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Breast Cancer Patients versus Their Insurers

Who Should Pay for "Experimental" Treatments?

by Denise S. Wolf

Public awareness of breast cancer has heightened in recent years, largely due to the relentless efforts of breast cancer patients. Breast cancer support networks and advocacy groups, as well as educational and research databases, have sprouted throughout the nation. Pressure on lawmakers has led to federal and state funding for research to find new therapies—and improve old therapies—for treating and curing breast cancer.

Breast cancer patients have met with less success, however, when dealing with their insurers. Insurers have in many cases refused to pay for high-dose chemotherapy autologous bone marrow transplants (HDC-ABMT) in women with advanced breast cancer because, according to insurers, this treatment is "experimental," "investigational," "not medically necessary," or "not medically accepted." Insurers argue that their purposes are to ration health care costs and to protect policyholders from wasteful, and even harmful, treatments, rather than to serve as charities or research institutions. Accordingly, insurers insist that they are not obligated to fund "experimental" medical treatments. This debate between insurers and their critics centers on the issue of whether a patient's medical treatment, such as HDC-ABMT for breast cancer, is truly experimental as defined by the health insurance policy.

As a result of this conflict, women with breast cancer, while trying to fight their disease, are simultaneously embattled with their insurers. Breast cancer patients have become not only angry, but also active. This time they are seeking remedies through the courts.

STARTING POINTS FOR LITIGATION

Increases in breast cancer patient litigation against insurers have forced courts to decide the experimental status of particular medical treatments. These decisions ultimately have broad implications on health care policy. Courts, however, are ill-equipped to make these decisions. Even the most well-intentioned judge lacks the knowledge and training necessary to determine whether a new medical treatment is experimental, safe, or superior to conventional treatments. Rather, the legislature is the most appropriate mechanism for meaningful resolution of such disputes. The legislature, unlike the judiciary, can benefit from public hearings and lobbying efforts and can respond on a large scale to the needs and concerns of the community.

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

In the absence of legislation, however, courts must be prepared to resolve disputes over the experimental status of new medical treatments. To date, the federal district courts and the various federal circuit courts of appeals are split on whether insurers must pay for HDC-ABMT for breast cancer. The Fifth and Seventh Circuits have characterized the treatment as experimental and have upheld insurers' denial of coverage. In the Third Circuit, a

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three-judge panel reached the same conclusion, but the decision was later reversed on a wholly unrelated legal technicality. The remaining circuits have not yet ruled on the issue.

A starting point for such litigation is that a health insurance policy is a contract. Courts have traditionally approached litigation between policyholders and insurers as a contract dispute. Because each insurance company's policy is unique, courts must analyze the specific contractual language on a case-by-case basis. Nevertheless, general guidelines can assist the determination of whether a new medical treatment is experimental under the terms of a given insurance policy. Courts have found the following conditions to be essential components in resolving disputes over insurance coverage for breast cancer treatments:

1) the policy must contain sufficient, objective criteria for defining what is "experimental,"
2) the insurer must not operate under a conflict of interest, and
3) the insurer must undertake reasonable efforts in making its coverage determination.

EXCLUSIONARY LANGUAGE

While experts within the medical community continue to argue about whether to endorse HDC-ABMT for breast cancer, all parties agree that further randomized controlled trials are necessary to determine the true value of HDC-ABMT for breast cancer as compared with conventional chemotherapy. The lack of definitive scientific proof on the overall effectiveness of HDC-ABMT, when measured against the physician's deeply rooted obligation to provide the best treatment for his or her patient, presents difficult challenges for oncologists treating women with breast cancer.

A 1991 study reported in the *Journal of Clinical Oncology*[1] found that the majority of oncologists polled would recommend HDC-ABMT for their breast cancer patients. Is widespread use of HDC-ABMT for breast cancer by specialists in the field evidence that it is no longer experimental? Some profess that such evidence does not automatically render it nonexperimental. Instead, they argue that institutions and specialists may use HDC-ABMT for ulterior motives, namely to gain directly through profits, research, and prestige.

In an age of escalating health costs, legitimate efforts to ration make good policy.

