMT for breast cancer, which indicated that the treatment was experimental.[272]

Oncologists testifying on behalf of Pirozzi responded that the most recent data on the efficacy of HDC-ABMT for breast cancer was more encouraging than that reflected by the published literature, a time lag explained by the substantial delay inherent in publishing a completed study.[273] Specifically, they testified that the treatment leads to higher median survival rates and tumor shrinkage than that achieved

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264. *Id.* at 588.
265. *See id.*
266. *See id.*
267. *Id.* at 589 (finding that although plan conferred discretionary authority to plan administrator for "medically necessary provision," no discretion was imbued to construe "experimental provision," and therefore administrator's decision was reviewed without deference).
268. *Id.* at 590.
269. *Id.*
270. *See id.* at 590-91. The Blue Cross-Blue Shield Association based its conclusion on five criteria set forth in its Technology Evaluation Criteria (TEC), as discussed *supra* note 136.
271. *See id.* at 591 (stating number of patients who had received HDC-ABMT was too small to draw conclusions).
272. *See id.* at 593.
273. *See id.* at 591-92 (citing studies where HDC-ABMT for breast cancer produced promising results); *id.* at 594 (noting that data from Dr. Stanley Watkins, Pirozzi's oncologist, showed HDC-ABMT to produce best results for patients with Stage IV metastic breast cancer).

under standard chemotherapy.[274] In addition, even the highest possible mortality rate for HDC-ABMT would not render the treatment experimental.[275] Finally, they contended that use of research protocols did not automatically indicate that the procedure was experimental; instead, the protocol was necessary to collect data to improve and refine the procedure.[276]

The court in *Pirozzi* rejected Blue Cross' application of the Experimental Exclusion because its coverage denial was based on criteria and recommendations from the Blue Cross Blue Shield Association (BCBSA), which had not been expressly incorporated into the health insurance policy.[277] Additionally, the health insurance policy did not establish that the insurer was compelled to adhere to the recommendations of the BCBSA.[278]

Absent defining criteria, the court in *Pirozzi* was left to determine whether HDC-ABMT for breast cancer was experimental under the Blue Cross plan. First, the court found the fact that numerous medical centers used the treatment to be convincing evidence that it had scientific value and was generally accepted as a medical practice.[279] Second, the court concluded that the procedure demonstrated tumor shrinkage that, in turn, correlated with increased survival.[280] Third, the court regarded HDC-ABMT to be safe given its low mortality rate.[281] Based on these findings, the court held that HDC-ABMT was not an experimental treatment, and was therefore not excluded by Pirozzi's Blue Cross plan.[282]

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274. *See id.* at 592 (noting median survival rate for standard dose chemotherapy without ABMT was only 12 months).

275. *See id.* at 593. Testimony indicated that the mortality rate for HDC-ABMT for breast cancer was actually four percent, but a 10-15% rate is presented to prospective patients and the public to account for varying risk factors such as age. *Id.*

276. *See id.* For example, the testimony showed that although chemotherapy treatment for testicular cancer is well-established, it is still being clinically evaluated in order to reduce toxicity and increase dose efficacy. *Id.* at 593 n.18.

277. *Id.* at 591.

278. *See id.* (noting that plan did not indicate that Blue Cross-Blue Shield Association criteria was determinative of treatment status).

279. *Id.* According to the court in *Pirozzi*, major medical centers using HDC-ABMT for treating breast cancer include:

> Duke University, Fairfax County Hospital, George Washington University, Georgetown University, Harvard University, Johns Hopkins University, Medical College of Virginia, Houston's M.D. Anderson Hospital, University of Chicago, University of Michigan, University of Nebraska, University of Texas—San Antonio, University of Virginia Medical Center, University of Wisconsin, Yale University Medical School, and all Florida teaching hospitals.

Id.

280. *Id.* at 594.

281. *Id.*

282. *Id.*

After reaching this conclusion, the court cautioned that its decision was "not a green light signalling a general expansion of coverage under group health policies," and that "[p]urveyors of quack remedies and fringe therapies should derive no comfort from this decision."[283] Rather, the decision was confined to the specific, expert medical testimony regarding a widely used state-of-the-art treatment for breast cancer patients.[284] The court suggested that it would have taken a more deferential approach to the coverage denial had the plan conferred broad discretion on the administrator.[285] The fact remains, however, that the plan at issue lacked defining criteria for the term "experimental."

Faced with such a plan, a court should determine whether a particular treatment is experimental by applying the "primary purpose to benefit the patient" standard. Critical to applying that test in *Pirozzi* would be the strong expert testimony regarding the efficacy and current use of HDC-ABMT. Therefore, even under a more deferential standard of review, the court should still have concluded that the treatment was not experimental.

This principle is exemplified by *Bucci v. Blue Cross-Blue Shield of Connecticut* [286] in which a federal district court held that an insurer's denial of benefits was arbitrary and capricious, notwithstanding a deferential standard of review.[287] Despite a mastectomy followed by nine months of conventional chemotherapy, Kathleen Bucci's breast cancer metastasized to her bones.[288] Her doctors recommended HDC-ABMT, but her insurer refused to pay, claiming that the procedure fell within her policy's Experimental Exclusion.[289] The exclusion provided that the insurer "will not pay for services . . . which are experimental or investigational in nature; meaning any treatment, [or] procedure . . . not recognized as accepted medical practice."[290]

The court in *Bucci* viewed the exclusion as ambiguous because it did not provide a set standard (such as a threshold ratio of statistical success, a level of data, or a particular test) to define when a medical procedure was nonexperimental and accepted.[291] The defendant

283. *Id.* The court noted that its decision was based on testimony from Board-certified specialists, not "self-proclaimed healers or figures from the fringes of medicine." *Id.* at 594-95.
284. *Id.* at 594.
285. *Id.*
286. 764 F. Supp. 728 (D. Conn. 1991).
287. Bucci v. Blue Cross-Blue Shield of Conn., 764 F. Supp. 728, 733 (D. Conn. 1991).
288. *See id.* at 730.
289. *See id.* at 729.
290. *Id.*
291. *See id.* at 732.

insurer was aware that more than sixty other health insurers covered HDC-ABMT for breast cancer,[292] and Kathleen Bucci's oncologist testified that the procedure yielded higher complete response and disease-free rates than conventional chemotherapy.[293] Consequently, the oncologist maintained, HDC-ABMT was not experimental, but an accepted procedure.[294] The court, noting that the absence of a threshold of acceptability[295] in the exclusionary language gave the insurer an unacceptable "floating standard which can rise or fall in any fact situation,"[296] held that the coverage denial was "arbitrary and capricious."[297]

After weighing the expert testimony, a federal district court in *Adams v. Blue Cross & Blue Shield of Maryland*[298] reached a similar conclusion, albeit in dicta.[299] For several reasons, the court concluded that the evidence presented at trial disproved the insurer's conclusion that HDC-ABMT for breast cancer was experimental.[300] First, the patient could expect longer disease-free survival with HDC-ABMT than with conventional chemotherapy.[301] Second, the patient would spend longer time "off therapy" after HDC-ABMT,[302] thereby improving her overall quality of life.[303] The likelihood of adverse side effects was substantially reduced during this off-therapy

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292. *See id.* at 731.

293. *See id.* at 730 (showing 59% complete response rate for HDC-ABMT versus 10-20% for low dose chemotherapy, as well as a 20-30% disease-free rate for two years for HDC-ABMT versus 0% for low dose chemotherapy).

294. *See id.* at 731 (characterizing procedure as one accepted by doctors).

295. *Id.* at 732.

296. *Id.* at 733.

297. *Id.*

298. 757 F. Supp. 661 (D. Md. 1991).

299. Adams v. Blue Cross & Blue Shield of Md., 757 F. Supp. 661, 676 (D. Md. 1991) (finding that Blue Cross decision to deny benefits to breast cancer patients seeking HDC-ABMT treatment was "arbitrary and capricious").

300. *Id.* at 676-77 (characterizing HDC-ABMT as generally accepted medical practice and finding Blue Cross' decision to refuse coverage for treatment to be unreasonable).

301. *Id.* at 674 (noting dramatic results in disease-free survival rates of women on HDC-ABMT, particularly those in Stage II/III primary breast cancer, 70% of whom achieved disease-free survival after 30 months, as compared with 20% survival rates in women on conventional chemotherapy). The court observed:

> [E]ven if a substantial number of those women were to die tomorrow and the overall survival rate were to drop to the level of low-dose therapy, at any one point in time more women will have lived longer free of disease than if they had been treated with low-dose therapy.

Id.

302. *Id.*

303. *Id.* (interpreting benefits of HDC-ABMT to include decrease in time during which patient experiences toxic side effects of chemotherapy and corresponding increase in patient's quality of life).

period, allowing the patient to spend more time outside the hospital.[304] In articulating why HDC-ABMT had proven medical value, the court in *Adams* thus applied what resembled a "primary purpose to benefit the patient" standard.[305]

As noted earlier, when an Experimental Exclusion does not provide defining criteria, courts have considered it inherently ambiguous.[306] In such instances, a court should weigh expert medical testimony, apply a "primary purpose to benefit the patient" standard, and ultimately make its own determination of whether or not a treatment is experimental,[307] regardless of whether the insurers' plan administrators and coverage decisionmakers are entitled to deferential review under ERISA. This approach thus effectively eliminates any deference to coverage decisions made by plan administrators, thereby promoting more uniformity in the outcomes of health insurance coverage disputes.[308] Additionally, it encourages those insurers that seek to limit their cost exposure for truly experimental treatments to carefully enumerate in their policies objective criteria for defining "experimental."[309]

2. *Reasonable efforts not undertaken by insurer*

Courts' inquiry should not end even when the exclusionary language in a health insurance policy is clear and is accompanied with defining criteria. Rather, the courts must still explore whether the insurer undertook reasonable steps in arriving at its coverage

304. *Id.* (referring to higher quality of life including reduced side effects, such as nausea and hair loss resulting, for patients under HDC-ABMT).

305. *Compare id. with* Taylor v. Blue Cross & Blue Shield of Mich., 517 N.W.2d 864, 869 (Mich. Ct. App. 1994) (explaining primary purpose to benefit patient standard as one where patient has opportunity to be free of cancer for "substantial period").

306. *See supra* note 235.

307. *See* Bucci v. Blue Cross & Blue Shield of Conn., 764 F. Supp. 728, 731-32 (D. Conn. 1991) (summarizing arguments of various experts and concluding that insurance company's reasoning was unsubstantiated); Adams v. Blue Cross & Blue Shield of Md., 757 F. Supp. 661, 676 (D. Md. 1991) (concluding that HDC-ABMT was medically accepted after weighing testimony of medical experts).

308. Otherwise, the following situation can theoretically result. Suppose patient *A* and patient *B* have identical stages of breast cancer, are both seeking HDC-ABMTs, and both have health insurance policies where the exclusionary language does not include the defining criteria. Upon denial of coverage from their respective insurers, both patients seek remedies through the courts. Although they appear to be similarly situated, it so happens that patient *A*'s health insurance policy is subject to a deferential standard of review whereas patient *B*'s is not. Consequently, the same court could potentially uphold the insurer's coverage denial for patient *A*, and not for patient *B*. The difference in outcomes appears not only confusing, but unfair.

309. *See* Harris v. Mutual of Omaha Cos., 992 F.2d 706, 713 n.4 (7th Cir. 1993) (pointing to various case examples as underscoring need for insurers and policyholders to use "greater care in their dealings," particularly where drafting of contracts is concerned).

determination. An insurer has an obligation to investigate the proposed treatment before making any such decision.[310]

In *White v. Caterpillar, Inc.*,[311] a federal district court applied a deferential standard of review to the insurer's coverage determination with respect to the exclusionary language and defining criteria of Betty White's health insurance policy.[312] Despite the policy's clarity on this point, the court held that the insurer's decision to deny Betty White coverage for HDC-ABMT as a treatment for breast cancer was "arbitrary and capricious."[313] The court focused its analysis on the insurer's failure to execute reasonable efforts for basing its coverage denial.[314]

The defining criteria in the health insurance policy stated: "'[The insurer] will use the reports of the Clinical Efficacy Assessment Project of the American College of Physicians and the Diagnostic and Therapeutic Assessment . . . of the American Medical Association as a guide to determine whether a surgical procedure is . . . generally accepted . . . .'"[315] In 1985, the Diagnostic and Therapeutic Technology Assessment (DATTA) report considered HDC-ABMT for breast cancer to be "investigational,"[316] the functional equivalent of "experimental." Five years later, however, the DATTA report found that HDC-ABMT was appropriate, established, and promising for the treatment of cancer, though it did not specifically address breast cancer.[317] Relying primarily on the 1985 DATTA report instead of the more recent 1990 DATTA report, the insurer denied Betty White coverage.[318]

The court in *White* held that the insurer had not made reasonable efforts to research HDC-ABMT for treating breast cancer prior to making the coverage decision.[319] First, the insurer relied on the

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310. *See Bucci*, 764 F. Supp. at 732 (referring to need for insurance company to conduct "inquiry" prior to refusing benefits); Anderson v. HMO Neb., No. A-92-489, 1993 WL 61839, at *7 (Neb. Ct. App. Mar. 9, 1993) (holding that investigation of treatment is required prior to denial of coverage on ground that treatment is "not medically necessary").

311. 765 F. Supp. 1418 (W.D. Mo.), *aff'd*, 985 F.2d 564 (8th Cir. 1991).

312. White v. Caterpillar, Inc., 765 F. Supp. 1418, 1420 (W.D. Mo.) (finding that health policy confers discretion upon administrator to make eligibility determinations by saying that administrator "shall have the sole and exclusive right to determine whether or not such procedure is a generally accepted surgical operation") (quoting insurance plan involved in case), *aff'd*, 985 F.2d 564 (8th Cir. 1991).

313. *Id.* at 1423.

314. *See id.* at 1422.

315. *Id.* at 1420 (quoting insurance plan).

316. *See id.* at 1421.

317. *See id.*

318. *See id.* at 1420-21 (discussing insurer's argument that 1985 findings were still accurate because they were never revised).

