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Current Legal Intervention Regarding Experimental Treatments Must Be Changed: An Analysis of High Doses of Chemotherapy with Autologous Bone Marrow Transplantation for Breast Cancer Patients

Emily Smayda

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CURRENT LEGAL INTERVENTION REGARDING
 “EXPERIMENTAL” TREATMENTS MUST BE CHANGED: AN
 ANALYSIS OF HIGH DOSES OF CHEMOTHERAPY WITH
 AUTOLOGOUS BONE MARROW TRANSPLANTATION FOR
 BREAST CANCER PATIENTS

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I. INTRODUCTION

A 35-year old woman, mother of three children, suffers from Stage IV metastatic breast cancer.¹ After finding a suspicious mass in her right breast, she underwent a mastectomy.² Nine months of chemotherapy and radiation followed, making the woman extremely ill.³ Despite efforts to battle the disease, the cancer was found to have progressed.⁴ The woman’s doctor told her that with conventional treatment the “disease will continue to progress and she will die.”⁵ Given her situation, the woman’s doctor suggested a relatively new approach to standard chemotherapy called High Dose Chemotherapy with Autologous Bone Marrow Transplantation

¹Pirozzi v. Blue Cross-Blue Shield of Va., 741 F. Supp. 586, 587 (E.D. Va., 1990). “Cancer is typically classified in terms of five stages of increasing severity from Stage I to Stage V. “Stage IV,” in connection with breast cancer, signifies that the cancer cells have metastasized, i.e. spread, to areas outside of the breast, the original site of the disease.” *Id.*

²*Id.* at 588.

³Kulakowski v. Rochester Hosp. Serv. Corp., 779 F. Supp. 710, 712 (W.D.NY. 1991).

⁴Bucci v. Blue Cross-Blue Shield of Conn., Inc., 764 F. Supp. 728, 730 (D. Conn. 1991).

⁵White v. Caterpillar, Inc., 765 F. Supp. 1418, 1419 (W.D. Mo. 1991).

("HDC-ABMT").⁶ The procedure involves the extraction of bone marrow, followed by near lethal doses of chemotherapy, finalized by the replacement of the damaged bone marrow, essentially rescuing the patient.⁷ Many doctors were "encouraged by the promising preliminary data from HDC-ABMT research."⁸ HDC-ABMT was not considered a cure for this woman's breast cancer. Instead, the procedure gave her a better chance of remission, a significantly less amount of time in a hospital and a shortened term of chemotherapy with its unavoidable side effects, that had previously plagued her.⁹ The treatment provided an extension of time to the woman's life and ensured a modicum of comfort.¹⁰

At this point, the woman felt that HDC-ABMT was her only chance of survival from a disease that was literally taking over her body. She decided to go through with the procedure. Before being admitted into the health care facility, however, the institution required pre-secured financing or pre-certification from a prospective patient's insurance company, guaranteeing that the treatment costs would be reimbursed.¹¹ The procedure costs between \$100,000 and \$150,000 per patient.¹² She automatically assumed that her insurance coverage would cover the expense.

Her insurance company denied her request, deeming High Doses of Chemotherapy with Autologous Bone Marrow Transplantation ("HDC-ABMT") as being "experimental" and "investigative", thus falling outside of coverage.¹³ The woman not only faced the emotional distress of realizing that conventional treatment could no longer help her, but now had to deal with the reality that her only course of action was now unattainable.¹⁴ When she signed her health insurance contract she thought she would be covered for anything. She had no idea that a provision, a simple sentence of text, would essentially cost her her life. As she paid her premiums every month, she felt secure, protected from any possible health conditions that she would encounter.

She had undergone treatments that had proven ineffective.¹⁵ She had been told that death was inevitable without HDC-ABMT.¹⁶ The health care institution which

⁶*Kekis v. Blue Cross & Blue Shield of Utica-Watertown, Inc.*, 815 F. Supp. 571, 574 (N.D.N.Y. 1993).

⁷*Id.* "A patient undergoing HDC-ABMT is hospitalized, often in intensive care, for approximately ten days of the treatment and requires full-time medical attention." *Id.*

⁸*Id.* at 574.

⁹*Kulakowski*, 779 F. Supp. at 714. Based on medical research results reported in medical literature before 1991, "achieving a remission in metastatic breast cancer, conventional chemotherapy is 30-60% effective and HDC-ABMT is 70-90% effective." *Id.*

¹⁰*Id.*

¹¹*Harris v. Mutual of Omaha Cos.*, 992 F.2d 706, 708 (7th Cir. 1993).

¹²*Id.*

¹³*Thomas v. Gulf Health Plan Inc.*, 688 F. Supp. 590, 593 (S.D. Ala. 1988). The decision to deny coverage was based on the fact that the plan excluded experimental or investigative procedures. *Id.*

¹⁴*Id.* at 594.

¹⁵*White*, 765 F. Supp. at 1419.

promised to provide her with such treatment required pre-payment, that her insurance company denied. Her options looked bleak. She decided to turn to the law for remedy.

Instead of entering into a personal injury lawsuit, she found herself involved in a contracts dispute. The language of the insurance contract was being scrutinized, instead of the injustice of the denial of coverage. The way in which the word “experimental” was defined became more important than how young this woman was and the number children she would leave behind if she was not able to receive HDC-ABMT treatment. The more ambiguous the term, the more likely she would receive a possible preliminary injunction, allowing her to have the amount of money to proceed with treatment.¹⁷

Unfortunately, the woman’s law suit against her insurance company was also preempted by the Employment Retirement Income Security Act of 1974 (ERISA).¹⁸ ERISA contains a vague preemption provision that supersedes “any and all State laws insofar as they may relate to any employee benefit plans.”¹⁹ The woman could not bring any further state common law claims, such as emotional distress, against her insurance company under ERISA.²⁰ She was also bound by the remedies provided by ERISA.²¹

Litigation lingered and the woman died before trial. The woman’s legal attempts proved futile. Her husband sued her insurance company for breach of contract, infliction of emotional distress, fraud and wrongful death, but ERISA preempted all four claims.²² The husband’s claims were preempted because they stemmed from the denial of benefits to his wife.²³ Further, under ERISA the husband could not personally bring a suit against the insurance company because he lacked standing.²⁴ Due to the fact that the woman died, an award of benefits no longer existed.²⁵

The hypothetical above combines the facts of numerous cases, that had developed between 1988 and 1997 regarding HDC-ABMT, and proceeds to bring to life the real issues that the legal community must face with insurance companies’ coverage of revolutionary treatments. “It is a society-wide problem of how to provide last-chance health care to a person who may have a small chance at survival if provided an expensive cutting edge treatment that she cannot afford out of her own

¹⁶*Id.*

¹⁷*Dahl-Eimers v. Mutual of Omaha Life Ins. Co.*, 986 F.2d 1379, 1381 (11th Cir. 1993).

¹⁸*Turner v. Fallon Community Health Plan, Inc.*, 127 F.3d 196, 197 (1st Cir. 1997)

¹⁹*Id.* at 199.

²⁰*Thomas*, 688 F. Supp. at 595. ERISA preempts state law doctrines, including that of estoppel, even though it is a contract cause of action. *Id.*

²¹Susan O. Scheutzow, *A Framework for Analysis of ERISA Preemption in Suits Against Health Plans and a Call for Reform*, 11 J. L. & HEALTH, 195, 209 (1996-1997).

²²*Foster v. Blue Cross & Blue Shield of Mich.*, 969 F. Supp.1020, 1024 (E.D. Mich. 1997).

²³*Id.*

²⁴*Id.*

²⁵*Id.*

resources”²⁶ This Note is not trying to solve this problem. Instead, the purpose of this Note is to recognize the flaws with the legal system’s dealings with insurance benefit denial.

