NOTES

INSURERS' AND COURTS' RESPONSE TO HIGH DOSE CHEMOTHERAPY WITH AUTOLOGOUS BONE MARROW TRANSPLANT IN THE TREATMENT OF BREAST CANCER: A TRAGEDY OR NECESSITY?

TABLE OF CONTENTS

I. INTRODUCTION

The pain of a spouse's or other relative's death from breast cancer is not comprehensible unless one has personally experienced such a loss. One widower chose to help cope with his loss with his pen:

> MY WIFE, VICTORIA, died in my arms.
>
> I was holding her so tight and so close that I could hear and feel the final few dozen heartbeats thumping . . . slower . . . slower through her nightgown and through the damp material of the shirt I had slept in all night at San Jose General Hospital.

> She smelled of baby powder and isopropyl alcohol. A faint stream of air whistled from her nostrils. I held on, face against hers, as if trying to conjure up a sudden, joyous resurrection.
>
> As the final moment approached I was lying on the right side of her once too-plump 34-year-old body, draping my right arm over her frail chest and my right leg softly over her legs. Her younger sister, Beverly, was on Vic's left side in that very same position.
>
> Her face was the picture of comatose serenity. She was about to escape the varietal agonies inflicted by three years of fighting breast cancer — the surgeries, the baldness, the vomiting, the sickening metallic stench of chemotherapy. The weight loss, the loss of control and, because the disease had also invaded her lungs, the agonizing work required just to draw a breath.
>
> The only payoff of this horrible moment was that all of it would soon be over: No more pain, Vic. No more pain. So we all lay there and listened to Vic's tiny whistling sound, to the barely audible thumps and finally to the silence.
>
> And then we both cried.[1]

This true account of a couple's bout with breast cancer is becoming, unfortunately, an all too common tragedy.[2] The tragedy begins when a physician diagnoses a woman with advanced infiltrating ductal carcinoma,[3] commonly

---

1. David E. Early, *A Personal Essay*, SAN JOSE MERCURY NEWS, Dec. 26, 1993, at 6.

2. *See* Mark Freedman, *When Insurers Refuse to Pay; Experimental Surgical Procedures*, BEST'S REVIEW—LIFE-HEALTH INS. EDITION, Apr. 1993, at 38. Beyond the real-life tragedy of a woman dying from breast cancer lies a treatment that is currently the subject of much litigation throughout the country. The drama of a woman with breast cancer seeking coverage for the treatment typically unfolds as follows:

> The physician of a woman suffering from advanced breast cancer says his patient's only hope of survival is to undergo high-dose chemotherapy combined with an autologous bone-marrow transplant. The patient's insurer refuses to pay for the procedure, claiming it is an unproven treatment for this type of cancer, and cites a clause in her insurance contract that excludes coverage for experimental procedures. The judge rules that the insurer is within its rights to deny payment. Yet in a case involving a similar diagnosis, treatment and contract, another judge agrees with the patient's lawyer that the therapy is not experimental and rules the insurer must pay.
>
> 'The central issue in these cases, then, is not whether insurers are justified in refusing to cover experimental procedures when the contract clearly excludes them. Rather, the question is how to determine what is experimental and who should make this determination. And from this issue flows a host of others, including such ethical and societal questions as where the responsibility for supporting medical research should rest.

Id.

3. Carcinoma is "[a]ny of the various types of malignant neoplasm derived from epithelial tissue in several sites, occurring more frequently in the skin and large intestine in both sexes, the bronchi and prostate gland in men, and the breast and cervix in women." THOMAS L. STEDMAN, STEDMAN'S MEDICAL DICTIONARY 245 (25th ed. 1990).

known as breast cancer.[4] The American Cancer Society has designated breast cancer the most common and deadly form of cancer among women.[5] In fact, one out of nine women will develop breast cancer, leaving only lung cancer responsible for more cancer deaths among women.[6] In 1993 alone, 180,000 American women contracted this deadly disease while 46,000 women lost their lives to breast cancer.[7] Early detection of breast cancer, through physical examinations and mammography,[8] and properly prescribed treatment has lowered the number of women who suffer and eventually die from the disease.[9] State legislatures have enacted statutes mandating that health insurance providers must include

---

4. Kekis v. Blue Cross & Blue Shield, 815 F. Supp. 571, 573 (N.D.N.Y. 1993). Cancer is "malignant neoplasms, most of which invade surrounding tissues, may metastasize to several sites, and are likely to recur after attempted removal and to cause death to the patient unless adequately treated." STEDMAN, *supra* note 3, at 236.

5. Kekis v. Blue Cross & Blue Shield, 815 F. Supp. at 573 n.2 (citing AMERICAN CANCER SOCIETY, FACTS ON BREAST CANCER 1 (1991)).

6. *Id.*

7. Harris Meyer, *Breast Study Woes Preview Reform Barriers*, AM. MED. NEWS, Mar. 8, 1993.

8. Mammography is "[r]oentgenographic examination of the breast by means of x-rays, ultrasound, nuclear magnetic resonance, etc." STEDMAN, *supra* note 3, at 917. Mammography has also been defined as "a method of screening that uses low-level radiation to detect tiny tumors in the breast before they can be felt." *Bad Medicine Contrary to What Alarmists Say, The U.S. Shouldn't Subsidize Needless Mammograms*, DAILY NEWS L.A., Dec. 29, 1993, at N14. "Because the correlation between age and breast cancer is so strong, the substantial benefits of regular mammogram testing in women 50 and over is not in doubt." *Id.*

The question of when women should begin having "regular mammograms has never been more perplexing or more disturbing." Gina Kolata, *Do Mammograms Save Lives? Screening of Younger Women in Question*, N.Y. TIMES, *reprinted in* S.F. CHRON., Dec. 27, 1993, at E9. "[Dr. Ellen B.] Mendelson, who directs the Breast Diagnostic Imaging Center of the Western Pennsylvania Hospital in Pittsburgh, said she knows four radiologists who had breast cancer when it was found after routine mammograms when they were in their late 30s or 40s. Mammography saved them, she said." *Id.* On the other hand, after

> years of recommending that women start having [mammograms] every year or two at age 40, the National Cancer Institute . . . has now changed its stance, saying instead that their benefits to women younger than 50 are not documented and that women should look at the facts and make up their own minds.

Id.

9. Judith Willis, *Why Women Don't Get Mammograms (And Why They Should)*, FDA CONSUMER (photo. reprint Oct. 1988) (May 1987), at 5.

> Mammography is presently the best method of detecting breast cancer at its earliest stages—before the cancer has spread and often before the tumor can be felt. Detecting the cancer this early means a higher chance of survival and perhaps less drastic surgery. One study estimates that for women 50 and over, physical examination alone has reduced deaths due to breast cancer by 18[%], but physical exam combined with annual mammography screening reduced breast cancer mortality by 56[%].

Id.

benefits for mammography screening in order to increase awareness of and prevent breast cancer.[10]

Hoping to further curb the number of women contracting breast cancer, researchers continue to search for the gene that makes certain women more susceptible than others to contracting cancer.[11] If a woman has a high risk for breast cancer, but a malignant tumor has not yet been diagnosed, she may consider having a preventive double mastectomy.[12] In addition, a new anti-cancer vaccine is being tested at a Pittsburgh Medical Center in hopes to someday be used to immunize healthy women who are at a higher risk of contracting breast cancer.[13]

If breast cancer is detected at an early stage, it is commonly treated by conventional, or low-dose, chemotherapy.[14] When low-dose chemotherapy becomes ineffective, other medical procedures are being tested. For example, a Food and Drug Administration (FDA) committee is urging the FDA to approve Taxol, a drug already used to combat ovarian cancer, to treat advanced breast cancer.[15] One approved treatment, high-dose chemotherapy followed by stem

---

10 . *See, e.g.*, VT. STAT. ANN. tit. 8, § 4100a (Supp. 1993). According to the statute: "Insurers shall provide coverage for screening by low-dose mammography for the presence of occult breast cancer. . . . Benefits provided shall be at least as favorable as coverage for other radiological examinations and subject to the same dollar limits, deductibles, and coinsurance factors within the provisions of the policy." *Id.*

11 . Laura Buterbaugh, *Researchers' Tests Vital in Finding Key Breast Cancer Gene*, DAILY NEWS OF L.A., Dec. 26, 1993, at L33. "Only 5 to 10[%] of all breast cancer cases are thought to be inherited. But these women, who carry the gene that predisposes them to breast cancer, have a high risk of developing the disease: a 59[%] chance of developing breast cancer by age 50, and an 82[%] chance of developing the disease by age 70." *Id.*

12. *Id.*

> A survey of 700 surgeons showed that many believe a preventive double mastectomy is a good way to help keep high-risk women from developing breast cancer. While the surgeons perform the operation on only about one patient per year, the procedure will be even more common once genetic testing becomes available.

Id. President Bill Clinton's mother, Virginia Kelley, underwent a mastectomy in her battle against the breast cancer, which ultimately took her life in January 1994. Gary Blonston, *Clinton's Exuberant Mother is Mourned*, SACRAMENTO BEE, Jan. 7, 1994, at A1.

13 . Fawn Vrazo, *Cancer Vaccine Tested on Patients*, SACRAMENTO BEE, Dec. 30, 1993, at A16. "Cancer experts emphasized that the new vaccine is in an early stage. . . . The new vaccine is the first of its kind to use synthetic cancer proteins that cause a specific T-cell response." *Id.* A senior staff member in the National Cancer Institute's (NCI) investigational drug branch called the new vaccine "promising." *Id.*

14 . Kekis v. Blue Cross & Blue Shield, 815 F. Supp. 571, 574 (N.D.N.Y. 1993). Chemotherapy has been generally defined as the "[t]reatment of disease by means of chemical substances or drugs; usually used in reference to neoplastic disease." STEDMAN, *supra* note 3, at 287.

15 . Fran Fritz, *FDA Committee Urges Taxol Approval*, DAILY NEWS L.A., Dec. 26, 1993, at W3. In one study, 29% of women treated with higher doses of Taxol responded, compared to 22% given a lower dose, with an eight month average duration. *Id.* "Patients under the higher dose had more toxic side effects, including depletion of a type of white blood cell called neutrophils, which increases the likelihood of infection." *Id.* The cost of Taxol ranges from 8 to 16 times the cost of low-dose chemotherapy. *Id.*; *see also* Elyse Tanouye, *FDA Clears Taxol from Bristol-Myers for Breast Cancer*, WALL ST. J., Apr. 15, 1994, at B5. Currently, only a small portion of

cell transplantation, is used to treat those with advanced breast cancer and has been the subject of litigation.[16] Another approved, yet highly controversial, procedure currently used in the treatment of breast cancer is high-dose chemotherapy with autologous bone marrow transplant (HDC-ABMT).[17]

This Note examines the historical and current trends in HDC-ABMT litigation, state insurance legislation geared toward mandating coverage of HDC-ABMT, and research currently being conducted to determine the medical efficacy of the treatment. This Note addresses various common law decisions involving insureds who have developed breast cancer and insurers who deny coverage for treatments beyond low-dose chemotherapy.[18] In most cases, the plaintiff, at the advice of her physician, seeks pre-authorization for coverage of HDC-ABMT to combat metastatic breast cancer.[19] Depending on the language of the insurance

---

182,000 women who will be diagnosed with breast cancer in 1994 will be candidates for Taxol treatment. *Id.* However, "approval as a first-line therapy would significantly expand the drug's market." *Id.*

16. *E.g.*, Jaecks v. National Ass'n of Letter Carriers Health Benefit Plan, No. 93-C-6855, 1993 WL 498286, at *1 (N.D. Ill. Dec. 1, 1993).