319. *Id.* at 1422.

outdated 1985 DATTA report, even when more current information was available.[320] The more recent report should have, at the very least, alerted the insurer to the need to inquire further.[321] Second, the insurer failed to read and consider four articles submitted by Betty White that related to the treatment.[322] Finally, the fact that the insurer had made a phone call to another insurance company seeking its recommendation on HDC-ABMT for breast cancer was insufficient.[323] For these reasons, the court admonished the insurer for "bury[ing] its head in the sand,"[324] instead of engaging in reasonable efforts to make a coverage determination.[325]

Reasonable efforts involve relevant inquiries and adequate research. At the very minimum, reasonable efforts should include: (1) a full evaluation of a policyholder's medical records and history; (2) a review of all materials and related articles submitted to the insurer by a policyholder and her treating oncologist; (3) an investigation into *recent* medical literature, reports, and evidence;[326] (4) consultations with experts in the relevant medical field; and (5) a comparison of other insurance companies' coverage policies.[327] When insurers fail to execute these reasonable efforts, courts should not uphold their coverage denials.

3. Conflict of interest

Courts must recognize when economic interests may have improperly motivated a coverage denial. Coverage denials made by plan administrators and coverage decisionmakers who operate under an inherent conflict of interest should not be upheld, even if their decisions are entitled to deferential review under ERISA.[328] This

320. *Id.* at 1421-22.

321. *Id.* (stating that "defendant steadfastly clung to the results of a five-year old study in denying plaintiff coverage," and noting that 1990 DATTA study should have been accorded more attention by insurer in reaching its decision).

322. *Id.* at 1422.

323. *Id.* at 1422 n.6.

324. *Id.* at 1422.

325. *Id.*

326. *See White*, 765 F. Supp. at 1421-22 (criticizing insurer's ill-advised decision to rely on outdated study); *cf.* Hawkins v. Mail Handlers Benefit Plan, No. CIV.A.1:94CV6, 1994 WL 214262, at *4 (W.D.N.C. Jan. 28, 1994) (pointing out that medical research is in constant state of flux, and that, therefore, up-to-the-minute inquiries should be conducted); Bucci v. Blue Cross & Blue Shield of Conn., 764 F. Supp. 728, 732 (D. Conn. 1991) (noting that medical information is "not static, but is developing").

327. *See* Heasley v. Belden & Blake Corp., 2 F.3d 1249, 1263 (3d Cir. 1993) (recommending that "judgment of other insurers and medical bodies" should be considered in determining whether procedure is experimental).

328. *See supra* notes 213-15 and accompanying text (discussing deference to plan administrator's determination under "arbitrary and capricious" standard of review under ERISA plans); *see also* Brown v. Blue Cross & Blue Shield of Ala., 898 F.2d 1556, 1565-66 (11th Cir.

conflict arises from the divergent interests to which a plan administrator owes a duty to the beneficiaries of the policy[329] and loyalty to the insurer.[330] Specifically, the plan administrator, who is employed by the insurance company, can maximize the insurer's profits[331] by exercising discretion to not pay claims, and thus operates under a conflict of interest.[332] A policyholder's claim may not receive an objective evaluation if the coverage review process involves such a

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1990) (holding that insurer is presumed to be influenced by conflict of interest, unless proven differently). *But cf.* Firestone Tire & Rubber Co. v. Bruch, 489 U.S. 101, 115 (1989) (finding that conflict of interest should be weighed as only "*a facto[r]* in determining whether there is an abuse of discretion'") (quoting RESTATEMENT (SECOND) OF TRUSTS § 187 cmt. d (1959)) (emphasis added); Bernards v. United of Omaha Life Ins. Co., 987 F.2d 486, 488 (8th Cir. 1993) (arguing that construing ambiguities against insurer under common contract principles is not appropriate in ERISA-governed plans (citing Finley v. Special Agents Mut. Benefit Ass'n, 957 F.2d 617, 619 (8th Cir. 1992))).

329. ERISA imposes a duty on the fiduciary of a health insurance policy to act "solely in the interest of the participants and beneficiaries . . . and for the exclusive purpose . . . of providing benefits . . . and defraying reasonable expenses." 29 U.S.C. § 1104(a)(1)(A) (1988); *see also* RESTATEMENT (SECOND) OF TRUSTS, *supra* note 328, § 170(1) (delineating trustee's duty to administer trust exclusively in beneficiaries' interest).

330. *See, e.g.*, Bechtold v. Physicians Health Plan of N. Ind., 19 F.3d 322, 325 (7th Cir. 1994) (stating plaintiff's argument that insurer would gain greater profit by denying claim and therefore administrator "was operating under a conflict of interest"); Reilly v. Blue Cross & Blue Shield United of Wis., 846 F.2d 416, 423 (7th Cir.) (noting that insurer's reliance on its own advisory groups created likelihood of abuse), *cert. denied*, 488 U.S. 856 (1988); Calhoun v. Complete Health Care, 860 F. Supp. 1494, 1500 (S.D. Ala. 1994) (stating that insurer saved money, by increasing profits or avoiding losses, when it refused to cover policyholders' claims); Hasty v. Central States, Southeast & Southwest Areas Health & Welfare Fund, 851 F. Supp. 1250, 1256 (N.D. Ind. 1994) (noting plaintiff's assertion that insurer was operating under conflict of interest that impacted its decision to refuse coverage); Wilson v. Group Hospitalization & Medical Servs., 791 F. Supp. 309, 312 (D.D.C. 1992) (finding that insurer's fiduciary role is in constant conflict with its role as profit-making entity); *see also* Jury Instruction No. SI16 requested by Defendant, Fox v. Health Net (Cal. Super. Ct. 1993) (No. 219262) (on file with *The American University Law Review*). The defendant's requested jury instruction in *Fox* stated:

> The insurer is bound to conduct itself with the utmost good faith for the benefit of its insured. However, the protection afforded by that relationship is not unlimited. The insurer has no duty totally to disregard its own interests when they conflict with the insured's interests. An insurer owes competing duties to other policyholders and stockholders not to honor meritless claims.

Id. The *Fox* jury instruction cited as authority the California case of *Thompson v. Cannon*, which discussed the divided loyalties of insurance adjusters and the unreasonableness of expecting that adjusters would work only in the insured's interests. Thompson v. Cannon, 274 Cal. Rptr. 608, 610 (1990).

331. A conflict of interest arises only when a coverage denial avoids a direct expense to an insurer, as opposed to a system that merely allocates its committed funds among beneficiaries. *Cf. Bechtold*, 19 F.3d at 325 (noting that insurer stood to gain profit from denying coverage, thereby signalling conflict of interest).

332. *See* Brown v. Blue Cross & Blue Shield of Ala., 898 F.2d 1556, 1561 (11th Cir. 1990) (noting that because insurance company pays out to beneficiaries from its own assets, its fiduciary role lies in perpetual conflict with its profit making role as business), *cert. denied*, 498 U.S. 1040 (1991); *Wilson*, 791 F. Supp. at 312 (discussing conflict of interest posed by insurance companies' two roles as fiduciary profit making business).

conflict of interest, a factor that a reviewing court should weigh heavily.[333]

Conflict of interest played a substantial role in *Doe v. Group Hospitalization & Medical Services*,[334] in which the Fourth Circuit concluded that a health insurer "abused its discretion" by denying HDC-ABMT coverage for a patient with multiple myeloma.[335] The court afforded less deference to the insurer's coverage denial given its clear financial interest: [336]

> [The insurer's] profit from the insurance contract depends on whether the claims allowed exceed the assumed risks. To the extent that [the insurer] has discretion to avoid paying claims, it thereby promotes the potential for its own profit. That type of conflict flows inherently from the nature of the relationship entered into by the parties . . . .[337]

Courts should follow the Fourth Circuit's approach and presume that a decision made by an insurer while operating under a conflict of interest is an abuse of discretion. The burden is on the plan administrator to prove that self-interest and profits did not motivate his or her decision.[338] In line with that approach, many courts have weighed the conflict of interest factor heavily against the insurer, even when the plan administrator's decisions were entitled to deference.[339] Other courts have merely used it to buttress their findings that the insurer's coverage denial was inappropriate.[340]

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333. Doe v. Group Hospitalization & Medical Servs., 3 F.3d 80, 86-87 (4th Cir. 1993) (stating that even careful, sensitive coverage decisionmaker may unconsciously favor profit interest of insurance company over interest of beneficiaries, leaving beneficiaries less protected).

334. 3 F.3d 80 (4th Cir. 1993).

335. *Id.* at 89.

336. *Id.*

337. *Id.* at 86.

338. *See* Brown v. Blue Cross & Blue Shield of Ala., 898 F.2d 1556, 1566 (11th Cir. 1990) (holding that burden shifts to fiduciary to prove that self-interest did not taint its interpretation of insurance plan provisions when beneficiary demonstrated substantial conflict of interest); Arthurs v. Metro. Life Ins. Co., 760 F. Supp. 1095, 1098-99 (S.D.N.Y. 1991) (applying less deferential standard of review because plan administrator had conflict of interest).

339. *See, e.g., Doe*, 3 F.3d at 87 (holding that although fiduciary's decision was entitled to some deference, lesser deference was warranted in order to neutralize influences resulting from conflict of interest when insurer and administrator of health benefits plan are same); Clark v. K-Mart Corp., No. 91-3723, 1992 WL 106935, at *8 (3d Cir. May 22, 1992) (Scirica, J., dissenting) (arguing that majority mistakenly applied arbitrary and capricious standard where less deferential standard was more appropriate due to conflict of interest); *Brown*, 898 F.2d at 1566 (holding that Blue Cross' fiduciary duty conflicted with its profit making role, and therefore, fiduciary could not act in exclusive best interest of beneficiaries); Boland v. King County Medical Blue Shield, 798 F. Supp. 638, 643 (W.D. Wash. 1992) (holding that standard of review was not purely deferential due to conflict of interest, even though plan administrator had been granted full discretionary authority by plan).

340. *See, e.g.*, Anderson v. HMO Neb., No. A-92-489, 1993 WL 61839, at *8 (Neb. Ct. App. Mar. 9, 1993) (bolstering its finding that coverage denial was arbitrary and capricious by alluding to conflict between insurer's role as administrator and payor); Kekis v. Blue Cross & Blue Shield

A jury trial before a lower state court in California in *Fox v. Health Net of California*,[341] dealt with the conflict of interest issue. This case gained national recognition[342] when the jury awarded $89 million in damages to a policyholder, by far the largest amount ever levied against an insurer for denial of medical benefits.[343] A substantial portion of the case focused on the insurance company decisionmaker's inherent conflict of interest, which stemmed from economic incentives to deny coverage built into Health Net's compensation structure.[344] The immense jury award, comprised of $12.1 million in compensatory damages and $77 million in punitive damages,[345] sends a strong message to the health insurance industry to revise its coverage review process, particularly by eliminating any conflict of interest.[346]

Viewed in light of the nationwide debate over health care reform, the *Fox* case demonstrates how managed health care and cost containment could lead to both decreased availability of health care and lower quality care.[347] At age thirty-eight, Nelene Fox, a mother

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of Utica-Watertown, Inc., 815 F. Supp. 571, 583 (N.D.N.Y. 1993) (interpreting unclear terms in favor of insured coupled where conflict of interest led to improper coverage denial); Bucci v. Blue Cross & Blue Shield of Conn., 764 F. Supp. 728, 733 (D. Conn. 1991) (buttressing its finding that benefits denial was arbitrary and capricious with conflict of interest factor because "denial avoids a direct expense to [insurer], not merely an allocation of committed funds"); *see also* Reilly v. Blue Cross & Blue Shield United of Wis., 846 F.2d 416, 423 (7th Cir. 1988) (indicating that insurer's reliance on its own advisory groups created inherent risk of abuse); Scalamandre v. Oxford Health Plans (N.Y.), Inc., 823 F. Supp. 1050, 1060 n.7 (E.D.N.Y. 1993) (mentioning that insurer was not entitled to broad discretion because it operated under conflict of interest when it paid benefits out of its own assets).

341. No. 219692 (Cal. Super. Ct., Dec. 23, 1993), *cited in California Jury Orders HMO to Pay $90 Million to Estate of Cancer Victim*, 3 Health L. Rep. (BNA) 18, 19 (Jan. 6, 1994). Although many courts have struggled with insurance coverage for breast cancer treatments, this case is one of a very few to be tried before a jury. *Id.*

342. *See generally* Erik Eckholm, *$89 Million Awarded Family Who Sued H.M.O.*, N.Y. TIMES, Dec. 30, 1993, at A1; Tom Gorman, *Jury Adds $77 Million to Judgment Against HMO*, L.A. TIMES, Dec. 29, 1993, at A1 (reporting that jury awarded $77 million in punitive damages and $12.1 million in compensatory damages to family of breast cancer victim); Michael Meyer & Andrew Murr, *Not My Health Care*, NEWSWEEK, Jan. 10, 1994, at 36 (indicating that jury award was "wake-up call" for health care industry and Washington policymakers who debate how to balance demands for innovative "high tech" medicine against rising costs); *"What's A Life Worth" - Health Insurance Injustice* (ABC television broadcast, Apr. 15, 1994) (portraying sentiments of family members, doctors dealing with insurance company, and jury).

343. Eckholm, *supra* note 342, at A1 (positing that high award "has sent nervous tremors through the health insurance industry"); *cf. HMO Settles Denial-of-Treatment Lawsuit in California Cancer Case*, 3 Health L. Rep. (BNA) 487, 487 (Apr. 14, 1994) (reporting that Health Net abandoned appeal in favor of settlement for undisclosed sum).

344. *See* Francis J. Serbaroli, *Denial of Payment for Medical Treatment: Concern for Insurers*, N.Y. L.J., Mar. 30, 1994, at 3, 4 (stating that "experimental" nature of HDC-ABMT was not major issue in jury deliberations).

345. *Id.*

346. *See* Meyer & Murr, *supra* note 342, at 36.

347. *Cf.* Gorman, *supra* note 342 (suggesting implications that *Fox v. Health Net* may have for health care industry).

of three daughters, was diagnosed with breast cancer.[348] Despite two mastectomies and conventional chemotherapy, her cancer spread to her bone marrow.[349] Fox's doctor informed her that she had at most eight months to live with continued conventional chemotherapy, but suggested that HDC-ABMT could provide a better quality of life and a prolonged life expectancy, as well as the possibility of cure.[350] Fox agreed to undergo the procedure.[351]

When Fox became eligible for treatment at the University of Southern California cancer center (U.S.C.),[352] her doctor wrote a letter to her HMO, Health Net,[353] discussing the necessity of her treatment.[354] Health Net, however, denied coverage, claiming HDC-ABMT for breast cancer was experimental and would not be effective because her cancer had reached advanced stages.[355] A short time later, Fox's doctor told her that he no longer recommended the procedure.[356]

Several days after the coverage denial, Health Net offered to pay for Fox's procedure, but only if a specified transplant facility other than U.S.C. approved her.[357] In order to determine her eligibility at another facility, Fox would have been forced to undergo more extensive, lengthy testing, a delay that would carry the risk that her cancer would spread further. If her cancer progressed during that

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348. *See* Trial Brief for Plaintiffs at 2, Fox v. Health Net (Cal. Super. Ct. 1993) (No. 219692) (on file with *The American University Law Review*).