Health insurers will pay for medical treatments that are scientifically proven to be safe, effective, and necessary, but will refuse to pay for procedures that have no definite scientific value. Through that practice insurers protect patients from unsafe, ineffective, and wasteful treatments, and curb premium costs for all plan participants. In an age of escalating health costs, legitimate efforts to ration make good policy.

Insurers avoid paying for medically unproven treatments through exclusionary language written into their policies. The exclusions in any particular policy can vary. Among the most frequently employed options are specific exclusions, provisions excluding a particular medical treatment from coverage, and experimental exclusions, broader provisions that exclude coverage for all medical treatments that are experimental.

Specific exclusions tend to be easily defensible in court because they are clearly stated for the policyholder to evaluate upon purchase. There are, however, disadvantages to specific exclusions. First, insurers will face administrative difficulties and costs because they must periodically reevaluate and update their list of specific exclusions. Second, state insurance commissions tend to disfavor specific exclusions as a matter of policy. Third, growing lists of specific exclusions may induce legislative intervention to mandate coverage in certain areas, a prospect that insurers view as undesirable. Finally, insurers risk having to cover all new unproven treatments claimed by policyholders. A policy that lists specific exclusions may give rise to the inference that any treatment not expressly excluded should be covered; in the absence of any specific exclusion, a court may presume that the insurer made an affirmative choice not to exclude the treatment at issue.

More prevalent than specific exclusions are experimental exclusions. A broad experimental exclusion clause simply states that any experimental treatment will be excluded from coverage. While some experimental exclusions do not define experimental, those that do are generally more defensible in court.

Insurers have developed various criteria for defining the experimental status of medical treatments and procedures. These criteria may relate to one or more of the following categories: scientific criteria, research criteria, and professional criteria.

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

Research criteria. The research category focuses on the administration of the treatment, whereby insurers, when making coverage determinations, may consider consent forms, research protocols, or clinical trials as indicia of a treatment's experimental nature.

Professional criteria. In the professional category, insurers place great emphasis on the consensus of medical professionals. Insurers may insist that the treatment be the standard, accepted practice among medical professionals either nationally or within a designated geographic area. Some insurers further require that the treatment be officially endorsed by a nationally recognized medical organization or a governmental body.

Insurers often consider any medical procedure that fails to meet any one of the criteria set forth in its policy as experimental.

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

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

Insurers have refused to cover HDC-ABMT for various cancers, including ovarian cancer, testicular cancer, multiple myeloma, cervical cancer, melanoma, lung cancer, brain cancer, soft tissue cancer, prostate cancer, and colon cancer, as well as for AIDS. When applying for the above-mentioned criteria, insurers have argued that HDC-ABMTs for these particular diseases were experimental. Insurers deny coverage for HDC-ABMT for breast cancer, however, more often than for other cancer therapies.

Some insurers argue that the HDC-ABMT is still subject to clinical trials and protocols, and therefore is not yet regularly practiced by the mainstream medical community. Other insurers cover HDC-ABMT only if it is performed in a medical center affiliated with the National Cancer Institute. Still other insurers, however, do not view HDC-ABMT for breast cancer as experimental, and therefore provide coverage unconditionally.

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

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LITIGATION AS A CONTRACT DISPUTE

Although the formulation of health care policy is outside the province of the judiciary, courts are being asked to determine the experimental status of medical treatments. Ideally, sympathies—either for the insurance company to make rational decisions in a climate of escalating medical costs or for the policyholder who is fighting against a tragic disease—should play little, if any, role in judicial review. Rather, courts should adhere strictly to interpreting the language set forth in a particular health insurance policy.

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

Experimental exclusions that are written into the policy in unambiguous terms should be easily enforceable. Litigation occurs, however, when terms are ambiguous—capable of two or more reasonable interpretations. Courts determine the reasonable meanings of such terms not according to the view of the insurance company, attorney, or physician, but according to the meaning understood by an average policyholder. Because each health insurer's policy is unique, the outcome in any given case is based on a court's interpretation of the policy's terms. Even so, emerging patterns show how courts are approaching disputes regarding health insurance coverage for HDC-ABMT for breast cancer.