17. Kekis v. Blue Cross & Blue Shield, 815 F. Supp. at 574.

> HDC-ABMT is a procedure by which bone marrow is extracted from the patient's body, frozen, and stored while the patient receives large, near lethal doses of chemotherapy. In some cases the chemotherapy is administered in doses in excess of one thousand times the standard dose. This high does [sic] chemotherapy kills not only the cancer, but much of the patient's remaining bone marrow as well. . . . [A]fter the chemotherapy is completed, the patient's stored bone marrow is returned to the patient's body to replace the damaged bone marrow and thereby "rescue" the patient.

Id.; *see also* Elisabeth Rosenthal, *Patient's Marrow Emerges as Key Cancer Tool*, N.Y. TIMES, Mar. 27, 1990, at C8. "Researchers hope that the technique might eventually help save patients with widespread breast cancer . . . [because] the autologous transplants theoretically can be applied to any tumor for which more chemotherapy is considered better." *Id.*

18. *See infra* text accompanying notes 74-201. Much litigation exists outside the scope of this Note between patients seeking coverage for HDC-ABMT to treat conditions such as multiple myeloma and AIDS and insurance companies which refuse to preauthorize coverage for the treatments. *See, e.g.*, Mire v. Blue Cross & Blue Shield, 43 F.3d 567 (11th Cir. 1994) (nongerm cell ovarian cancer); Hendricks v. Central Reserve Life Ins. Co., 39 F.3d 507 (4th Cir. 1994) (small cell lung cancer); Hooper v. DEMCO, Inc., 37 F.3d 287 (7th Cir. 1994) (multiple myeloma); Pitman v. Blue Cross & Blue Shield, 24 F.3d 118 (10th Cir. 1994) (multiple myeloma); Doe v. Group Hospitalization & Medical Servs., 3 F.3d 80 (4th Cir. 1993) (multiple myeloma); Heasley v. Belden & Blake Corp., 2 F.3d 1249 (3d Cir. 1993) (gastrinoma); Bernards v. United of Omaha Life Ins. Co., 987 F.2d 486 (8th Cir. 1993) (germ cell cancer).; Snell v. Travelers Ins. Co., No. 93-0001, 1993 WL 274240 (E.D. Pa. June 30, 1993) (adenocarcinoma); Leonhardt v. Holden Business Forms Co., 828 F. Supp. 657 (D. Minn. 1993) (multiple myeloma); McLeroy v. Blue Cross & Blue Shield, 825 F. Supp. 1064 (N.D. Ga. 1993) (glioblastoma multiforme); Berry v. Blue Cross, 815 F. Supp. 359 (W.D. Wash. 1993) (ovarian cancer); Davis v. SelectCare, Inc., 834 F. Supp. 197 (E.D. Mich. 1993) (rhabdomyosarcoma of the prostate); Phatak v. Blue Cross & Blue Shield, No. C-92-2804, 1992 WL 281382 (N.D. Cal. Aug. 3, 1992) (multiple myeloma); Rollo v. Blue Cross & Blue Shield, No. 90-597, 1990 WL 312647 (D.N.J. March 22, 1990) (malignant tumor); Dozsa v. Crum & Forster Ins. Co., 716 F. Supp. 131 (D.N.J. 1989) (multiple myeloma); Bradley v. Empire Blue Cross & Blue Shield, 562 N.Y.S.2d 908 (N.Y. Sup. Ct. 1990) (AIDS).

19. *See, e.g.*, Bechtold v. Physicians Health Plan, 19 F.3d 322, 324 (7th Cir. 1994).

contract, this request is commonly denied[20] by either a federal or state health care agency or private health insurance company.[21] In answer to the denial, the insured can either go to court and argue the insurance contract covers HDC-ABMT[22] or pay for the treatment out of her own pocket. The legal clash resulting from such disputes commonly becomes complicated by the emotional outcry from the woman suffering from breast cancer and the public support for her cause.[23]

II. HIGH DOSE CHEMOTHERAPY WITH AUTOLOGOUS BONE MARROW TRANSPLANT IN THE TREATMENT OF BREAST CANCER: HISTORY AND LEGISLATION

According to medical experts, procedures beyond low-dose chemotherapy are required to treat patients with advanced, or metastatic,[24] breast cancer.[25] Breast cancer has been classified in terms of five stages of increasing

---

20. *See* George Anders, *Researchers Call Insurers 'Arbitrary' in Covering Bone-Marrow Transplants*, WALL ST. J., Feb. 17, 1994, at B12 (criticizing insurance companies for denying coverage of HDC-ABMT). *But see* Don Colburn, *Bone Marrow Transplants: Do They Work? Who Pays?*, WASH. POST NAT'L WKLY. EDITION, Apr. 25 - May 1, 1994, at 7. According to a recent study of 533 cases by William P. Peters of the Duke University Cancer Center, there is a "substantial inconsistency" between insurers concerning coverage of HDC-ABMT in clinical trials: "Coverage was approved in 77[%] of the cases, and more than half of the patients denied coverage eventually underwent the treatment anyway." *Id.* at 7-8.

21. Jennifer Belk, Note, *Undefined Experimental Treatment Exclusions in Health Insurance Contracts: A Proposal for Judicial Response*, 66 WASH. L. REV. 809, 809 (1991). "Some health service contracts, [such as a major medical insurance policy,] technically are not insurance contracts because they do not indemnify for medical expenses incurred by the subscriber, but arrange for provision of medical services on a pre-paid basis." *Id.* at 809 n.6. Such is the case for most insureds seeking coverage for HDC-ABMT. *Id.* at 809.

22. *See, e.g.*, Rocky Mountain Hosp. & Medical Serv. v. Phillips, 835 F. Supp. 575, 576 (D. Colo. 1993) (Insurer denied coverage claiming HDC-ABMT in the treatment of breast cancer was not "medically necessary") *aff'd*, 28 F.3d 113 (10th Cir. 1994), *cert. granted*, 115 S. Ct. 714, *and cert. dismissed*, 115 S. Ct. 1424 (1995); Madonia v. Blue Cross & Blue Shield, 11 F.3d 444, 446 (4th Cir. 1993), *cert. denied*, 114 S. Ct. 1401 (1994). After the insurer denied plaintiff's request for coverage of HDC-ABMT to treat her advanced breast cancer, the plaintiff sued the insurer for breach of contract, bad faith, intentional infliction of emotional distress, and unfair trade practices. *Id.*

23. *See* Tom Gorman, *Jury Adds $77 Million to Judgment Against HMO*, L.A. TIMES, Dec. 29, 1993, at 1A. In a landmark California case, which is discussed *infra* text accompanying notes 74-82, the family and friends of the plaintiff suffering from breast cancer mounted a community-wide fund raising effort which allowed the woman to undergo HDC-ABMT two months after her HMO denied coverage. *Id.*

24. Metastasis is as "[t]he spread of a disease process from one part of the body to another, as in the appearance of neoplasms in parts of the body remote from the site of the primary tumor." STEDMAN, *supra* note 3, at 955.

25. Kekis v. Blue Cross & Blue Shield, 815 F. Supp. 571, 574 (N.D.N.Y. 1993). Though conventional chemotherapy has long been employed in the treatment of breast cancer, various studies have indicated 55% to 87% of women with metastatic breast cancer "suffer a relapse within five years of the initial diagnosis, despite receiving standard chemotherapy treatment." *Id.*; *see also*

severity from Stage I to Stage V.[26] Those with metastatic breast cancer have normally progressed to Stage III or IV[27] and have a limited "window of opportunity" in which to receive treatment before death.[28] One treatment, HDC-ABMT, is currently being administered in hospitals and research institutes throughout the country to treat several different types of cancer.[29] In particular, "[m]ost Blue Cross-Blue Shield plans pay for [HDC-ABMT] for patients with cancers such as Hodgkin's disease, some types of lymphoma and leukemia, and neuroblastoma."[30] The entire procedure can commonly cost as much as $150,000.[31] As one commentator noted, there is a "growing body of state and federal decisions ordering insurance companies to pay for treatments that, while likely beneficial to the patient, lack the kind of time-tested proof that insurance companies have traditionally required."[32] Increased outcry from insureds, the

---

Richard S. Saver, Note, *Reimbursing New Technologies: Why Are the Courts Judging Experimental Medicine?*, 44 STAN. L. REV. 1095, 1111-12 (1992).

26. Stage I breast cancer occurs when the cancer is no greater than two centimeters in size and has not spread outside the breast. *The National Cancer Institute's Physician Data Query Database*, July 1993, at 2. In Stage II, the cancer is less than five centimeters, and may have spread to the lymph nodes under the arms, or is larger than five centimeters, but has not spread to the lymph nodes. *Id.* Stage III is divided into two stages, Stage A and Stage B. *Id.* In Stage IIIA, the cancer is larger than five centimeters and has spread to the lymph nodes under the arm. *Id.* In Stage IIIB, the cancer has either spread to lymph nodes near the collarbone or has spread to tissues near the breast, such as the chest wall, including the ribs and chest muscles. *Id.* Stage IV is diagnosed when the cancer has spread to other organs of the body. *Id.* *See* Lauri McGinley, *Health: Breast Cancer Patients Get More Assertive by Doing Research and Asking Questions*, WALL ST. J., May 9, 1994, at B1 (discussing a variety of cancer information services offered by the National Cancer Institute).

27. Pirozzi v. Blue Cross & Blue Shield, 741 F. Supp. 586, 588 n.3 (E.D. Va. 1990) (citing THE MERCK MANUAL OF DIAGNOSIS & THERAPY 2076 (14th ed. 1982)) (stating Stage IV, in connection with breast cancer, signifies the cancer cells have spread to areas outside the breast, or metastasized).

28. Harris v. Mutual of Omaha Co., IP 92-1089-C, 1992 WL 421489, at *4 (S.D. Ind. Aug. 26, 1992), *aff'd*, 992 F.2d 706 (7th Cir. 1993); Kulakowski v. Rochester Hosp. Serv. Corp., 779 F. Supp. 710, 717 (W.D.N.Y. 1991); Rollo v. Blue Cross & Blue Shield, Civ. A. No. 90-597, 1990 WL 312647, at *1 (D.N.J. Mar. 22, 1990).