349. *See id.*

350. *See id.* at 2-3.

351. *See id.* at 3.

352. *See id.*

353. Health Net is a federally qualified Health Maintenance Organization that offers prepaid health care plans to employers in California. *See* Trial Brief for Defendant at 2, Fox v. Health Net (Cal. Super. Ct. 1993) (No. 219692) (on file with *The American University Law Review*). Nelene Fox obtained health insurance through her husband's employer, the Temecula Unified School District, which employed him as a public high school teacher. *See* Trial Brief for Plaintiffs, *supra* note 348, at 2. Of the plans offered by his employer, Mr. Fox had selected Health Net to be the comprehensive health care insurer for his family. *See* Trial Brief for Defendants at 3.

354. *See* Trial Brief for Plaintiffs, *supra* note 348, at 4. *But see* Trial Brief for Defendant, *supra* note 353, at 20 (clarifying that doctor's letters were "solely for the purpose of attempting to assist [Nelene Fox] in obtaining insurance coverage for the treatment," and that doctor later admitted his letters misrepresented nature of Fox's medical condition, as well as risks and benefits of HDC-ABMT for her condition).

355. *See* Trial Brief for Defendant, *supra* note 353, at 11-12.

356. *See* Trial Brief for Plaintiffs, *supra* note 348, at 3.

357. *See* Trial Brief for Defendant, *supra* note 353, at 14. Fox's family alleged that Health Net's offer was motivated by stall tactics so that Fox's illness would spread and she would soon become ineligible for HDC-ABMT at any facility. *See* Trial Brief for Plaintiffs, *supra* note 348, at 33. *But see* Trial Brief for Defendant, *supra* note 353, at 31 (stating that offer for second opinion was "*solely* due to the concern of [Health Net's Vice President] that the treatment was very risky for Mrs. Fox and that she may not have made a truly informed decision to undergo it") (emphasis in original).

period, she in turn risked becoming medically ineligible for HDC-ABMT at any transplant facility.[358] For that reason, Fox decided to proceed with the HDC-ABMT at U.S.C. on a self-pay basis.[359] Family and friends helped raise the necessary funds through nationwide public appeals, softball tournaments, garage sales, bake sales, art auctions, dinner parties, and other fundraising events.[360]

In their suit against *Health Net*, Fox's family argued, among other things,[361] that Fox's claim did not receive fair and objective review because Health Net's coverage review process operated under a conflict of interest.[362] Fox's family alleged that her doctor's "change of mind" was due to the Health Net's improper influence.[363] A bonus plan supplemented the salary of the Health Net executive responsible for making coverage determinations,[364] under which the Health Net coverage reviewer received a bonus beyond his salary "based on reductions in medical loss ratio attributable to his efforts."[365] In other words, Health Net's decision whether to cover costly medical procedures, such as HDC-ABMT, affected not only the company's losses and medical loss ratios, but also the bonuses of the individual's deciding whether to provide coverage.[366] While the jury

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358. *See* Trial Brief for Plaintiffs, *supra* note 348, at 33.

359. *See* Trial Brief for Plaintiffs, *supra* note 348, at 5.

360. *See* Trial Brief for Plaintiffs, *supra* note 348, at 4-5. *But cf.* Trial Brief for Defendant, *supra* note 353, at 29-30 (emphasizing that fundraising activities began before Health Net was contacted about coverage for HDC-ABMT).

361. In their lawsuit, Nelene Fox's family alleged breach of contract, breach of the covenant of good faith and fair dealing (bad faith denial of coverage), and intentional infliction of emotional distress. Trial Brief for Plaintiffs, *supra* note 348, at 8. Nelene Fox died during the pendency of this litigation. Fox v. Health Net, 37 ATLA L. Rep. 178 (June 1994).

362. *See* Trial Brief for Plaintiffs, *supra* note 348, at 34-35 (submitting that Health Net's doctor who made coverage decision affecting plaintiff was its Vice President and Associate Medical Director, and whose salary was supplemented by merit bonus plan based on Health Net's financial condition).

363. Trial Brief for Plaintiffs, *supra* note 348, at 31 (indicating that doctor's recommendation changed immediately following his conversation with HMO officials).

364. Trial Brief for Plaintiffs, *supra* note 348, at 34.

365. *See* Trial Brief for Plaintiffs, *supra* note 348. The following is an excerpt from a deposition taken of Health Net's Medical Director:

> Q. Do you believe by refusing requests for bone marrow transplants, [the coverage decisionmaker] would benefit in any way by this plan?
>
> A. Given the structure, yes, the incentive is there to deny services. Given the individual [coverage decisionmaker] and the fact that he has a long-term view, which says such practices cost you a tremendous amount down the line, I am convinced that would never happen.

Trial Brief for Plaintiffs, *supra* note 348, at 34-35.

366. *See* Trial Brief for Plaintiffs, *supra* note 348, at 34-35. *See generally Lead Witness, Evidence of Financial Motive Assist Plaintiff in Bad Faith Trial*, 8 INSIDE LITIG., Apr. 1994, at 6 (discussing HMO's bonus programs that influenced decision to reject breast cancer patient's claim). *But cf.* Eckholm, *supra* note 342, at 1 (mentioning Health Net medical director's denial of accusation that Health Net officials had financial incentive to withhold useful treatments).

apparently calculated punitive damages[367] to deter further abuses specifically by Health Net,[368] the exorbitant award further conveyed a warning to all HMOs against providing financial incentives for withholding treatments.[369]

As this Comment has recommended, courts should heavily weigh a conflict of interest against the insurer, and advise jurors to do the same.[370] This will compel insurers to modify their coverage decisionmaking process so that any financial incentive to control costs, which at the same time compromises patients' interests, would be eliminated.[371] This could be accomplished in either of two ways. Insurers could designate independent committees, comprised of medical professionals, to assess policyholders' claims.[372] Coverage determinations made by the independent committee must be binding on the insurer; otherwise, the conflict of interest will not be eliminated. Alternatively, insurers could structurally detach the decisionmaking process from the insurer's assets. From a policy perspective, these changes would protect the policyholders by ensuring an objective review of medical coverage claims.

C. Case Law Analysis—Insurer Prevails

For a variety of reasons, three circuit courts[373] and numerous

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367. The jury instructions for punitive damages read as follows:

> If you determine that punitive damages should be assessed against a defendant, in arriving at the amount of such an award, you must consider: (1) The reprehensibility of the conduct of the defendant (2) The amount of punitive damages which will have a deterrent effect on the defendant in the light of defendant's financial condition (3) That the punitive damages must bear a reasonable relation to the injury, harm, or damage actually suffered by the plaintiff.

Jury Instruction No. 14.72.2 (1989 Re-Revision) Fox v. Health Net (Cal. Super. Ct. 1993) (No. 219692) (on file with *The American University Law Review*).

368. *See "What's a Life Worth," supra* note 342, at 5 (quoting juror as saying "we're aware that possibly they were saving money by denying the treatment and therefore there would be more money for business").

369. *See supra* notes 342-46 and accompanying text.

370. *See* Heasley v. Belden & Blake Corp., 2 F.3d 1249, 1260 n.12 (3d Cir. 1993) (advising that courts scrutinize more closely decisions by insurers acting under conflict of interest).

371. *Cf.* Rodwin, *supra* note 185, at 605 (noting that managed care providers may reduce physicians' income if number of referrals or tests ordered exceeds threshold costs that health maintenance organization sets).

372. *See Heasley*, 2 F.3d at 1260 n.12 (suggesting that organization reference in insurance policy should be independent to avoid conflict of interest); *see also* Grace P. Monaco & Rebecca L. Burke, *Insurer as Gatekeeper—Part Two: Policy Obstacles in Unproven Methods Litigation*, 20 FORUM 400, 409-10 (1985) (discussing options for insurers in defining experimental treatments). *But cf.* Neugebauer, *supra* note 219, at 83, 84 (noting that after *Fox* case was settled, Health Net amended its plan specifically to exclude coverage of HDC-ABMT for breast cancer).

373. *See* Fuja v. Benefit Trust Life Ins., 18 F.3d 1405, 1412 (7th Cir. 1994) (indicating that despite court's compassion for patient, it was institutionally unequipped to decide larger social question reserved for political branches and was empowered only to decide legal issues); Harris v. Mutual of Omaha Cos., 992 F.2d 706, 713 (7th Cir. 1993) (holding that denial of coverage

federal district courts[374] have upheld insurers' coverage denials for HDC-ABMT in the treatment of breast cancer. As discussed earlier, this Comment argues that courts should uphold an insurers' coverage denial only when *all* of the following three conditions have been satisfied: (1) the policy contains reasonable criteria for defining "experimental";[375] (2) reasonable efforts have been made on which to base the coverage decision;[376] and (3) the coverage decisionmaker operates under no conflict of interest.[377] In the following cases, courts have taken a different approach and upheld the insurer's coverage denial because some, though not all, of these conditions were fulfilled.

In *Hasty v. Central States, Southeast and Southwest Areas Health and Welfare Fund*,[378] a federal district court found that an insurer's decision to deny Loretta Hasty coverage for her breast cancer treatment was not arbitrary and capricious.[379] The insurer, Central States, was a not-for-profit trust fund,[380] which was governed and administered by a Board of Trustees that was responsible for making coverage determinations.[381] The Board's coverage denial was based on an exclusionary clause in Hasty's health insurance policy that stated that the insurance company would not pay for "care, treatment,

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was not arbitrary and capricious, primarily because experimental exclusion was defined); Clark v. K-Mart Corp., No. 91-3723, 1992 WL 106935, at *6 (3d Cir. May 22, 1992) (agreeing with insurer that HDC-ABMT was not yet established treatment for breast cancer); Holder v. Prudential Ins. Co. of Am., 951 F.2d 89, 91 (5th Cir. 1992) (upholding trial court's finding that HDC-ABMT for breast cancer was experimental). *But cf.* Gallinari, *supra* note 147, at 39-40 (arguing that outcomes in Third and Fifth Circuits are not really detrimental to breast cancer patients).

374. *See, e.g.*, Hasty v. Central States, Southeast & Southwest Areas Health & Welfare Fund, 851 F. Supp. 1250, 1260 (N.D. Ind. 1994) (holding that insurer's decision to deny coverage was not "arbitrary and capricious"); Lowery v. Health Chicago, No. 92-C-7657, 1994 WL 194265, at *6 (N.D. Ill. May 16, 1994) (holding that insurer's denial of coverage was proper under either "arbitrary and capricious" or *"de novo"* standard of review); Uhrich v. Caterpillar Inc., No. 93-C-5271, 1993 WL 478990, at *5 (N.D. Ill. Nov. 18, 1993) (holding that insurer did not abuse its discretion in denying coverage for HDC-ABMT procedure); Arrington v. Group Hospitalization & Medical Servs., 806 F. Supp. 287, 290 (D.D.C. 1992) (finding HDC-ABMT for breast cancer clearly excluded under insurance policy's language).

375. *See supra* Part II.B.1.

376. *See supra* Part II.B.2.

377. *See supra* Part II.B.3.

378. 851 F. Supp. 1250 (N.D. Ind. 1994).

379. Hasty v. Central States, Southeast & Southwest Areas Health & Welfare Fund, 851 F. Supp. 1250, 1260 (N.D. Ind. 1994). The court in *Hasty* found that the health insurance policy, which constituted an employee welfare benefit plan subject to ERISA, *id.* at 1253, conferred discretionary authority on the Board of Trustees, *id.* at 1255 (quoting insurance policy as stating that insurer "is the only group having the authority to change or interpret any part of this Plan"). Therefore, the Trustee's decision warranted a deferential standard of review. *Id.* at 1254.

380. *See id.* at 1253. All assets and income were used only to pay medical claims or defray administrative expenses. *See id.*

381. *See id.*

services and supplies which are not uniformly and professionally endorsed by the general medical community as standard medical care, including care, treatment, services, and supplies which are experimental in nature."[382]

The Board of Trustees undertook reasonable efforts in arriving at its decision.[383] First, Central States transmitted Hasty's medical records to the Pittsburgh Cancer Institute, an independent, objective third party, for evaluation.[384] The Institute reported that, given Hasty's condition, the proposed treatment was not uniformly and professionally endorsed by the medical community as standard medical care.[385] In addition, the Board of Trustees reviewed all materials relating to Hasty's medical records, as well as affidavits submitted by her treating oncologist.[386] Further, they considered medical literature regarding the treatment, as well as the outcome of prior litigation.[387] The court concluded that overall, this comprehensive review, which involved information advocating positions both for and against the proposed treatment,[388] constituted reasonable efforts on the part of the insurer or, more specifically, the Board of Trustees.

In addition to noting the Board's reasonable efforts,[389] the court in *Hasty* found that the Board of Trustees did not operate under any conflict of interest.[390] The Board of Trustees was not *both* the administrator and the insurer.[391] Rather, the two were structurally distinct; the Trustees represented the administrator and the insurer was the Trust itself.[392] Also, denial of benefits would not produce profits, because the insurer was a not-for-profit entity.[393] Consequently, the Board of Trustees had no incentive to deny benefits to policyholders.[394] Additionally, unlike the decisionmaker in *Doe*,[395]

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382. *Id.* at 1254.
383. *See id.* at 1253 (remarking that coverage reviewers sat down with 66 page agenda and more than 900 pages of supporting documents when making coverage determination).
384. *See id.*
385. *See id.*
386. *See id.*
387. *See id.* at 1253-54. These seven articles also discussed the proposed treatment's overall acceptance within the medical community. *See id.*
388. *Id.* at 1254.
389. *Id.* at 1258.
390. *Id.* at 1256.
391. *See id.* at 1257.
392. *See id.*
393. *See id.* (noting that denial of benefits left more funds available for other claims).
394. *Id.*
395. Doe v. Group Hospitalization & Medical Servs., 3 F.3d 80 (4th Cir. 1993). In *Doe*, Blue Cross and Blue Shield of the National Capital area was both the administrator and the insurer. *See id.* at 86; *see supra* notes 333-40 and accompanying text (discussing court's decision in *Doe*).

the Board of Trustees' decisions to approve coverage would not reduce funds from its own pockets.[396] Instead, the Trustees acted as "impartial judges."[397]

Nevertheless, this Comment maintains that when experimental exclusions stand alone, unaccompanied by objective defining criteria, the exclusions are inherently ambiguous. The Experimental Exclusion in Hasty's policy did not contain defining criteria.[398] The reviewing court should therefore have resolved the necessarily ambiguous exclusion by weighing expert testimony and applying a "primary purpose to benefit the patient" standard. The court refused, however, to consider Hasty's evidence that the proposed treatment for breast cancer was endorsed by the general medical community as standard medical care.[399] Instead, the court concluded that a deferential standard of review was appropriate and simply deferred to the conclusion reached by the Board,[400] rather than making its own determination.[401]

The health insurance policies before the Seventh Circuit in *Fuja v. Benefit Trust Life Insurance Co.*,[402] and the Fifth Circuit in *Holder v. Prudential Insurance Company of America*,[403] did contain defining criteria for disputed Experimental Exclusions.[404] The threshold issue in *Fuja* was whether one of the defining criteria—"in connection with medical or other research"—was itself ambiguous.[405] After

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396. *Compare Hasty*, 851 F. Supp. at 1257 (noting that Board of Trustees do not lose funds when claims are approved) *with Doe*, 3 F.3d at 86 (finding Blue Cross' profits dependent upon claims approved).

