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"Experimental" Chemotherapy Treatment for Advance Stage Breast Cancer: Judicial Interpretation of Insurance Policy Coverage

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A woman who has tried all forms of therapy talks about her eleven year journey through breast cancer. She was cancer-free for eight years, then had a recurrence. She went through a clinical trial, a bone marrow transplant, which she went into as a fantasy but now says was horrible. But what made it all worthwhile is that she has had three years cancer-free, without the chemotherapy that traditional treatment would have offered. Now, instead of asking herself "What if I die?", she is asking "What if I live?" That is keeping her sane. Having the choice of experimental treatment has given her freedom.

INTRODUCTION

Since the late 1980's, litigation concerning insurance coverage for investigational or experimental medical treatments has proliferated. Compared to the early litigation of the late 1980's, over the past five years courts have begun finally to permit women to challenge successfully insurance policy contracts -- the reward being insurance coverage that may play the largest role in saving their lives.

This article traces the evolution of judicial enforcement of insurance coverage for questionably experimental chemotherapy treatment administered to women with advanced-stage breast cancer. First, this article explains the disease, the controversial treatment, and the efficacy of the treatment. Second, this article explores the reasons why insurance policies typically exclude coverage for this particular chemotherapy treatment and addresses the outcome of litigation from the late 1980's, as opposed to the current judicial strategy. Finally, this article will explore...
recent litigation and some of the alternative approaches taken by the courts when interpreting and enforcing insurance contracts.

DISEASE AND TREATMENT OF BREAST CANCER

The disease of breast cancer is classified into four stages according to the extent of the disease. In Stage I, the solid tumor is typically less than one inch thick and is considered small. By Stage II, the tumor is larger, approximately one to two inches, and the cancer has spread to the auxiliary lymph nodes. In Stage III, the tumor is greater than two inches and adheres to the chest wall. Finally, by Stage IV, the cancer has "metastasized," or spread to other organs or parts of the body.

Breast cancer is the most common type of cancer among women in the United States today. More than 1.6 million women living in the United States today have been treated for breast cancer. In addition, more than one-quarter of these women diagnosed with breast cancer will eventually die from the disease. In the last several years, breast cancer has been a focus of public attention, as patients have taken it upon themselves to increase public awareness of the disease through dissemination of information regarding detection, treatment, cure, and consequences. This heightened public awareness has in turn, put pressure on lawmakers to provide both federal and state funding for research to find alternative therapies to traditional radiation and chemotherapy, in order to treat and cure breast cancer.

Over the last ten years, physicians have been administering high-dose chemotherapy treatment in conjunction with autologous bone-marrow

3 Id.
4 Id.
5 Id.
6 Id.
7 Id. at 2031.
8 Id.
9 Id.
10 Id. at 2032.
11 Id.
transplants (HDCT-ABMT), a two step procedure, as an alternate treatment for women with Stage IV breast cancer as an alternative treatment. The high-dose chemotherapy treatment consists of the administration of a combination of powerful drugs intended to kill the cancer cells. However, these drugs also have a myeloblastic effect. Although they destroy malignant cancer cells, they also destroy a woman’s healthy bone marrow cells which produce badly needed red and white blood cells and platelets. Without a minimum number of red or white blood cells or platelets, a patient is highly susceptible to infection and bleeding.

To counter the drug’s destructive effect, before administering the chemotherapy a physician will extract the patient’s own bone marrow cells (harvesting the cells) and place them temporarily in frozen storage. The physician then administers the high-dose chemotherapy to the patient. Finally, the patient's own healthy bone marrow is intravenously reinfused in an “autologous transplant” to replace the bone marrow that the chemotherapy destroyed. The use of the patient’s own bone-marrow for reinfusion reduces any additional complications that could be caused by rejection of donor marrow.

Given a choice between this aggressive and expensive experimental therapy, and a less-grueling and seemingly far less successful standard therapy, women with advanced breast cancer are having no difficulty choosing. Rather, patients with advanced breast cancer are flocking to receive these high-dose chemotherapy and autologous bone marrow transplants, placing their hope in what phase II studies have shown to result in a 20 percent a year disease-free survival rate, as opposed to the 2 percent rate cited for standard chemotherapy.