29. *See, e.g.*, Fred Hutchinson Cancer Research Ctr. v. United of Omaha Life Ins. Co., 821 F. Supp. 644, 645 (D. Or. 1993) (Fred Hutchinson Cancer Research Center performs HDC-ABMT in the treatment of breast cancer); Fuja v. Benefit Trust Life Ins. Co., 809 F. Supp. 1333, 1336 (N.D. Ill. 1992), *rev'd on other grounds*, 18 F.3d 1405 (7th Cir. 1994) (University of Chicago Hospitals perform HDC-ABMT in the treatment of breast cancer); Kulakowski v. Rochester Hosp. Serv. Corp., 779 F. Supp. at 711 (Bone Marrow Transplant Clinic at Stron Memorial Hospital in Rochester, New York specializes in administering HDC-ABMT to cancer patients); Pirozzi v. Blue Cross & Blue Shield, 741 F. Supp. at 593 n.16 (Johns Hopkins Medical Center and the Fairfax County Hospital administer HDC-ABMT to cancer patients).

30. Lawrence K. Altman, *Insurer to Finance Test of a Treatment for Breast Cancer*, N.Y. TIMES, Nov. 12, 1990, at A1.

31. Kekis v. Blue Cross & Blue Shield, 815 F. Supp. 571, 575 (N.D.N.Y. 1993) (citing Schnitker v. Blue Cross & Blue Shield, 787 F. Supp. 903, 905 (D. Neb. 1991)). *But see* Colburn, *supra* note 20, at 7. At the Duke University Cancer Center, the cost of treating metastatic breast cancer by way of HDC-ABMT has declined from over $150,000 to below $100,000, as the treatment is currently done on an outpatient basis without need of overnight hospitalization. *Id.*

public, and the courts may play a critical role in how insurance companies choose to draft their exclusionary language in their current and future health policies.

Predating the confusion in the courts over HDC-ABMT is widespread controversy[33] throughout medical laboratories and hospitals studying HDC-ABMT.[34] Although the efficacy of HDC-ABMT as compared to standard chemotherapy is "hardly settled . . . and is the subject of widespread controversy within the medical community,"[35] patients die without the treatment because no proven treatment is available to combat the metastatic cancer.[36] In order to increase awareness and determine the efficacy of HDC-ABMT in the treatment of breast cancer, research institutes such as the Blue Cross and Blue Shield Association[37] and the Duke University Cancer Center[38] are conducting random clinical trials to determine the procedure's efficacy in comparison to standard chemotherapy.[39]

---

32. Jim Puzzanghera, *AIDS Ruling and the Courts: Bradley Case Verdict Helps Patients Battle Insurance Companies*, NEWSDAY, Aug. 13, 1990, at 7.

33. As one commentator noted, HDC-ABMT in the treatment of breast cancer is "'the most controversial issue in American Medicine.'" Colburn, *supra* note 20, at 7 (quoting William T. McGivney, Vice-President for Clinical Evaluation and Research at Aetna Health Plans).

34. *Id.* One such medical laboratory is the Duke University Cancer Center, where more than 800 women have received HDC-ABMT for treatment of their advanced breast cancer. *Id.*

35. Kekis v. Blue Cross & Blue Shield, 815 F. Supp. at 574 (citing Gary Taylor, *Insurers Deny Coverage: Cancer Treatment Focus of Suits*, NAT'L L.J., Jan. 25, 1993, at 3). Nelson Erlick, a senior researcher with the Emergency Care Research Institute and co-author of a recent 300-page HDC-ABMT study, opined HDC-ABMT is commonly administered to patients who are most receptive to low-dose chemotherapy, and "no proof" exists that gains observed after HDC-ABMT treatment could not be likewise obtained through use of conventional chemotherapy. Colburn, *supra* note 20, at 7.

36. Wilson v. Group Hospitalization & Medical Servs., Inc., 791 F. Supp. 309, 313-14 (D.D.C. 1992); Leonhardt v. Holden Business Forms Co., 828 F. Supp. 657, 664 (D. Minn. 1993) (holding the plaintiff had "a reasonable possibility of long-term remission or cure of the cancer" with the treatment; without it, she would die).

37. Colburn, *supra* note 20, at 7. Over three years ago, Blue Cross & Blue Shield agreed to assist in the financing of three national clinical trials addressing Stage II, Stage III and Stage IV, or metastatic breast cancer patients. *Id.* The trials, coordinated by the NCI, involve the efforts of over 40 prominent medical research and treatment centers throughout the country, including Georgetown University Medical Center where more than 60 patients have been treated since 1988. *Id.*

38. William P. Peters, a leading HDC-ABMT researcher and director of the bone marrow transplant program of Duke University Cancer Center, reported promising results in a June 1993 study involving women with metastatic breast cancer. *Id.*

> In a study of 85 women whose cancer has spread to 10 or more lymph nodes, 72[%] were alive and disease-free after HDC-ABMT . . . . In half the cases, it had been at least [two and one-half] years since the treatment. In three other studies of comparable patients treated with standard chemotherapy alone, between 38 and 52[%] survived that long.

Id. In addition, Peters opined the treatment is becoming less dangerous: "During the late 1970s and 1980s, the mortality rate from HDC-ABMT was very high; nearly one in four patients died within 100 days. Since 1990, the Duke [cancer research] group reports, the mortality rate has dropped below [three] percent." *Id.*

A more pessimistic view concerning the efficacy of HDC-ABMT is found in a new report by the Emergency Care Research Institute (ECRI), a non-profit, technology assessment body: "Current data suggests that it is unlikely that controlled trials [such as the trials conducted at the

Aside from organizational testing of HDC-ABMT, the reality of the cancer patient is to confront the disease on two fronts: First, at the medical level to seek a safe, effective treatment, and second, if insured, at her insurance company to obtain pre-authorization for the treatment sought.[40] Both battles are currently being waged in the courtrooms[41] and legislatures[42] throughout the country. Recent insurance legislation mandating coverage of bone marrow transplants can be found in a handful of states throughout the country.[43]

Duke University Cancer Center,] will demonstrate any substantive improvement in the quality of life or survival times for patients with metastatic breast cancer." *Id.*

39. *Id.*

40. Kekis v. Blue Cross & Blue Shield, 815 F. Supp. 571, 574-75 (N.D.N.Y. 1993).

41. *See generally id.* (addressing the common issues in dispute in a typical insured/insurer dispute over coverage for HDC-ABMT).

42. *See* Colburn, *supra* note 20, at 8.

> The issue has . . . reached state legislatures. A new Virginia law requires employers to offer workers insurance policies that would cover HDC-ABMT for breast cancer. A Massachusetts law goes further, requiring insurers to pay for bone marrow transplants for women with metastatic breast cancer treated in a controlled clinical trial. [A law] in New Hampshire mandate[s] coverage for all women with breast cancer.

Id.; *see also* Peter Baker, *Breast Cancer Victim Beats the System: Crusade Results in Law Requiring Insurers to Offer Special Coverage*, WASH. POST, Apr. 4, 1994, at A1.

43. *See, e.g.*, N.H. REV. STAT. ANN. § 415:18-c (Supp. 1993).

> Each insurer that issues or renews any policy of group or blanket accident or health insurance providing benefits for medical or hospital expenses, shall provide to each group, or to the portion of each group comprised of certificate holders of such insurance who are residents of this state and whose principal place of employment is in this state, 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.

Id.; *see also id.* §§ 419:5-c, 420:5-d, 420-A:7-e, 420-B:8-e; MASS. GEN. LAWS ANN. ch. 176B, § 40 (West Supp. 1994).

> Any subscription certificate under an individual or group medical service agreement that shall be delivered, issued or renewed in the commonwealth shall provide as a benefit for all individual subscribers or members within the commonwealth and all group members having a principal place of employment within the commonwealth, coverage for a bone marow transplant or transplants 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.

Id.; *see also id.* ch. 176G, § 4F; VA. CODE ANN. § 38.2-3418.1:1(A) (Michie Supp. 1994).

> Each insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis, each corporation providing individual or group accident and sickness subscription contracts, and each health maintenance organization providing a health care plan for health care services shall offer and make available coverage under such policy, contract or plan delivered, issued for delivery or renewed in this Commonwealth on and after January 1,

Although a few, select insurance companies have chosen to cover the procedure,[44] notwithstanding the state legislation discussed above, most insurers claim the treatment is experimental[45] under the terms of the contract and ultimately litigate to defend their denial of coverage.[46] With sympathy for the woman suffering from breast cancer usually a factor in such disputes,[47] insurance companies (and sometimes insureds) must convince jurors and judges that contractual language must be the primary focus of these emotional cases. Insurance companies cannot deny that jurors and judges are living, breathing, and caring human beings.[48] Such a reality presents a constant clash between emo-

---

> 1995, for the treatment of breast 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 any United States medical teaching college including, but not limited to, National Cancer Institute protocols that have been favorably reviewed and utilized by hemotologists or oncologists experienced in dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants.

Id.; *see also* N.J. STAT. ANN. § 17:48-6b (West 1985).

> Every subscription certificate and group and individual contract providing hospital service benefits delivered, issued, executed or renewed in this State, or approved for issuance or renewal in this State by the Commissioner of Insurance on or after the effective date of this act, shall provide benefits for reconstructive breast surgery, including but not limited to: . . . benefits for outpatient chemotherapy following surgical procedures in connection with the treatment of breast cancer shall be included as a part of the outpatient x-ray or radiation therapy benefit.

Id.; *see also* MICH. COMP. LAWS ANN. § 500.3406d (West 1993).

> (1) Subject to the dollar limits, deductibles, and coinsurance provisions that are not less favorable than those for physical illness generally, an insurer which delivers, issues for delivery, or renews in this state a hospital, medical, or surgical expense incurred policy shall offer or include coverage for . . . breast cancer outpatient treatment services. . . . (3)(d) "Breast cancer outpatient treatment services" means a procedure intended to treat cancer of the human breast, delivered on an outpatient basis, including but not limited to . . . chemotherapy.

Id.; *see also id.* § 500.3616.

44. Meyer, *supra* note 7. Travelers, Blue Cross & Blue Shield of North Carolina, Blue Cross & Blue Shield of Massachusetts will cover HDC-ABMT while Independence Blue Cross of Philadelphia agreed to cover the treatment outright. *Id.*

45. "[D]enial of coverage for . . . bone marrow transplant services on the basis that they are 'experimental' often results in legal or regulatory challenges, which create additional risks and expenses [for health plans]." Donna Peterson & Bob Carey, *Costlier Organ Transplants; Rising Costs and Frequency of Transplants Increases Risk for Health Plans*, BUS. INS., Feb. 24, 1992, at 23.

46. *Id.*

47. *But see* Arrington v. Group Hospitalization & Medical Servs., Inc., 806 F. Supp. 287, 291 (D.D.C. 1992) ("The [c]ourt has sympathy for plaintiff's situation, but this consideration cannot be material to a decision on the merits of this case.").