397. *Hasty*, 851 F. Supp. at 1258.

398. *See id.* at 1253 (citing language of policy).

399. *Id.*

400. *Id.* at 1259.

401. *Id.*

402. 18 F.3d 1405 (7th Cir. 1994).

403. 951 F.2d 89 (5th Cir. 1992).

404. In *Fuja*, the policy only covered treatments

> given in accordance with generally accepted principles of medical practice in the U.S. at the time furnished; *and that are approved for reimbursement by the Health Care Financing Administration*; and that are not deemed to be experimental, educational or investigational in nature by any appropriate technological assessment body established by any state or federal government; and *that are not furnished in connection with medical or other research.*

Fuja v. Benefit Trust Life Ins. Co., 18 F.3d 1405, 1408 (7th Cir. 1994).

In *Holder*, the policy provided that it would not cover

> [a]nything . . . not reasonably necessary for medical care of sickness or injury. To be "reasonably necessary" a service . . . 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* . . . .

Holder v. Prudential Ins. Co. of Am., 951 F.2d 89, 90 n.3 (5th Cir. 1992).

405. *Fuja*, 18 F.3d at 1409.

concluding that it was not,[406] the Seventh Circuit applied the criterion to the Grace Fuja's request that her insurer cover her HDC-ABMT treatment.[407] The Fifth Circuit, on the other hand, did not even pause to address whether the policy's criterion—"education or experimental in nature"—was ambiguous. Instead, the court proceeded with the case as if the policy language was clear.[408]

Finding that HDC-ABMT as a treatment for breast cancer was legitimately precluded by Experimental Exclusions, both the Fifth and Seventh Circuits denied coverage.[409] Both courts were persuaded largely by the consent forms and protocols utilized in the administration of the policyholders' treatment.[410] For instance, Fuja's protocols and consent forms repeatedly invoked phrases such as "research project," "research study," and noted that "safety and efficacy . . . will be evaluated."[411] Likewise, Wanda Holder's signed consent form

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406. *Id.* at 1410.

407. *Id.* at 1412. The court determined that the Benefit Trust Insurance contract unambiguously denied coverage for the HDC-ABMT treatment. *Id.*

408. *Holder*, 951 F.2d at 90-92 (beginning discussion by focusing on expert's opinion and trial court's finding).

409. *Fuja*, 18 F.3d at 1411; *Holder*, 951 F.2d at 90-91. The Fifth Circuit in *Holder* emphasized that its decision was based on the circumstances in 1987, leaving open the possibility that any future litigation may turn in favor of the breast cancer patient. *Holder*, 951 F.2d at 91. The court observed: "Of course, it is the nature of medical research that what may one day be experimental may the next be state of the art treatment. Had [the insured cancer patient] undergone a similar treatment more recently under an accepted protocol, this case may have turned out differently." *Id.* The court went on to note: "Several recent studies and the cases in which they have been applied to compel coverage of HDC-ABMT treatment for Stage IV metastatic breast cancer lead to the conclusion that the treatment, under a different protocol than that administered to [the cancer patient], may no longer be considered experimental." *Id.* at 91 n.5.

410. *See Fuja*, 18 F.3d at 1411; *Holder*, 951 F.2d at 90.

411. *Fuja*, 18 F.3d at 1411; *see* Brief for Appellant at 20-21, Fuja v. Benefit Trust Life Ins. Co., 18 F.3d 1405 (7th Cir. 1994) (No. 93-1150) (discussing evidence demonstrating that HDC-ABMT falls within medical research criterion) (on file with *The American University Law Review*). Appellant Benefit Trust stated that:

> The protocol, under which [the treating oncologist] is currently the "principal *investigator*," describes itself as "a study" and provides that "[o]ur studies have been *one of the first in this area of investigation* . . ." and that data "provide impetus for continued *investigation* of high-dose intensification therapy in Stage IV breast cancer." [Grace Fuja's] informed consent, which identifies [the treating oncologist] as the "Doctor(s) Directing *Research*," is entitled: "Consent by Subject for Participation in *Research Protocol*." It advises that "[y]ou are being asked to participate in a *research study*," and that "[i]n order to decide whether or not you want to be a part of this *research study*, you should understand enough about its risks and benefits to make an informed judgment." The "Purpose of Study," according to the informed consent, is "to use a two-step approach in the treatment of advanced breast cancer," stating that "[t]he safety and efficacy of this two-step approach in the treatment of breast cancer *will be* evaluated." Under the "Agreement to Consent" provisions, it advises that "[t]he *research project* and the treatment procedures associated with it have been fully explained to me" and that "I, the undersigned, hereby consent to participate as a subject in the above described *research project* conducted at the University of Chicago Medical Center." Clearly, then, the documentary evidence conclusively demonstrates that the HDC-

described the treatment as an "experimental study"[412] and her protocol was given to only twenty women nationwide.[413]

Several commentators have concluded that both Circuits' rulings are overly generous to insurers.[414] Insurers should be required to enumerate objective standards and criteria against which a proposed treatment can be measured. The phrases "educational or experimental in nature" and "in connection with medical or other research" do not constitute a definite standard, and therefore are ambiguous.[415]

In the Fifth and Seventh Circuits, health insurers are now free to exploit such broad provisions,[416] invoking them to deny coverage for any treatment performed as part of a medical study or research, even if the treatment is well-established.[417] While the Seventh Circuit admitted that this result was conceivable, it found that the insurer before it had not exploited the contract terms.[418] Unfortunately, the deferential nature in both the Fifth and Seventh Circuits' holdings

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> ABMT treatment is part and parcel of, and furnished in connection with, medical research.

Brief for Appellant at 20-21, *Fuja* (No. 93-1150) (alterations in original).

412. *Holder*, 951 F.2d at 90 n.1.

413. *Id.* at 90.

414. *See* Dave Lenckus, *Cancer Coverage Dispute*, BUS. INS., Apr. 11, 1994, at 2, 36.

415. *See* Fuja v. Benefit Trust Life Ins. Co., 809 F. Supp. 1333, 1341 (N.D. Ill. 1992) (finding that phrase "in connection with medical or other research" ambiguous because it was "undefined in the policy and defie[d] a single interpretation"), *rev'd*, 18 F.3d 1405 (7th Cir. 1994). The district court noted that this ambiguity was illustrated by the insurer's reimbursement for standard chemotherapy even though treatment was "furnished in connection with medical or other research." *Id.*

416. *But see* Brief for Appellant at 28-29, *supra* note 411 (arguing that insurer cannot deny coverage randomly and that insurer does not exploit broad medical research criterion). The insurer argued:

> First, . . . Benefit Trust has paid for [Grace Fuja's] standard-dose chemotherapy to date, it is evident that Benefit Trust has in no way attempted to give the phrase "in connection with medical research" the kind of reading which the [district] court suggests is possible. Second, there is no evidence that all cancer treatment, let alone all treatment for all kinds of disease, is research and, therefore, falls within the phrase "in connection with medical research." In fact, [the treating oncologist] stated that [Grace Fuja's] initial cancer treatment itself was *not* part of research; that more cancer treatment is actually given in a community setting than in an academic medical setting; and that even in an academic medical setting, some breast cancer treatments are not part of research. Consequently, the District Court had absolutely no factual basis to suggest that Benefit Trust reads, or could reasonably read, the phrase "in connection with medical research" to deny coverage "in virtually any instance."

Id.

417. *See Fuja*, 809 F. Supp. at 1341. The court further hypothesized:

> If an orthopedic surgeon either decided to conduct a time-study of how quickly she could apply casts to the broken bones of her patients or decided to publish results of how quickly the plaster hardened on those casts, [the insurer] could invoke the "in connection with medical research" clause to deny coverage for the common treatment of applying a cast to a broken arm.

Id.

418. *Fuja*, 18 F.3d at 1410.

creates little, if any, incentive for insurers to revise and clarify their policies.

D. Discrimination Claims

An increasing number of breast-cancer plaintiffs are alleging that insurers' refusal to cover HDC-ABMT constitutes discrimination in violation of state human rights laws,[419] Title VII of the federal Civil Rights Act,[420] and/or the Americans with Disabilities Act.[421] In 1993, for instance, Memorial Sloan-Kettering Cancer Center in New York City filed a lawsuit against an insurance company, Empire Blue Cross and Blue Shield, for refusing to cover transplants for cancer patients.[422] Many of those patients were breast cancer patients receiving HDC with blood product support, a procedure analogous to HDC-ABMT.[423] According to Memorial, Empire covered HDC with blood product support for cancers "that have a disproportionate incidence among males (e.g., testicular cancer), and cancers that have a gender neutral incidence (e.g., lymphoma)," yet refused to pay for analogous cancer treatments that have "a disproportionately high incidence

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419. *See, e.g.*, Plaintiff's Complaint at 17-18, Bougie v. Gillette Health Care Plan (D. Minn., filed Oct. 11, 1994) (No. 4-94-CV-883) (on file with *The American University Law Review*) (alleging that insurer's refusal to provide coverage for HDC-ABMT in treatment of breast cancer "constitutes discriminatory treatment against and has a discriminatory impact on women as a sex" in violation of Minnesota Human Rights Act).

420. 42 U.S.C. §§ 2000e-1 to -15 (1988 & Supp. V 1993); *see, e.g.*, Plaintiff's Brief at 2-9, Reger v. Espy, 836 F. Supp. 869 (N.D. Ga. 1993) (No. 1:93-CV-2213-RLV) (arguing that insurer discriminated against women by failing to cover treatment for breast cancer); Plaintiff's Complaint at 16-17, *Bougie* (No. 4-94-CV-883) (alleging that coverage denial violated Civil Rights Act).

421. 42 U.S.C. §§ 12110-12112 (1988 & Supp. V 1993); *see, e.g.*, Dodd v. Blue Cross & Blue Shield Ass'n, 835 F. Supp. 888, 891 (E.D. Va. 1993) (rejecting breast cancer patient's claim that plan violated Americans with Disabilities Act); Plaintiff's Complaint at 15-16, *Bougie* (No. 4-94-CV-885) (alleging that insurer's acts of covering HDC-ABMT for some types of diseases, but not for breast cancer, "constitute[d] wrongful disability-based discrimination in violation of Americans with Disabilities Act").

422. *See* Plaintiff's Complaint at 1, Memorial Hosp. for Cancer & Allied Diseases v. Empire Blue Cross & Blue Shield (N.Y. Sup. Ct., filed Aug. 19, 1993) (No. 93-2911) [hereinafter *Plaintiff's Complaint for Memorial*] (on file with *The American University Law Review*); *see also* Memorial Hosp. for Cancer & Allied Disease v. Empire Blue Cross & Blue Shield, 18 Employee Benefits Cas. (BNA) 1911-12 (S.D.N.Y. Apr. 12, 1993) (discussing original state court filing).

That same year, the State of Texas, led by Attorney General Dan Morales, filed a lawsuit against Prudential Insurance Company of America seeking injunctive relief to prevent Prudential from continuing to deny coverage for HDC-ABMT to breast cancer patients. *See* Plaintiff's Original Petition in the Nature of Quo Warranto and Application for Injunction at 4, 12, Texas v. Prudential (Dist. Ct. Travis County Tex. 1993) (No. 93-11381). The lawsuit was subsequently settled so that Prudential has to cover this treatment in all pending and future claims. *See* Office of the Attorney General Press Release, Morales Settles Lawsuit with Prudential Over Breast Cancer Treatment, Mar. 21, 1994 (on file with *The American University Law Review*); *see also* Office of the Attorney General Press Release, Morales Sues Prudential Insurance Company's Policies Forbid Life-Saving Cancer Drug, Sept. 23, 1993 (discussing Prudential's coverage denial) (on file with *The American University Law Review*).

423. *See Plaintiff's Complaint for Memorial, supra* note 422.

among females, such as breast cancer."[424] Memorial's complaint concluded, among other things,[425] that this gender correlation in coverage was discriminatory[426] in violation of the New York State Human Rights Law and the Civil Rights Laws of the Administrative Code of New York City.[427] As of 1995, the case was still pending, and settlement negotiations were ongoing.[428]

To date, *Reger v. Espy* [429] is the only reported decision to rule on a gender discrimination claim involving HDC-ABMT for breast cancer. Bonnie Reger was a federal employee[430] insured by Blue Cross and Blue Shield of Georgia.[431] Her policy explicitly excluded as experimental coverage for HDC-ABMT for breast cancer.[432] The plan did, however, cover HDC-ABMT for five other cancers.[433]

Reger filed suit in federal district court, alleging that the plan's facially neutral[434] exclusion violated Title VII of the Civil Rights Act of 1964 because it had a disparate impact on females.[435] Two factors were critical to this claim. First, over ninety-nine percent of all breast cancers occur in women.[436] Second, breast cancer is the most

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424. *See Plaintiff's Complaint for Memorial, supra* note 422; *cf.* Declaration of Jay P. Klarnet at 2, O'Connell v. King County Medical Blue Shield (Wash. Sup. Ct. 1992) (No. 92-2-11265-5) (asserting that results of HDC-ABMT for breast cancer are comparable and possibly superior to HDC-ABMT for testicular germ cell cancer); Respondent's Brief at 49-50, King County Medical Blue Shield v. O'Connell (Wash. Ct. App. 1993) (No. 31949-O-I) (arguing that because health insurance plan covered cancers that tend to occur more often in males, such as lymphoma and leukemia, whereas "women's cancers," such as breast and epithelial ovarian cancer, were considered experimental, it discriminated against women).