12 See Bechtold v. Physicians Health Plan of Northern Indiana, Inc., 19 F.3d 322, 324 (7th Cir. 1994).
13 Id.
14 Id.
15 Id.
16 Id.
17 See Bechtold v. Physicians Health Plan of Northern Indiana, Inc., 19 F.3d 322, 324 (7th Cir. 1994).
18 Id.
19 Id.
20 Id.
21 Id.
HEALTH INSURANCE AND HDCT-ABMT

Insurance companies typically exclude coverage for HDCT-ABMT in health insurance policies for two reasons. First, HDCT-ABMT is an expensive treatment compared to traditional chemotherapy treatment. While costs vary according to the exact combination of drugs administered per patient, HDCT-ABMT may cost at least $100,000 per patient as compared to the $15,000 - $40,000 price tag for standard chemotherapy treatment. Second, while the treatment has proven effective in treating certain kinds of cancerous blood diseases, such as Leukemia and Hodgkin's Disease, the efficacy of the treatment when used on solid-type tumors, such as breast cancer, is disputed among health care providers. Thus, although women with advanced-stage breast cancer may have a greater than 65 percent chance of survival beyond five years with the treatment compared to a 20 percent chance of survival without treatment, insurance companies are still refusing to pay for treatment they consider to be "experimental." Instead, these insurers believe it's neither appropriate nor feasible for them to cover the care for patients hospitalized for the sole purpose of research.

Insurance policies are considered contracts for the purposes of judicial interpretation. Additionally, since insurance companies draft their own policies, courts must keep in mind that the insurer has the power to define all terms included in the contract. While it is an insurance company's prerogative to cover some treatments and exclude others from coverage, an insurance company has a responsibility to its subscribers to outline clearly what procedures will and will not be indemnified.

Insurance polices are fraught with ambiguities in craftsmanship,
and often in logic. While private health insurance policy contracts usually have provisions denying coverage for "experimental" treatment, there are as many definitions of "experiment" as there are suits challenging whether a procedure is alternative (and covered by insurance), or investigational (and not covered). The exact definition of "experimental treatment" remains unclear.

In defining its policies regarding treatment, an insurance company must consider a number of factors in order to define what should be "investigational" or "experimental" therapy. Some of the major questions involved include the insurers' views on the following:

(1) Is the therapy administered under an Institutional Review Board (IRB) approved protocol considered "experimental?"

(2) If a therapy is considered standard for one type of illness, is it therefore standard treatment for other forms of the same disease?

(3) If a patient receives "standard" therapy, however defined, for a serious or life-threatening illness and the treatment fails, does the standard of care require use of "investigational therapy" and, if so, is payment thus required?

The answers reached by insurance companies to these questions are as diffuse as the questions themselves. Indeed, insurers have been known to refuse payment arbitrarily based upon the advice an administrator receives from "friends who are doctors," or based upon the decision of an insurance company's employee physician, who is usually not a specialist in the field in question.

Because insurance companies prefer to avoid paying for expensive medical treatments at all costs, they are consistently expanding their list of

28 Id. at 795.
29 Id.
treatments that will not be covered. Some policies provide simply that a company may refuse to pay for any therapy it deems "experimental" or "investigational" based upon criteria it selects. Other health insurers define experimental services as those that are under "clinical investigation by health professionals," and "not generally recognized by the medical professionals tested and accepted medical practice." These insurers will still try to refuse coverage even when affidavits attesting to the acceptance of the therapy are submitted by recognized experts in the field. Finally, some insurers do specify criteria in their policies excluding treatments "not generally acknowledged as accepted medical practice by the suitable medical specialty practicing in [this state], as decided by us," or by requiring that all treatments be approved by the Health Care Financing Administration, the federal agency that determines payments for Medicare patients.

Ultimately, since health insurance is a contract drafted independently by each agency, definitions of "investigational" or "experimental" vary. Thus, one insurer may willing pay for treatment X for Y disease while another may refuse even when supplied with identical medical facts.

JUDICIAL APPROACH TO INSURANCE COVERAGE FOR EXPERIMENTAL TREATMENT

Until recently, the issue of insurance coverage for investigational or experimental treatment received little or no publicity. Within the past several years, however, the amount of litigation challenging refusals to cover "investigational treatment," and the publicity surrounding these cases, have come center stage.

In the late 1980's, when courts were first confronted by an insurance
company's refusal to pay for some form of therapy on the grounds that it was "experimental" or "investigational," the courts did not bother to distinguish between the therapies involving "alternative" treatments, and experimental studies conducted in mainstream research. Consequently, insurance companies were victorious in virtually all lawsuits brought against them.