The initial, and perhaps most crucial, consideration is the nature of the insurance policy itself. This determines whether the case could be heard in state or federal court, as well as the appropriate standard of review. Private insurance policies, HMO plans, and government plans are subject to state law. Self-insured health plans and employee welfare benefit plans are subject to federal law under the Employee Retirement Income Security Act of 1974 (ERISA).

ERISA establishes a fiduciary's duties under a health insurance plan. A fiduciary must ensure that the policy is operating solely in the interest of its beneficiaries. In addition, a fiduciary has the duty to act diligently and provide a "full and fair review" of claim requests. From a policy perspective, these standards serve to protect employees from

unfair coverage denials. ERISA exempts self-insured group health plans from state insurance laws, regulations, and coverage mandates.

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

GENDER DISCRIMINATION?

An increasing number of breast cancer plaintiffs are alleging that insurers' refusal to cover HDC-ABMT constitutes discrimination in violation of state human rights laws, Title VII of the federal Civil Rights Act, and/or the Americans With Disabilities Act. In 1993, for instance, Memorial Sloan-Kettering Cancer Center in New York City filed a lawsuit against an insurance company, Empire Blue Cross and Blue Shield, for refusing to cover transplants for cancer patients. Many of those patients were breast cancer patients receiving HDC with blood product support. According to Memorial, Empire covered HDC with blood product support for cancers "that have a disproportionate incidence among males (e.g., testicular cancer), and cancers that have a gender neutral incidence (e.g., lymphoma)," yet refused to pay for analogous cancer treatments that have a "disproportionately high incidence among females, such as breast cancer." Memorial's complaint concluded, among other things, that this gender correlation in coverage was discriminatory in violation of New York State Human Rights Law and the Civil Rights Laws of the Administrative Code of New York City. As of the end of 1995, the case was still pending, and settlement negotiations were ongoing.

To date, two federal district courts in *Reger v. Espy* and *Linker v. Blue Cross and Blue Shield of Oregon*, and the federal Court of Appeals in the Eighth Circuit in *Henderson v. Bodine Aluminum, Inc.*, have heard gender discrimination claims involving HDC-ABMT for breast cancer. Of these, only *Roger v. Espy* has gone to trial, while the others involved preliminary proceedings that have yet to go to trial on the merits. Bonnie Reger was a female employee insured by Blue Cross and Blue Shield of Georgia. Her policy explicitly excluded, as experimental, coverage for HDC-ABMT for breast cancer. The plan did, however, cover HDC-ABMT for five other cancers.

Reger filed suit in federal district court alleging that the plan's neutral exclusion violated Title VII of the Civil Rights Act of 1964 because it had a disparate impact on females. Two factors were critical to this claim. First, more than 99 percent of all breast cancers are in women. Second, breast cancer is the most commonly occurring cancer in women in the United States and is the most common reason for performing HDC-ABMT.

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

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

In light of the Supreme Court's reasoning in *General Electric Company v. Gilbert*, gender discrimination claims relating to the exclusion of HDC-ABMT for the treatment of breast cancer may not ultimately prevail. *Gilbert* involved an insurance package that excluded disabilities arising from pregnancy. The Court reasoned that the insurance package was nondiscriminatory because "[t]here is no risk from which men are protected and women are not. Likewise, there is no risk from which women are protected and men are not." The Court, finding no proof that the insurance package was worth more to men than to women, found no gender-based discriminatory effect. Thus, the Court held that failure to cover pregnancy-related disabilities did not constitute gender discrimination in violation of Title VII of the Civil Rights Act of 1964.

STATE MANDATES AND STATUTES

In response to the growing controversy surrounding insurance coverage of HDC-ABMT for breast cancer, several states have intervened and enacted legislation. They include Minnesota, Georgia, Massachusetts, New Hampshire, Rhode Island, Virginia, and Florida. Similar legislation is pending in other states. Legislative action addressing this issue has taken four approaches: mandates, multitier systems, devising committees to mandate coverage, and establishing criteria for coverage of cancer therapies.

Mandates bar insurers from denying coverage for particular medical treatments under experimental exclusions. To date, Minnesota, Massachusetts, and New Hampshire are the only states to pass legislation mandating that insurers cover HDC-ABMT for breast cancer. Similar proposals are pending in California, New York, Connecticut, and Ohio. All the proposed bills, as well as the Minnesota and New Hampshire statutes, cover all women with breast cancer. The Massachusetts mandate, however, applies only to women

with metastatic breast cancer.