The specific analysis of HDC-ABMT will help the reader to realize that the medical procedures being dealt with by litigation are not necessarily wildly innovative. Insurance companies are hiding behind the guise of words such as “experimental” to avoid paying for treatments that are both feasible and needed. Further, HDC-ABMT being used for breast cancer patients, suggests a possible discriminatory aspect that cannot be reached with current legal intervention.

This Note suggests ways of dealing with insurance coverage denial on a more direct level. Instead of being bogged down by contract language and ERISA preemption, proposals for national standards and expert committees would rectify the injustice of benefit denial by taking away insurance company discretion. Then Courts could deal with case by case scenarios according to the actual denial, not the language of a provision in a contract.

II. MEDICAL BACKGROUND

Based on medical studies, one out of eight or nine women today will be diagnosed with breast cancer.²⁷ This is a dramatic increase from the 1940's where only one out of twenty women were diagnosed with the disease.²⁸ The sudden escalation of victims has greatly heightened public fear.²⁹ This heightened fear has put pressure on the medical field to produce a treatment to combat breast cancer. Currently, there is no curative approach to stage IV breast cancer.³⁰ Conventional uses of chemotherapy and radiation, used in other cancers, proved to be not extremely effective with advance stage patients.

The increasing of dose intensity has been a successful way of improving the effect of many drugs.³¹ In the past ten years there has been a sudden interest in dose intensity of chemotherapy in breast cancer treatment.³² Most studies showed a higher complete and total response rate to high-dose chemotherapy than lower

²⁶*Turner*, 127 F.3d at 200.

²⁷Eric J. Feuer et al., *The Lifetime Risk of Developing Breast Cancer*, 85 J. NAT'L CANCER INST. 892 (1993). Statistical calculations were derived from a multiple decrement life table applying age-specific incidence and mortality rates against population data. *Id.*

²⁸*Id.* The dramatic increase was thought to have stemmed from the fact that women are living longer and dying less often of other causes. *Id.* at 896.

²⁹*Id.*

³⁰Stephanie F. Williams et al., *High-Dose Consolidation Therapy with Autologous Stem Cell Rescue in Stage IV Breast Cancer*, 7 J. CLINICAL ONCOLOGY 1824 (1989). Doctors do believe that autologous transplants might be curative in women with stage IV breast cancer because it promotes a higher complete response rate. *Id.* at 1829.

³¹VINCENT T. DEVITA ET AL., *CANCER PRINCIPALS & PRACTICE OF ONCOLOGY* 343 (5th ed. 1997).

³²JAMES HOLLAND ET AL., *CANCER MED.* 1286 (4th ed. 1997).

amounts.³³ Higher dosages of chemotherapy produces a larger amount of toxicity, rendering the immune system defective.³⁴ Escalating treatment doses causes irreversible bone marrow suppression.³⁵ Bone marrow transplantation, however, allows improvement with response rates without the toxic level ramifications.³⁶

Autologous bone marrow transplantation (ABMT) was first tested in humans in the 1950s.³⁷ The procedure involves the harvesting of a patient's own bone marrow and later reinfusing the substance back into the person's system.³⁸ "Bone marrow is placed into a heparinized tissue culture medium, passed through wire mesh to remove aggregates, and infused intravenously," where hematopoietic stem cells produce new cells.³⁹ Autologous bone marrow transplants allow higher doses of chemotherapy. The return of bone marrow rescues a patient's immune system from the serious life threatening effects of aggressive chemotherapy treatments.⁴⁰

As with other treatments there are complications with HDC-ABMT that could cause patients problems. About 5% of patients will die of infections and other complications during the time period where bone marrow is growing back to support their immune system.⁴¹ Long-term survivors have a greater risk of developing secondary leukemias.⁴² Infertility and difficulties with sexual functions further damage the procedures' success.⁴³

The real question that counters the treatment, however, is whether HDC-ABMT is truly superior to conventional chemotherapy for later stage breast cancer patients. The medical advisory board of Chicago's Technology Evaluation Center found HDC-ABMT a "viable option for some women with advanced metastatic breast cancer" based on new assessments of the procedure done in 1996.⁴⁴ Yet the

³³*Id.* "Retrospective analysis and perspective clinical trials have demonstrated a dose-response relationship in terms of objective response, duration of remission, and quality of life." *Id.*

³⁴Richard L. Souter et al., *Bone Marrow Transplantation*, 310 BRITISH MED. J. 31 (1995).

³⁵*Id.*

³⁶*Id.*

³⁷Emory School of Medicine, *Bone-Marrow Transplants Increase Survival for Breast Cancer Patients*, CANCER WKLY., May 25, 1992, at 7 [hereinafter Emory].

³⁸*Id.*

³⁹ALEXANDER FEFER ET AL., *MEDICAL ONCOLOGY BASIC PRINCIPLES AND CLINICAL MANAGEMENT OF CANCER* 1117 (2d ed. 1993).

⁴⁰Emory, *supra* note 37, at 7.

⁴¹Kara Smigel, *Women Flock to ABMT for Breast Cancer Without Final Proof*, 87 J. NAT'L CANCER INST. 952 (1995).

⁴²*Id.* Greater risk of secondary leukemias based on long-term survivors of high-dose regimens for other cancers. *Id.*

⁴³Souter et al., *supra* note 34, at 34.

⁴⁴Mark Hagland, *Technology and Treatments on Trial*, 70 HOSP. & HEALTH NETWORK 40 (1996). Center's assessment noted this treatment actually got better results than conventional therapy. *Id.* at 41.

procedure fails to be considered a “standard treatment” for advanced staged breast cancer patients because of the “lack of controlled studies and the presence of numerous biases” when compared to standard chemotherapy.⁴⁵ Randomized controlled trials comparing HDC-ABMT and conventional-dose chemotherapy are needed to prove HDC-ABMT’s effectiveness.⁴⁶ One of the reasons that clinical trials are not being administered as often as they are needed to standardize the treatment is that patients refuse to be randomized.⁴⁷ The chance of not receiving high-dose chemotherapy is preventing many women from entering into clinical trials.⁴⁸ Further, insurance companies are less likely to cover involvement with clinical trials because of the “experimental” nature of the programs.

Essentially, HDC-ABMT is not being covered by insurance because it is deemed “experimental”. The procedure is considered “experimental” because the treatment has not gone through enough clinical trials comparing HDC-ABMT to standard dose chemotherapy. Clinical trials involving HDC-ABMT and conventional chemotherapy have not been successful because insurance will not cover clinical trials since they are “experimental”. Thus, the word “experimental” is preventing a procedure that has been found to save people’s lives from becoming a standard which would allow a larger amount of people to benefit.

III. REASONS WHY INSURANCE SHOULD AUTOMATICALLY COVER TREATMENT

HDC-ABMT is not a radically innovative concept. The procedure is taking a standard cancer treatment, elevating the dosage and inserting a protective measure to insure recovery. Insurance companies are not compensating such a treatment because it has not been proven to be superior to conventional-doses of chemotherapy. Yet, HDC-ABMT has been proven to save people’s lives. Furthermore, the quality of life that patients experience after treatment is encouraging.⁴⁹ A year or longer after treatment, patients reported little limitations or resulting problems.⁵⁰

The fact that HDC-ABMT has been suggested to patients as a last resort for later stage breast cancer, should also be taken into consideration. If the treatment has been proven to successfully combat the disease in other types of cancer, then the procedure should not be denied for breast cancer patients. Insurance companies should not have the discretion of choosing which cancer patients should essentially live or die.

⁴⁵Nancy E. Davidson, *Out of the Courtroom and into the Clinic*, 10 J. CLINICAL ONCOLOGY 517 (1992).

⁴⁶*Id.*

⁴⁷Elisabeth de Vries et al., *Breast Cancer Studies in the Netherlands*, 348 LANCET 407 (1996).