Today, courts are starting to realize that insurance policies are often ambiguous in defining what procedures they do or do not cover. As a result, policy holders who contract with insurance companies for health care coverage may not be completely aware of the coverage for which they have contracted. It is this vagueness with which health insurance policies are riddled, and which courts are now starting to construe against the drafters through application of fundamental contract law and with an eye on public policy. Consequently, more and more women are winning their challenges against insurance companies and are being granted access to treatment which may save their lives.

One of the most significant decisions regarding an insurance company's denial of HDC/AMBT thus far is Bailey v. Blue Cross/Blue Shield of Virginia. In Bailey, the plaintiff was suffering from stage IV breast cancer when her physician recommended that she undergo a form of HDC/ABMT treatment as her best chance for survival. Bailey sought coverage for the procedure from Blue Cross, to which she had access through her husband's company. Blue Cross denied Bailey coverage for the treatment based on an amendment to her insurance policy that stated, "Autologous bone marrow transplants or other forms of autologous stem cell rescue with high dose chemotherapy or radiation are not covered."

In response to her insurer's denial, Bailey conceded that the PSCR portion of her treatment was explicitly excluded from the treatment. However, she argued that the insurance contract did not specifically

39 Id. at 796.
40 Id.
41 Bailey v. Blue Cross/Blue Shield of Va., 67 F.3d 53 (4th Cir. 1995).
42 Id.
43 Id.
44 Id.
exclude high-dose chemotherapy, but in fact expressly provided coverage for chemotherapy and did not distinguish the kind of chemotherapy it intended to cover. In response, Blue Cross maintained that its use of the term "with" unambiguously meant "and," thus when stem cell rescue and high dose chemotherapy were used together, its policy excluded coverage for the entire treatment.

The Court of Appeals for the Fourth Circuit approached the issue in Bailey as one of pure contract interpretation, and found that the language of the insurance contract was ambiguous as a matter of law. In turn, since ambiguous contract provisions are construed against the drafter, the Appeals Court upheld the grant of summary judgment in favor of the plaintiff and prohibited Blue Cross from denying coverage for Bailey's high dose chemotherapy.

As evidenced by Bailey, courts are finally considering insurance policy contracts while keeping both the women and the insurance companies in mind. The courts have achieved this balance by maintaining legal objectivity through application of basic contract law, while recognizing the demands of public policy and considering whether the terms of the contract are ambiguous as to what procedures will and will not be covered based upon a treatment's experimental nature. Since the function of a court in construing an insurance policy is to ascertain and enforce the intent of the parties as expressed in a contract, courts must be wary of allowing sympathies and desires to vitiate clear principles of contract law. Alternatively, when a policy is explicit as to

45 Id.
46 Bailey v. Blue Cross/Blue Shield of Va., 67 F.3d 53 (4th Cir. 1995).
47 Id.
48 Id.
50 Id. at 1158.
51 Id. at 1159.
52 Id. at 1156. See also Scottish Guaranty Ins. Co., Ltd. v. Dwyer, 19 F.3d 307 (7th Cir. 1994); Dahl-Eimers v. Mutual of Omaha Life Ins., 986 F.2d 1379, 1381 (11th Cir. 1993).
what kind of treatments it will not indemnify, the courts will find for the insurance company.

In the Seventh Circuit, for instance, the Court of Appeals determined that language which details the excluded treatment cannot be ambiguous as a matter of law. In Betchold v. Physician's Health Plan of Northern Indiana, Inc., the Court found that the particular insurance policy excluded autologous bone marrow transplantation as unreasonable and unnecessary treatment for solid tumors. Breast cancer was specifically listed under this solid tumor exception. Consequently, the court concluded that the plaintiff was "attempting to create an ambiguity in the contract language where no ambiguity exists."

Likewise, in Harris v. Mutual of Omaha Companies and Rural Carrier Benefit Plan, the Seventh Circuit found that since the policy at issue explicitly defined Phase I, II, or III clinical trials as experimental, and the plaintiff's treatment would be administered according to a clinical trial protocol identifying the procedure as "Phase II trial," the contract did not cover the treatment.

Finally, in Fuja v. Benefit Trust Life Insurance Company, the court determined that the insurance policy's exclusion of coverage for treatment administered "in connection with medical or other research" explicitly permitted the insurance company to refuse payment for medical treatment whose medical efficacy is questioned, and that is still under investigation in medically recognized and accepted research studies.

