Experimental Medical Treatments: Who Should Decide Coverage?

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INTRODUCTION

Imagine you or your wife, your sister, your mother, your aunt, or your best friend, has just been diagnosed with breast cancer. Treatment is expensive. What if you or your loved one does not have medical insurance? Worse yet, what if you or your loved one has medical insurance, but it does not cover the treatment you need to survive?

What are you going to do? Can you pay for the treatment out of pocket? What if it costs anywhere from $100,000-$300,000? If you do not have that kind of money sitting in the bank, can you raise the money? Will friends and family and the community donate their hard earned dollars to save a life? In the case of Nelene Fox, her family and community did just that.¹

Unfortunately, the efforts of family and community were too late. By the time Nelene raised enough money to afford the High Dose Chemotherapy and Bone Marrow Transplant (HDC-ABMT) her doctor recommended, the cancer had advanced and her body had deteriorated to such a degree that the procedure could not help her.² Nelene Fox had health insurance coverage through her employer, but was denied coverage for the treatment by her health maintenance organization, HealthNet, because HealthNet deemed the coverage to be experimental.

What caused the death of Nelene Fox: the cancer or the inability to get the treatment that she so desperately needed when she needed

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2. Id.
it? If a treatment can add a few years to someone like Nelene Fox's life, should an HMO be required to pay for the treatment? Does it matter what an insurer should do in those circumstances, or is the only relevant consideration what the insurer must do according to the terms of the insurance policy? As the law stands, coverage decisions with regard to experimental treatment provisions are left to the whim of the insurer or the rushed decision of a trial court. No uniform method exists on which insurers, policyholders, doctors, or courts can rely when determining whether an experimental treatment should be covered. As a result, coverage determinations are erratic and inconsistent.

For example, with regard to HDC-ABMT, some courts have ruled that HDC-ABMT is not experimental. Others have ruled the treatment is experimental. Still others have declined to decide whether the treatment is experimental and have determined coverage based on other grounds. In light of the inconsistent judicial opinions, some state legislatures have taken matters into their own hands. Eleven states have passed legislation that requires health benefit providers to offer or provide autologous bone marrow transplants for breast cancer patients regardless of experimental or investigational contract provisions. Unfortunately, the legislation currently written is inconsistent and is not available to all breast cancer patients.

HDC-ABMT for breast cancer patients is not the only controversial procedure to be classified as experimental or investigative. The same concerns arise when dealing with any new or experimental treatment. To illustrate the controversy surrounding experimental treatment provisions in general, this Comment examines the case law and resulting legislation pertaining to HDC-ABMT as a treatment for breast cancer. Part I presents background information on autologous bone marrow transplants generally, and how the treatment relates specifically to breast cancer patients. Part II presents a survey of current law regarding coverage of HDC-ABMT for breast cancer. Part III explores the merits and limits of judicial and legislative determinations of whether a particular treatment is covered under an insurance

6. California, Florida, Georgia, Kentucky, Massachusetts, Minnesota, Missouri, New Hampshire, New Jersey, Tennessee, and Virginia have promulgated such legislation. Illinois and Maine are considering similar bills. See also infra notes 119-148 and accompanying text.
policy. Part III then concludes that while judicial and legislative intervention may be appropriate, these methods fail to uniformly secure treatment for breast cancer sufferers. Part IV presents alternatives to existing judicial and legislative determinations. Specifically, this Comment recommends more expansive legislation that addresses experimental procedure exclusions generally and proposes a model statute.

I. UNDERSTANDING HDC-ABMT AND BREAST CANCER

To understand the numerous variables that are considered when determining whether a procedure is experimental, it is helpful to look at background information about both the disease—breast cancer, and the treatment—HDC-ABMT. Decisionmakers must take into consideration factors such as how common the disease is, whether the treatment is used to treat other diseases, and what kinds of success rates accompany the procedure. Breast cancer is an appropriate example because the disease is common and touches many peoples' lives. If you think the disease will not affect your life or your loved ones, the statistics prove you wrong. Each year the number of women in the United States who are diagnosed with breast cancer exceeds 180,000. Breast cancer ranks as the most common form of cancer in women, numbering 184,300 new invasive cases in 1996. Breast cancer is the second leading cause of cancer death in women, with an estimated 44,300 deaths in 1996.

HDC-ABMT has emerged as a last resort treatment for breast cancer patients. Despite the wide use of HDC-ABMT in the treatment of other cancers such as leukemia or Hodgkin's disease,

7. Breast cancer is cancer initiating in breast tissue. Generally, cancer occurs when cells which make up the various organs of the body divide in an uncontrolled or disorderly manner. Typically, cells divide and produce more cells only when they are needed. In a cancer patient, cells divide when new cells are not needed and form an extra mass of tissue commonly called a tumor. Only malignant tumors are cancerous.

Cancer cells may invade nearby tissues and organs or they may enter the bloodstream or lymphatic system. This spread of cancer is called metastasis. When cancer spreads in this manner and attacks other parts of the body, the disease carries the same name as the primary cancer. For example, if a person was afflicted with breast cancer and the cancer cells spread, the disease is referred to as metastatic breast cancer. NATIONAL CANCER INSTITUTE, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, NIH PUB. NO. 94-1556, WHAT YOU NEED TO KNOW ABOUT BREAST CANCER 2-3 (1993).