⁴⁸*Id.*

⁴⁹William P. Peters et al., *High-Dose Chemotherapy and Autologous Bone Marrow Support as Consolidation After Standard-Dose Adjuvant Therapy for High Risk Primary Breast Cancer*, 11 J. CLINICAL ONCOLOGY 1141 (1993).

⁵⁰*Id.*

A. Just a Higher Dosage of Chemotherapy

One way of looking at HDC-ABMT is not to see the procedure as a new treatment. Instead, ABMT “simply allows for higher doses of chemotherapy.”⁵¹ Chemotherapy emerged in the early 1900s with the work of Paul Ehrlich.⁵² Alkylating agents, used in early chemotherapy, were a product of gas warfare used in World War I and II.⁵³ Even though chemotherapy created an exciting vehicle to use against cancer, the treatment was flawed in that the tumors inevitably grew back.⁵⁴ Chemotherapy successfully treating childhood leukemias and Hodgkin’s disease in the 1960s, actually proved that different manipulations of the drug could cure cancer. The positive results of chemotherapy forced research to focus on the application of the treatment toward solid tumors.

The failure of chemotherapy with solid tumors was thought to stem from the variation in growth characteristics and multidrug resistance.⁵⁵ The emphasis of studies was on maximizing the interaction of the chemotherapy with the cycling cancer cell.⁵⁶ There appears to be a threshold dose of chemotherapy that produces a response in tumors.⁵⁷ Some tumors require a higher dosage to improve drug responsiveness.⁵⁸

Chemotherapy has been proven by numerous experiments in many different cancers to be a successful treatment. Chemotherapy has been the most known and effective way of battling cancer for the last thirty years. HDC-ABMT is not dealing with a new drug or revolutionary concept. HDC-ABMT is simply utilizing a standard treatment that has already been proven effective and raising the dosage to a higher level to produce the needed response for solid tumors in breast cancer patients.

B. Considered a Standard Treatment with Other Cancers

The idea of increasing the level of intensity of chemotherapy and using a bone marrow transplant to revitalize the patient is not a new concept based on the fact that HDC-ABMT has proven effective in other cancers. “HDC-ABMT was first used to treat a number of other cancers, including leukemia, lymphoma, and Hodgkin’s disease.”⁵⁹ Many health care providers found HDC-ABMT as a standard treatment for these cancers and covered the procedure.⁶⁰

⁵¹Nancy Volkens, *Cover Costs, Test Treatments, Pay Patients: Health Care Reform Hearings Hot on Hill*, 86 J. NAT’L CANCER INST. 336 (1994).

⁵²DEVITA ET AL., *supra* note 31, at 333.

⁵³*Id.*

⁵⁴*Id.*

⁵⁵*Id.* at 334.

⁵⁶*Id.*

⁵⁷*Id.* at 344.

⁵⁸DEVITA ET AL., *supra* note 31, at 334.

⁵⁹*Kulakowski*, 779 F. Supp. at 711.

⁶⁰*Id.*

HDC-ABMT has been extensively used in different leukemias.⁶¹ “Most patients achieve complete remission.”⁶² The treatment has even provided complete remissions in advanced stage cancer patients.⁶³ HDC-ABMT has accomplished prolonged disease-free survival in leukemia victims.⁶⁴

Lymphoma patients also experienced complete remission with HDC-ABMT.⁶⁵ Approximately one-third of patients actually have survived in remission for several years.⁶⁶ Most of the patients exposed to HDC-ABMT had a failed response to standard dose chemotherapy.⁶⁷ Research performed involving this treatment with lymphoma patients has revealed that very intensive regimens of chemotherapy are capable of eradicating the disease resistant to standard treatment.⁶⁸

Standard combination chemotherapy and radiation proved ineffective in patients with Hodgkin’s disease.⁶⁹ Patients turned to HDC-ABMT when standard dose chemotherapy failed.⁷⁰ HDC-ABMT not only proved effective, but produced sustained remissions in high risk patients.⁷¹ Further, HDC-ABMT has been used in cancers that relapse or even progress during standard chemotherapy, such as multiple myeloma.⁷² The majority of patients suffering from multiple myeloma achieved a marked reduction or disappearance of paraprotein after HDC-ABMT.⁷³

HDC-ABMT has been used in the treatment of many different types of chemotherapy-responsive tumors, including ovarian cancer, testicular/germ cell carcinomas and small cell carcinoma of the lung.⁷⁴ A number of malignant tumors that poorly respond to conventional treatment have been treated with HDC-ABMT and the treatment has increased response rates and has produced remissions.⁷⁵

HDC-ABMT for breast cancer patients should not be considered “experimental” and should be automatically covered by insurance because the treatment is considered standard and successful in so many other types of cancers. “Thousands of patients have received this therapeutic approach, and the results are consistent and

⁶¹CHARLES M. HASKELL, CANCER TREATMENT 193 (4th ed. 1995).

⁶²*Id.* at 194.

⁶³*Id.* at 200.

⁶⁴*Id.* at 194.

⁶⁵*Id.* at 200. Approximately seventy percent of patients have their leukemia recur within two years, but this poses the major cause of treatment failure. *Id.*

⁶⁶*Id.*

⁶⁷HASKELL, *supra* note 61, at 200.

⁶⁸*Id.*

⁶⁹*Id.* at 201.

⁷⁰*Id.*

⁷¹*Id.*

⁷²*Id.* at 202.

⁷³HASKELL, *supra* note 61, at 202.

⁷⁴*Id.* at 203.

⁷⁵*Id.*

well documented.”⁷⁶ “Nearly every study has determined that the response rate is improved over standard-dose alternatives and a fraction of patients have achieved prolonged disease-free survival.”⁷⁷

Patients dealing with later stage breast cancer are considered to be at high risk. Advanced breast cancer has proven resistant to standard dose chemotherapy. Other cancer patients have turned to HDC-ABMT when faced with similar circumstances. Insurance companies should allow breast cancer patients the same freedom. If HDC-ABMT is considered a standard treatment in other cancers, the procedure should at least be covered by insurance when utilized by breast cancer patients. The treatment itself has not changed; only the type of cancer it is battling.

C. Suggested by Doctors as a Last Resort

“If the patient does not receive this treatment in the very near future, the chances of recurrence and resulting death are extremely high.”⁷⁸ Many advanced stage breast cancer patients are taunted by similar words by their doctors. A larger percentage of women are hearing such words since breast cancer has become the most common form of cancer among American women.⁷⁹ HDC-ABMT has become a last resort for many of these women, since their breast cancer has metastaticized, spreading all over their bodies.⁸⁰ “Many women believe that they have little to lose with ABMT and that it is the only reasonable approach in an otherwise hopeless situation.”⁸¹

Many physicians promote HDC-ABMT based on the possibility that the woman would have a longer life expectancy.⁸² When surgery, radiation and standard dose chemotherapy fail to stop breast cancer progression, physicians are left suggesting HDC-ABMT as a last chance for survival.⁸³ Women with advanced stage breast cancer see HDC-ABMT as their only hope.⁸⁴

HDC-ABMT serves as a last combat maneuver against breast cancer.⁸⁵ The treatment essentially kills everything. HDC-ABMT prevents cancer from growing back.⁸⁶ HDC-ABMT not only permits intense amounts of chemotherapy, but also

⁷⁶*Id.*

⁷⁷*Id.*

⁷⁸*Judge Asked to Force Insurer to Pay for Cancer Treatment: Mutual of Omaha*, CANCER WKLY., Aug. 31, 1992, at 7.

⁷⁹Sandy Lutz, *HMO to Finance Trials of Cancer Treatment*, MODERN HEALTH CARE, Apr. 8, 1991, at 20.

⁸⁰Medical College of Wisconsin, *ABMT Has Benefits for Metastatic Breast Cancer, but May Be Too Expensive*, CANCER WKLY., Apr. 20, 1992, at 10.