425. *Plaintiff's Complaint for Memorial, supra* note 422, at 11-16 (alleging breach of contract, breach of duty of good faith and fair dealing, and violations of state insurance laws).

426. *Plaintiff's Complaint for Memorial, supra* note 422, at 16.

427. *Plaintiff's Complaint for Memorial, supra* note 422, at 16.

428. Telephone Interview with counsel for Memorial Sloan-Kettering Cancer Center (Jan. 11, 1995).

429. 836 F. Supp. 869 (N.D. Ga. 1993).

430. *See* Reger v. Espy, 836 F. Supp. 869, 870 (N.D. Ga. 1993).

431. *Id.* (noting that Blue Cross offered insurance to federal employees pursuant to contract with Office of Personnel Management as authorized by Federal Employees Health Benefits Act).

432. *See id.* at 871 (mentioning that insurers excluded coverage for HDC-ABMT for breast cancer because available data was inconclusive as to whether treatment was superior to standard chemotherapy). The plan did not cover

> [s]ervices or supplies for or related to surgical transplant procedures for artificial or human organ/tissue transplants not listed as specifically covered such as breast cancer . . . . Related services or supplies include administration of high dose chemotherapy when supported by transplant procedures.

Id.

433. *See id.* (noting coverage for acute lymphocytic or non-lymphocytic leukemia, advanced Hodgkin's lymphoma, advanced non-Hodgkin's lymphoma, advanced neuroblastoma, and testicular, mediastinal, retroperitoneal, and ovarian germ cell tumors).

434. *See id.* at 873.

435. *See id.* at 870.

436. *See* Plaintiff's Response in Opposition to Federal Defendant's Partial Motion to Dismiss at 3, Reger v. Espy, 836 F. Supp. 869 (N.D. Ga. 1993) (on file with *The American University Law Review*).

commonly occurring cancer in women in the United States and is the most common reason for performing HDC-ABMT.[437]

The court rejected Reger's claim on the ground that Blue Cross' policy excluded from coverage HDC-ABMTs for most types of cancers, only one of which was breast cancer.[438] On the whole, the preclusion of coverage for most cancers affected men and women equally.[439] Therefore, the court in *Reger* held that the health insurance policy's facially neutral exclusion did not have a disparate impact on women.[440]

In a subsequent motion, Reger objected to the court's consideration that more than one hundred forms of cancer are excluded from the plan's coverage.[441] She claimed that only those cancers for which HDC-ABMT has proven to be medically valuable (such as breast, ovarian, testicular, leukemia, Hodgkin's and non-Hodgkin's lymphoma, and multiple myeloma) were relevant.[442] Of these, the plan excluded only breast cancer and multiple myeloma.[443] According to Reger, while multiple myeloma affects men and women equally,[444] breast cancer overwhelmingly affects women, causing the policy's exclusion to have an unlawful disparate impact on women.[445]

In light of the Supreme Court's reasoning in *General Electric Company v. Gilbert*,[446] gender discrimination claims relating to the exclusion of HDC-ABMT for the treatment of breast cancer may not ultimately prevail.[447] *Gilbert* involved an insurance package that excluded disabilities arising from pregnancy.[448] The Court reasoned

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437. *See id.*

438. *Reger*, 836 F. Supp. at 872 & n.4 (noting that there are more than 100 types of cancers, most of which were not covered by plan).

439. *See id.* at 872-73.

440. *Id.* at 873.

441. Plaintiff's Response in Opposition to Federal Defendant's Partial Motion to Dismiss, *supra* note 436, at 4.

442. Plaintiff's Response in Opposition to Federal Defendant's Partial Motion to Dismiss, *supra* note 436, at 4.

443. Plaintiff's Response in Opposition to Federal Defendant's Partial Motion to Dismiss, *supra* note 436, at 6.

444. Plaintiff's Response in Opposition to Federal Defendant's Partial Motion to Dismiss, *supra* note 436, at 6.

445. Plaintiff's Response in Opposition to Federal Defendant's Partial Motion to Dismiss, *supra* note 436, at 7.

446. 429 U.S. 125 (1976).

447. *See also* Geduldig v. Aiello, 417 U.S. 484, 497 (1974) (holding that pregnancy exclusion from disabilities plan did not violate Equal Protection Clause of 14th Amendment). Although Congress rejected the particular results in *Gilbert* and *Geduldig* through the 1978 Pregnancy Discrimination amendment to the Civil Rights Act of 1964, 42 U.S.C. § 2000e(k) (1982), the Supreme Court's reasoning still applies to a gender-based disparate impact challenge.

448. General Elec. Co. v. Gilbert, 429 U.S. 125, 127 (1976).

that the insurance package was facially nondiscriminatory because "'[t]here is no risk from which men are protected and women are not. Likewise, there is no risk from which women are protected and men are not.'"[449] The Court, finding no proof that the insurance package was worth more to men than to women, found no gender-based discriminatory effect.[450] Thus, the Court held that failure to cover pregnancy-related disabilities did not constitute gender discrimination in violation of Title VII of the Civil Rights Act of 1964.[451]

E. Breast Cancer Syndrome and Prophylactic Mastectomy

Prophylactic (also known as preventive) mastectomies, which involve the surgical removal of a breast or both breasts to prevent the onset of cancer,[452] are controversial[453] and rare.[454] Even so, women at high risk for developing breast cancer sometimes choose to have their "healthy" breasts surgically removed.[455] They want to lead a life free from the fear of breast cancer,[456] or at the very least, they want to substantially reduce their risks.[457]

Many physicians will not recommend this procedure. A prophylactic mastectomy does not guarantee that a women will never develop

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449. *Id.* at 138 (quoting *Geduldig*, 417 U.S. at 496-97).

450. *Id.*

451. *Id.* at 145-46.

452. *See* Jane E. Brody, *Why Cancer-Free Women Have Breasts Removed*, N.Y. TIMES, May 5, 1993, at C13; *see also* Katskee v. Blue Cross & Blue Shield of Neb., 515 N.W.2d 645, 652 (Neb. 1994) (mentioning that surgery was prophylactic to prevent onset of cancer).

453. *See* Wally J. Temple et al., *Technical Considerations for Prophylactic Mastectomy in Patients at High Risk for Breast Cancer*, 161 AM. J. SURGERY 413, 413-14 (1991) (noting controversy surrounding question of whether total removal of all breast tissue is necessary to prevent cancer); Irene L. Wapnir et al., *A Reappraisal of Prophylactic Mastectomy*, 171 GYNECOLOGY & OBSTETRICS 171, 172 (1990) (noting controversy surrounding prophylactic mastectomy has heightened due to "further understanding of the biology of carcinoma of the breast, human genetics and the risk of carcinoma of the breast in benign disease"); Lane D. Ziegler & Stephen S. Kroll, *Primary Breast Cancer After Prophylactic Mastectomy*, 14 AM. J. CLINICAL ONCOLOGY 451, 453 (1991) (discussing controversial nature of prophylactic mastectomy).

454. *See* Carol Ann Campbell, *Cheating Cancer*, BERGEN REC., May 15, 1994, at A1, A8 (noting that only several hundred women per year choose prophylactic mastectomies).

455. *See generally* Sandra G. Boodman, *Gambling on Radical Surgery*, WASH. POST, Jan. 5, 1993, (Health), at 11, 13, 15, 17 (recounting personal stories of women who opted to have prophylactic mastectomies); Brody, *supra* note 452, at C13 (discussing risk factors that motivate women to have prophylactic mastectomies).

456. *See* Wapnir et al., *supra* note 453, at 178 (stating that cancerphobia continually influences decision to undergo prophylactic mastectomies).

457. *See* Ziegler & Kroll, *supra* note 453, at 453 (reporting that risk of breast cancer after prophylactic mastectomy is 1.18% as compared to average woman's lifetime risk of 7-8%). *See generally* LATOUR, *supra* note 61, at 396-400 (discussing personal accounts of women who choose prophylactic mastectomy).

breast cancer.[458] Further, some argue that no proof exists to suggest that a prophylactic mastectomy is superior to less extreme and disfiguring alternatives, such as mammographic screening, self-examination, and regular examinations by a physician.[459] Cosmetic dissatisfaction and medical complications are additional drawbacks to the procedure.[460]

Yet, for some women, a prophylactic mastectomy is appropriate. For example, it may be well suited for those women who are in high risk categories.[461] The most potent high risk factors include a women's family history[462] and whether she has inherited the breast cancer gene.[463] Women falling into these high risk categories

458. *See* LOVE, *supra* note 59, at 371 (cautioning that cancer may develop in tissues left behind after mastectomy); *see also* Ziegler & Kroll, *supra* note 453, at 451 (illustrating case where doctor diagnosed woman with breast cancer despite her bilateral prophylactic mastectomies 18 years earlier); Boodman, *supra* note 455, at 13 (quoting Dr. Susan Love's statement that "[t]here have been no studies, and there's no data to show that doing [a prophylactic mastectomy] decreases your risk . . . . It makes intuitive sense that it should, but a lot of things in medicine that are later proven wrong or harmful like [diethylstilbestrol, the anti-miscarriage drug later found to cause cancer,] made sense at the time.").

459. *See* Wapnir et al., *supra* note 453, at 178-80 (arguing that prophylactic mastectomies are not necessarily best option, especially in light of psychological and aesthetic consequences of surgery). *But cf.* Malcolm Gladwell, *How Safe Are Your Breasts?*, NEW REPUBLIC, Oct. 24, 1994, at 22, 24 (noting National Cancer Institute's declaration that there is no evidence showing routine mammography results in "statistically significant reduction in mortality").

460. *See* Heinz H. Bohmert, *Subcutaneous Mastectomy: Advantages and Problems*, *in* CONTROVERSIES IN BREAST DISEASE: DIAGNOSIS AND MANAGEMENT 235, 247-55 (Sharon Gundfest-Broniatowski & Caldwell B. Esselstyn, Jr. eds., 1988) (discussing unsatisfactory cosmetic results and infections caused by prophylactic mastectomies).

461. *See* Victor G. Vogel & Anita C. Yeomans, *Evaluation of Risk and Preventive Approaches to Breast Cancer*, 45 CANCER BULL. 489, 489-91 (1993) (listing family history, benign breast disease, lobular carcinoma in situ, diet, and estrogen replacement therapy as risk factors for breast cancer); RESOURCE LIST, *supra* note 6, at 29-30 (summarizing risk factors, such as age, family history, early menstruation, late menopause, and poor diet); Sandra G. Boodman, *Fear of Breast Cancer*, WASH. POST, Jan. 5, 1993, (Health), at 10, 12 (mentioning that hormonal factors due to early menstruation, late menopause, or late pregnancy elevate risk of breast cancer); Geoffrey Cowley et al., *In Pursuit of a Terrible Killer*, NEWSWEEK, Dec. 10, 1990, at 66, 67 (listing family history, diet, alcohol consumption, increased estrogen exposure, including early menstruation and late menopause, as risk factors for breast cancer); *see also* Isabelle Romieu et al., *Oral Contraceptives and Breast Cancer: Review and Meta-Analysis*, 66 CANCER 2253, 2261-62 (1990) (concluding that use of oral contraceptives for long period increased risk for breast cancer). *But see* Pamela Murray et al., *Oral Contraceptive Use in Women with a Family History of Breast Cancer*, 73 OBSTETRICS & GYNECOLOGY 977, 977 (1989) (reporting no evidence of increased risk for breast cancer with use of oral contraceptives).

462. *See* Ziegler & Kroll, *supra* note 453, at 452 (stating that women who have two or more immediate relatives diagnosed with breast cancer, particularly if relatives were premenopausal and had bilateral breast cancer, have up to 50% chance of developing breast cancer in their lifetimes); Boodman, *supra* note 461, at 12 (stating that risk increases in proportion to number of first-degree relatives with breast cancer).

463. *See* Michael Waldholz, *Feud Brewing Over Breast-Cancer Gene Patent*, WALL ST. J., Oct. 17, 1994, at B1 (mentioning that five percent of breast cancer cases are caused by inheriting mutated form of breast cancer gene, called BRCA1); *see also* Boodman, *supra* note 461, at 12 (distinguishing between genetic and hereditary risk).

sometimes may suffer from "breast cancer syndrome,"[464] in which women experience stress and anxiety over the substantial likelihood of developing the disease.[465] Such stress and anxiety is similar to what courts have recognized as "cancer-phobia," typically stemming from exposure to cancerous chemicals.[466]

Advances in both gene technology[467] and understanding of the biology of breast cancer, which enable medical professionals to more accurately identify those women who are at higher risk of developing breast cancer,[468] pose far-reaching implications for health insurance.[469] Among them is whether an insurer should pay for a prophylactic mastectomy.[470] Payment often depends on whether the procedure is considered medically necessary.[471] In addition, the insurer may consider how substantial the likelihood of developing breast cancer must be before it is obligated to pay.[472]

The issue is beginning to surface in the courts as well.[473] When Sindie Katskee's doctors recommended removing her uterus, ovaries,

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464. *See* Ziegler & Kroll, *supra* note 453, at 452 (defining "familial breast cancer syndrome" as family with two or more immediate family members affected by breast cancer, usually before age of 45); *see also* Katskee v. Blue Cross & Blue Shield of Neb., 515 N.W.2d 645, 651 (Neb. 1994) (noting that women diagnosed with syndrome have at least 50% chance of developing breast cancer, whereas unaffected women have only 1.4% risk).

465. *See Katskee*, 515 N.W.2d at 651-52.

466. *See, e.g.*, Coburn v. Sun Chem. Corp., No. 88-0120, 1989 WL 83518, at *1 (E.D. Pa. July 24, 1989) (noting plaintiff's allegation that hazardous waste facility's negligence resulted in "cancer-phobia"); Gergel v. Chemlawn Serv. Corp., No. 87-1138, 1988 WL 71312, at *1 (E.D. Pa. July 5, 1988) (discussing plaintiff's fear of cancer due to exposure of dangerous chemicals); Bush v. Union Carbide Corp., No. 84-936, 1986 WL 15243, at *8 (E.D. La. Dec. 30, 1986) (discussing seaman's claim for damages of mental anguish due to "cancer phobia" when soaked with toxic chemicals); Mauro v. Owens-Corning Fiberglas Corp., 542 A.2d 16, 24 (N.J. Super. Ct. App. Div. 1988) (discussing plaintiff's fear of cancer arising from asbestos exposure), *aff'd*, 561 A.2d 257, 258 (N.J. 1989).