8. Id. at 28.


10. Id. at 11-12.

11. Fuja, 18 F.3d at 1407.
insurance coverage for HDC-ABMT treatment of breast cancer has been erratic at best.

HDC-ABMT is a type of systemic treatment for cancer that involves a two-part procedure. First, a physician extracts from the patient her own bone marrow cells which are then frozen. Next, the patient undergoes high-dose chemotherapy in an attempt to kill the cancer cells. The dose of chemotherapy is near lethal, and may be one thousand times more potent than that of standard chemotherapy. The patient’s remaining bone marrow is destroyed in the chemotherapy process. Once chemotherapy is completed, the patient’s own, “autologous,” frozen marrow is reinfused intravenously into the patient’s bloodstream. After the chemotherapy and transplant, the patient’s immune system is essentially nonfunctional until the bone marrow begins producing new blood cells. Because of susceptibility to viral infections, great care, including extensive hospitalization, must be taken to prevent the patient from becoming infected. The cost of this procedure carries an expensive price tag, ranging from $100,000-$300,000.

The HDC-ABMT procedure has been criticized for having an “excessive” mortality rate. The high dose chemotherapy used to kill cancerous cells, coupled with the bone marrow transplantation, imposes serious trauma on the body. However, current studies indicate higher response and survival rates from HDC-ABMT treatment as compared

12. Many treatment options are available to breast cancer patients. The method of treatment varies according to the size and location of the tumor, various test results, and the stage of the disease. However, there are two basic methods of treatment, local or systemic. Local treatments remove or destroy the cancer cells in a specific area and include surgery and radiation therapy. Systemic treatments, which destroy or control cancer cells all over the body, are used when the cancer has metastasized. Chemotherapy and hormone therapy are two kinds of systemic treatments. NATIONAL CANCER INSTITUTE, supra note 7, at 12-13.
13. Fuja, 18 F.3d at 1407.
14. Id.
16. Id. Replacement marrow may also be donated by another person. This treatment is called allogenic bone marrow transplantation. NATIONAL CANCER INSTITUTE, supra note 7, at 33.
18. Id. See also Nessium v. Mail Handlers Benefit Plan, 995 F.2d 804, 805 (8th Cir. 1993) (procedure cost $160,000); Kekis, 815 F. Supp. at 575 (procedure cost $150,000); White v. Caterpillar, Inc., 765 F. Supp. 1418, 1420 (W.D. Mo.), aff'd, 985 F.2d 564 (8th Cir. 1991) (procedure cost $195,000); Pirozzi, 741 F. Supp. at 588 (procedure cost $100,000); Insurance Bad Faith, supra note 1, at 84 (procedure cost $212,000).
19. Fuja, 18 F.3d at 1411.
to patients treated with standard chemotherapy. HDC-ABMT also causes tumor shrinkage, which in turn leads to an increased survival rate. Despite research which indicates that HDC-ABMT results in higher response, survival, and tumor shrinkage rates when compared to standard chemotherapy, HDC-ABMT still has a low survival rate overall. Depending on the data analyzed, the survival rates of persons undergoing bone marrow transplants range from five to twenty percent.

Because of the low survival rates and the high cost of the procedure, insurance companies are hesitant to pay for HDC-ABMT and physicians do not recommend the procedure unless it is the patient’s last hope. Therefore, the recommendation and coverage of this treatment has led to extensive litigation.

II. SURVEY OF CURRENT LAW

A. Case Law

The case law surrounding HDC-ABMT reflects the controversial nature of its subject matter. Decisions show that the courts cannot make consistent individual determinations, let alone broad policy statements. The cases described below demonstrate that the courts are an inappropriate forum for coverage determinations regarding experimental treatment provisions.

Judicial interpretation of experimental treatment provisions have been inconsistent. The 3rd, 5th, and 7th Circuits have ruled that HDC-ABMT as a treatment for breast cancer is experimental and not covered. In contrast, the 8th Circuit characterized HDC-ABMT as experimental only with regard to treating some forms of cancers such as melanomas, but not with regard to treating advanced cancer. Other courts have not addressed the issue of whether the treatment is experimental, but have ruled in favor of requiring insurance companies

20. See infra notes 169-183 and accompanying text.
22. Hardester, supra note 17, at 294.
to pay for the treatment on other grounds.25 Finally, the 4th Circuit skirted the experimental treatment issue by upholding the insurer's decision to deny coverage based on the express policy language.26

The inconsistent body of precedent allows courts to ignore the issue of the character of the treatment and either deny or provide coverage by relying on contract principles and the language of the insurance policies. The inconsistency also allows courts to order or deny coverage based on expert testimony regarding the utility and efficacy of the treatment. As the case law stands, medical decisions that should be decided on a doctor-patient level, as well as insurance decisions that should be decided on a insurer-insured level, are being decided on a judicial level. Unfortunately, at the judicial level the decisionmaker is least interested in the outcome, and least knowledgeable about the medical consequences.