⁸¹*Id.*

⁸²*Id.*

⁸³*Autologous Bone Marrow Transplants for Advanced Breast Cancer*, 20 HEALTHFACTS 4 (1995).

⁸⁴*Id.*

⁸⁵Medical College of Wisconsin, *Researchers Pioneer New Bone Marrow Transplant Techniques*, CANCER WKLY., July 6, 1992, at 15.

⁸⁶*Id.*

attacks recurrent cancer by stimulating an immune response against the tumor.⁸⁷ Whatever the high dose chemotherapy fails to dissolve, the immune response stimulated by the drug used to reinfuse bone marrow will clean-up.⁸⁸ HDC-ABMT serves as a last resort that launches a double attack on cancer cells.

HDC-ABMT is not a trivial, merely cosmetic treatment that a patient could live with or without. For patients who do not respond to conventional treatment, HDC-ABMT offers the “best opportunity for long survival.”⁸⁹ Women turn to this treatment as a last effort to survive breast cancer. Insurance denial of benefits for HDC-ABMT is essentially costing women’s lives. Allowing a woman benefits is costing an insurance company money. Denying a woman benefits is costing a woman all remaining hope.⁹⁰

IV. CURRENT LEGAL APPROACH MUST BE CHANGED

Under current legal means, the courts are bound by the contract language of insurance policies. Courts are unable to directly counter benefit denial. The “Court’s role is limited to determining whether interpretation (of the insurance policy) was made rationally and in good faith — not whether it was right.”⁹¹ If a treatment is specifically not covered by the insurance policy, the court cannot alter the terms of the plan.⁹² Courts are, however, able to clarify the terms of the policy when the language is ambiguous.⁹³

The problem with strictly relying on contract language is that when a policy specifically states refusal to pay for a certain treatment or procedure there is no way for the insured to fight against the benefit denial. Many women are encountering provisions in their insurance policies that specifically exclude HDC-ABMT for breast cancer.⁹⁴ According to current legal intervention, if the meaning of a provision is clear, the analysis is over.⁹⁵ Courts cannot punish an insurance company for merely applying a clearly stated provision of a contract previously agreed upon by both the insured and the insurer.

Litigation surrounding benefit denial is thrust solely into contract dispute not only by way of policy language but also through ERISA. ERISA, Employment

⁸⁷*Id.*

⁸⁸*Id.*

⁸⁹Pierre L. Triozzi, *Autologous Bone Marrow and Peripheral Blood Progenitor Transplant for Breast Cancer*, 344 LANCET 418 (1994).

⁹⁰*Kulakowski*, 779 F. Supp. at 717.

⁹¹*Thomas*, 688 F. Supp. at 595.

⁹²*Id.*

⁹³Michael Rembold, *Serving the Patient, or Self-Serving?*, 27 J. HEALTH & HOSP. L. 142 (1994).

⁹⁴*Caudil v. Blue Cross and Blue Shield of N.C.*, 999 F.2d 74, 79 (4th Cir. 1993). Policy specifically states, “Autologous bone marrow transplants for breast cancer are not listed.” (holding reaffirmed granting defendants summary judgment, based on contract language). *Id.* at 80.

⁹⁵*Pirozzi*, 741 F. Supp. at 589.

Retirement Income Security Act of 1974, contains a vague preemption provision that supersedes all state claims.⁹⁶ If ERISA provides a specific remedy for an alleged wrong, then all other claims are preempted.⁹⁷ Even if the insured wanted to bring other causes of action, to divert from specific contract language analysis, most insurance policies would not allow such an action to proceed since most insurance companies are governed by ERISA. Claims for breach of contract, negligent misrepresentation, fraud, wrongful death, bad faith and infliction of emotional distress are all preempted by ERISA.⁹⁸

“Insurance is obtained for its coverage and protection, and the natural presumption of the policyholder could be expected to be covered.”⁹⁹ Public interest must also factor into court decisions.¹⁰⁰ Courts must look beyond the language of the contract and take into account not only the reliance people put into insurance coverage, but also weigh the medical necessity of the treatment.¹⁰¹ Further, the language of the policy may not have been changed to meet the advancements in medicine.¹⁰²

The law acts as an equalizer. Allowing legal intervention to strictly adhere to contract language interpretation completely destroys the reasoning behind litigation. “The courts must continue to evaluate the intent of the carriers, the benefits offered, and the meaning of those benefits to the average person to allow both sides in this significant arena to be on a level playing field.”¹⁰³ Strict contract language interpretation merely takes into account the meaning of the terms used and the structure of the contract. The procedure, condition of the patient, and the ramifications of benefit denial is not considered with current legal intervention. Further, the actual denial of benefits for treatment is not addressed. Instead, the ambiguity of the provision and the interpretation of the contract language by the insurance companies are scrutinized.

There have been courts that have looked at benefit denial from a patient’s perspective.¹⁰⁴ “Very often, the courts have ruled in favor of the patient’s best chance of survival in spite of the language of a given exclusion, and in spite of the

⁹⁶*Turner*, 127 F.3d at 199. The Supreme Court recently set some new limitations on preemption by holding that certain laws were not sufficiently “related” to ERISA to deserve preemption. *Id.*

⁹⁷*Foster*, 969 F. Supp. at 1020.

⁹⁸*Id.*

⁹⁹*Rembold*, *supra* note 93, at 143.

¹⁰⁰*Id.* at 144.

¹⁰¹*Id.*

¹⁰²*Id.* at 145.

¹⁰³*Id.*

¹⁰⁴Mark Freedman, *When Insurers Refuse to Pay: Experimental Surgical Procedures*, 93 BEST’S REV. — LIFE-HEALTH INS. ED. 38, 43 (1993). Courts, by actually stepping in and making decisions in favor of certain medical advancement, cause therapies that should not necessarily be considered standard mainstream without medical backing. *Id.*

fact that the therapy may indeed be investigational or experimental.”¹⁰⁵ “Judges have been willing not only to interpret contracts liberally, but sometimes to bypass them altogether and order coverage for care that is ostensibly excluded under the policy.”¹⁰⁶ Patients, however, cannot rely on the chance that the court system will lean in their direction. There is a definite need for legal intervention to have a universal standard in which all patients are assured a chance to counter benefit denial equally.

The pressure of negative publicity caused by the possible threat of numerous lawsuits have forced many insurers to automatically cover HDC-ABMT.¹⁰⁷ The social threat placed on insurers may be beneficial to HDC-ABMT for breast cancer right now, but if the procedure advanced and changed in a few years the social pressure would take time to catch up with the newly developed treatment. Reliance on fear generated by society is not a solid enough basis to ensure benefits to a dying patient. Benefit denial must be dealt with another way.

A. *Strictly Confined to the Language of the Contract*

Under present law, courts are bound to interpret the language of the specific insurance contract.¹⁰⁸ Courts are unable to amend or expand coverage that is already defined in the contract.¹⁰⁹ Insurance coverage has been traditionally considered a contract.¹¹⁰ “The insured pays premiums and the insurer agrees to protect the insured from the harm insured against, should it occur.”¹¹¹ However, insurance contracts contain certain provisions that exclude treatments and procedures.

Language such as “benefits are not provided for services and supplies ... that are investigational or experimental or mainly for research” lull insured into believing that as long as they do not develop some strange disease their insurance policy will cover their procedure.¹¹² Patients detrimentally rely on insurance coverage to fund any disease treatment that may be needed. When patients are denied coverage, they automatically look at the procedure and determine that the treatment was not experimental in the context of the medical profession and that the refusal was wrong. The benefit denial may in fact be wrong, but according to the contract, the insurance company did nothing wrong to deserve legal punishment. The insurance company was simply adhering to their policy.

¹⁰⁵Jeffery L. Lenow et al., *Experimental Treatment: Who Pays?*, 9 J. BUS. & HEALTH 104 (1991).

¹⁰⁶E. Haavi Morreim, *Redefining Quality by Reassigning Responsibility*, 20 AM. J.L. & MED. 79, 84 (1994).