On the other hand, courts have held that when a contract is silent as to the meaning of its terms, the terms are ambiguous. For example, in Dahl-Eimers v. Mutual of Omaha Life Insurance Company and Pirozzi v. Blue Cross/Blue Shield of Virginia, the United States Court of

53 Betchold v. Physicians Health Plan of Northern Indiana, Inc., 19 F.3d 322, 324 (7th Cir. 1994).
54 Id. at 324.
55 Id.
56 Harris v. Mutual of Omaha Companies and Rural Carrier Benefit Plan, 592 F.2d 765, 712-713 (7th Cir. 1979).
57 Id.
59 Id.
Appeals for the Eleventh Circuit and the United States District Court for the Eastern District of Virginia, respectively held that when an insurance policy uses the phrase "considered experimental" to define treatment standing alone in a major medical insurance policy, the use of the term "experimental" is ambiguous as a matter of law. Both courts acknowledged that the insurance policies failed to define the term "experimental" or set forth how it would be determined whether a treatment was experimental. Thus, the contract phrase 'considered experimental,' without more, gives rise to a genuine uncertainty about who will determine whether a particular treatment is experimental and how that determination will be made. In Dahl-Eimers, the insurance company even conceded that there could be more than one way to make such a determination.

INTERPRETATION OF UNAMBIGUOUS INSURANCE POLICIES DENYING MEDICAL TREATMENT

Even when an insurance policy is unambiguous as to what treatments it will not cover because they may be considered experimental, courts may still enable women to receive HDCT-ABMT. A policy which is clear as to what treatment it considers to be "experimental," does not prevent a court from examining whether or not the treatment truly is experimental, and justifiably excluded by the policy.

Because judges themselves are no more qualified to reach medical conclusions regarding the investigational nature of cancer treatments than are insurance policy drafters, they often look to physicians. Physicians themselves, however, cannot decide whether HDCT-ABMT is an experimental treatment. As a result, judges are beginning to listen to testimony of many physicians who specialize in the field, and draw conclusions based upon this expert testimony. In looking beyond the insurance plan to consider the actual treatment, judges are giving women even more chances to receive HDCT-ABMT.

62 Id.
64 Dahl-Eimers, 986 F.2d at 1381-1382.
While jurisdictions remain split on the issue of the experimental nature of HDCT-ABMT, at least insurance companies are no longer being given carte blanche to determine independently what kind of treatment is or is not experimental. For instance, in *Holder v. Prudential Insurance Company of America*, the Fifth Circuit held that HDCT-ABMT is experimental treatment because it is not administered under a specific, accepted protocol. Similarly, in *Hooper v. Demco, Incorporated*, the Seventh Circuit concluded that the treatment is experimental. On the other hand, in the relatively recent case of *Wolf and Wolf v. Prudential Insurance Company of America*, the Tenth Circuit concluded the treatment was not experimental when the plaintiff presented evidence from two specializing oncologists that HDCT-ABMT for a woman in plaintiff's situation was not experimental in 1990-1991 under any reasonable definition of the term.

**ALTERNATIVE MEANS OF CHALLENGING INSURANCE POLICIES WHICH DENY TREATMENT**

Although increasing litigation promises still greater analysis of insurance policy contracts and the experimental nature of HDCT-ABMT, women have been finding alternative avenues to contract challenges in order to secure judicial enforcement of insurance coverage for their cancer treatment.

In *Henderson v. Bodine Aluminum, Inc., et al.*, for example, Karen and James Henderson brought suit under the Americans with Disabilities Act of 1990 (ADA) to appeal a district court's refusal to issue a preliminary injunction against her health plan and insurance providers. The Hendersons maintained that Karen's health plan discriminated against her when it denied her physician's request for certain treatment on the ground

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65 *Holder v. Prudential Ins. Co. of Am.*, 951 F.2d 89, 90 (5th Cir. 1992).
66 *Id.*
67 *Hooper v. Demco, Inc.*, 37 F.3d 287, 294 (7th Cir. 1994).
68 *Id.*
69 *Wolf v. Prudential Ins. Co. of Am.*, 50 F.3d 793, 800 (10th Cir. 1995).
70 *Id.*
that as to breast cancer, the treatment was experimental.\textsuperscript{72}

In April 1995, Karen Henderson was diagnosed with an aggressive form of breast cancer.\textsuperscript{73} Her physician recommended that she enter a clinical trial program that randomly assigns half its participants to a regimen of high dose chemotherapy treatment (HDCT).\textsuperscript{74}