1. Determining Whether Treatment is Experimental or Not

Some courts have defined HDC-ABMT as nonexperimental. In Jenkins v. Blue Cross Blue Shield of Michigan,27 the court found that HDC-ABMT did not fall under the provision excluding services that are experimental or investigational.28 In Jenkins, the claimant's insurance policy included two "riders"—the Rider BMT and the Rider GLE-1.29 The Rider BMT provided that HDC-ABMT would only be covered when performed to treat specified diseases, of which breast cancer was not listed.30 The court found that this language was clear and that the procedure was not covered under this provision.31

However, the court went on to assess whether the Rider BMT excluded coverage for high dose chemotherapy where chemotherapy is a covered treatment for breast cancer under the plan. Under those circumstances, the court held that the insurer could deny coverage for bone marrow transplants but not for high dose chemotherapy.32 The court further adopted the reasoning of the court in Doe v. Group

27. No. 8:93 CV 7295, 1994 WL 901184 (N.D. Ohio May 9, 1994).
28. Id. at *8.
29. Id. at *1. The Rider BMT sought to exclude autologous bone marrow transplants for breast cancer patients. The Rider GLE-1 excludes services that are "experimental" or "investigative.
30. Id. at *5.
31. Id. at *6.
32. Id. at *6-8.
Hospitalization & Medical Services, that the actual treatment for breast cancer is the high dose chemotherapy and that the bone marrow transplant is only necessary to avoid the disastrous side effects of the chemotherapy. \(^{34}\)

Finally, the court analyzed whether, despite coverage of standard chemotherapy, Rider GLE-1 excluded coverage for HDC because it was experimental. The court found the treatment was not experimental and therefore not excluded from coverage. \(^{35}\) The court relied heavily upon the testimony of the plaintiff's expert, Dr. Bolwell. \(^{36}\) Dr. Bolwell testified that HDC-ABMT is "accepted as standard therapy for treatment of many malignancies. This procedure is not 'experimental' in the treatment of patients such as [plaintiff] with inflammatory carcinoma of the breast." \(^{37}\) Dr. Bolwell also testified that although the treatment was administered pursuant to a study, that did not support the treatment as experimental. \(^{38}\) Further, Dr. Bolwell testified that the procedure was being performed in "virtually every major cancer center in this country. . . . 'Leading oncologists throughout the country recognize the importance of continued treatment for selected patients with breast cancer using [ABMT].'" \(^{39}\) The court ultimately concluded with very strong language that "[r]easonable minds could only conclude that HDC [for breast cancer] is neither experimental nor investigational." \(^{40}\) "Clearly, HDC in conjunction with ABMT is now accepted nationwide as a treatment for breast cancer." \(^{41}\)

\(^{33}\) See also Jenkins, 1994 WL 901184, at *7-8. The court explained, To allow Blue Cross to rely on Rider BMT to avoid payment for high dose chemotherapy when it is undisputed that chemotherapy is covered elsewhere in the Policy would be, as the Wilson court held, to let the tail wag the dog. It is the high dose chemotherapy that kills the cancer cells; the bone marrow transplant merely protects the patient's bone marrow.

\(^{34}\) Jenkins, 1994 WL 901184, at *8. See also Tepe v. Rocky Mountain Hosp. and Med. Serv., 893 P.2d 1323 (Colo. Ct. App. 1994) (upholding decision to provide coverage where policy expressly provided coverage for bone marrow transplants and chemotherapy procedures; finding that read together these provisions supported the trial court determination that HDC-ABMT for breast cancer was covered under the policy).

\(^{35}\) Jenkins, 1994 WL 901184, at *11.

\(^{36}\) Id. at *10. Brian Bolwell, M.D. specializes in HDC-ABMT and is the Director of the Bone Marrow Transplant Program at Cleveland Clinic. Id.

\(^{37}\) Id. at *10 (citing Bolwell affidavit at para. 17).

\(^{38}\) Id. at *11.

\(^{39}\) Id. at *11 (citing Bolwell affidavit at para. 19).

\(^{40}\) Id. at *12.

\(^{41}\) See also Taylor v. Blue Cross/Blue Shield of Michigan, 517 N.W.2d 864 (Mich. Ct. App. 1994) (holding that in light of medical testimony indicating HDC-ABMT is an effective
Similarly, in Adams v. Blue Cross/Blue Shield of Maryland, Inc., the court ruled that HDC-ABMT treatment for breast cancer was not experimental and that the procedure was generally acknowledged as accepted medical practice. The plaintiffs in Adams sought pre-authorization for HDC-ABMT as the best available care for their breast cancer. Blue Cross/Blue Shield denied coverage, acknowledging that HDC-ABMT was covered for other diseases such as Hodgkin's Lymphoma, acute leukemia and testicular cancer, but claiming the treatment was experimental when used to treat breast cancer. The claimant's insurance policy in Adams defined the term "experimental or investigative" to mean "any treatment . . . not generally acknowledged as accepted medical practice by the suitable medical specialty practicing in Maryland."

The court found that at the time Blue Cross/Blue Shield denied coverage, Maryland oncologists generally acknowledged HDC-ABMT as accepted medical practice. The testimony revealed that oncologists regularly refer breast cancer patients to institutions which administer HDC-ABMT. Moreover, experts testified that the treatment was being offered at major medical centers nationwide. The court found this evidence to be persuasive that the treatment was generally accepted medical practice; and, therefore, did not fall under the definition of "experimental" as set out in the insurance policy.

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43. Id. at 669. This case is a consolidation of two cases, one brought by Mrs. Adams and one by Mrs. Whittington. Mrs. Adams was a thirty-four-year-old mother of two. She was diagnosed in 1990 with "Stage II" or "Stage III" breast cancer. Mrs. Adams’ cancer had spread to 18 of her 27 lymph nodes by the time the cancer was detected. Mrs. Whittington was a twenty-nine-year-old mother of two who was diagnosed with "Stage IV" breast cancer in 1990. Id. at 664-665.

In "Stage II," the tumor measures from two to five centimeters and has spread to the lymph nodes under the arm. In "Stage III," the tumor measures more than five centimeters and involves auxiliary nodes, or lymph nodes near the breast. In "Stage IV," the cancer has metastasized or spread to other organs of the body. Id. at 664-665. See also NATIONAL CANCER INSTITUTE, supra note 7, at 18-19.