¹⁰⁷*Lawsuits, Publicity Driving Transplants*, 70 HOSPS. 71 (1996).

¹⁰⁸*Bechtold v. Physicians Health Plan*, 19 F.3d 322, 327 (7th Cir. 1994).

¹⁰⁹*Id.*

¹¹⁰Keith J. Allred, *Death of Insured No Bar to Tort Cause of Action for Bad Faith Denial of Coverage of Medical Treatment*, 28 J. HEALTH & HOSP. L. 38 (1995).

¹¹¹*Id.* Early insurance contracts provided only indemnity, insure contracted to repay the insured for any sums he became liable for and actually paid. *Id.*

¹¹²*Harris*, 992 F.2d at 707.

Currently, courts determine if an insurance company's actions in benefit denial are wrong by way of contract language. If there is a question of a term's ambiguity, the court reviews the case de novo based on contract language.¹¹³ If there is a conflict with an employee of the insurance company's interpretation of a provision, the court decides if the decision was arbitrary and capricious using the language of the contract as a guide.¹¹⁴ The court tends not to focus on the actual benefit denial since legal intervention has been brought down to a contract dispute. In order for an insurance company to be found liable, they must have done something wrong. An insurer can exclude HDC-ABMT treatment for breast cancer patients as long as the language of the policy contract clearly allows such denial.¹¹⁵

Simply using the term "experimental" does not place a policy provision in the realm of ambiguity.¹¹⁶ Courts must take an insurance contract as a whole.¹¹⁷ An insurance policy is ambiguous when one interpretation results in coverage and another ends in exclusion.¹¹⁸ Ambiguity also arises when a term is not properly "defined or clarified" by the contract.¹¹⁹ Courts cannot create ambiguity where no discrepancy exists.¹²⁰ If a provision bluntly states: "HDC-ABMT is not covered for breast cancer patients" then courts have a hard time countering benefit denial by way of ambiguity.¹²¹

Courts can, however, still counter benefit denial if coverage of the treatment is granted elsewhere in the contract.¹²² For instance in *Jenkins*, the women's insurance policy allowed HDC, but excluded ABMT.¹²³ Without ABMT, the patient would die when treated with HDC.¹²⁴ HDC and ABMT are used in conjunction with one another.¹²⁵ Excluding ABMT and allowing HDC created an ambiguity in the exclusion provision, thus creating a discrepancy for the court to act upon.

The experimental nature of a procedure and the medical necessity of the treatment is only brought up in court when the contract specifically uses such terms to describe what the policy covers. For example in *Pirozzi*, HDC-ABMT's

¹¹³*Fuja v. Benefit Trust Life Ins. Co.*, 18 F.3d 1405, 1408 (7th Cir. 1994).

¹¹⁴*Caudill*, 999 F.2d at 79.

¹¹⁵*T.D.J.V., Insurance: Private Insurers Not Required to Cover HDC-ABMT Treatment*, 27 J. HEALTH & HOSP. L. 314 (1994).

¹¹⁶*Dahl-Eimers*, 986 F.2d at 1380.

¹¹⁷*Id.* at 1381.

¹¹⁸*Id.*

¹¹⁹*Id.* at 1382. Absence of a definition does not create ambiguity per se. *Id.*

¹²⁰*Id.*

¹²¹*Caudill*, 999 F.2d at 80.

¹²²*Jenkins v. Blue Cross Shield of Mich.*, No. 3:93 CV7295, 1994 WL 901184 at *1, *7 (N.D. Ohio May 9, 1994).

¹²³*Id.* at *8.

¹²⁴*Id.*

¹²⁵*Id.*

experimental status based upon medical use and scientific data became important because the insurance contract specifically denied coverage to “experimental or clinical investigative procedures”.¹²⁶ The successful results of current tests and the frequent use of the treatment would never have been mentioned or utilized as criteria by the court if the contract provision had specifically excluded HDC-ABMT. Further, as seen in *Grethe*, the appropriateness of the procedure would not be weighed along side of the condition of the woman, if the contract had not required that the treatment be “medically necessary” in order to be covered.¹²⁷ Factors such as test data and patient condition that should be automatically considered when analyzing a benefit denial, are not considered by the court unless the contract language of the policy forces the court to recognize such criteria. Legal intervention is deeply rooted in contract text. If the provision does not address a certain issue, the court will refrain from taking the issue into consideration when making its decision.

Exclusive focus on contract language not only holds true when dealing with term ambiguity, but also is seen in determining the appropriateness of a provision’s interpretation. When determining the intent behind an administrator or employee of the insurance company’s interpretation of a provision, courts turn to the plain language of the document.¹²⁸ If the language of the contract vested a broad discretionary authority to the plan’s administrator then the court must decide if the decision was arbitrary and capricious.¹²⁹ In order for a court to determine if an insurance company had used its discretionary power in an overabundant manner, the wording of the expressed exclusion is taken into consideration.¹³⁰ If the interpretation of the provision is not “plainly erroneous and is consistent with the provision,” then the court will find in favor of the insurer.¹³¹ Even if the court would come to a different conclusion, the agency’s decision, as long as the interpretation is rational according to the contract language, would be considered the correct decision according to the law.¹³²

Patients’ chance of countering benefit denial based upon an administrator’s interpretation of contract language becomes extremely difficult when the exclusionary language of the contract is clear.¹³³ It is impossible to show bad faith when the contract language justifies the denial of benefits.¹³⁴ Further, an administrator’s actions are justified because he/she would not be fulfilling his/her fiduciary duty if the terms of the contract language were expanded.¹³⁵ Insurance carriers owe a fiduciary duty to shareholders and boards of directors to refuse to pay

¹²⁶*Pirozzi*, 741 F. Supp. at 588.

¹²⁷*Grethe v. Trustmark Ins. Co.*, 881 F. Supp. 1160, 1164 (N.D. Ill. 1995).

¹²⁸*Rembold*, *supra* note 93, at 142.

¹²⁹*Adams v. Blue Cross & Blue Shield of Md., Inc.*, 757 F. Supp. 661, 665 (D. Md. 1991).

¹³⁰*Dodd v. Blue Cross & Blue Shield Assoc.*, 835 F. Supp. 888, 891 (E.D. Va. 1993).

¹³¹*Id.* at 891.

¹³²*Caudill*, 999 F.2d at 79.

¹³³*Dodd*, 835 F. Supp. at 890.

¹³⁴*Allred*, *supra* note 110, at 40.

¹³⁵*Thomas*, 688 F. Supp. at 595.

for treatments that are costly that do not adhere to the policy provisions.¹³⁶ An insurance company must keep its own financial interests in mind.¹³⁷ HDC-ABMT is an expensive treatment, costing between \$50,000 and \$200,000 per patient.¹³⁸ Denying this procedure would be in the best interest of the insurer. When the language of the provision is clear and unambiguous, an administrator has every right to decide the only logical interpretation of the contract.¹³⁹ Not denying benefits for HDC-ABMT when the language of the contract clearly stated such denial would completely be against an insurance carrier's fiduciary duty.

Courts have even found insurers immune from liability when an administrator incorrectly interpreted a contract's benefit denial provision.¹⁴⁰ In *Nesseim* the Court held that even though the insurance company looked to the "Surgical Benefits" section instead of the section referring to chemotherapy, the decision to deny benefits was not arbitrary and capricious.¹⁴¹ As long as the decision was not an "abuse of discretion," the law will not intervene by allowing benefits to be given and essentially punishing the insurer.¹⁴² A reasonable interpretation of a plan provision, made in good faith, following a rather detailed factual background investigation of the claim completely overrides any discrepancy that an insured could bring to a court of law.¹⁴³

Current legal intervention allows insurance companies to incorrectly interpret its contract language, make decisions without taking important considerations into account and deny benefits that are not only justified but essential to a person's life. The only thing that an insurance company is obligated to do is clearly deny a specific treatment or procedure in its contract to completely avoid any liability. The actual contract, terms and structure, is the only thing that the courts look at to make their decisions. A court is "empowered to decide legal issues presented by specific cases or controversies."¹⁴⁴ It is not the court's duty to engage in analyzing broader social and ethical questions.¹⁴⁵ The legislation has the prerogative of enacting statutes to implement public policy.¹⁴⁶ Under the present state of law, courts are bound to interpret the language of the insurance contract because that is the only thing that courts are presented with to analyze.¹⁴⁷ Once legislation has enacted laws regarding

¹³⁶Rembold, *supra* note 93, at 144.