467. *See generally* Cowley, *supra* note 58, at 46-52 (describing search for breast cancer gene, BRCA1); J. Madeleine Nash, *Stopping Cancer in Its Tracks*, TIME, Apr. 25, 1994, at 54, 56 (discussing progress of gene technology in combatting cancer cells).

468. *See generally* R. Steven Brown, *Genetic Revolution: Rapid Advances in Genetics Are Affecting State Insurance, Health and Criminal Justice Policies* (1993) (warning about breakdown of insurance system if insurers deny coverage because of person's genetic risks), *reprinted in Biomedical Ethics and U.S. Public Policy: Hearing before the Senate Comm. on Labor and Human Resources*, 103d Cong., 1st Sess. 14, 15 (1993).

469. *See id.* at 15 (describing concern that knowledge of increased risk will lead insurers to deny coverage to individuals after genetic testing).

470. *See infra* notes 473-95 and accompanying text.

471. *See infra* notes 473-95 and accompanying text.

472. *See infra* notes 473-95 and accompanying text.

473. *See* Katskee v. Blue Cross & Blue Shield of Neb., 515 N.W.2d 645, 653 (Neb. 1994) (holding that genetic condition is illness within meaning of insurance policy); Anderson v. HMO Neb., No. A-92-489, 1993 WL 61839, at *8 (Neb. App. Mar. 9, 1993) (concluding that medical evidence established prophylactic bilateral mastectomy was appropriate treatment), *rev'd on other grounds*, 505 N.W.2d 700 (Neb. 1993).

and fallopian tubes[474] due to breast-ovarian carcinoma syndrome,[475] her insurer insisted that the procedure was not covered by her policy.[476] Specifically, the insurer determined that Katskee did not have an illness as defined by her policy.[477] In *Katskee v. Blue Cross & Blue Shield of Nebraska*,[478] the Supreme Court of Nebraska reviewed that determination.[479]

Applying a plain-and-ordinary-meaning test to the term "illness,"[480] the court held in favor of Katskee.[481] The court reasoned that because Katskee's genetic makeup consisted of hereditary cancer,[482] her condition was "a deviation from what is considered a normal, healthy physical state."[483] Her breast-ovarian carcinoma syndrome was therefore an illness within the meaning of the policy.

The same court in *Anderson v. HMO Nebraska*,[484] heard a case involving thirty-three-year-old Cindy Anderson, who had fibrocystic disease in her breasts in addition to having a family history of breast cancer.[485] Given this condition, her doctors recommended a prophylactic mastectomy.[486] Her insurer denied coverage based on

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474. *See Katskee*, 515 N.W.2d at 647. Although this case involved removal of reproductive organs rather than prophylactic removal of the breasts, the issues raised and analysis presented are relevant to a discussion of prophylactic mastectomy.

475. *See id.* at 647, 651 (noting that oncologist diagnosed genetic condition, breast-ovarian carcinoma syndrome, whereby Sindie Katskee had 50% chance of developing breast cancer).

476. *See id.* at 648-49 (explaining that insurer denied coverage because treatment was not "medically necessary," which was defined in policy as "[a]ppropriate for the symptoms and diagnosis of the patient's Illness, Injury or Pregnancy").

477. *Id.* at 649 (noting that insurer defined illness as "bodily disorder or disease").

478. 515 N.W.2d 645 (Neb. 1994).

479. *Id.* at 649.

480. *Id.* at 651. The court defined illness as

> any abnormal condition of the body or its components of such a degree that in its natural progression would be expected to be problematic; a deviation from the healthy or normal state affecting the functions or tissues of the body; an inherent defect of the body; or a morbid physical or mental state which deviates from or interrupts the normal structure or function of any part, organ, or system of the body and which is manifested by a characteristic set of symptoms and signs.

Id.

481. *Id.* at 653.

482. *Id.* at 651. Sindie Katskee's condition was detected by tracing instances of hereditary cancer in her family history. At the time of her diagnosis, no conclusive physical test existed that could identify a cancer gene, though Katskee's doctor stated that research was progressing in that direction. *See id.*

483. *Id.* at 652.

484. No. A-92-489, 1993 WL 61839 (Neb. App. Mar. 9, 1993), *rev'd on other grounds*, 505 N.W.2d 700 (Neb. 1993).

485. *See* Anderson v. HMO Neb., No. A-92-489, 1993 WL 61839, at *2 (Neb. App. Mar. 9, 1993) (mentioning that distortions of breast are caused by fibrocystic disease and will diminish ability to detect breast cancer even with routine surveillance), *rev'd on other grounds*, 505 N.W.2d 700 (Neb. 1993).

486. *See id.*

its view that the procedure was not medically necessary[487] and was experimental.[488] The insurer insisted that Anderson did not have an illness, despite her family history of breast cancer, her fibrocystic disease, and her "cancer-phobia."[489] Just because Anderson had a predisposition to breast cancer, they argued, did not necessarily mean she would develop the disease, a prerequisite to coverage.[490]

The court rejected the insurer's medical evidence,[491] reasoning that a danger would exist if she did not have a prophylactic mastectomy.[492] The court concluded that the procedure was therefore appropriate and in accordance with local standards of medical practice,[493] and held that the insurer must cover the costs involved.[494]

Courts should approach coverage disputes for prophylactic mastectomies in the same fashion as with HDC-ABMTs.[495] Courts should weigh expert testimony and medical literature against a "primary purpose to benefit the patient" standard.[496] Courts should also inquire whether the insurer engaged in reasonable efforts to arrive at its coverage decision,[497] and whether the insurer was operating under a conflict of interest.[498] If the insurer fails to meet any one of these requirements, courts should rule against the insurer.

III. LEGISLATIVE RESPONSES

Legislatures are better equipped to meaningfully resolve tough health care issues than are courts. This Comment recommends that, to be effective, legislation must embody the legitimate interests of

487. *See id.* at *3 (restating insurer's conclusion that breast removal was not appropriate before patient was diagnosed with breast cancer).

488. *See id.*

489. *See id.*

490. *See id.* at *8.

491. *Id.* (finding that insurer did not present sufficient evidence to show that prophylactic mastectomy was not medically necessary).

492. *Id.*

493. *Id.* (referring to opinions of three doctors overwhelmingly supporting procedure for Anderson).

494. *Id.* The court did not reach the issue of whether cancer-phobia alone constitutes an illness. *Id.*

495. *See supra* Part II.B (describing judicial treatment of HDC-ABMT cases).

496. *See supra* Part II.B.1 (suggesting adoption of this standard by courts).

497. *See supra* Part II.B.2 (explaining inquiry into insurers' efforts to establish reasonable basis for coverage determinations).

498. *See supra* Part II.B.3 (detailing conflict of interest concerns in insurance coverage decisions).

both the insurance industry and breast cancer patients.[499] Further, legislation should be couched in general, far-reaching terms, so that it applies not only to treatments for breast cancer, but also to emerging medical treatments in other disciplines of medicine.[500]

A. State Legislation

In response to the growing controversy surrounding insurance coverage of HDC-ABMT for breast cancer, several states have intervened and enacted legislation. They include Minnesota,[501] Georgia,[502] Massachusetts,[503] New Hampshire,[504] Rhode Island,[505] Virginia,[506] and Florida.[507] Similar legislation is pending in other states, including New York,[508] Ohio,[509] California,[510] New Jersey,[511] Louisiana,[512] Connecticut,[513] and Missouri.[514] Legislative action addressing this issue has taken four approaches: (1) mandates;[515] (2) multi-tier systems;[516] (3) devising committees to mandate coverage;[517] and (4) establishing criteria for coverage of cancer therapies.[518]

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499. *See infra* notes 531-34 and accompanying text (exposing dangers of ignoring concerns of insurance companies).

500. *See infra* Part III.A.3 (recommending committee system as model for future medical issues).

501. 1995 Minn. House File 1742, 79th Legis. Reg. Sess. (to be codified at MINN. STAT. § 62A.307).

502. *See* 1995 Ga. H.B. 369, 143d Gen. Assembly, Reg. Sess. (1995-96) *available in* WL, State-Bills, Georgia Bill Tracking (indicating enactment of bill).

503. MASS. GEN. LAWS ANN. ch. 32A, § 17A (West Supp. I 1994).

504. N.H. REV. STAT. ANN. § 415:18-c (Supp. 1994).

505. R.I. GEN. LAWS § 27-18-36.2 (1994).

506. VA. CODE ANN. § 38.2-3418.1:1 (Michie 1994).

507. FLA. STAT. ch. 627.4236 (Supp. 1992).

508. 1993 N.Y. Assembly B. 11533, 215th Gen. Assembly, 2d Reg. Sess. (1994).

509. 1993 Ohio H.B. 592, 120th Gen. Assembly, Reg. Sess. (1993-94).

510. 1993 Cal. Assembly B. 3654, Reg. Sess. (1994); 1993 Cal. Assembly B. 3752, Reg. Sess. (1994).

511. 1994 N.J. Assembly B. 1997, 206th Legis. 1st Reg. Sess. (1994); 1994 N.J. S.B. 1320, 206th Legis., 1st Sess. (1994).

512. 1995 La. H.B. 1222, Reg. Sess. (1995).

513. 1995 Conn. H.B. 6100, Reg. Sess. (1995).

514. 1995 Mo. S.B. 27, 88th Gen. Assembly, 1st Reg. Sess. (1995); 1995 Mo. H.B. 339, 88th Gen. Assembly (1995).

515. *See infra* Part III.A.1.

516. *See infra* Part III.A.2.

517. *See infra* Part III.A.3.

518. *See infra* Part III.A.4.

1. Mandating HDC-ABMT for breast cancer

Mandates bar insurers from denying coverage for particular medical treatments under Experimental Exclusions. To date, Minnesota,[519] Massachusetts[520] and New Hampshire[521] are the only states to pass legislation mandating that insurers cover HDC-ABMT for breast cancer. Similar proposals are pending in California,[522] New York,[523] Connecticut,[524] and Ohio.[525] All of the proposed bills,

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519. 1995 Minn. House File 1742, 79th Legis. Reg. Sess. (to be codified at MINN. STAT. § 62A.307). The bill reads:

> Every health plan . . . must provide . . . coverage for the treatment of breast cancer by high-dose chemotherapy with autologous bone marrow transplantation and for expenses arising from the treatment.

Id.; *see Governor Signs Bill Requiring Coverage of Bone Marrow Transplants*, Health Care Daily (BNA) d3 (June 12, 1995) (stating bill has taken effect).

520. The Massachusetts statute reads:

> [Insurers must provide] coverage for a bone marrow transplant for persons who have been diagnosed with breast cancer that has progressed to metastatic disease provided, however, that said person shall meet the criteria established by the department of public health. The department of public health shall promulgate rules and regulations establishing criteria for eligibility for coverage hereunder which shall be consistent with medical research protocols reviewed and approved by the National Cancer Institute.

MASS. GEN. LAWS ANN. ch. 32A, § 17A (West Supp. 1994).

521. The New Hampshire statute reads: "[Insurers must provide] coverage for expenses arising from the treatment of breast cancer by autologous bone marrow transplants according to protocols reviewed and approved by the National Cancer Institute." N.H. REV. STAT. ANN. § 415:18-c (Supp. 1994).

522. *See* 1993 Cal. Assembly B. 3572, Reg. Sess. (1993-94). The bill requires health insurers to "provide coverage for experimental procedures and treatment for breast cancer when the procedure or treatment is provided within a clinical trial," according to the following criteria:

> (A) Treatment is provided with a therapeutic intent.
> (B) Treatment is provided pursuant to a clinical trial that has been approved by the National Cancer Institute, or any of its cancer centers, cooperative groups, or community clinical oncology programs; the Food and Drug Administration in the form of an investigational new drug exemption; the Department of Defense; the Department of Veterans Affairs; or a qualified nongovernmental research entity as identified in the guidelines for National Cancer Institute cancer center support grants.
> (C) The proposed therapy has been reviewed and approved by a qualified Institutional Review Board.
> (D) The facility and personnel providing the treatment are capable of doing so by virtue of their experience or training.
> (E) There is no noninvestigational therapy that is clearly superior to the protocol treatment.
> (F) The available clinical or preclinical data provide a reasonable expectation that the protocol treatment will be at least as efficacious as noninvestigational therapy.

Id.

523. 1993 N.Y. Assembly B. 11533, 215th Gen. Assembly, 2d Reg. Sess. (1994). The New York bill states:

> Every [health insurer] . . . shall include coverage for a bone marrow transplant or transplants for persons who have been diagnosed with breast cancer; provided, however, that said person shall meet the criteria established by the Department of Health. The Department of Health shall promulgate rules . . . which shall be consistent with medical research protocols reviewed and approved by the National Cancer Institute.

Id.

as well as the Minnesota and New Hampshire statutes, cover all women with breast cancer.[526] The Massachusetts mandate, however, applies only to women with metastatic breast cancer.[527]

All of the mandates require HDC-ABMTs to be performed in clinical trials approved by or consistent with either the National Cancer Institute or another governmental or qualified nongovernmental research entity.[528] The clinical trial requirement not only enhances data collection efforts and research, but also ensures that women receive proper treatment.[529]

Although the adoption of mandates for HDC-ABMT coverage is a major victory for breast cancer activists, as a policy matter mandates are short-sighted in that they completely ignore the insurance industry's legitimate concerns.[530] First, mandates severely distort the marketplace,[531] causing premiums to rise.[532] Second, the proliferation of mandates increases the likelihood that employers will switch to an ERISA self-funded plan, which is exempt from state mandates.[533] Third, the genre of mandates sets a dangerous precedent,

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524. 1995 Conn. H.B. 6100, Reg. Sess. (1995) ("requir[ing] the payment for bone marrow transplantation as a treatment for breast cancer").

525. 1993 Ohio H.B. 592, 120th Gen. Assembly, Reg. Sess. (1993-94). This bill requires all insurers to provide "benefits for the expenses arising from the treatment of breast cancer by autologous bone marrow transplants according to protocols reviewed and approved by the National Cancer Institute." *Id.*

526. *See supra* notes 519-25 (quoting text of state legislation).

527. *See supra* note 520 (quoting text of Massachusetts statute). In practice, this distinction may make no substantial difference because HDC-ABMTs are typically used to treat breast cancer that has already metastasized.

528. *See supra* notes 519-25 (quoting specific requirements in each mandate).

529. *See* 1993 Cal. Assembly B. 3572, Reg. Sess. (1993-94) (discussing importance of clinical trials in determination of treatment effectiveness). *But see* Gallinari, *supra* note 147, at 41-42 (stating that requiring protocols to be approved by NCI is problematic because many reputable protocols do not have formal NCI approval).