45. Id.
46. Id. at 663.
47. Id.
48. Id.
49. Id. at 676. The court also noted that the fact that the treatment was being provided in connection with a research protocol in no way transforms the generally accepted practice into an "experimental" procedure. Id. at 675.
Along similar lines, courts have also provided coverage where HDC-ABMT has sufficiently proven medical value, and where the procedure is in accordance with generally accepted medical standards. In Pirozzi v. Blue Cross-Blue Shield of Virginia, the plaintiff was suffering from Stage IV metastatic breast cancer. She received numerous methods of treatment throughout the course of her cancer including a mastectomy, six cycles of chemotherapy, and radiation therapy. Because the cancer continued to spread throughout Pirozzi’s rib cage, her treating physician recommended this thirty-five-year-old mother of three undergo HDC-ABMT as her “best chance for any type of meaningful survival.”

Pre-authorization for the procedure was denied based on an experimental procedure exclusion. Pirozzi argued that the treatment is not experimental but is “the medically indicated, state of the art, generally accepted treatment for her disease.” To resolve this dispute, the court analyzed the plain meaning of the contract language and the expert testimony presented at trial. The court interpreted the contract language to mean if a treatment has a scientifically proven value or is in accordance with generally accepted standards of medical practice then it is not experimental.

Further, the court relied on the expert testimony of Dr. Beveridge, in charge of bone marrow transplants at Fairfax County Hospital in Virginia. Dr. Beveridge testified that the treatment was “the medically necessary and effective treatment for plaintiff given her condition.” Further, he explained that the treatment is used at most major medical centers. Based on this testimony and the extensive

51. Id. at 588. “Stage IV” refers to cancer that has metastasized. This means it has spread to other organs of the body. Id. at 588, n.3.
52. Id.
53. Id.
54. Id. at 590. The court found that the insurance contract excluded three types of treatments: 1) experimental or clinical investigative treatments, 2) treatments of no scientifically proven value, and 3) treatments not in accordance with generally accepted standards of medical practice. Id.
55. Id.
56. Id. at 591.
57. Id.
58. Id. The major medical centers cited by Dr. Beveridge as using HDC-ABMT include: Duke University, Fairfax County Hospital, George Washington University, Georgetown University, Harvard University, Johns Hopkins University, Medical College of Virginia, Houston’s M.D. Anderson Hospital, University of Chicago, University of Michigan, University of Nebraska, University of Texas—San Antonio, University of Virginia Medical Center, University of Wisconsin, Yale University Medical School, and all Florida teaching hospitals.
evidence presented at trial, the court concluded that the treatment has scientifically proven value and is in accordance with generally accepted standards of medical practice. Thus, the treatment was not experimental.

In contrast, other courts have denied coverage based on a finding that the treatment is not medically necessary. In Fuja v. Benefit Trust Life Insurance Co., thirty-seven-year-old Grace Rodela Fuja sued her insurer for denying coverage for HDC-ABMT to treat her breast cancer. The insurance contract required that the policyholder show the treatment was "medically necessary" according to five criteria, including treatment that is "not furnished in connection with medical or other research." Mrs. Fuja failed to meet this burden because evidence presented at trial indicated the treatment was clearly "in connection with medical or other research." The court further indicated that the testimony presented to the trial court established the "uncertain medical value" of HDC-ABMT.

Other courts have ruled that HDC-ABMT as a treatment for breast cancer is experimental under the terms of the insurance policy. In Harris v. Mutual of Omaha, the plaintiff's insurance policy contained an experimental treatment exclusion. The policy provided that a treatment was experimental if "Reliable Evidence" showed either that the treatment was the subject of on-going Phase I, II, or III clinical trials; or under study to determine its maximum tolerated dose, its toxicity, or its efficacy; or that there was a consensus of opinion

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59. Id. at 594.
60. Id. The court limited its holding requiring coverage to the Plan described in this case based on the expert testimony presented in this particular trial. Id.
61. 18 F.3d 1405 (7th Cir. 1994).
62. Id. at 1407.
63. Id. at 1408. The contract defined "medically necessary" as treatments that are:
[1] required and appropriate for care of the Sickness or the injury; or that are [2] given in accordance with generally accepted principles of medical practice in the U.S. at the time furnished; and that are [3] approved for reimbursement by the Health Care Financing Administration; and that are [4] not deemed to be experimental, educational or investigational in nature by any appropriate technological assessment body established by any state or federal government; and that are [5] not furnished in connection with medical or other research.

Id. Because the "medically necessary" requirement falls under the "benefits" section as opposed to the "exclusions" portion of the contract, Mrs. Fuja bore the burden of proving the treatment was medically necessary. Id.
64. Id. at 1410.
65. Id. at 1412.
66. 992 F. 2d 706 (7th Cir. 1993).
67. Id. at 708.
among experts that further studies or clinical trials were necessary to determine the maximum tolerated dose, toxicity, or efficacy.68 “Reliable Evidence,” according to the policy, was a term of art and was limited to published reports and articles in authoritative medical and scientific literature, written protocols used by the treating facility, and written informed consent used by the treating facility.69

The plaintiff in Harris received the treatment as part of a Phase II clinical trial, the goal of which was to gather data on response rate, toxicity and survival rates.70 The court reviewed eighteen articles which concluded that HDC-ABMT was currently in the developmental stage and required more clinical research before it could be considered standard treatment for breast cancer.71 Based on the evidence presented, the court found the treatment was experimental according to the policy’s definition and, therefore, not covered.72