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

Although the adoption of mandates for HDC-ABMT coverage is a major victory for breast cancer activists, as a policy matter mandates are short-sighted in that they completely ignore the insurance industry's legitimate concerns. First, mandates severely distort the marketplace, causing premiums to rise. Second, the proliferation of mandates increases the likelihood that employers will switch to an ERISA self-funded plan, which is exempt from state mandates. Third, the genre of mandates sets a dangerous precedent, in that future coverage mandates may involve medical procedures that are truly experimental in that they have not yet successfully and fully completed any scientific trials.

A multitier system operates as a type of "opt-in" approach. For example, in Virginia, insurers must offer coverage for HDC-ABMT for breast cancer. Policyholders, however, must also expressly request the coverage and pay higher premiums for it. Georgia, Tennessee, New Jersey, and Missouri legislators also passed a bill requiring that insurers make available coverage for bone marrow transplants for the treatments of breast cancer. Similar legislation has been introduced in Louisiana.

This approach recognizes the interests of both the insurance company and the breast cancer patient. A multitiered system offers standard care to all policyholders, while providing the option of additional nonstandard care. Yet it places a substantial burden on consumers to request, research, and understand the complex insurance coverage options. Because individuals often purchase a coverage option ignorantly or without full information, they have equal bargaining power with the insurer in only the most technical sense. Moreover, the multitier legislation does not always cap the premiums an insurer may charge for additional coverage. As such, a policyholder who wants additional coverage due to her family history of breast cancer may still be unable to afford such coverage. To resolve the question of whether insurers should provide coverage for HDC-ABMT, Judge John L. Coffey of the Seventh Circuit, in Fuja v. Benefit Trust Life Insurance, recommended establishing regional cooperative committees comprised of oncologists, internists, surgeons, experts in medical ethics, medical school administrators, economists, representatives of the insurance industry, patient advocates, and politicians. Judge Coffey's suggestion closely matches legislation enacted in Florida.

Florida's statute mandates that health insurance policies cover all bone marrow transplants for specifically designated cancers. These cancers are chosen by a committee, Florida's Bone Marrow Transplant Advisory Board. The committee is comprised of both oncologists and insurance representatives. Through this process, Florida's approach, unlike the mandates in Massachusetts, Minnesota and New Hampshire, takes into consideration the insurance industry's interests.

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

Let the Record Show

by Karen L. Illuzzi Gallinari

The insurance industry's attempts to deny coverage for medically necessary treatments that are still being studied and refined have caused an unfortunate stampede of lawsuits. Over the past five years there have been numerous lawsuits throughout the United States involving insurance coverage for state-of-the-art medical treatments, such as high-dose chemotherapy supported by bone marrow or peripheral stem cell rescue for breast cancer. Until recently, most insurance policies have had some type of general exclusion for experimental or investigational treatment. Today many insurance companies are attempting to deny coverage by drafting very specific exclusions.

The following excerpts from a few court decisions exemplify the urgency and reality of this continuing problem. In *Rollo v. Blue Cross/Blue Shield* (1990), a case in which the court ordered coverage for a bone marrow transplant for Wilms' tumor in an eight-year old girl, United States District Judge Maryann Barry commented:

> "What is seen here are physicians on the frontiers of knowledge, who for many years have been improving an existing procedure. What is seen here is ABMT with high-dose chemotherapy for relapsed Wilms' tumor having been medically accepted to the point where it is performed at prestigious hospitals across the country and throughout the world. What is seen here are children who now live when, before, they would surely die."

In a different United States District Court decision involving a bone marrow transplant for brain cancer in a thirteen-year-old boy, the District Court judge denied coverage under a policy that covered bone marrow transplants only for a few diseases specifically listed. Unfortunately, the child's type of brain cancer was not among those specifically listed. In *McLeroy v. Blue Cross/Blue Shield* (1993), the District Court judge noted:

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Unlike legislation in other states that specifically addresses HDC-ABMTs, Rhode Island's approach allows for the evolution of all cancer therapies. The Rhode Island statutes require that all health insurance organizations cover experimental cancer therapies, provided, however, that certain delineated criteria are met. These criteria include stipulations that governmental organizations approve treatment pursuant to Phase III and IV clinical trials, and that there is no existing superior alternative treatment. Also, the statute insists that patients meet all protocol requirements. Finally, the procedure must be performed in appropriate facilities with experienced personnel.