530. Arguably, mandating insurance coverage for HDC-ABMT in the treatment of breast cancer is not unfair to insurers because insurers presumably had ample opportunity to lobby legislatures to voice their views against general mandates, and to show that HDC-ABMT in the treatment of breast cancer is experimental. Despite the insurance industry's efforts, legislatures still mandated specific coverage of this disease. In other words, the assertion that legislatures, reacting to emotional whims, blindly support mandates for health insurance for breast cancer treatments is debatable.

531. *Cf.* NEW JERSEY BUS. & INDUS. ASS'N, THE CASE AGAINST MANDATED HEALTH INSURANCE BENEFITS (1983) (urging legislatures to reject mandating benefits because it distorts marketplace). *But see* Thomas G. McGuire & John T. Montgomery, *Mandated Mental Health Benefits in Private Health Insurance*, 7 J. HEALTH POL., POL'Y & L., 380, 382-86 (1982) (discussing how mandates correct inefficiencies in market, notably mental health benefits).

532. *See* JON GABEL & GAIL JENSEN, HEALTH INS. ASS'N OF AM., RESEARCH BULLETIN: THE PRICE OF STATE MANDATED BENEFITS 11-12 (1989) (arguing that mandated benefits increased price of family coverage); *see also* Cova, *supra* note 2, at 744 (asserting that coverage of expensive, unproven technologies increases costs of covering other treatments known to be effective, thereby increasing premiums).

533. *See* GABEL & JENSEN, *supra* note 532, at 15-16 (arguing that employers will self-insure when faced with increasing mandates); PUBLIC POL'Y INST. OF N.Y. STATE, INC., CURE, OR CAUSE?

in that future coverage mandates may involve medical procedures that are truly experimental, in that they have not yet successfully and fully completed any scientific trials.[534]

2. Multi-tier system

A multi-tier system operates as a type of "opt-in" approach. For example, in Virginia,[535] insurers must offer coverage for HDC-ABMT for breast cancer.[536] Policyholders, however, must also expressly request the coverage and pay higher premiums for it.[537] The legislation reads, in pertinent part:

> [Insurers] *shall offer and make available coverage under such policy, . . .* for the treatment of breast cancer by dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants when pursuant to protocols approved by the institutional review board of any United States medical teaching college including, but not limited to, National Cancer Institute protocols that have been favorably reviewed and utilized by hematologists or oncologists experienced in dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants.[538]

Georgia legislators also passed a bill requiring that insurers make available coverage for bone marrow transplants for the treatment of breast cancer.[539] Similar legislation has been introduced in New Jersey,[540] Louisiana,[541] and Missouri.[542]

HOW GOVERNMENT MANDATES LIMIT ACCESS TO HEALTH INSURANCE 16-17 (1989) (asserting that mandates cause companies to self-insure, thus causing fewer people to be covered for mandated services).

534. *See Breast Cancer Treatment Legislation Causes Controversy* (NPR radio broadcast, Jan. 15, 1994) (stating that Massachusetts' mandate removes traditional dividing line between coverage for experimental and nonexperimental treatments).

535. *See* VA. CODE. ANN. § 38.2-3418.1:1 (Michie 1994) (requiring that insurers provide coverage for treatment of breast cancer by HDC-ABMT, which shall not be subject to greater copayment than that applicable to other coverage provided by insurers).

536. *Id.*

537. *See* Anna Billingsley, *Allen Puts Signature on Breast Cancer Bill*, RICHMOND TIMES, Apr. 21, 1994, at A7 (describing how bill received widespread bipartisan support); *see also* Paul E. Kalb, *Controlling Health Care Costs By Controlling Technology: A Private Contractual Approach*, 99 YALE L.J. 1109, 1120 (1990) (arguing that insurers should offer more than one coverage option to accommodate those consumers who are willing to pay higher price for additional coverage).

538. VA. CODE ANN. § 38.2-3418.1:1 (emphasis added).

539. *See* 1995 Ga. H.B. 369, 143d Gen. Assembly, Reg. Sess. (1995-96) *available in* WL, State-Bills, Georgia Bill Tracking (indicating that H.B. 369 passed both House and Senate, and was signed by Governor in April 1995).

540. 1994 N.J. Assembly B. 1997, 206th Legis., 1st Reg. Sess. (1994). The bill requires that all insurers

> offer to provide coverage for the treatment of cancer by dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants when performed pursuant to protocols approved by the institutional review board of the United States medical teaching college including, but not limited to, National Cancer Institute protocols favorably reviewed and utilized by hematologists or oncologists experienced

This approach recognizes the interests of both the insurance company and the breast cancer patient.[543] A multi-tiered system offers standard care to all policyholders, while providing the option of additional, nonstandard care.[544] As such, premiums will increase only for those policyholders who desire access to nonstandard, experimental treatments.[545] In addition, an option to purchase additional coverage elevates the perceived bargaining power of the policyholder. This, however, may harm many policyholders if courts choose not to presume that the health insurance policy is an adhesion contract.[546] Consequently, the policyholder may not be entitled to protections afforded in an adhesion contract, such as construing ambiguities against the insurer.[547]

Admittedly, a multi-tier system has other potential drawbacks. The approach places a substantial burden on consumers to request, research, and understand complex insurance coverage options. Because individuals often purchase a coverage option ignorantly or without full information, they have equal bargaining power with the insurer in only the most technical sense.[548] Moreover, the multi-tier

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in dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants.

Id.

541. 1995 La. H.B. 12221, Reg. Sess. (1995). It reads, in pertinent part:

[All insurance policies, plans, and contracts] shall include coverage for the expenses for the treatment of breast cancer by autologous bone marrow transplants, according to the protocols reviewed and approved by the National Cancer Institute.

Id.

542. 1995 Mo. S.B. No. 27, 88th Legis., 1st Reg. Sess. (1995). It reads, in pertinent part: Each insurer . . . shall offer and make available coverage under such policy . . . for the treatment of breast cancer by dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants when performed pursuant to nationally accepted peer review protocols utilized by breast cancer treatment centers experienced in dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants.

Id.

543. *See, e.g.*, Neil M. Cohen, *Cohen Bone-Marrow Cancer Treatment Bill Advances* (July 6, 1994) (press release) (on file with *The American University Law Review*). Neil Cohen, a New Jersey Assemblyman and sponsor of the New Jersey bill, stated: "In an effort to seek broad support for this measure, we have addressed the concerns of the business community." *Id.*

544. *See Insurers in Virginia Must Cover Experimental Breast Cancer Treatment*, BNA HEALTH CARE DAILY, Apr. 20, 1994, at 2.

545. *See* Kalb, *supra* note 537, at 1122-23.

546. *See* Kalb, *supra* note 537, at 1125 (insisting that courts should abandon presumption that all health insurance policies are adhesion contracts).

547. *See* Kalb, *supra* note 537, at 1125-26 (suggesting how courts should interpret health insurance contracts under multi-tier approach).

548. To alleviate any potential information gap, legislation should also require that health insurance plans inform prospective policyholders of how their choice may be affected. Legislation currently proposed in California, for instance, addresses this issue. *See* 1993 Cal. Assembly B. 3654, Reg. Sess. (1993-94) (requiring that information be provided to prospective enrollees of any health care service plan regarding whether, and to what extent, insurance plan covers bone marrow treatment for breast cancer). It suggests that the following notice be conspicuously placed in every policy: "PLEASE READ THE FOLLOWING INFORMATION SO

legislation does not cap the premiums an insurer may charge for additional coverage.[549] As such, a policyholder who wants additional coverage due to her family history of breast cancer may still be unable to afford such coverage. A related effect is that those who purchase the lowest priced option may be subject to lesser quality health care.[550] Despite these drawbacks, a multi-tiered approach adequately addresses concerns of both breast cancer patients and insurers and is preferable to general mandates.

3. Devising committees to mandate coverage

In order to resolve the question of whether insurers should provide coverage for HDC-ABMT, Judge John L. Coffey of the Seventh Circuit, in *Fuja v. Benefit Trust Life Insurance*,[551] recommended establishing "regional cooperative committees comprised of oncologists, internists, surgeons, experts in medical ethics, medical school administrators, economists, representatives of the insurance industry, patient advocates and politicians."[552] Judge Coffey's suggestion closely matches legislation enacted in Florida.

Florida's statute mandates that health insurance policies cover all bone marrow transplants for specifically designated cancers.[553]

YOU WILL KNOW WHETHER THIS PLAN GUARANTEES COVERAGE OF EXPERIMENTAL TREATMENTS, SUCH AS BONE MARROW TRANSPLANT TREATMENT FOR BREAST CANCER PATIENTS." *Id.*

549. *But cf.* Kalb, *supra* note 537, at 1123 (asserting that system-wide cost reductions would result under multi-tier insurance scheme).

550. *But see* Kalb, *supra* note 537, at 1124 (arguing that consumers buying lowest-priced option might receive better care than current insurance scheme because all covered procedures would have proven medical value).

551. 18 F.3d 1405 (7th Cir. 1994).

552. Fuja v. Benefit Trust Life Ins., 18 F.3d 1405, 1412 (7th Cir. 1994).

553. *See* FLA. STAT. ch. 627.4236 (Supp. 1992). It reads, in pertinent part:

> (2) An insurer may not exclude coverage for bone marrow *transplant procedures* . . . if the particular use of the bone marrow transplant procedure is determined to be . . . *not experimental pursuant to subsection* (3).
>
> (3) (a) The Secretary of Health and Rehabilitative Services must adopt rules specifying the bone marrow transplant procedures that are accepted . . . . The rules must be based upon recommendations of an advisory panel appointed by the secretary, composed of:
>
> 1) One adult oncologist, . . . recommended by the Florida Medical Association;
> 2) One pediatric oncologist, . . . recommended by the Florida Pediatric Society;
> 3) One representative of the J. Hillis Miller Health Center at the University of Florida;
> 4) One representative of the H. Lee Moffitt Cancer Center and Research Institute, Inc.;
> 5) One consumer representative, . . . recommended by the Insurance Commissioner;
> 6) One representative of the Health Insurance Association of America;
> 7) Two representatives of health insurers, one of whom represents the Insurer with the largest Florida health insurance premium volume and one of whom represents the insurer with the second largest Florida health insurance

These cancers are chosen by a committee,[554] Florida's Bone Marrow Transplant Advisory Panel.[555] The committee is comprised of both oncologists and insurance representatives.[556] Through this process, Florida's approach, unlike the mandates in Massachusetts, Minnesota and New Hampshire, takes into consideration the insurance industry's interests.

Eighteen months after Florida enacted this statute, the Advisory Panel recommended mandatory coverage of bone marrow transplants for breast cancer.[557] The recommendations stipulated that transplants for Stage IV breast cancer must be conducted as part of clinical trials.[558] As of this writing, that recommendation was awaiting final approval from Florida's Department of Health and Rehabilitative Services.[559]

Like a multi-tier approach, Florida's legislation embraces the interests of both the insurance industry and the breast cancer patient. Although the legislation addresses only bone marrow transplants, it could serve as a model for emerging medical treatments. For example, for new treatments of heart disease, the panel members could be composed of cardiologists, instead of oncologists.

4. Establishing explicit criteria for coverage of cancer therapies

Unlike legislation in other states that specifically addresses HDC-ABMTs, Rhode Island's broad approach allows for the evolution of all cancer therapies.[560] The Rhode Island statute requires that all health insurance organizations cover experimental cancer therapies, provided, however, that certain delineated criteria are met.[561] These criteria include stipulations that governmental organizations approve treatment pursuant to Phase III and IV clinical trials, and that there is no existing superior alternative treatment.[562] Also, the statute

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premium volume; and

8) One representative of the insurer with the largest Florida small group health insurance premium volume . . . .

Id. (emphasis added).

554. *Id.*

555. *See* Carol Gentry, *Marrow Transplants to Receive Coverage*, ST. PETERSBURG TIMES, July 21, 1994, at 1A (reporting that Florida's Bone Marrow Transplant Advisory Panel compiled list of cancers for which insurers should pay for treatment's costs).

556. *See* FLA. STAT. ch. 627.4236.

557. *See* Gentry, *supra* note 555, at 1A.

558. *See* Gentry, *supra* note 555, at 9A.

559. *See* Gentry, *supra* note 555, at 1A.

560. *See* R.I. GEN. LAWS § 27-18-36.2 (1994) (requiring that insurers provide coverage for new cancer therapies still under investigation).

561. *See id.*

562. *Id.* The relevant section of the Rhode Island statute reads:

insists that patients meet all protocol requirements.[563] Finally, the procedure must be performed in appropriate facilities with experienced personnel.[564]

In essence, this legislation preempts any criteria for defining applicable Experimental Exclusions that are enumerated in a health

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[C]overage shall be extended to new cancer therapies still under investigation when the following circumstances are present:

(a) Treatment is being provided pursuant to Phase III or IV clinical trial which has been approved by the National Institutes of Health (NIH) in cooperation with the National Cancer Institute (NCI); Community clinical oncology programs; the Food and Drug Administration in the form of an Investigational New Drug (IND) exemption; the Department of Veterans' Affairs; or a qualified nongovernmental research entity as identified in the guidelines for NCI cancer center support grants; and

(b) The proposed therapy has been reviewed and approved by a qualified institutional review board (IRB); and

(c) The facility and personnel providing the treatment are capable of doing so by virtue of their experience, training, and volume of patients treated to maintain expertise; and

(d) The patients receiving the investigational treatment meet all protocol requirements; and

(e) There is no clearly superior, noninvestigational alternative to the protocol treatment; and

(f) The available clinical or preclinical data provide a reasonable expectation that the protocol treatment will be at least as efficacious as the noninvestigational alternative.

Id.

563. *Id.*

564. *Id.* Legislation should recognize the importance of appropriate facilities. *See* Release and Compromise Settlement Agreement, Texas v. Prudential Ins. Co., No. 93-11381 (Dist. Ct. Travis County Tex. Mar. 9, 1994) Exhibit A (on file with *The American University Law Review*) (requiring that each HDC-ABMT cancer treatment facility meet NCI or American Society of Clinical Oncology guidelines). The guidelines state:

1. Perform at least ten to twenty bone marrow transplants per year;
2. Designated transplant unit with two or more designated transplant beds;
3. Protocol for cryopreservation of autologous hematopoietic stem cells;
4. The transplant unit must have in place facilities and a policy for the required isolation (e.g., high pressure, filtered air, or laminar air-flow rooms);
5. Twenty-four hour laboratory and radiology support, which must include red cells, platelets, and other blood components;
6. Physicians performing the procedure at the institution must have documented experience;
7. There must be a broad range of subspecialty consultants in both medical and surgical specialties which should be immediately available;
8. Nurse to patient ratio of 2:1;
9. Full-time bone marrow support transplant coordinators and adequate support from social services;
10. The unit must maintain a registry of all transplants performed, and compare outcomes with other centers;
11. Physicians performing the procedure should report their data to available registries (e.g., International Bone Marrow Transplants Registry) and, when appropriate, publish important observations in the medical literature.