48. Harris v. Mutual of Omaha Co., IP 92-1089-C, 1992 WL 421489, at *1 (S.D. Ind. Aug. 26, 1992), *aff'd*, 992 F.2d 706 (7th Cir. 1993).

> 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

tions and the law which cannot easily be resolved without sacrifice.[49] In denying the plaintiff's request for coverage of HDC-ABMT in *Uhrich v. Caterpillar*,[50] the judge opined:

> This is not the result our hearts would have us reach, but is the result our heads tell us is required by the Plan language in this case, which vests discretion in the Plan Administrator and limits the scope of our review. *We note with regret that this ruling perpetuates the problem*: by denying Uhrich coverage to participate in a study that could help HDC-ABMT gain "generally accepted" status, the Plan postpones the day that enough data will be available to prove, or disprove, the safety and efficacy of the treatment and which could lead to the treatment becoming generally accepted.[51]

III. DEFINING "EXPERIMENTAL"

What exactly does the term "experimental"[52] or "investigational"[53] mean, and why do insurance companies commonly use such exclusionary language in

---

> 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 of the judiciary.

Id. Judge Tinder continued: "Judy Harris 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 ruling, as this court must, no personal satisfaction is taken, but the law was followed."; *see* Jerry Geisel, *Experimental Treatment: Who Pays?; Not the Insurer, One Judge Rules, But Others Differ*, BUS. INS., Jan. 4, 1993, at 3.

49. "[T]he court is left to answer this difficult question within the limiting structures imposed by the law. . . . [T]he law only permits the court to look at the insurance plan. . . . Consequently, a greater fairness or more equitable result is beyond the grasp of the court." Harris v. Mutual of Omaha Co., IP 92-1089-C, 1992 WL 421489, at *1 (S.D. Ind. Aug. 26, 1992), *aff'd*, 992 F.2d 706 (7th Cir. 1993). Judge Coffey, of the Seventh Circuit Court of Appeals, premised his denial of HDC-ABMT coverage on a similar view of our judicial system:

> There is no doubt that the policy questions posed in cases like this are of grave concern to all of us, yet we, as a court of law, are called upon to make legal determinations. [footnote omitted]. The issue in this case is very straightforward: Does the [Physicians Health Plan] . . . authorize coverage of HDC/ABMT? This is a matter of contract interpretation that does not implicate the broader policy issues involved in whether insurers *should* cover medical procedures that are presently of unknown medical value and extremely costly.

Bechtold v. Physicians Health Plan, 19 F.3d 322, 324-25 (7th Cir. 1994).

50. Uhrich v. Caterpillar, No. 93-C-5271, 1993 WL 478990 (N.D. Ill. Nov. 18, 1993).

51. *Id.* at *1 (emphasis added).

52. "Experiment . . . [means] a test performed . . . to ascertain the efficacy of something previously untried." Pirozzi v. Blue Cross & Blue Shield, 741 F. Supp. 586, 590 n.7 (E.D. Va. 1990) (quoting WEBSTER'S II NEW RIVERSIDE UNIVERSITY DICTIONARY 454 (1984)).

53. Generally speaking, "today there are as many definitions of "investigational" as there are cases questioning whether a procedure is alternative (and covered by insurance) or investiga-

their policies? Experimental procedures have been defined as those that are "untested or unproved or are . . . not related to the [patient's therapy] but rather performed solely for the purpose of obtaining scientific data."[54] One reason insurance companies commonly exclude coverage for experimental procedures is that each has "a role to play in eliminating incompetent, worthless and unnecessary medical treatments," the use of which violates public policy.[55] As one commentator noted, however, in the case of a patient who is terminally ill and needing treatment to survive, the existence of an experimental exclusion is many times irrelevant and treatment will be provided.[56]

In today's world of advancing medical science, what may be experimental to one oncologist[57] may be acceptable to another. On the same note, a treatment that may be considered experimental, thus excludable, by one insurance company[58] may be fully covered by another insurance company.[59] In *Fuja v.*

---

tional (and not covered)." Angela R. Holder, *Funding Innovative Medical Treatment*, 57 ALB. L. REV. 795, 796 (1994).

54. Belk, *supra* note 21, at 813 n.41 (citing Dale H. Cowan, *Innovative Therapy Versus Experimentation*, 21 TORT & INS. L.J. 619, 622 (1986)). In addition, experimentation has been defined as "an activity designed to test a hypothesis, permit conclusions to be drawn and thereby to develop or contribute to generalizable knowledge." *Id.* at 811 n.41.

One health care provider, Principal Heath Care of Iowa, Inc., defines experimental in its Certificate of Coverage:

> "Experimental, Investigational or Unproven Procedures"—medical, surgical, psychiatric, substance abuse or other health care services, supplies, treatments, procedures, drug therapies or devices that are determined by Plan . . . to be either: (1) not generally accepted by informed health care professionals in the United States as effective in treating the condition, illness or diagnosis for which their use is proposed, or (2) not proven by scientific evidence to be effective in treating the condition, illness or diagnosis for which their use is proposed.

Principal Health Care of Iowa, Inc., *Certificate of Coverage*, May 15, 1992, at 3.

55. James S. Cline & Keith A. Rosten, *The Effect of Policy Language in the Containment of Health Care Cost*, 21 TORT & INS. L.J. 120, 131 (1985); *see also* Grace P. Monaco & Rebecca Burke, *Insurer as Gatekeeper: Handling Claims for Unproven Methods of Medical Management*, 18 FORUM 591, 591-96 (1983).

56. Cline & Rosten, *supra* note 54, at 131-34.

57. An oncologist is one who is a specialist in oncology. STEDMAN, *supra* note 3, at 1086. Oncology is the "study or science dealing with the physical, chemical, and biologic properties and features of neoplasms, including causation, pathogenesis, and treatment." *Id.*

58. Harris v. Mutual of Omaha, 992 F.2d 706, 708 (7th Cir. 1993). The court held HDC-ABMT was excludable as a service because the insurance company brought forth reliable evidence demonstrating that HDC-ABMT is investigational or experimental or is mainly used for research purposes. *Id.* at 713.

59. *See, e.g.*, Fuja v. Benefit Trust Life Ins. Co., 809 F. Supp. 1333 (N.D. Ill. 1992), *rev'd on other grounds*, 18 F.3d 1405 (7th Cir. 1994). The district court held the insured met her burden of proof by showing HDC-ABMT was a medically necessary treatment under the terms of the policy. *Id.* at 1342. Of the five factors that had to be proven by the insured, the court considered the fourth factor to be the most controversial; it required HDC-ABMT must "not [be] deemed to be experimental . . . by any appropriate technological assessment body established by any state or federal government." *Id.* at 1340-41.

Benefit Trust Life Insurance Co.,[60] the court held the technological assessment body[61] qualifier largely removed any ambiguity[62] from the term experimental.[63] One such technological assessment body, the National Cancer Institute (NCI), has stated in its literature the terms experimental or investigational[64] cannot be simply or unambiguously used to define new cancer therapies.[65]

To the dismay of courts, insureds, and insurance companies, there "are no agreed-upon criteria according to which innovative or experimental practices become accepted standard medical practice."[66] If the insurance policy does not define experimental, countless definitions can be implemented by the interpreting court.[67] Others have defined experimental treatments as those "that are untested or unproved with respect to clinical efficacy, or are by their very nature not related to the therapy of the patient but rather performed solely for the purpose of obtaining scientific data."[68]

---

60. Fuja v. Benefit Trust Life Ins. Co., 809 F. Supp. 1333 (N.D. Ill. 1992), *rev'd on other grounds*, 18 F.3d 1405 (7th Cir. 1994).

61. Generally, a technological assessment body is an agency established and/or funded by the federal or a state government which produces "technology assessments" of new procedures being introduced into the marketplace. Belk, *supra* note 21, at 811 n.12. "Technology assessment" broadly describes a variety ways to assess the evidence of a new technology's safety and effectiveness. *Id.* One example of an independent, non-profit technology assessment institute is the ECRI. *See generally* Colburn, *supra* note 20, at 7. The ECRI team recently completed a 300-page research report on the efficacy of HDC-ABMT in the treatment of breast cancer. *Id.* The study, which focused on women who had metastatic, or Stage IV, breast cancer, concluded that there is insufficient data for assessing the treatment of high-risk patients with Stage II or Stage III cancer. *Id.*

62. A clause within an insurance contract is ambiguous if it is susceptible to two or more reasonable interpretations. Dahl-Eimers v. Mutual of Omaha Life Ins. Co., 986 F.2d 1379, 1381 (11th Cir.), *cert. denied*, 114 S. Ct. 440 (1993).

63. Fuja v. Benefit Trust Life Ins. Co., 809 F. Supp. at 1340 n.4.

64. Although neither courts nor insurers typically differentiate between the terms, one insurer went so far as to state in its policy that "investigational procedures are considered experimental." Sweeney v. Gerber Prods. Co., 728 F. Supp. 594, 595 (D. Neb. 1989).

65. Fuja v. Benefit Trust Life Ins. Co., 809 F. Supp. at 1340. The court cited two NCI bulletins published in January 1992 and November 1992 from which the court concluded the NCI had not deemed the treatment to be investigational. *Id.* The parties stipulated before trial that no technological assessment body had deemed the treatment to be experimental. *Id. But see* Uhrich v. Caterpillar, Inc., No. 93-C-5271, 1993 WL 478990, at *3 (N.D. Ill. Nov. 18, 1993). In denying a request for coverage for HDC-ABMT, the court relied on a 1991 DATTA report which "specifically addressed HDC-ABMT for treating breast cancer. Of the panelists responding in that report, none rated the treatment as 'established.' Instead, most rated it 'investigational.'" *Id.*

66. Cowan, *supra* note 54, at 626.

67. *See supra* note 54 (stating various definitions). The *Dahl-Eimers* court held the experimental clause was ambiguous because the insurance contract did not "clearly specify who will determine whether a treatment is considered experimental or how that determination will be made." Dahl-Eimers v. Mutual of Omaha Life Ins. Co., 986 F.2d 1379, 1383-84 (11th Cir.), *cert. denied*, 114 S. Ct. 440 (1993).