¹³⁷*Id.*

¹³⁸*Id.*

¹³⁹*Dodd*, 835 F. Supp. at 890.

¹⁴⁰*Nesseim v. Mail Handlers Benefit Plan*, 995 F.2d 804, 807 (8th Cir. 1993).

¹⁴¹*Id.*

¹⁴²*Id.* at 808.

¹⁴³*Sweeney v. Gerber Products Co. Med. Benefit Plan*, 728 F. Supp. 594, 596 (D. Neb. 1989).

¹⁴⁴*Bechtold*, 19 F.3d at 327.

¹⁴⁵*Id.*

¹⁴⁶*Id.*

¹⁴⁷*Id.* at 328.

benefit denial, an all inclusive analysis can take place. All of the issues that should be taken into consideration would be addressed if a broader concept, such as a statute, as opposed to a contract, was imposed.

Current legal intervention also encourages insurance companies to specifically exclude medical treatments and procedures in its contract language. Courts are forcing insurance carriers to specify specific conditions when a procedure would be covered.¹⁴⁸ For example in *Jenkins*, ABMT is covered by insurance if it is used to treat “Hodgkin’s Disease (Stage III or IV), Non-Hodgkin’s Lymphoma (intermediate or high grade), Neuroblastoma (Stage III or IV), Acute Lymphocytic Leukemia, Acute Non-Lymphocytic Leukemia, and Germ Cell Tumors of Ovary, Testes, Mediastinum, Retroperitoneum.”¹⁴⁹ This contract excludes not only breast cancer but stage II Hodgkin’s Disease and low grade Non-Hodgkin’s Lymphoma which seems contradictory since not only is the same procedure being used, but the same disease is being treated. Specifying coverage to this extreme discriminates against a higher percentage of people. Basing legal decisions strictly on contract language leaves this higher percentage of people with no remedy. Courts have in actuality forced insurance companies to discriminate against more people, essentially taking any chance of compensation away from a higher percentage of insured. Courts finding phrases such as “experimental and investigational” and “medically necessary” as being ambiguous and punishable, has coerced insurance companies into creating clearer contract language that excludes a larger amount of procedures and treatments, essentially effecting more people’s lives. Instead of helping, legal intervention has adversely effected benefit denial since the language of insurance contracts is the only thing courts are able to consider.

B. ERISA Further Constricts Legal Intervention

“Due to the proliferation of employee benefit plans and their effect on the well-being of millions of employees and their dependants, Congress in 1974 enacted the Employee Retirement Income Security Act (ERISA) (29 U.S.C.A. § 1001 et seq.) to protect individuals from being deprived of these benefits.”¹⁵⁰ The purpose of ERISA was to “ensure that plans and plan sponsors would be subject to a uniform body of benefits law; the goal was to minimize the administrative and financial burden of complying with conflicting directives among States [and to prevent] the potential for conflict in substantive law.”¹⁵¹ ERISA was enacted “to promote the interests of employees and their beneficiaries in employee benefit plans and to protect contractually defined benefits.”¹⁵²

¹⁴⁸*Jenkins*, 1994 WL 901184, at *3.

¹⁴⁹*Id.* at *5.

¹⁵⁰John A. Bourdeau, Annotation, *Propriety of Denial of Medical or Hospital Benefits for Investigative, Educational, or Experimental Medical Procedures Pursuant to Exclusion, Contained in ERISA-Governed Health Plan*, 122 A.L.R. FED. 1 (1994).

¹⁵¹*Foster*, 969 F. Supp. at 1027.

¹⁵²*Firestone Tire & Rubber Co. v. Brunch*, 489 U.S. 101, 113 (1989).

ERISA provides a private right of action to recover benefits due under federal law.¹⁵³ “ERISA does not require employers to provide benefit plans but does strictly regulate how voluntary, self-insured, plans may be administered.”¹⁵⁴ For an insurance company to be governed by ERISA it must be considered an “employee welfare benefit plan.”¹⁵⁵ Certain criteria must be met in order for an insurance plan to be deemed as an “employee welfare benefit plan,” thus governed by ERISA.¹⁵⁶ This criteria encompasses “a plan, fund, or program established or maintained by an employer or by an employee organization for medical, surgical, or hospital care or benefits, or benefits in the event of sickness, accident, disability and to participants or their beneficiaries.”¹⁵⁷ If the criteria is not met, the claim for benefit denial regarding a self-insured plan cannot not be brought under ERISA.¹⁵⁸

Insurer’s liability became limited because ERISA contains a vague but broadly worded preemption provision.¹⁵⁹ ERISA “shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan.”¹⁶⁰ ERISA provides a specific remedy for benefit denial, thus preempting all other claims.¹⁶¹ The statute carefully sets forth six civil enforcement provisions that specifically authorizes detailed remedy.¹⁶² Courts are reluctant to allow other causes of action when the statute specifically enumerates adequate remedy.¹⁶³ ERISA governs benefit denial. Resorting to other sources to claim recovery is unnecessary and incorrect since remedy has already been established by an act.¹⁶⁴

ERISA’s preemption to all other claims, forces courts to once again strictly adhere to contract language. According to ERISA, analysis of benefit denial properly begins with the plan’s terms.¹⁶⁵ With ERISA, patients who are denied benefits are pushed solely into contract dispute since their other causes of action are preempted. Patients are unable to turn to other claims such as breach of contract, bad faith, negligent misrepresentation or fraud when the contract language of the exclusion provision specifically excludes a certain treatment or provision.¹⁶⁶

¹⁵³Robinson v. Employers Health Ins. Co., No. 91C1375, 1991 WL 152519, at *1 (N.D. Ill. July 30, 1991).

¹⁵⁴Scheutzow, *supra* note 21, at 208.

¹⁵⁵Nancy A. Wynstra, *Breast Cancer: Selected Legal Issues*, 74 *CANCER* 493 (1994).

¹⁵⁶*Id.* at 500.

¹⁵⁷*Id.*

¹⁵⁸*Id.*

¹⁵⁹*Turner*, 127 F.3d at 199.

¹⁶⁰29 U.S.C. § 1144(a).

¹⁶¹*Foster*, 969 F. Supp. at 1028.

¹⁶²*Trademark Ins. Co. v. University of Chi. Hosps.*, No. 94-C4692, 1997 WL 610294, at *4 (N.D. Ill. Sept. 29, 1997).

¹⁶³*Id.* at *4.

¹⁶⁴*Id.*

¹⁶⁵*Pirozzi*, 741 F. Supp. at 589.

¹⁶⁶*Foster*, 969 F. Supp. at 1024.

Further, “under ERISA the insurance carrier has the contractual power to change the terms of the insurance policy.”¹⁶⁷ The insurance company can completely change what it will cover as long as it gives the employer notice of such changes in a timely manner.¹⁶⁸ The employer, who is the sponsor of the ERISA benefit plan, is then given the option of discontinuing the plan and seeking another carrier.¹⁶⁹ The insurance company is given a massive amount of power in a court of law since it is in control of amending the contract language. The insured is not only deprived alternate causes of action, but is subjected to contract term alteration with no redress.