Id. See generally The American Society of Clinical Oncology and American Society of Hematology Recommended Criteria for the Performance of Bone Marrow Transplants, 8 J. CLINICAL ONCOLOGY 563, 563-64 (1990) (emphasizing importance of facilities, nursing team, transplant physicians, and institutional support when performing bone marrow transplants).

insurance policy. Insurers, however, still must include defining criteria for Experimental Exclusions, as this legislation applies solely to cancer therapies.[565] Although Rhode Island's statute does not specifically include the insurance industry in determining the necessary criteria, it adequately protects the industry's interests. The criteria are demanding, thereby eliminating potentially abusive demands for coverage of wasteful, harmful, or ineffective therapies.

B. Federal Policy

Not only have state legislatures recognized the importance of treating breast cancer with HDC-ABMT, but so too has the federal government through its health benefits to all federal employees. The Federal Employees Health Benefits Act (FEHBA)[566] authorizes the Office of Personnel Management (OPM) to contract with private insurance companies to provide health benefits to all federal employees.[567] OPM has final authority to decide benefits and exclusions in all FEHBA plans.[568] Many of the insurance plans provided by carriers that OPM contracts with explicitly limit coverage for HDC-ABMTs to a set of specific diseases, which does not include breast cancer.[569] OPM has accordingly denied policyholders coverage for HDC-ABMTs for breast cancer,[570] a practice upheld by the courts.[571]

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565. *See* R.I. GEN. LAWS § 27-18-36.2.

566. 5 U.S.C. §§ 8901-8914 (1988 & Supp. V 1993) (outlining regulations regarding health insurance coverage and other benefits for federal employees).

567. *See id.* §§ 8902(a)-8903 (1988).

568. *Id.* § 8902(d). *See* Arrington v. Group Hospitalization & Medical Servs., 806 F. Supp. 287, 289 (D.D.C. 1992) (finding that district court must defer to OPM's decisions regarding such matters, unless court finds OPM's decision clearly erroneous or inconsistent with terms of its contract plan or regulations).

569. *See* Caudill v. Blue Cross & Blue Shield of N.C., 999 F.2d 74, 80 (4th Cir. 1993) (explaining that breast cancer is not listed as covered for ABMTs); *Arrington*, 806 F. Supp. at 288 (explaining that HDC-ABMT for breast cancer is clearly excluded under insurance plan); *see also* Letter from James B. King, Director, Office of Personnel Management, to Congresswoman Eleanor Holmes Norton, Chair, Subcommittee on Compensation and Employee Benefits 3 (Oct. 22, 1993) (on file with *The American University Law Review*). Director King stated:

> OPM does not mandate the coverage by all carriers because HDC/ABMT treatment of breast cancer has not yet proven to be as, or more effective than, traditional treatment. . . . HDC/ABMT has a higher treatment related mortality rate, a higher rate of nonmortal toxicity, and a higher rate of side effects. . . . [OPM] will not hesitate to modify [its] coverage requirements as soon as reliable clinical evidence indicates that this treatment is an effective as conventional treatment for breast cancer.

Id.

570. *See Caudill*, 999 F.2d at 80 (finding that unlisted transplants and high dose chemotherapy were specifically excluded); Reger v. Espy, 836 F. Supp. 869, 871 (N.D. Ga. 1993) (noting that HDC-ABMT coverage for breast cancer was specifically excluded under policy).

571. *See Caudill*, 999 F.2d at 80; Nesseim v. Mail Handlers Benefit Plan, 995 F.2d 804, 808 (8th Cir. 1993); *Reger*, 836 F. Supp. at 872.

A major development, however, is a new OPM policy, which took effect in 1995,[572] that requires all plans to cover HDC-ABMT for breast cancer.[573] At a minimum, all plans must cover *non-randomized* clinical trials.[574] This policy reversal represents a victory for those advocating that HDC-ABMT is not an experimental treatment for breast cancer.

Closer examination of the OPM policy reveals, however, that this coverage expansion contains some limitations for women receiving treatment through *randomized* clinical trials. These limitations depend on the particular plan sold to the federal employee. For example, if the federal employee's plan is from the Government Employees Hospital Association, coverage is limited to clinical trials at designated facilities.[575] In other words, if a federal employee with such a plan receives a HDC-ABMT for breast cancer in a nondesignated facility, no benefits will be paid.[576]

IV. RECOMMENDATIONS

The legislature, through public hearings, has ample access to the medical profession, the insurance industry, and breast cancer interest groups. It is therefore the most appropriate institution for determining whether insurers should provide coverage for emerging medical treatments. Legislation should account for the legitimate, yet competing interests, of both the insurance industry and the breast cancer patient. Legislation that sets forth a multi-tier system, or enumerates objective criteria against which new treatments can be

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572. *See* Alan Bavley, *Choices in Health Coverage?*, KANSAS CITY STAR, Oct. 2, 1994, at A1; Mike Causey, *For Some, a Healthy Choice*, WASH. POST, Sept. 30, 1994, at D2.

573. *See* Letter from James B. King, Director, Office of Personnel Management, to Congresswoman Eleanor Holmes Norton, Chair, Subcommittee on Compensation and Employee Benefits 1 (Sept. 29, 1994) (on file with *The American University Law Review*) [hereinafter Sept. Letter] (stating that OPM has "decided to require all FEHB plans to provide coverage immediately for HDC/ABMT for the treatment of breast cancer, multiple myeloma and epithelial ovarian cancer"); *see also* Causey, *supra* note 572.

574. *See* Sept. Letter, *supra* note 573.

575. *See* Fax from OPM, "Summary of Mandated FEHB Coverage for HDC/ABMT" to Congresswoman Eleanor Holmes Norton (Sept. 1994) (on file with *The American University Law Review*) [hereinafter Fax from OPM]. The American Postal Workers Union (APWU) Health Plan, National Association of Letter Carriers (NALC) Health Benefit Plan, Postmasters Benefit Plan, Alliance Health Benefit Plan, and Mail Handlers Benefit Plan contain no special limits and therefore will cover the procedure. *Id.* Under the Blue Cross Blue Shield (BCBS) Benefit Plan, however, coverage is provided through clinical trials "limited to protocols approved and funded by the National Cancer Institute (NCI) and performed at NCI-approved facilities." *Id.* In the absence of an available clinical trial, the Plan will provide the same level of coverage as for any other covered transplant. *Id.*; *see also* Nancy Chockley & Kathleen Evie, *What's Covered: Standards and Resolutions*, LEGAL TIMES, Dec. 19, 1994, at 24 (analyzing government health care reform and controversy surrounding coverage of HDC-ABMT).

576. Fax from OPM, *supra* note 575.

measured, or establishes a committee comprised of all relevant interest groups to make coverage determinations for health insurance, more effectively accounts for these competing interests than does a general mandate.

Until legislative approaches are enacted, however, courts must resolve disputes between insurers and breast cancer patients regarding coverage of HDC-ABMT. It is not enough for courts to examine the terms of a disputed health insurance policy. Instead, they must look beyond the face of the contract and scrutinize the process by which coverage determinations are made. Courts should uphold an insurer's coverage denial for HDC-ABMT for breast cancer that is based on an Experimental Exclusion only when: (1) the policy clearly defines "experimental" through objective criteria; (2) the insurer does not operate under a conflict of interest; and (3) the insurer executes reasonable efforts on which to base its coverage decision. Unless all of these requirements are adequately satisfied, coverage denials should not be upheld, even if the insurer is entitled to deference under ERISA. Unchecked deference to coverage decisionmakers and plan administrators under ERISA perpetuates, if not actively condones, abusive conduct by insurers.

A. Defining Experimental Through Objective Criteria

Courts should compel an insurer to define Experimental Exclusions clearly in its policy through objective, unambiguous criteria. Insurers have many options in attempting to satisfy this requirement:

- Require formal endorsements from national medical organizations (e.g., the National Institutes of Health, American Medical Association, or American Society of Clinical Oncology) or governmental bodies (e.g., the Food and Drug Administration or Medicare);
- Expressly exclude or include treatments involved in Phase I, II, III, or IV clinical trials;
- Insist that research protocols be consistent with procedures endorsed by a nationally recognized medical organization;
- Insist that board certified physicians and nurses perform the medical treatment in appropriate facilities;
- Require that the proposed medical treatment be reviewed and approved by a qualified institutional review board;
- Require that the proposed medical treatment be received favorably by the most recent medical conferences and peer-reviewed literature;
- Insist that there exists no therapy that is clearly superior to the proposed treatment; and/or

- Require that the primary purpose of the treatment is therapeutic, with research merely a collateral goal.

In the absence of such defining criteria, courts should view an Experimental Exclusion as inherently ambiguous. If the policy is subject to state law, ambiguities must be construed against the insurer in accordance with rules of contract construction. If the policy is subject to ERISA, the court should resolve the ambiguity by making its own determination as to whether or not a treatment is experimental. This determination should be made through *de novo* review without deferring to the ERISA plan administrator. To do this, courts must independently weigh medical expert testimony and literature.

In conducting *de novo* review, courts should measure the proposed treatment against a "primary purpose to benefit the patient" standard. If the primary purpose is for research or education, then the court should deem the proposed treatment to be experimental. Otherwise, if the primary purpose is to benefit the patient, and research is merely collateral, then the proposed treatment is not experimental.

A "primary purpose to benefit the patient" standard ensures coverage for treatments that are still under investigation, while at the same time requiring that these treatments have some proven medical value. This value, however, may be substantially lower than would be required had the insurer enumerated objective criteria with higher standards. Yet the patient, not the insurer, should benefit from any ambiguities in a policy. When this standard is applied specifically to HDC-ABMT for breast cancer, courts should conclude that the treatment is in fact not experimental, given the medical community's consensus that at least the short-term effects of the treatment are favorable.

B. No Conflict of Interest

Courts should not uphold a coverage denial if the insurer is operating under a conflict of interest. Insurers must be forced to modify their decisionmaking process in order to ensure an objective coverage review. This could be achieved in several ways:

- Immediately eliminate any internal bonus scheme (whereby plan administrators have incentives to keep costs down through coverage denials or, in the case of HMOs, eliminating referrals to specialists); instead, implement schemes that discourage administrators from making inappropriate decisions;
- Designate an independent committee, consisting of medical experts, to make binding coverage determinations on a case-by-case basis; if the insurer is free to reject the findings of the

independent committee, then the conflict of interest has not been fully eliminated; and/or

- Structurally detach its coverage pool of funds from any profit-maximizing aims of the business, such as by establishing a trust.

Any of these modifications should ensure a more objective review by a neutral, disinterested third party. Such modifications will not only provide the policyholder with additional protections, but will also absolve the insurance industry of villainous depictions by the media,[577] and from public criticisms that insurers care solely about profits and not people.[578]

C. Reasonable Efforts

Courts should not uphold an insurer's coverage decision if the insurer did not execute reasonable efforts in arriving at its coverage determination. First and foremost, coverage decisions should be made only by competent medical directors, preferably those who are board certified and experienced in the specific discipline of medicine that governs the proposed treatment, such as oncologists in the case of HDC-ABMT for breast cancer.[579] Accordingly, courts should be immediately suspect of coverage decisionmakers who are retired physicians and have not treated patients for a substantial period of time, or who are not specialists in the relevant area of medicine.

Reasonable efforts include making all relevant inquiries and researching all pertinent data and literature regarding the treatment in question. Examples include the following:

- Reviewing thoroughly all materials submitted by a policyholder and her physician, which may include a policyholder's medical records, letters, and articles in support of the proposed treatment;
- Conferring with specialists in the proposed treatment area about the appropriateness of the proposed treatment specifically in relation to the policyholder's condition; and/or
- Consulting the official positions of nationally recognized medical organizations.

Most important, insurers must not rely on outdated materials.

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577. *See* Robin E. Margolis, *Federal Courts Still Split on Autologous Bone Marrow Transplants*, 11 HEALTH SPAN 20, 24 (Dec. 1992) (mentioning how insurers are portrayed villainously by media when insurers assert technicalities and exclusion clauses).

578. *Id.*; *see also* William M. Sage, *Easy Targets, Difficult Issues*, LEGAL TIMES, July 4, 1994, at 26 (noting that insurers' profit motives have led them to be classified as villains and as principal cause for health care crisis).

579. *See* Leonhardt v. Holden Bus. Forms Co., 828 F. Supp. 657, 669 (D. Minn. 1993) (noting that insurer relied on information from internist who was "not board-certified in either oncology or hematology" when denying coverage for ABMT).

A reasonable efforts requirement will encourage insurers to give a full and fair review to each claim on a case-by-case basis. Any potential that the insurer will deny coverage in a "rubber stamp" fashion will be diminished, if not eliminated entirely.

CONCLUSION

HDC-ABMTs are being increasingly used in the treatment of breast cancer. To oncologists and their patients with breast cancer, this is a "state-of-the-art" treatment that offers hope for a cure where none previously existed. To some insurance companies and other health professionals, this is an "experimental" treatment, the efficacy of which is still unknown. As such, HDC-ABMTs in the treatment of breast cancer have become one of the most controversial emerging medical technologies today.

In the meantime, insurers are claiming that HDC-ABMTs for breast cancer fall within the Experimental Exclusions set forth in their health insurance policies, and consequently, are refusing to pay for the treatment. Women, who are being denied this health coverage, are fighting their insurers both through their state legislatures and in the courts. Various legislation has been either proposed or enacted in several states.

In the absence of legislation, however, courts must be prepared to resolve these disputes between insurers and breast cancer patients. Courts should require insurers to clearly define Experimental Exclusions through objective criteria. Moreover, courts should require that insurers revise their coverage decisionmaking process to ensure that reasonable efforts are executed, and to eliminate any existing conflict of interest. Requiring objective criteria, no conflict of interest, and reasonable effects will instill more equity into a system where unequal bargaining power exists, ultimately providing greater protection for the policyholder, while simultaneously achieving the insurer's goal of eliminating harmful, wasteful treatments. Consistent, uniform court decisions promoting these aims will help transform the relationship between a breast cancer patient and her insurer from one of conflict to one of cooperation. After all, neither insurers nor breast cancer patients can afford more battles.