68. Barbara A. Fisfis, Comment, *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.

It is commonly accepted that any ambiguity in an insurance contract will be strictly construed against the drafter.[69] If the policy does include a definition of experimental, the courts need not be concerned with all of the external definitions available.[70] Even if the policy does not contain an explicit definition of experimental, few courts simply deem the clause ambiguous and hold for the insured.[71] In addition, if the policy does not define experimental as those treatments tested through protocols, courts have not deemed existence of a protocol the sole factor in determining whether the treatment is experimental.[72] Regardless of whether an insurance policy defines experimental, the courts generally defer to medical experts when deciding whether to enjoin the company from denying coverage.[73]

IV. LITIGATION EXPLOSION OVER HDC-ABMT IN THE TREATMENT OF BREAST CANCER

A. *An $89.3 Million Jury Verdict*

On occasion, HDC-ABMT litigation does not arise until after the breast cancer has taken the victim's life. In one such case, the insured's estate sued a California-based health maintenance organization alleging the company wrongly denied coverage for HDC-ABMT, and, as a result, a woman needlessly lost her

---

L. REV. 777, 778 n.6 (1993) (citing M.L. NORTON, WHEN DOES AN EXPERIMENTAL INNOVATIVE PROCEDURE BECOME AN ACCEPTED PROCEDURE? 107 (1978)).

69. *See* Continental Casualty Co. v. Cole, 809 F.2d 891, 895 (D.C. Cir. 1987) (citing 2 COUCH ON INSURANCE § 15:74 (2d ed. 1984)); Heasley v. Belden & Blake Corp., 2 F.3d 1249, 1257 (3d Cir. 1993) (citations omitted); Hansen v. Continental Ins. Co., 940 F.2d 971, 982 (5th Cir. 1991); *see also* Gaunt v. John Hancock Mut. Life Ins. Co., 160 F.2d 599, 602 (2d Cir.), *cert. denied*, 331 U.S. 849 (1947) (Judge Learned Hand stated: "Insurers who seek to impose upon words of common speech an esoteric significance intelligible only to their craft, must bear the burden of any resulting confusion.").

70. *See, e.g.*, Fuja v. Benefit Trust Life Ins. Co., 809 F. Supp. 1333, 1336 (N.D. Ill. 1992), *rev'd on other grounds*, 18 F.3d 1405 (7th Cir. 1994) (providing a definition of medically necessary within which the treatment sought must not have been deemed experimental by any appropriate technological assessment body); Kekis v. Blue Cross & Blue Shield, 815 F. Supp. 571, 575 (N.D.N.Y. 1993) (The contract stated the company would not provide coverage for experimental/investigative services which are defined as those with no proven medical value.).

71. *See, e.g.*, Sweeney v. Gerber Prods. Co., 728 F. Supp. 594, 596-97 (D. Neb. 1989) (holding HDC-ABMT was experimental, or not commonly and customarily recognized throughout the doctor's profession as appropriate in the treatment of metastatic breast cancer, after consideration of relevant medical testimony before the court). *But see* Pirozzi v. Blue Cross & Blue Shield, 741 F. Supp. 586, 594 (E.D. Va. 1990) (holding for the insured after interpreting what experimental meant based on expert testimony).

72. Leonhardt v. Holden Business Forms Co., 828 F. Supp. 657, 669 (D. Minn. 1993); *see also* Adams v. Blue Cross & Blue Shield, 757 F. Supp. 661, 675 (D. Md. 1991) ("[T]he fact that the treatment is administered as part of an experimental protocol designed to facilitate the collection of data does not necessarily mean that the treatment is by definition experimental."); Pirozzi v. Blue Cross & Blue Shield, 741 F. Supp. at 593 ("Use of a protocol does not, by itself, indicate that a procedure is experimental.").

73. Fisfis, *supra* note 68, at 797 (citing Paul Molino, *Reimbursement Disputes Involving Experimental Medical Treatment*, 11 J. HEALTH & HOSP. L. 329, 330 (1991)).

life to breast cancer.[74] In December 1993, a Woodland Hills County jury returned a landmark, $89.3 million verdict in *Fox v. Health Net, Inc.* [75] The jury originally awarded the decedent's estate $12.1 million in compensatory damages and $212,000 in medical expenses,[76] finding Health Net's denial of coverage caused "reckless infliction of emotional distress."[77] One week later, the jury awarded the family of the decedent an additional $77 million in punitive damages.[78] This case is also unique because the estate's counsel was not just another California lawyer; he was the victim's brother.[79]

Unlike the many other HDC-ABMT cases, this case demonstrates the power and compassion a jury can wield.[80] Unlike numerous judges in HDC-ABMT cases, who quickly and quietly resolve insurance disputes during brief, preliminary injunction hearings, this California jury listened to one month of testimony and returned a verdict the jury considered "equitable."[81] According to one ethicist from the University of Southern California, Alexander M. Capron, jury verdicts based on emotion could prove suicidal to our health care system: "The notion that health plans must provide everything that people can claim would be of possible benefit would be ludicrous medical care and disastrous health care financing with or without the President's health care plan."[82]

B. *Burden of Proof in HDC-ABMT Cases*

Because parties do not usually stipulate to HDC-ABMT coverage, courts must decide cases on the merits before it will compel coverage.[83] One of the first issues that must be addressed by courts when deciding HDC-ABMT cases on the merits is which party sustains the burden of proof.

---

74. Tom Gorman, *Jury Adds $77 Million to Judgment Against HMO*, L.A. TIMES, Dec. 29, 1993, at 1A3. (indicating a Woodland Hilss County Superior Court jury in California decided *Fox v. Health Net, Inc.* in December 1993).

75. *Id.*

76. Erik Eckholm, *$89.3 Million Judgment Worries Health Industry HMO Declined to Pay for Bone-Marrow Transplant*, SACRAMENTO BEE, Dec. 30, 1993, at A3.

77. Gorman, *supra* note 74, at 1A3.

78. *Id.*

79. *Id.*

80.

> The jury verdict strikes a widely shared emotional chord that no patient facing death should be denied a treatment, even with only a small chance of success, because an insurer deems it too expensive and unproven. Particularly when a family member is at risk, most of us are ready to believe that no hope is too small or too costly to clutch at.

Medicine by Hope?, SACRAMENTO BEE, Jan. 2, 1994, at F04.

81. *Id.*

82. Gorman, *supra* note 74, at 1A3.

83. *E.g.*, Fuja v. Benefit Trust Life Ins. Co., 809 F. Supp. 1333, 1333 (N.D. Ill. 1992), *rev'd*, 18 F.3d 1405 (7th Cir. 1994) (court of appeals reversed an injunction ordered by the district court that prohibited Benefit Trust from denying coverage for HDC-ABMT.).

In a typical case scenario, an insured is required to prove the insurance company pre-authorized coverage before the treating physician will administer HDC-ABMT.[84] When an insured requests coverage for HDC-ABMT, the insurance agent has four possible responses to such a request: First, HDC-ABMT is covered under the terms of the policy; second, the treatment does not fall within the purview of the benefits section of the policy and thus is not covered;[85] third, an exclusionary clause exists which takes HDC-ABMT outside of the realm of covered treatments and is, therefore, excludable from coverage;[86] or fourth, preauthorize coverage for treatment while reserving the question of whether the treatment is actually coverable under the terms of the health insurance policy.[87] The first response is, for obvious reasons, not frequently litigated. Responses two and three, on the other hand, are the roots of the litigation explosion over the issue.

If, when denying coverage for treatment, the insurance company gives response two, that is, the treatment does not fall within the benefits section and thus is not covered,[88] the burden of proof rests with the insured to show by a preponderance of the evidence that HDC-ABMT falls within the benefits section of the policy.[89] If this burden cannot be sustained, courts should not, in theory, reverse the insurance company's denial of coverage.[90] Creative insurance companies, such as the Benefit Trust Life Insurance Company, commonly draft exclusionary language within the definition of "medically necessary" in an effort to avoid being assigned the burden of proof if litigation over coverage for procedures such as HDC-ABMT should arise.[91] Insurance policies such as those offered by Benefit Trust Life Insurance Company typically read:

---

84. *See, e.g.,* Nesseim v. Mail Handlers Benefit Plan, 995 F.2d 804, 805 (8th Cir. 1993); Kekis v. Blue Cross & Blue Shield, 815 F. Supp. 571, 575 (N.D.N.Y. 1993).

85. *See, e.g.,* Dahl-Eimers v. Mutual of Omaha Life Ins. Co., 986 F.2d 1379, 1380 (11th Cir.), *cert. denied*, 114 S. Ct. 440 (1993); Farley v. Benefit Trust Life Ins. Co., 979 F.2d 653, 658 (8th Cir. 1992); Fuja v. Benefit Trust Life Ins. Co., 809 F. Supp. at 1336; White v. Caterpillar, Inc., 765 F. Supp. 1418, 1420 (W.D. Mo. 1991), *aff'd*, 985 F.2d 564 (8th Cir. 1991).

86. *See, e.g.,* Nesseim v. Mail Handlers Benefit Plan, 995 F.2d at 805; Harris v. Mutual of Omaha Co., 992 F.2d 706, 708 (7th Cir. 1993); Clark v. K-Mart Corp., 979 F.2d 965, 966 (3d Cir. 1992); Holder v. Prudential Ins. Co., 951 F.2d 89, 90 (5th Cir. 1992); Roseberry v. Blue Cross & Blue Shield, 821 F. Supp. 1313, 1316-17 (D. Neb. 1992); Kekis v. Blue Cross & Blue Shield, 815 F. Supp. at 575; Wilson v. Group Hospitalization & Medical Servs., Inc., 791 F. Supp. 309, 311 (D.D.C. 1992), *appeal dismissed*, 995 F.2d 306 (D.C. Cir. 1993); Kulakowski v. Rochester Hosp. Serv. Corp., 779 F. Supp. 710, 713 (W.D.N.Y. 1991); Pirozzi v. Blue Cross & Blue Shield, 741 F. Supp. 586, 588 (E.D. Va. 1990); Sweeney v. Gerber Prods. Co., 728 F. Supp. 594, 595-96 (D. Neb. 1989).

87. Fred Hutchinson Cancer Research Ctr. v. United of Omaha Life Ins. Co., 821 F. Supp. 644, 645-46 (D. Or. 1993).

88. *See supra* text accompanying note 85.

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

90. *Id.* at 1412; *see also* Farley v. Benefit Trust Life Ins. Co., 979 F.2d 653, 658 (8th Cir. 1992).

91. *See generally* Farley v. Benefit Trust Life Ins. Co., 979 F.2d at 653.

> [The company] *will provide benefit coverage* for health care and treatment that is "medically necessary" . . . . [A "medically necessary" treatment is one that is] (1) required and appropriate for care of the sickness or the injury; (2) given in accordance with generally accepted principles of medical practice in the U.S.; (3) approved for reimbursement by the Health Care Financing Administration; (4) not deemed to be experimental, educational, or investigational in nature by any appropriate technological assessment body established by any state or federal government; [and] (5) not furnished in connection with medical or other research.[92]

For a plaintiff with limited resources, the burden of proof can be a critical factor in predicting whether a court will enjoin an insurance company from denying preauthorization for coverage of HDC-ABMT. Regardless of where the burden of proof ultimately rests, however, it is apparent each party must marshall all resources to demonstrate why its argument should prevail.