The Henderson's health care plan refused to pre-certify Henderson for the treatment in the event that she was chosen to receive the treatment. As a result, she and her husband instituted this action under the ADA, claiming her health plan discriminated against her based on her cancer type.\textsuperscript{75} The Hendersons sought a preliminary injunction requiring Bodine to assure payment for any possible bone marrow therapy.\textsuperscript{76}

In its denial of plaintiff's request for a preliminary injunction, the district court argued that Henderson failed to provide sufficient evidence to show a likelihood of prevailing on her ADA claim because the insurance plan specifically excluded coverage for most cancers and HDCT coverage.\textsuperscript{77} In response, Henderson argued that high-dose chemotherapy treatment for her kind of cancer is not only proven effective, but is an accepted treatment.\textsuperscript{78} In turn, since Bodine covers HDCT for cancers, denying HDCT treatment for breast cancer is discrimination based on disability type, and such discrimination is prohibited by the ADA.\textsuperscript{79}

On appeal, the Eighth Circuit concluded that Henderson's argument might have a chance of succeeding on its merits.\textsuperscript{80} Not only did Henderson provide a range of medical testimony showing that HDCT is safe, widely used, and a valuable treatment, but Bodine failed to introduce any significant evidence to the contrary.\textsuperscript{81}

The ADA is based on Section 504 of the Rehabilitation Act, the basic purpose of which is to ensure that handicapped individuals are not denied jobs or other benefits because of the prejudiced attitudes or ignorance of

\textsuperscript{72} Id.
\textsuperscript{73} Id.
\textsuperscript{74} Id.
\textsuperscript{75} Id. at 960.
\textsuperscript{76} Henderson v. Bodine Aluminum, Inc., 70 F.3d 958, 960 (8th Cir. 1995).
\textsuperscript{77} Id.
\textsuperscript{78} Id.
\textsuperscript{79} Id.
\textsuperscript{80} Id.
\textsuperscript{81} Henderson v. Bodine Aluminum, Inc., 70 F.3d 958, 961 (8th Cir. 1995).
The ADA contemplated the problem of disability-based administration of employee benefits when it set forth the following requirements necessary to establish a violation of the ADA:

1. He or she is a qualified individual with a disability;
2. He or she was either excluded from participation in or denied benefits of some public entity's services, programs, or activities, or was otherwise discriminated against by a public entity; and
3. That such discrimination is by reason of plaintiff's disability.

Although the ADA provides millions of disabled and ill individuals the means to challenge unfair treatment in the workplace, including discriminatory administration of benefits as evidenced by Henderson, use of the ADA to challenge an insurer's refusal to cover HDCT-ABMT accomplishes little more than a policy contract challenge since the issues are subject to analysis of the same factors. For instance, in the face of their ADA challenge the Hendersons still had to grapple with the insurance policy's definitions of covered types of cancer and cancer treatments and the "experimental nature" of the treatment. Fortunately for Karen Henderson, several medical professionals were willing to step forward and extol the virtues of HDCT-ABMT as an accepted treatment for women with advanced-stage breast cancer. Additionally, since the defendant failed to present any evidence to the contrary, Karen Henderson's ADA claim survived review by the Eighth Circuit Court of Appeals.

Ultimately, an ADA claim still subjects a dying woman or her bereaved family to muddle through insurance policy ambiguities with a hope they can find physicians who will support their plight for treatment. However, it is still the insurance contract which remains the pivotal issue and its interpretation by the courts can determine whether a dying patient is entitled to treatment.

CONCLUSION AND UPDATE

In 1990, Blue Cross and Blue Shield took a bold step and decided to cover costs for breast cancer patients in clinical trials of HDCT-ABMT. The effects of this action were three-fold. First, this action removed the cost-barrier to patients for the expensive therapy. Second, by removing the cost-barrier, more patients were enabled to participate in clinical trials, thus speeding up the process of determining the therapeutic value of the treatment. Finally, although Blue Cross and Blue Shield still considers the treatment "experimental," its action may help speed the process of getting that "label" removed and encourage other insurance companies to follow in their footsteps.

84 U.S. Department of Health and Human Services, Journal of the National Cancer Institute, Blue Cross/Blue Shield Decides to Cover Costs for Some Clinical Trials (1994).
85 Id.
86 Id.