Similarly, in Holder v. Prudential Insurance Co.,73 the court found that HDC-ABMT was experimental both with regard to the policy terms and as a matter of law.74 The plaintiff’s insurance policy specifically excluded from coverage treatment that was not medically necessary for medical care.75 For a treatment to be reasonably necessary, the policy required that it be ordered by a doctor, customarily recognized as appropriate, and not experimental.76 The lower court relied on evidence that clinical studies showed that HDC-ABMT for the treatment of breast cancer was still being investigated at the time the plaintiff underwent the procedure.77 The lower court also noted that the plaintiff was one of only twenty to thirty women nationwide to receive the treatment pursuant to the particular protocol she received.78 Based on this evidence, the circuit court ruled there was no error in the lower court’s finding that the treatment was experimental under the policy’s terms.79

The plaintiff’s argument that HDC-ABMT for breast cancer is not experimental as a matter of law was also rejected by the court.

68. Id.
69. Id.
70. Id. at 709.
71. Id. The articles were all published between 1986 and 1992.
72. Id. at 713.
73. 951 F.2d 89 (5th Cir. 1992).
74. Id. at 90-91.
75. Id. at 90.
76. Id.
77. Id.
78. Id.
79. Id. at 91.
The court went on to distinguish cases where various courts allowed coverage despite exclusionary provisions.\textsuperscript{80} This part of the decision is undermined, however, by the court's statement that "[h]ad [plaintiff] undergone a similar treatment more recently under an accepted protocol, this case may have turned out differently."\textsuperscript{81} As the court explained in a footnote: "Several recent studies and the cases in which they have been applied to compel coverage . . . lead to the conclusion that the treatment, under a different protocol than that administered to [plaintiff], may no longer be considered experimental."\textsuperscript{82}

2. Determining Coverage on Other Grounds

From a procedural standpoint, some courts have been willing to grant injunctive relief and treatment coverage when insurers denied coverage without following the procedures in their own policies. In \textit{Kekis v. Blue Cross and Blue Shield of Utica-Watertown, Inc.},\textsuperscript{83} Ms. Kekis suffered from particularly high risk breast cancer.\textsuperscript{84} With standard chemotherapy, her doctors were not optimistic about her survival. Ms. Kekis's treating oncologist recommended HDC-ABMT and Ms. Kekis was able to enroll in a research protocol.\textsuperscript{85} When the hospital performing the research sought pre-authorization, it was denied based on a clause in Ms. Kekis's policy which excluded experimental or investigative services from coverage.\textsuperscript{86}

In analyzing the evidence presented at trial, the court focused on the \textit{determination} of the nature of the procedure, rather than evidence about the procedure itself. The court found that Blue Cross and Blue Shield (BC/BS) did not follow the provisions in the policy with regard to determining experimental or investigative exclusions.\textsuperscript{87}

The court found that BC/BS applied a dictionary definition of what is experimental when they denied coverage.\textsuperscript{88} Because BC/BS

\textsuperscript{80} \textit{Id.}\textsuperscript{81} \textit{Id.}\textsuperscript{82} \textit{Id. at 91, n.5 (citing White v. Caterpillar, 765 F. Supp. 1418 (W.D. Mo.), aff'd, 985 F.2d 564 (8th Cir. 1991); Bucci v. Blue Cross-Blue Shield Inc., 764 F. Supp. 728 (D. Conn. 1991); Adams, 757 F. Supp. at 661).}\textsuperscript{83} \textit{Id. at 573 (N.D.N.Y. 1993).}\textsuperscript{84} \textit{Id. at 574.}\textsuperscript{85} \textit{Id. at 575.}\textsuperscript{86} \textit{Id. at 579.}\textsuperscript{87} \textit{Id. The policy itself provided a working definition of what was considered to be experimental or investigative treatment by BC/BS: a procedure is experimental/investigative under the policy only if, in the view of BC/BS, the service or procedure has no proven medical value. If BC/BS determines
did not follow the definition in its own policy, the court held the BC/BS reviewer’s determination to be arbitrary and capricious. In contrast, Kekis was able to show through expert testimony that HDC-ABMT has proven medical value. On this evidence, the court granted the injunction.

The Kekis court relied on Dosza v. Crum & Forster Insurance Co. in reaching its conclusion. Dosza involved HDC-ABMT for a multiple myeloma patient. The insurer in Dosza denied coverage based on an experimental procedure exclusion clause. The court held such denial was arbitrary and capricious because the determination did not conform with the terms set out in the health plan. In essence, the insurance company ignored the actual language of the plan and added a new exclusion which denied coverage for investigational treatment. The court granted the injunction.

Courts have also allowed coverage when the insurer failed to assess the most recent medical data for determining the experimental nature of the treatment. In White, the plaintiff’s treating physician recommended HDC-ABMT, believing that without the treatment the plaintiff had no chance of survival. Plan administrators denied coverage. Because the plan administrators refused to assess the most recent medical studies regarding the efficiency of ABMT as it pertained to breast cancer, the court found the decision not to cover the procedure arbitrary and capricious. The court granted injunctive relief requiring coverage of the treatment.

More frequently, courts have denied treatment because HDC-ABMT is either expressly or implicitly not covered by the policy. In

that a service or procedure does have proven medical value, then the experimental/investigative exclusion clause does not provide a legitimate basis for denying coverage.