In general, "'[o]nce the insured shows that a [covered] loss has occurred, the insurer shoulders the burden of demonstrating that the loss claimed is excluded expressly from coverage under the policy terms.'"[93] Such a situation arises if the insurance company gives the third possible response; that is, the company denies coverage behind the veil of an experimental exclusion clause.[94] A typical experimental exclusion clause reads:

---

92. Fuja v. Benefit Trust Life Ins. Co., 809 F. Supp. 1333, 1336 (N.D. Ill. 1992), *rev'd on other grounds*, 18 F.3d 1405 (7th Cir. 1994) (emphasis added); *see* Farley v. Benefit Trust Life Ins. Co., 979 F.2d at 658.

Insurers commonly draft a definition of "medically necessary" into their insurance contracts. For example, Principal Heath Care of Iowa, Inc. has the following defintion drafted into its Certificate of Coverage:

> "Medically Necessary" - those Health Services which are determined by Health Plan to be necessary to meet the basic health needs of an individual. Determination of Medical Necessity is done on a case-by-case basis and considers several factors including, but not limited to, the standards of the medical community. The fact that a physician has performed or prescribed a procedure or treatment or the fact that *it may be the only available treatment for a particular Injury, Sickness or Mental Illness does not mean it is Medically Necessary.* In addition, the service must: (1) be consistent with the diagnosis of and prescribed course of treatment for the patient's condition or be generally accepted by the medical community as a preventive Health Service; (2) be required for reasons other than the convenience of the patient or his or her Physician or not be required solely for custodial, comfort or maintenance reasons; (3) be performed in the most cost-efficient type of setting appropriate for the condition; and (4) be rendered at a frequency which is accepted by the medical community as medically appropriate.

PRINCIPAL HEALTH CARE OF IOWA, INC., CERTIFICATE OF COVERAGE, May 15, 1992, at 4 (emphasis added). The emphasized language would preclude the argument for coverage made in many HDC-ABMT cases that the treatment is the only hope left for the insured. *Id.*

93. Kekis v. Blue Cross & Blue Shield, 815 F. Supp. 571, 578 (N.D.N.Y. 1993) (quoting M.H. Lipiner & Son, Inc. v. Hanover Ins. Co., 869 F.2d 685, 687 (2d Cir. 1989)).

94. *See supra* text accompanying note 86.

> In addition to certain exclusions and limitations already described in this rider, *we will not pay* under this rider when any of the following apply to you: . . . Experimental/Investigative Services. *We will not pay* for any service or procedure we do not recognize as accepted medical practice as we determine has no proven medical value.[95]

If the insurance company cannot meet its burden of proof required when invoking an exclusionary clause, the court will enjoin the company from denying coverage.[96] On the other hand, courts have not hesitated to rule in favor of the insurance company if it has met its burden of proof.[97] In one such case, the district court judge stated:

> As much as this Court sympathizes with the plaintiff, and understands her desire to undergo the treatment which is the subject of this lawsuit in hopes of prolonging her life, the Court cannot order the defendant medical benefits plan to do that which it is not legally obligated to do. There is no question that [HDC-ABMT] as a treatment for breast cancer, remains today a treatment which is in an experimental and investigational stage. There is also no question that the defendant medical benefits plan excludes coverage for such treatment.[98]

---

95. Kekis v. Blue Cross & Blue Shield, 815 F. Supp. at 575 (emphasis added) (holding HDC-ABMT has at least "some proven medical value" and, therefore, did not fall within the experimental/investigative exclusion clause).

As expected, each insurer or health care provider has the liberty of defining the scope and breadth of its policy's exclusionary language. For example, Principal Health Care of Iowa, Inc. defines its experimental exclusions as follows:

> Health Services and associated expenses for Experimental, Investigational or Unproven Procedures, treatments, devices and pharmacological regimens. The fact that an Experimental, Investigational or Unproven Procedure, treatment, device or pharmacological regimen is the only available treatment for a particular condition will not result in Coverage if the procedure is considered to be Experimental, Investigational or Unproven in the treatment of that particular condition.

Principal Health Care of Iowa, Inc., *Certificate of Coverage* § 11.1(f), May 15, 1992, at 35. For a definition of "Experimental, Investigational or Unproven Procedures," see *supra* note 53.

96. *See, e.g.*, Kekis v. Blue Cross & Blue Shield, 815 F. Supp. at 585; Wilson v. Group Hospitalization & Medical Servs., Inc., 791 F. Supp. 309, 314 (D.D.C. 1992); Kulakowski v. Rochester Hosp. Serv. Corp., 779 F. Supp. 710, 717 (W.D.N.Y. 1991); Pirozzi v. Blue Cross & Blue Shield, 741 F. Supp. 586, 595 (E.D. Va. 1990).

97. *See, e.g.*, Nesseim v. Mail Handlers Benefit Plan, 995 F.2d 804, 807-08 (8th Cir. 1993); Harris v. Mutual of Omaha Co., 992 F.2d 706, 713-14 (7th Cir. 1993); Clark v. K-Mart Corp., 979 F.2d 965, 968 (3d Cir. 1992); Holder v. Prudential Ins. Co., 951 F.2d 89, 91 (5th Cir. 1992); Roseberry v. Blue Cross & Blue Shield, 821 F. Supp. 1313, 1318 (D. Neb. 1992); Sweeney v. Gerber Prods. Co., 728 F. Supp. 594, 597 (D. Neb. 1989).

98. Sweeney v. Gerber Prods. Co., 728 F. Supp. at 597. The holding in *Sweeney* is not, however, an accurate representation of the direction of the courts in the 1990s. *See infra* text accompanying notes 114-187. In fact, there is evidence to suggest if *Sweeney* were tried again in

Response four, that is, preauthorization of coverage, is uniquely demonstrated in *Fred Hutchinson Cancer Research Center v. United of Omaha Life Insurance Co.*[99] In this case, United of Omaha initially denied coverage for HDC-ABMT arguing the procedure was "investigational in nature and therefore not covered by the group policy."[100] The party requesting coverage for HDC-ABMT filed a motion for preliminary injunction seeking coverage for the treatment.[101] Before the court could rule on the motion, United of Omaha and the party stipulated as follows:

> 1. That [United of Omaha] cease denying coverage for [HDC-ABMT];
> . . . .
> 3. That the parties proceed in due course in this case after full discovery to secure a judicial determination after a hearing on the merits on the issues of whether [the] proposed treatment is "medically appropriate," "medically necessary," or "investigative, and not proven safe and effective" within the meaning of the subject policy.[102]

After the stipulation, the Fred Hutchinson Center provided and United of Omaha paid for HDC-ABMT treatment for approximately one month until the breast cancer patient died.[103] When United of Omaha refused to pay any more claims submitted by the Fred Hutchinson Center, the district court held the stipulation constituted a contract[104] and ordered United of Omaha to pay for the remaining claims.[105]

C. *Standard of Review in HDC-ABMT Cases*

As with the burden of proof playing a critical role at the district court level in HDC-ABMT cases, the standard of review at the appellate court also is of great concern to those seeking reversal of a district court judgment. Generally, appellate courts review factual findings of the district courts under the clearly erroneous standard.[106] Conclusions of law, however, are reviewed de novo.[107] In

---

1993, the court may have held for the insured because HDC-ABMT is now almost uniformly accepted within the medical community. *See infra* text accompanying notes 114-187.

99. Fred Hutchinson Cancer Research Ctr. v. United of Omaha Life Ins. Co., 821 F. Supp. 644 (D. Or. 1993).

100. *Id.* at 645.

101. *Id.*

102. *Id.* at 646.

103. *Id.*

104. *Id.* at 647 (citing United States v. McKinney, 758 F.2d 1036, 1047 (5th Cir. 1985)).

105. *Id.*

106. FED. R. CIV. P. 52(a); *see, e.g.*, Newell v. Prudential Ins. Co., 904 F.2d 644, 649 (11th Cir. 1990), *aff'd*, 35 F.3d 577 (11th Cir. 1994). For cases heard at the state court level, as opposed to federal district court, state rules of appellate procedure may use a different standard of review than the federal rules.

107. Dahl-Eimers v. Mutual of Omaha Life Ins. Co., 986 F.2d 1379, 1381 (11th Cir.), *cert. denied*, 114 S. Ct. 440 (1993).

many of the HDC-ABMT cases, plaintiffs initially seek a preliminary injunction due to the nature of the dispute and the serious threat of death if the matter is not resolved in an expedited manner; if such a preliminary injunction is sought and refused, courts hold such a denial is a question of law subject to "broad review."[108]

Although some HDC-ABMT litigation has arisen in state courts,[109] a vast majority of published decisions are brought by federal employees under ERISA[110] or a comparable federal statute.[111] In those cases, particular standards of review have been established. If the administrator of an ERISA plan has retained discretion to determine entitlement to benefits, the administrator's decision is overturned only if "arbitrary and capricious."[112] Non-discretionary ERISA decisions, however, are reviewed de novo.[113]

D. *When an Insurance Policy Clearly Excludes a Treatment, Courts Interpret the Plain Meaning of the Contract*

To determine whether a treatment is covered under an insurance policy, courts begin by analyzing the plain language of the contract.[114] When the policy clearly excludes a treatment, courts generally follow the policy language.[115] A recent ERISA decision demonstrates the "controlling" effect the language of an insurance policy has on the court's conclusions of law.[116] In *McLeroy v. Blue Cross & Blue Shield*,[117] the policy covered HDC-ABMT, "but only if required in the treatment of: non-Hodgkin's lymphoma, Hodgkin's disease after fist [sic] or subsequent relapse, neuroblastoma, acute lymphocytic leukemia, [or] acute non-lymphocytic leukemia."[118] The policy included a specific exclusion for any type

---

108. E. Remy Martin & Co. v. Shaw-Ross Int'l Imports, Inc., 756 F.2d 1525, 1529 (11th Cir. 1985).

109. Comprecure Ins. Co. v. Snow, No. 92-CV-8087, 1993 WL 330929 (Colo. Dist. Ct. Feb 16, 1993).

110. Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. §§ 1001-1461 (1988) (ERISA is a statute which regulates certain federal employee benefit plans.); *see* Madonia v. Blue Cross & Blue Shield, 11 F.3d 444, 446 (4th Cir. 1993), *cert. denied*, 114 S. Ct. 1401 (1994).

111. One such statute is the Federal Employees Health Benefits Act of 1959 (FEHBA), 5 U.S.C. § 8901 (1988).

112. Firestone Tire & Rubber Co. v. Bruch, 489 U.S. 101, 115 (1989); *see also* 5 U.S.C. §§ 701(b)(2), 706(2)(A) (1988).

113. Firestone Tire & Rubber Co. v. Bruch, 489 U.S. at 115.

114. Pirozzi v. Blue Cross & Blue Shield, 741 F. Supp. 586, 589 (E.D. Va. 1990) (stating contract analysis properly begins with the plan's terms).