In essence this legislation preempts any criteria for defining applicable experimental exclusions that are enumerated in a health insurance policy. Insurers, however, still must include defining criteria for experimental exclusions, as this legislation applies solely to cancer therapies. Although Rhode Island's statute does not specifically include the insurance industry in determining the necessary criteria, it adequately protects the industry's interests.

In states that have not enacted such legislation, courts must be prepared to resolve disputes between insurers and breast cancer patients. Courts should require insurers to clearly define experimental exclusions through objective criteria. Moreover, courts should require that insurers modify their decision-making process to ensure an objective coverage review. This could be achieved in several ways.

- Immediately eliminate any internal bonus scheme, whereby plan administrators have incentives to keep costs down through coverage denials or, in the case of HMOs, eliminating referrals to specialists. Instead, implement schemes that discourage administrators from making inappropriate decisions.
- Designate an independent committee, consisting of medical experts to make binding coverage determinations on a case-by-case basis. If the insurer is free to reject the findings of the independent committee, then a conflict of interest has not been fully eliminated.
- Structurally detach its coverage pool of funds from any profit-maximizing aims of the business, such as establishing a trust.

Courts should not uphold an insurer's coverage decision if the insurer did not execute reasonable efforts in arriving at its coverage determination. First and foremost, coverage decisions should be made only by competent medical directors, preferably those who are board certified and experienced in the specific discipline of medicine that governs the proposed treatment, such as oncologists in the case of HDC-ABMT for breast cancer. Reasonable efforts include reviewing thoroughly all materials submitted by a policyholder and the patient's physician, conferring with specialists in the proposed treatment area about the appropriateness of the proposed treatment, and consulting the official positions of nationally recognized medical organizations.

Requiring objective criteria, no conflict of interest, and reasonable efforts will instill more equity into a system where unequal bargaining power exists, provide greater protection for the policyholder, and achieve the insurer's goal of eliminating harmful, wasteful treatments. Consistent, uniform court decisions promoting these aims will help transform the relationship between a breast cancer patient and her insurer from one of conflict to one of cooperation. After all, neither insurers nor breast cancer patients can afford more battles.

> "The record shows that without the requested [HDC/ABMT], Andrew McLeroy has a possible life expectancy of only from about three to six months (perhaps... less than that at this point in time). There is no question that the requested treatment is medically appropriate under the circumstances and is the only treatment which holds any promise whatever of benefit to the plaintiff. Decision in this case, therefore, may be literally a matter of life and death."

The judge then implored the Appellate Court to immediately review the case and implied that he hoped it would reverse his decision.

In *Goepel v. Mail Handlers Benefit Plan* (1993), the court denied coverage to a woman seeking a bone marrow transplant for breast cancer due again to the unusual specificity of the policy language. The judge stated:

> "Neither the federal or state courts are the proper vehicles to make health care policy, a task which our constitutional system leaves to the legislative and executive branches of our state and federal governments... [T]he pain of health care rationing must be dealt with in the political arena, not in the courts."

Consumers continue to persuade their state legislatures that something must be done. Varieties of legislation continue to crop up in state after state. Ten states—Florida, Georgia, Massachusetts, Minnesota, Missouri, New Hampshire, New Jersey, Rhode Island, Tennessee, and Virginia—have already passed versions of legislation requiring that coverage be available for appropriate new treatments. Insurance companies that serve more than one state need to deal with differences in legislation. The lack of consistent coverage standards is also a serious concern for regulators and employers. Some sensible compromise is clearly needed to put medical decisions back in the hands of qualified physicians.

A panel of the National Association of Insurance Commissioners led by the Washington State Insurance Commissioner, Deborah Senn, drafted a model statute that would prevent insurers from excluding any treatment or therapy that conforms to certain medical criteria. Anyone may obtain a copy by contacting the association in Kansas City, Mo.

REFERENCE

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