Id.
89. Id. at 581.
90. Id. at 584.
91. Id.
94. Dosza, 716 F. Supp. at 134.
95. Id. at 137.
96. Id. at 138.
97. Id. at 140.
99. Id.
100. Id. at 1424.
Nesseim v. Mail Handlers Benefit Plan, the court held that HDC-ABMT was not covered by a health plan which did cover chemotherapy, but limited coverage of ABMT to specified diseases not including breast cancer. The court upheld the Office of Personnel Management’s decision not to cover the treatment based on the terms of the plan. Similarly, in Caudill v. Blue Cross and Blue Shield of North Carolina, a plan which covered HDC-ABMT for only specified diseases, which did not include breast cancer, was upheld and the denial of benefits was considered the “only logical interpretation of the policy.”

In addition, the court denied an injunction in Goepel v. Mail Handlers Benefit Plan based on the following evidence: the contract expressly did not cover HDC-ABMT for breast cancer, the materials and brochure were unambiguous so that plaintiffs had the opportunity to make an informed choice regarding their insurance, and the plaintiffs were given adequate notice regarding the change in plan benefits.

Finally, the court in Wolf v. Prudential Insurance Co. denied coverage based on a different provision in the contract. In Wolf, the experimental procedure exclusion specifically excluded from coverage the medical use of a service or supply that is still under study, and is not recognized as a safe and effective diagnosis or treatment. Such treatment included clinical trials. The HDC-ABMT received by Ms. Wolf was administered as part of a clinical trial. Because the policy expressly excluded procedures administered through a clinical trial, HDC-ABMT as it was administered to Ms. Wolf was denied.

The decisions in this section demonstrate the ways in which courts have avoided the real issues of how to determine whether treatment is experimental and who is the proper party to make the determination.

101. 995 F.2d at 805 (8th Cir. 1993).
102. Id.
103. 999 F.2d 74 (4th Cir. 1993).
104. Id. at 80.
106. Id. at *6.
107. Id. at *6-7.
108. Id. at *7-8.
109. 50 F.3d 793 (10th Cir. 1995).
110. Id. at 795.
111. Id. at 795-796.
112. Id. at 796.
113. Id.
114. Id. at 799.
Decisions based on principles of contract interpretation and principles of informed contracting lend little to the debate addressed in this Comment. The purpose they serve is to provide the court an avenue through which it can deny coverage without setting any precedent with regard to experimental treatment exclusions.

Based on the foregoing, it is apparent that an alternative method of analysis must be employed to ensure that treatment is provided to those who need it to survive and to ensure that decisions about insurance coverage are made based on a consistent analysis of factors. One approach has been to legislate in this area and to require insurance companies to provide or offer to provide coverage for HDC-ABMT for breast cancer patients. The following sections discuss the similarities and differences of the legislation passed.

B. Legislative Mandates

Legislatures have responded to the confusing and unhelpful line of precedents in two ways. One response has been to enact statutes that mandate health insurers to provide coverage for HDC-ABMT under certain circumstances.\(^{115}\) This includes certifying and paying for the treatment. Other states merely require that insurers offer an option to purchase additional coverage for the treatment, usually at an additional cost, as part of their general insuring arrangement.\(^{116}\)

While some states have adopted legislative mandates to ensure that women will get the treatment they need, such mandates are not a panacea. Legislative mandates only reach a small number of breast cancer sufferers in limited areas of the nation.\(^{117}\) Furthermore, since some of the legislation only requires that insurance companies offer to provide coverage under their policies and does not actually compel coverage,\(^{118}\) mandates, while a step in the right direction, are more of a band-aid than a cure.

1. Mandates to Provide

California,\(^{119}\) Minnesota,\(^{120}\) New Hampshire,\(^{121}\) Ken-

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115. See infra notes 119-136 and accompanying text.
116. See infra notes 137-148 and accompanying text.
117. See supra note 6.
118. See infra notes 137-148 and accompanying text.
119. CAL. HEALTH & SAFETY CODE § 123985 (West 1995) provides in part as follows: § 123985. Bone marrow transplant; reimbursement; conditions
   (a) A bone marrow transplant for the treatment of cancer shall be reimbursable under this article, when all of the following conditions are met:
tucky, Massachusetts, and Florida have enacted legislation

(1) The bone marrow transplant is recommended by the recipient’s attending physician.
(2) The bone marrow transplant is performed in a hospital that is approved for participation in the California Children’s Services program.
(3) The bone marrow transplant is a reasonable course of treatment and is approved by the appropriate hospital medical policy committee.
(4) The bone marrow transplant has been deemed appropriate for the recipient by the program’s medical consultant. The medical consultant shall not disapprove the bone marrow transplant solely on the basis that it is classified as experimental or investigational.

(b) The program shall provide reimbursement for both donor and recipient surgery.

See also CAL. WELF. & INST. CODE § 14133.8 (West 1995) which provides in part as follows: §14133.8. Bone marrow transplant; reimbursement; conditions
(a) A bone marrow transplant for the treatment of cancer for beneficiaries, shall be reimbursable under this chapter, when all of the following conditions are met:
(1) The bone marrow transplant is recommended by the recipient’s physician.
(2) The bone marrow transplant is performed in a hospital that is approved for participation in the Medi-Cal program.
(3) The bone marrow transplant is a reasonable course of treatment and is approved by the hospital medical policy committee when there is an existing committee or a committee can be established.
(4) The bone marrow transplant has been deemed appropriate for the recipient by the program’s medical consultant. The medical consultant shall not disapprove the bone marrow transplant solely on the basis that it is classified as experimental or investigational.
(5) Full federal financial participation is available for reimbursement for the performance of the bone marrow transplant.