115. *See* Reger v. Espy, 836 F. Supp. 869, 871 (N.D. Ga. 1993). In *Reger* the court denied ordering coverage for HDC-ABMT by interpreting contract language, which read: "What is not Covered. Services 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." *Id.*

116. McLeroy v. Blue Cross & Blue Shield, 825 F. Supp. 1064, 1064 (N.D. Ga. 1993).

117. McLeroy v. Blue Cross & Blue Shield, 825 F. Supp. 1064 (N.D. Ga. 1993).

118. *Id.* at 1067.

of HDC-ABMT not enumerated within the policy's exclusionary section.[119] The plaintiff in *McLeroy* sought coverage for a HDC-ABMT treatment not covered.[120] Accordingly, the court denied the injunction.[121]

Another court upheld an insurer's denial of HDC-ABMT coverage for a plaintiff suffering from advanced breast cancer in *Roseberry v. Blue Cross & Blue Shield*.[122] The court reviewed the Office of Personnel Management (OPM)[123] decision denying the plaintiff's request for coverage under the arbitrary and capricious standard.[124] Much like the policy in *McLeroy*, the plaintiff's policy enumerated which bone marrow transplants were covered and specifically excluded any treatments not listed.[125] Because HDC-ABMT was not specifically enumerated for the treatment of breast cancer, the language of the policy required exclusion.[126] "*Sadly*, I find that the defendant's motion for summary judgment should be granted."[127]

In *Holder v. Prudential Insurance Co.*,[128] the Fifth Circuit reviewed the ERISA claim of an insured seeking coverage for HDC-ABMT performed in 1987.[129] Before the treatment was performed, the insured signed a consent form which defined the procedure as an experimental study.[130] The district court denied the injunction, and the appellate court would not reverse unless the error was clearly erroneous.[131] This standard was not met because of the "split case law" on the issue.[132] Although HDC-ABMT was arguably experimental when the plaintiff received her treatment in 1987, the court recognized, in dicta, that "several recent studies . . . of HDC-ABMT treatment for Stage IV metastatic breast cancer lead to the conclusion that the treatment . . . may no longer be considered experimental."[133] The court also stated, in dicta, "it is the nature of medical research that what may one day be experimental may the next be state of the art treatment."[134] The court could not, however, conclude the trial court made clearly erroneous findings due to the existence of the consent form signed by the plaintiff supplemented by the expert testimony presented by the defense.[135]

---

119. *Id.*
120. *Id.*
121. *Id.* at 1074.
122. Roseberry v. Blue Cross & Blue Shield, 821 F. Supp. 1313 (D. Neb. 1992).
123. United States Office of Personnel Management, 5 U.S.C. §§ 706(2)(A), 8902(d), (j) (1988) (federal agency charged with administering FEHBA).
124. Roseberry v. Blue Cross & Blue Shield, 821 F. Supp. at 1316.
125. *Id.* at 1317-18.
126. *Id.* at 1318.
127. *Id.* (emphasis added).
128. Holder v. Prudential Ins. Co., 951 F.2d 89 (5th Cir. 1992).
129. *Id.* at 90.
130. *Id.*
131. *Id.* at 91.
132. *Id.*
133. *Id.*
134. *Id.*
135. *Id.*

E. *When an Insurance Policy Does Not Specifically Exclude a Treatment, Courts First Interpret the Policy Language to Determine Whether HDC-ABMT is Covered*

In each case addressed below, HDC-ABMT in the treatment of breast cancer was not specifically excluded from coverage. When a treatment such as HDC-ABMT is not specifically excluded, the administrator's role in ERISA[136] and FEHBA[137] cases is often enhanced.[138] In such cases, the federal employee first seeks coverage from her insurance company issuing the policy.[139] If the request is denied, the insured can appeal to the third party administrator or administrative agency, such as the OPM, which determines whether the employee's specific health insurance contract does or does not cover the treatment.[140] The agency may then deny or accept the insured's appeal for coverage.[141] If the trial court finds the agency has discretionary authority, the

---

136. *See supra* note 110.

137. *See supra* note 111.

> The administrative procedures used in the FEHBA setting are somewhat unique. While 5 U.S.C. § 8902(j) permits a plan participant to appeal the denial of benefits to OPM, such administrative review is not mandatory. In fact, neither FEHBA nor its implementing regulations give any insight into the elements of the appeal process or the criteria the OPM is to use in reviewing the decision. . . . While OPM's own regulations, 5 C.F.R. § 890.105, provide that an employee "may make a written request to OPM for a review to determine whether the plan's denial is in accord with the terms of the OPM's contract with the carrier of the plan," the regulatory language is clearly permissive. Moreover, 5 C.F.R. § 890.107 expressly provides for actions at law against the carrier of the health plan to recover on claims for health benefits. In sum, neither Congress nor OPM has manifested any intent to make OPM review either an exclusive remedy or a mandatory prerequisite to judicial resolution of disputes over contract interpretation.

Goepel v. Mail Handlers Benefit Plan, No. CIV.A.93-3711 (JEI), 1993 WL 384498, at *5 (D.N.J. Sept. 24, 1993), *vacated*, 36 F.3d 306 (3d Cir. 1994), *cert. denied*, 115 S. Ct. 1691 (1995).

138. Firestone Tire & Rubber Co. v. Bruch, 489 U.S. 101, 115 (1989); *see also* 5 U.S.C. §§ 701(b)(2), 706(2)(A) (1988).

139. *E.g.*, Roseberry v. Blue Cross & Blue Shield, 821 F. Supp. 1313, 1314 (D. Neb. 1992).

140. *Id.* at 1314.

> Assuming a claimant submits to this optional administrative appeal, the issue then becomes the appropriate degree of deference to be accorded the OPM decision. On the one hand, the agency has been given authority under FEHBA to conduct such appeals, and presumably it has garnered certain expertise in the interpretation of insurance contracts as a result of that authority. Deference to OPM decisions would allow for greater uniformity in decisions, thereby reducing the need for litigation in the area.

Goepel v. Mail Handlers Benefit Plan, No. CIV.A.93-3711 (JEI), 1993 WL 384498, at *5-6 (D.N.J. Sept. 24, 1993).

141. *See generally id.*

court must apply the arbitrary and capricious standard of review.[142] Under this deferential standard, trial courts often uphold the agency's decision.[143]

1. *Appellate Courts Applying the Arbitrary and Capricious Standard of Review*

The procedure described above is clearly outlined in the Seventh Circuit's decision in *Harris v. Mutual of Omaha Co.*[144] After the plaintiff was denied coverage, she filed under FEHBA against the insurance company in federal district court.[145] The court reviewed the postal worker's claim to enjoin her insurance company from denying coverage for HDC-ABMT for advanced breast cancer.[146] The court held HDC-ABMT fell within the exclusionary clause of the policy, which required the treatment be supported by reliable evidence.[147] The policy defined "reliable evidence" as published reports and articles in authoritative medical and scientific literature, written protocol used by the treating facility, or the written informed consent used by the treating facility.[148]

The OPM, which administers the FEHBA, determined HDC-ABMT was not covered under the policy.[149] On review, the court applied the highly deferential arbitrary and capricious standard of review to the decision of the OPM.[150] Because of this deferential standard, the court affirmed the OPM decision, despite a study produced by several oncologists that concluded HDC-ABMT should no longer be considered investigational.[151] Other courts have held for insurers under the arbitrary and capricious standard.[152]

The Third Circuit found HDC-ABMT to be experimental in *Clark v. K-Mart Corp.*[153] The district court originally overturned the insurer's denial of coverage under de novo review.[154] The Third Circuit held the trial court should have applied the arbitrary and capricious standard because the OPM had discretionary authority.[155] The court then applied the arbitrary and capricious standard to the insurer's denial of coverage.[156] Under this deferential standard, it

---

142. Roseberry v. Blue Cross & Blue Shield, 821 F. Supp. at 1316.
143. *Id.* at 1318.
144. Harris v. Mutual of Omaha Co., 992 F.2d 706 (7th Cir. 1993).
145. *Id.* at 706-07.
146. *Id.* at 707-08.
147. *Id.* at 713-14.
148. *Id.* at 708.
149. *Id.* at 707.
150. *Id.* at 712.
151. *Id.* at 710, 712.
152. *See, e.g.*, Nesseim v. Mail Handlers Benefit Plan, 995 F.2d 804, 807 (8th Cir. 1993); Sweeney v. Gerber Prods. Co., 728 F. Supp. 594, 597 (D. Neb. 1989).
153. Clark v. K-Mart Corp., No. 91-3723, 1992 WL 106935 (3d Cir. May 22, 1992), *vacated*, 979 F.2d 965, 966 (3d Cir. 1992).
154. *Id.* at *7.
155. *Id.* at *4.
156. *Id.* at *5-6.

upheld the denial.[157] *Clark* demonstrates the impact of the standard of review. The insured was granted a preliminary injunction under de novo review, but it was denied under the arbitrary and capricious standard.[158]

In *Kulakowski v. Rochester Hospital Service Corp.*,[159] an early ERISA action, a court enjoined an employer from denying HDC-ABMT coverage for advanced breast cancer.[160] The plan administrator had discretion to determine eligibility of those requesting preauthorization for treatment.[161] The court demonstrated why a deferential standard of review is not necessarily determinative: "while the defendants are, indeed, entitled to a deferential review of their construction and enforcement of the contract, a reading of the applicable exclusion denying coverage to a procedure which is not experimental, not unsafe, and not inefficacious, is clearly arbitrary and cannot be upheld."[162]

In holding for the plaintiff, the court stated "HDC-ABMT offer[ed] the best chance of achieving and maintaining remission from [the plaintiff's] present cancer and her only chance of 'long-term remission.'"[163] The court relied on expert testimony concluding "in achieving a remission in metastatic breast cancer, conventional chemotherapy is 30-60% effective and HDC-ABMT is 70-90% effective."[164] Further, all experts agreed HDC-ABMT was not experimental and was "efficacious" in the treatment of breast cancer.[165]

In *Kekis v. Blue Cross & Blue Shield*,[166] another insured brought an ERISA action seeking to enjoin the insurer from denying coverage of HDC-ABMT for breast cancer.[167] The policy included an exclusionary clause for "Experimental/ Investigational Services," which granted the insurer discretionary power to determine what treatments were experimental.[168] Applying the arbitrary and capricious standard of review, the court held the denial of coverage was unwarranted.[169]

2. *Appellate Courts Applying De Novo Standard of Review*

Under de novo review, appellate courts generally take a closer look at the findings of fact, in particular, as to the efficacy of HDC-ABMT and give no def-

---

157. *Id.* at *7.
158. *Id.*
159. Kulakowski v. Rochester Hosp. Serv. Corp., 779 F. Supp. 710 (W.D.N.Y. 1991).
160. *Id.* at 717.
161. *Id.* at 716.
162. *Id.*
163. *Id.* at 712.
164. *Id.*
165. *Id.* at 716.
166. Kekis v. Blue Cross & Blue Shield, 815 F. Supp. 571 (N.D.N.Y. 1993).
167. *Id.* at 573.
168. *Id.* at 575.
169. *Id.* at 578; *see also* White v. Caterpillar, Inc., 765 F. Supp. 1418, 1418 (W.D. Mo. 1991); Bucei v. Blue Cross & Blue Shield, 764 F. Supp. 728, 732 (D.C. Conn. 1991) ("[I]t is clear that the treatment is not faulted as in any way contrary to sound medical practice. It is logical, scientifically.").