The law has made it difficult to counter ERISA. “A reasonable interpretation of the ERISA plan will stand unless participants can show not only that a potential conflict of interest exists, but that the conflict affected the reasonableness of the decision.”¹⁷⁰ There is an innate conflict of interest found in insurance companies deciding benefit coverage.¹⁷¹ The insurance carrier has the fiduciary duty to deny or grant benefits properly, while keeping the profit-making objective of the insurance company.¹⁷² Essentially, the insurance company that interprets the plan, determining coverage, ultimately pays those expenses from its own coffers.¹⁷³ However, this conflict of interest, insurers interpreting their own contracts, does not constitute a violation of ERISA.¹⁷⁴

The language of ERISA also determines who has standing to bring a claim for benefit denial.¹⁷⁵ Only “participants” and “beneficiaries” have standing under ERISA to bring a claim countering benefit denial.¹⁷⁶ A “fiduciary”, a person who has discretionary authority over the plan,” has the right to bring a claim for equitable relief, but only the participant of the insurance plan or the person who was actually denied the benefits can claim under ERISA.¹⁷⁷

Limiting the category of the people that can bring a claim of benefit denial has caused some real problems when the person denied actually dies.¹⁷⁸ Families of people who die are unable to bring a cause action against the insurer because ERISA preempts wrongful death.¹⁷⁹ The idea behind not allowing families to claim stems

¹⁶⁷*Wilson v. Group Hospitalization & Med. Svcs.*, 791 F. Supp. 309, 311 (D.D.C. 1992).

¹⁶⁸*Id.*

¹⁶⁹*Id.*

¹⁷⁰*Whitney v. Empire Blue Cross & Blue Shield*, 106 F.3d 475, 476 (2d Cir. 1997).

¹⁷¹*Id.* at 476.

¹⁷²*Id.*

¹⁷³*Wilson*, 791 F. Supp. at 312.

¹⁷⁴*Whitney*, 106 F.3d at 476.

¹⁷⁵*Kendal Corp. v. Inter-County Hospitalization Plan*, 771 F. Supp. 681, 684 (E.D. Pa. 1991).

¹⁷⁶29 U.S.C. § 1132(a)(1).

¹⁷⁷*Kendal*, 771 F. Supp. at 684.

¹⁷⁸*Turner*, 127 F.3d at 199.

¹⁷⁹*Foster*, 969 F. Supp. at 1024.

from the concept that once the person dies, an award of benefits no longer exists.¹⁸⁰ Allowing families to claim would essentially allow an award of extra contractual damages which ERISA does not cover.¹⁸¹ Further, even if the family member were to claim on behalf of their dead family member, they would be directly countering language set forth in ERISA.¹⁸² ERISA only provides standing to “participants,” “beneficiaries,” and “fiduciaries.” The family member would not fall under any of the three categories, thus allowing the member to claim would create a violation of the statute.¹⁸³ The idea behind ERISA is to provide compensation for wrongful denial of benefits to someone who will benefit from litigation, not for the deceased who may not have benefited from the treatment or procedure.¹⁸⁴

V. PROPOSALS TO RECTIFY PROBLEMS SURROUNDING BENEFIT DENIAL

Essentially, insurance exists to provide protection.¹⁸⁵ Current legal intervention is not taking into consideration the reliance that people put into insurance coverage. Rarely does a person take the time to actually check what their policy covers.¹⁸⁶ Patients detrimentally believe that insurance will cover anything. It is not until a person is in a life threatening situation and the insurance company refuses benefits, that people realize that they signed a contract that denied them certain coverage.¹⁸⁷

Courts cannot step in and simply override an insurance contract.¹⁸⁸ The language of the contract determines what is in fact covered.¹⁸⁹ There are, however, numerous other factors that should be considered. The contract language should be adhered to and focused on by courts when determining if a benefit denial was appropriate, but other factors, such as the treatment serving as a last resort for the patient and the similarity of the procedure to others that are covered, should also be taken into account.

When a costly state of the art treatment, such as HDC-ABMT, is denied coverage there should be a way for the legal community to counter automatic denial.¹⁹⁰ Insurance companies are not obligated to periodically update its list of coverable treatments.¹⁹¹ Therefore, when insurance contracts specifically exclude certain procedures, based on the concept that the treatment is “experimental”, when the

¹⁸⁰*Id.*

¹⁸¹*Id.*

¹⁸²*Id.*

¹⁸³*Id.*

¹⁸⁴*Turner*, 127 F.3d at 200.

¹⁸⁵Rembold, *supra* note 93, at 145.

¹⁸⁶Wayne Hicks, *Women Seeking Breast Cancer Treatment Fight Two Battles*, 45 DENV. BUS. J. 8, 11 (1994).

¹⁸⁷*Id.* at 8.

¹⁸⁸*Thomas*, 688 F. Supp. at 595.

¹⁸⁹*Id.*

¹⁹⁰*See Pirozzi*, 741 F. Supp. at 594.

¹⁹¹*T.D.J.V.*, *supra* note 115, at 315.

treatment is no longer considered experimental in the medical community, courts should be able to intervene. Based on strict contract language interpretation, the procedure's denial would be legal. Based on the reason behind denying the treatment, the denial should be reversed.

A national committee made up of medical and economic experts could be used to constantly update what procedures and treatments should be deemed experimental.¹⁹² Insurance companies would then be forced to cover a larger range of cutting edge medical techniques. Not only would this concept benefit patients, but it would rapidly advance medicine. Areas of medicine would develop because more people could gain access to new procedures, allowing more assessments to be performed by medical experts, leading to possible progress.¹⁹³

Legal intervention being strictly bound to contract language could be alleviated if there was a national mandated coverage of benefits. Creating a national law mandating coverage of all procedures would completely take away any discretionary power from insurance companies.¹⁹⁴ Insurance carriers could no longer decide which procedures or treatments would be covered.¹⁹⁵ This concept would lead to higher insurance premiums, but benefit denial would never occur.¹⁹⁶ A person in a life threatening situation could then rely on his/her insurance.

A national committee and a national law mandating benefits are only two proposals suggested to remedy the problems arising from current legal intervention. These two proposals are not necessarily the best or worst ideas that could be used, but only should serve as suggestions to ponder. Even though, the trend, as seen on a lower level, seems to be pointing in a similar direction.

A. National Committee to Determine If Experimental

There is a "relentless technological momentum" driving advancements in medicine at a fast rate.¹⁹⁷ Legal intervention tends to be behind the times. "The old maxim that "the wheels of justice move slowly" is usually all too true."¹⁹⁸ Constant medical advancement is posing a problem when defining the word "experimental". At what point does a procedure or treatment stop being considered experimental? Allowing insurance companies the discretionary power to determine what is experimental poses problems when medical advancements are happening so rapidly. Further, there is no duty that the insurance company must update its list of coverable

¹⁹²Earl P. Steinberg, *Insurance Coverage for Experimental Technologies*, HEALTH AFFAIRS, Winter 1995, at 8.

¹⁹³*Id.*

¹⁹⁴Wayne J. Guglielmo, *Curbing HMO Treatment Denials: Is a Trend Taking Hold?*, 17 MED. ECON. 100 (1997).

¹⁹⁵*Id.*

¹⁹⁶John L. Cova, *A Swift Response to a "Modest" Proposal*, 84 J. NAT'L CANCER INST. 744 (1992).

¹⁹⁷Rembold, *supra* note 93, at 145.

¹⁹⁸David B. Brushwood, *Challenging Denial of Coverage for Innovative Therapy*, 54 AM. J. HEALTH-SYS. PHARM. 573 (1997).

advancements.¹⁹⁹ Thus, insurance contract coverage is based on provisions possibly set forth twenty years earlier. Courts are then relying on terms that have essentially been outdated for years.