(b) The program shall provide reimbursement for both donor and recipient surgery.

120. MINN. STAT. § 62A.309 (1996) provides in part as follows:

62A.309 Breast Cancer Coverage
Subdivision 2. Required Coverage. Every health plan . . . provide to each covered person who is a resident of Minnesota coverage for the treatment of breast cancer by high-dose chemotherapy with autologous bone marrow transplantation and for expenses arising from the treatment.

Subdivision 3. Greater Coinsurance or Copayment Prohibited. Coverage under this section shall not be subject to any greater deductible than that applicable to any other coverage provided by the health plan.

Subdivision 4. Greater deductible prohibited. Coverage under this section shall not be subject to any greater deductible than that applicable to any other coverage provided by the health plan.

121. N.H. REV. STAT. ANN. § 419.5-c (1995) provides as follows:
§ 419:5-c Coverage for Autologous Bone Marrow Transplants.
Every hospital service corporation, and every other similar corporation licensed under the laws of another state, shall provide to each group, or to the portion of each group comprised of certificate holders of such insurance who are residents of this state and whose principal place of employment is in this state, coverage for expenses arising from the treatment of breast cancer by autologous bone marrow transplants according to protocols reviewed and approved by the National Cancer Institute.

122. 1996 Ky. Acts 114 provides in part as follows:
Insurance — Health—Coverage for Breast Cancer Treatment
Section 1. A New Section ofSubtitle 17 of KRS Chapter 304 is Created to Read as Follows:
(1) All insurers issuing individual health insurance policies in this Commonwealth which provide coverage for treatment of breast cancer by chemotherapy on an expense-incurred basis shall also provide coverage for treatment of breast cancer by high-dose chemotherapy with autologous bone marrow transplantation or stem cell transplantation.
(2) The administration of high-dose chemotherapy with autologous bone marrow transplantation or stem cell transplantation shall only be covered when performed in institutions that comply with the guidelines of the American Society for Blood and Marrow Transplantation or the International Society of Hematotherapy and Graft Engineering, whichever has the higher standard.
(3) Treatment of breast cancer by high-dose chemotherapy with autologous bone marrow transplantation or stem cell transplantation shall not be considered experimental or investigational. Coverage for transplantation under this section shall not be subject to any greater coinsurance or copayment than that applicable to any other coverage provided by the health plan.
Sections 2-5 of the Act provide that coverage for HDC-ABMT be provided by: (1) insurers issuing group or blanket health insurance policies which provide benefits for the treatment of breast cancer by chemotherapy; (2) nonprofit hospital, medical-surgical, dental and health services corporations issuing contracts to provide benefits for treatment of breast cancer by chemotherapy; health maintenance organizations issuing contracts which provide benefits for treatment of breast cancer with chemotherapy; and (4) health benefit plans which provide for treatment of breast cancer by chemotherapy. Id.
123. MASS. GEN. LAWS ch. 175, § 47M (1996) provides as follows:
§ 47M. Accident and sickness insurance benefits for bone marrow transplants
Any individual policy or accident and sickness insurance issued pursuant to section one hundred and eight, and any group blanket policy of accident and sickness insurance issued pursuant to section one hundred and ten, shall provide coverage for a bone marrow transplant or transplants for persons who have been diagnosed with breast cancer that has progressed to metastatic disease; provided, however, that said person shall meet the criteria established by the department of public health. The department of public health shall promulgate rules and regulations establishing criteria for eligibility for coverage hereunder which shall be consistent with medical research protocols reviewed and approved by the National Cancer Institute.
See also MASS. GEN. LAWS ch. 176G, § 4F (1996) (providing similar coverage for those persons covered under a group health maintenance contract); MASS. GEN. LAWS ch. 176A, § 8O (1996) (providing similar coverage for those covered under any contract between a subscriber and a corporation under an individual or group hospital service plan); MASS. GEN. LAWS ch. 176B, § 40 (1996) (providing similar coverage for those covered under an individual or group medical service agreement); MASS. GEN. LAWS ch. 32A, § 17A (1996) (providing similar coverage for any active or retired employee of the commonwealth who is insured under group insurance coverage).
124. FLA. STAT. ANN. § 627.4236 (West 1996) provides, in relevant part, as follows:
(2) An insurer or a health maintenance organization may not exclude coverage for bone marrow transplant procedures recommended by the referring physician and the treating physician under a policy exclusion for experimental, clinical investigative, educational, or similar procedures contained in any individual or group health insurance policy or health maintenance organization contract issued, amended, delivered, or renewed in this state that covers treatment for cancer, if the particular use of the bone marrow transplant procedure is determined to be accepted within the appropriate oncological specialty and not experimental pursuant to subsection (3).
(3)(a) the Secretary of Health and Rehabilitative Services must adopt rules specifying the bone marrow transplant procedures that are accepted within the appropriate oncological specialty and are not experimental for purposes of this section. The rules must be based
which requires insurers to provide coverage for HDC-ABMT for breast cancer.

The legislation of these states have several similarities and differences. Similarities among them include the following: Minnesota and Kentucky provide that the coverage of HDC-ABMT cannot be subject to greater coinsurance or greater deductible;\(^1\) the New Hampshire and Minnesota statutes impose a residency requirement;\(^2\) and California and Florida require that the treatment be

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upon recommendations of an advisory panel appointed by the Secretary, composed of:

1. One adult oncologist, selected from a list of three names recommended by the Florida Medical Association;
2. One pediatric oncologist, selected from a list of three names recommended by the Florida Pediatric Society;
3. One representative of the J. Hillis Miller Health Center at the University of Florida;
4. One representative of the H. Lee Moffitt Cancer Center and Research Institute, Inc.;
5. One consumer representative, selected from a list of three names recommended by the Insurance Commissioner;
6. One representative of the Health Insurance Association of America;
7. Two representatives of health insurers, one of whom represents the insurer with the largest Florida health insurance premium volume and one of whom represents the insurer with the second largest Florida health insurance premium volume; and
8. One representative of the insurer with the largest Florida small group health insurance premium volume.