erence to the agency denying coverage.[170] In *Pirozzi v. Blue Cross & Blue Shield*,[171] for example, HDC-ABMT was found to be not experimental in the treatment of breast cancer under de novo review.[172] Pirozzi's policy contained an exclusionary clause which the insurer argued encompassed HDC-ABMT, though the policy did not define experimental.[173] In holding the treatment not experimental, the court reasoned if HDC-ABMT "is in accordance with generally accepted standards of medical practice and is of scientifically proven value, it is surely not also experimental or clinically investigational."[174]

In addition, courts have granted preliminary injunctions in part because no technological assessment body has deemed the treatment experimental.[175] In *Fuja v. Benefit Trust Life Insurance Co*,[176] the court found the "qualifier largely removes any ambiguity" and deemed HDC-ABMT "required and appropriate" and "medically necessary" for treatment of the plaintiff's metastatic breast cancer.[177] The court reviewed de novo because it found the insurer did not have the authority to determine eligibility.[178] The court also held "[a]bsent direct evidence that [the National Cancer Institute] has deemed the procedure 'investigational,' the NCI bulletins support [the plaintiff's] contention that no technological assessment body . . . has deemed the procedure 'investigational.'"[179]

Finally, one court reviewed HDC-ABMT under both standards of review. In *Adams v. Blue Cross & Blue Shield*,[180] two breast cancer victims received a declaratory judgment to compel coverage of HDC-ABMT.[181] Under their policies, an experimental procedure is one not "generally acknowledged as accepted medical practice by the suitable medical specialty practicing in Maryland."[182] The court found Maryland oncologists generally acknowledged the treatment as an accepted medical procedure and concluded it was not experimental under the insurer's plan.[183] Moreover, the court held "the evidence strongly favors the conclusion that [when used to treat advanced breast cancer, HDC-ABMT] is superior to alternative currently available therapeutic approaches."[184] The court

---

170. *See supra* text accompanying note 107.
171. Pirozzi v. Blue Cross & Blue Shield, 741 F. Supp. 586 (E.D. Va. 1990).
172. *Id.* at 594.
173. *Id.* at 588.
174. *Id.* at 590.
175. Fuja v. Benefit Trust Life Ins. Co., 809 F. Supp. 1333, 1340 (N.D. Ill. 1992), *rev'd on other grounds*, 18 F.3d 1405 (7th Cir. 1994).
176. Fuja v. Benefit Trust Life Ins. Co., 809 F. Supp. 1333 (N.D. Ill. 1992), *rev'd on other grounds*, 18 F.3d 1405 (7th Cir. 1994).
177. *Id.* at 1337.
178. *Id.*
179. *Id.*
180. Adams v. Blue Cross & Blue Shield, 757 F. Supp. 661, 677 (D. Md. 1991).
181. *Id.* at 677.
182. *Id.* at 663.
183. *Id.* at 677.
184. *Id.* at 673 n.8.

noted it would have reached this conclusion under either the de novo or arbitrary and capricious standard.[185]

In sum, these cases demonstrate the conclusion reached in *Helman v. Plumbers & Steamfitters Local 166*.[186] The court held, "in the final analysis . . . recent cases have determined that a finding that [HDC-]ABMT is 'experimental' cannot be sustained even under the most deferential standard of review."[187] In support of this holding, many prominent insurers, such as Blue Cross & Blue Shield, are no longer uniformly excluding the treatment as experimental.[188]

F. *Alternative Causes of Action in HDC-ABMT Cases*

1. *Title VII Violation*

Plaintiffs' attorneys in HDC-ABMT cases are beginning to innovate their pleadings in hopes of broadening their chances for recovery. For example, in *Reger v. Espy*,[189] the plaintiff pleaded the following:

> In Count I, the plaintiff alleges that the exclusion of coverage for HDC-ABMT for breast cancer violates 5 U.S.C. § 1809(f) of FEHBA and is an arbitrary and capricious decision. In Count II, the plaintiff alleges that the denial of coverage by the Department of Agriculture violates Title VII of the Civil Rights Act of 1964, in that the exclusion of HDC-ABMT treatment for breast cancer has a disparate impact upon females.[190]

As to Count I, the court held the health insurance plan specifically excluded transplant procedures for breast cancer and it was rational for the plan to exclude coverage: "To date no conclusions have been formed as to whether HDC-ABMT is better than, worse than, or equal to conventional therapy in terms of disease-free overall survival."[191] Likewise, the court rejected the plaintiff's argument as to Count II.[192] In denying plaintiff's claim of disparate impact on women, the court held as follows: "It is clear from the language of the Plan . . . that HDC-ABMT benefits are not available for most types of cancers, only one of

---

185. *Id.* at 667, 676; *see also* Arrington v. Group Hospitalization & Medical Servs., Inc., 806 F. Supp. 287, 291 (D.D.C. 1992).

186. Helman v. Plumbers & Steamfitters Local 166, 803 F. Supp. 1407, 1413 (N.D. Ind. 1992).

187. *Id.*; *see also* Dahl-Eimers v. Mutual of Omaha Life Ins. Co., 986 F.2d 1379, 1384 (11th Cir.), *cert. denied*, 114 S. Ct. 440 (1993); Clark v. K-Mart Corp., 979 F.2d 965, 966 (3d Cir. 1992).

188. Wilson v. Group Hospitalization & Medical Servs., Inc., 791 F. Supp. 309, 311 (D.D.C. 1992).

189. Reger v. Espy, 836 F. Supp. 869 (N.D. Ga. 1993).

190. *Id.* at 870.

191. *Id.* at 872. The court further held: "After review of all the material, it is clear to the court that there is a lack of consensus within the medical profession regarding the appropriateness of using HDC-ABMT in the treatment of breast cancer at this time." *Id.*

192. *Id.* at 873.

which is breast cancer."[193] Furthermore, the court found the exclusion to be facially neutral and "the decision not to provide HDC-ABMT benefits for all but the five listed diagnoses affect[ed] both men and women equally."[194] Though the plaintiff lost this argument, plaintiffs in the future will surely develop increasingly creative arguments to break through the insurers' stronghold barring coverage of HDC-ABMT in the treatment of breast cancer.

2. *Rehabilitation Act and ADA Violation*

In addition to raising Title VII causes of action in HDC-ABMT cases, plaintiffs are questioning whether the exclusion of HDC-ABMT coverage in health policies violates the Rehabilitation Act of 1973[195] or the Americans with Disabilities Act of 1993 (ADA).[196] In *Dodd v. Blue Cross & Blue Shield Ass'n*[197] the plaintiff argued the "exclusion of coverage [of HDC-ABMT for breast cancer] runs afoul of the Rehabilitation Act by providing HDC-ABMT for some forms of cancer . . . but not for others [such as breast cancer]."[198] In rejecting this argument on the merits, the court held it was the OPM's responsibility, not the insurance company's, to comply with the Rehabilitation Act.[199] Therefore, the plaintiffs had no remedy against the insurance company under the Rehabilitation Act.[200] Plaintiffs also cited the ADA in support of their argument "that the Association is liable for alleged discriminatory exclusions in the Service Benefit Plan."[201] In rejecting this argument, the court held "[b]ecause the Association is not an employer of federal employees enrolled in the Service Benefit Plan, it may not be sued under the ADA. The OPM is also excluded from the scope of the ADA's coverage."[202]

V. CONCLUSION

Medical centers and research institutes throughout the United States and the world will continue to research breast cancer treatments such as HDC-ABMT in hopes of increasing treatment efficacy while containing (and even lowering) treatment costs. State legislatures, the insurance industry, and lawyers will each play a role in the continued development and accessibility of HDC-ABMT. Before our society can win the war against breast cancer, it is critical that government agencies, such as the OPM, and private health insurance companies pay close attention to ongoing research and protocols being conducted by organiza-

---

193. *Id.* at 872.
194. *Id.* at 872-73.
195. *See generally* Rehabilitation Act of 1973, 29 U.S.C. §§ 701-797b (1988).
196. *See generally* Americans with Disabilities Act of 1990, 42 U.S.C. §§ 12101-12213 (1993).
197. Dodd v. Blue Cross & Blue Shield Ass'n, 835 F. Supp. 888 (E.D. Va. 1993).
198. *Id.* at 891.
199. *Id.*
200. *Id.*
201. *Id.*
202. *Id.*

tions such as the National Cancer Institute and the Emergency Care Research Institute to determine the efficacy of HDC-ABMT in the treatment of breast cancer. In addition, various state and federal agencies and private insurance companies are assisting in the financing of some of the research and testing currently being conducted.

When the efficacy of HDC-ABMT is established at a reasonable level, it is the responsibility of the OPM, private health insurance companies, and state legislatures to make HDC-ABMT readily available in the treatment of breast cancer. Persons drafting policy language must do so clearly and specifically in order for a reasonable insured to understand the policy coverage. If the cost of making HDC-ABMT standard coverage is too great, insurance companies can deem such coverage optional and allow the insured, such as those at high-risk of contracting breast cancer, the opportunity to purchase coverage at an additional premium. Lastly, when HDC-ABMT is finally deemed to be a standard treatment for breast cancer, insurance companies should strive to provide coverage for HDC-ABMT at a reasonable premium. The reality remains, however, that insurance is governed by the law of economics, and companies simply cannot provide coverage for all treatments and still charge an affordable premium.

Judge Coffey of the Seventh Circuit recently called for the creation of regional cooperative committees to address insurance coverage of expensive, cutting-edge treatments such as HDC-ABMT:

> In order to resolve the question of whether health insurance providers should cover treatments like HDC-ABMT, the prudent course of action might be to establish some sort of 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. Through such a collective task force perhaps some consensus might be reached concerning the definition of experimental procedures, as well as agreement on the procedures, which are so cost prohibitive that requiring insurers to cover them might result in the collapse of the health care industry. While such a committee would in no way be a panacea for our skyrocketing health care costs, it may help to reduce the incidence of suits in which one "expert" testifies that a procedure is experimental and another equally qualified "expert" testifies to the opposite effect.[203]

Courts throughout America are performing their difficult job well. In addition to continuing to interpret the policy language that binds the parties in a dispute, courts must continue to express great regret and sympathy in their opinions when the policy language compels the denial of coverage. Courts and commentators also must continue to scrutinize insurance companies for denying coverage solely because HDC-ABMT is an expensive treatment.

---

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

Although debate continues over the medical efficacy and insurance coverage of HDC-ABMT, we can all agree that no treatment for breast cancer costs more than a human life.

Peter J. Thill