Insurance carriers are not doctors. Insurance companies are overriding the word of a doctor with no medical background or training. To possibly resolve the problem of allowing a medically uneducated establishment from defining a medically emersed term, experimental, a committee may be imposed. A composition of “ontologists, internists, surgeons, experts in medical ethics, medical school administrators, economists, representatives of the insurance industry, patient advocates and politicians” may be able to define “experimental” in a more universal manner, taking all aspects of the reviewed procedure or treatment under consideration.²⁰⁰ “Through such a collective task force perhaps some consensus might be reached concerning the definition of experimental procedures” that would balance insurers concern with costs with insured medical worries.²⁰¹

Utilizing a diverse task force would incorporate the concerns that current legal intervention is unable to consider. Further, contract ambiguity posed by the term “experimental” would be eliminated. No universally acceptable definition of experimental and nonexperimental currently exists.²⁰² “Experimental” would continuously be defined by the committee. Therefore, insurance companies could use the term without any chance of liability. The word “experimental” would be used instead of specific exclusionary language, thus providing insureds a better chance of coverage for procedures that are considered on the crux of development.

A national committee defining experimental procedures and treatments would avoid numerous legal disputes, since benefit denial would be continually reviewed. Besides, a committee would keep courts from making medical determinations that it is not trained to make.²⁰³ “Judges and juries should not be asked to make determinations of clinical efficacy” when the information is surrounded by medical terminology too convoluted for the average person to understand.²⁰⁴

A national committee would judge the experimental nature of a treatment objectively.²⁰⁵ Even though each member of the committee may be biased by their area of expertise, they still would be outsiders deciding if a specific procedure should be covered.²⁰⁶ None of the members would be directly effected by the decision they made. Whereas, insurance companies were making decisions that determined the amount of money taken away from the company.

¹⁹⁹T.D.J.V., *supra* note 115, at 315.

²⁰⁰*Bechtold*, 19 F.3d at 327.

²⁰¹*Id.*

²⁰²*Cova*, *supra* note 196, at 745.

²⁰³*King County Medical Blue Shield to Participate in National Cancer Institute Trials*, PR NEWSWIRE, Dec. 30, 1992, at 1230.

²⁰⁴*Id.*

²⁰⁵*Guglielmo*, *supra* note 194, at 102.

²⁰⁶*Id.*

A national committee would solve a lot of the problems surrounding current legal intervention regarding benefit denial. Insurance companies' discretionary power would be limited. An insurance carrier could no longer determine what procedures and treatments would be covered and which would be denied. Instead, a diverse group of individuals would have the authority based on their individual expertise to determine the experimental nature of a treatment.

B. Nationally Mandated Benefits

Many states have enacted statutes that require insurance policies to cover certain treatments and procedures.²⁰⁷ Legislation has intervened, establishing a series of uniform, statewide standards to override specific contract exclusions set forth by insurance companies.²⁰⁸ State statutes were created to implement the same public policy that legal intervention was unable to consider in its decision.²⁰⁹ The statutes specifically stated the procedure or treatment that it mandated.

For example in Massachusetts, a statute bluntly states that "any individual policy of accident and sickness insurance . . . shall provide coverage for a bone marrow transplant or transplants for persons who have been diagnosed with breast cancer that had progressed to metastatic disease."²¹⁰ In New Hampshire "each insurer that issues or renews any policy of group or blanket accident or health insurance . . . shall provide . . . coverage for expenses arising from the treatment of breast cancer by autologous bone marrow transplants according to protocols reviewed and approved by the National Cancer Institute."²¹¹ Legislation stepped in and countered benefit denial by simply mandating benefits.

A national standard mandating all benefits would ensure that all persons would have access to promising technologies.²¹² If specific mandated benefits have been enacted at a state level, mandating benefits at a national level should be allowed as well. Mandating benefits nationally would completely negate insurance contract exclusions. Insurance companies could no longer exclude a certain procedure or treatment because under the national standard everything would be covered. Further, ERISA would be overruled. Taking benefit denial to a national level would override any legislation enacted on a federal one, thus erasing ERISA.

Along with the equality that a national standard produces comes the limitless amounts of money that such a concept would require.²¹³ Insurance companies would be required to cover every possible benefit for everyone.²¹⁴ Insurance companies could never be able to afford such expenses. A national standard would "force

²⁰⁷Wynstra, *supra* note 155, at 504.

²⁰⁸Guglielmo, *supra* note 194, at 100.

²⁰⁹*Bechtold*, 19 F.3d at 327.

²¹⁰Mass. Gen. Laws. ch. 175 § 47R (1999).

²¹¹N. H. Rev. Stat. Ann. § 415:18-c (1999).

²¹²Steinberg, *supra* note 192, at 8.

²¹³Morreim, *supra* note 106, at 92.

²¹⁴*Id.*

insurers and employers to impose “taxes” in the form of higher premiums.”²¹⁵ Premiums would have to be increased to compensate insurers.²¹⁶ “The adverse consequences of this expansion are greatest for individuals at the lower end of the income scale.”²¹⁷ These are the same people that originally found themselves involved in legal disputes over benefit denial. Raising the premiums may allow universal and all inclusive coverage, but if the premiums become so high that people are unable to access insurance the whole point of a national standard becomes moot.

A national standard would produce a uniform approach to benefit denial.²¹⁸ When a doctor suggested a procedure, an insurance company could no longer override the physician’s recommendation.²¹⁹ A national standard would eliminate any problems arising from current legal intervention because essentially benefit denial would no longer exist. Insurance companies would be forced to cover everything. Insurance carriers would no longer have the discretionary power to decide benefit accessibility. The enactment of a national standard, however, may open a whole new bundle of problems that the law will have to face. Higher premiums would allow universal coverage but at the same time may completely exclude general insurance to people by pushing coverage to an unattainable amount. People would no longer be denied benefits, but insurance premiums may become so high that people could be denied insurance coverage altogether.

VI. CONCLUSION

Current legal intervention is fatally flawed by the fact that it is unable to draw from all directions to decide if insurance benefit denial was appropriate. Courts are bound by the language that insurance companies set forth in their policies. Instead of being able to take the whole forest into consideration, courts are constrained to strictly looking at the trees.

Specifically analyzing HDC-ABMT has shown the real injustice of courts being forced to make decisions based solely on contract language. The fact that HDC-ABMT simply allows for a higher dosage of an already proven treatment cannot be taken into account by courts. Nor can the fact that this same procedure is automatically covered by insurance policies when it is used for a different type of cancer. Even the fact that this procedure is the last resort that many women have left to survive, must be negated. Courts have only the words of a contract, that specifically excludes a treatment or procedure, to base its’ decision. If a policy excludes the treatment, then the benefit denial is valid, even though the insured detrimentally relied on the coverage.

Strictly adhering to contract interpretation adversely effects the patient. When the insureds signed their contract they were under the assumption that they would be protected from everything. People tend not to read all the exclusions stated in their insurance policy. However, courts solely judge benefit denial on such exclusions.

²¹⁵Cova, *supra* note 196, at 744.

²¹⁶*Id.*

²¹⁷*Id.*

²¹⁸Guglielmo, *supra* note 194, at 103.

²¹⁹Mark Tatge, *Life May Not Be Priceless After All*, PLAIN DEALER (Cleveland), Feb. 17, 1998, at 10-A.

As long as the language of the contract is clear and insurance carriers base denial on this language, insureds will not win in a court of law.

This Note is not inferring that courts are wrong in their actions. Nor is the Note stating that insurance companies are necessarily evil when they exclude certain costly procedures. The Note is simply focusing on the fact that current legal intervention does not look at the whole picture when deciding benefit denial. Legal intervention must change to include all aspects touching the denial because insurance policies are becoming more specific and are excluding more procedures.

Establishing a nationally mandated benefits act and a diverse committee to decide what should be considered experimental may not necessarily be the answer. Allowing legal intervention to continue to progress in the same direction, is definitely not the answer. Current legal intervention must be changed before more lives are lost to a contract provision.

EMILY SMAYDA