(b) The Secretary must appoint a member of the advisory panel to serve as chairperson.
(c) The Office of the Deputy Secretary for Health of the Department of Health and Rehabilitative Services must provide, within existing resources, staff support to enable the panel to carry out its responsibilities under this section.
(d) In making recommendations and adopting rules under this section, the advisory panel and the Secretary shall:

1. Take into account findings, studies, or research of the federal Agency for Health Care Policy, National Cancer Institute, National Academy of Sciences, Health Care Financing Administration, and Congressional Office of Technology Assessment, and any other relevant information.
2. Consider whether the federal Food and Drug Administration or National Cancer Institute are conducting or sponsoring assessment procedures to determine the safety and efficacy of the procedure or substantially similar procedures, or of any part of such procedures.
3. Consider practices of providers with respect to requesting or requiring patients to sign a written acknowledgment that a bone marrow transplant procedure is experimental.

(e) The advisory panel shall conduct, at least biennially, a review of scientific evidence to ensure that its recommendations are based on current research findings and that insurance policies offer coverage for the latest medically acceptable bone marrow transplant procedures.

(4) Any rule adopted under this section applies only to claims filed under policies issued or renewed after the effective date of the rule.

125. MINN. STAT. § 62A309(3); 1996 Ky. Acts 114 § 1(3).
126. MINN. STAT. § 62A.309(1); N.H. REV. STAT. ANN. § 419.5-c.
recommended by a treating physician. On the other hand, Kentucky is the only state that specifically proclaims that HDC-ABMT for breast cancer is not experimental. Kentucky also is alone in only requiring insurers to provide coverage for HDC-ABMT if the policy provides coverage for standard chemotherapy for breast cancer.

The most common and significant thread running through the legislative mandates to provide, however, is the requirement that the procedure be an appropriate course of treatment and be reviewed and approved by an appropriate body. California requires that the treatment be approved by the appropriate hospital medical policy committee and deemed appropriate for the recipient by a medical consultant. New Hampshire requires coverage for expenses arising from the treatment of breast cancer by ABMT according to protocols reviewed and approved by the National Cancer Institute.

The Massachusetts statute takes a somewhat different approach to mandating coverage. In that state, insurers must provide coverage for metastatic breast cancer if they meet criteria established by the Department of Public Health. The statute goes on to provide that the Department of Public Health may promulgate rules establishing criteria for eligibility for coverage consistent with research protocols, reviewed and approved by the National Cancer Institute. Under this statute, an independent agency is charged with establishing criteria for coverage, but the main requirement is that coverage be consistent with approved research protocols.

The Florida statute mandating coverage goes one step beyond the Massachusetts statute. In Florida, an insurer cannot deny coverage for HDC-ABMT as recommended by a treating physician if the procedure is "accepted within the appropriate oncological specialty and not experimental." The statute also provides for an advisory panel made up of oncologists, consumer representatives, and insurance representatives to make recommendations to the Secretary of Health and Rehabilitative Services as to which ABMT procedures are accepted and not experimental, and enumerates a list of factors that should

127. CAL. HEALTH & SAFETY CODE § 123985(a)(i); FLA. STAT. ANN. § 627.4236(2).
130. CAL. HEALTH & SAFETY CODE § 123985(a)(3)-(4).
131. N.H. REV. STAT. ANN. § 419.5-c.
132. MASS. GEN. LAWS ch. 175, § 47M.
133. Id.
134. FLA. STAT. ANN. § 627.4236(2).
135. FLA. STAT. ANN. § 627.4236(3)(a).
be taken into account by the advisory panel in making recommenda-
tions and by the Secretary in making the final determination.\textsuperscript{136}

The Florida statute presents the most appropriate legislative
response to the question of who should decide coverage. The Florida
statute, which offers a broad, versatile, and responsive solution, will be
discussed in more detail in Part IV of this Comment.

2. Mandates to Offer

Five states including Missouri,\textsuperscript{137} New Jersey,\textsuperscript{138} Virginia,\textsuperscript{139}

\textsuperscript{136} FLA. STAT. ANN. § 627.4236(3)(d).
\textsuperscript{137} MO. REV. STAT. § 376.1200 (1996) provides in part as follows:
1. Each entity offering individual and group health insurance policies providing
coverage on an expense-incurred basis, individual and group service or indemnity type
contracts issued by a health services corporation, individual and group service contracts
issued by a health maintenance organization, all self-insured group arrangements to the
extent not preempted by federal law and all managed health care delivery entities of any
type or description, that are delivered, issued for delivery, continued or renewed in this
state on or after January 1, 1996, shall offer coverage for the treatment of breast cancer
by dose-intensive chemotherapy/autologous bone marrow transplant or stem cell
transplants when performed pursuant to nationally accepted peer review protocols
utilized by breast cancer treatment centers experienced in dose-intensive chemothera-
py/autologous none marrow transplants or stem cell transplants. The offer of benefits
under this section shall be in writing and must be accepted in writing by the individual
or group policyholder or contract holder.
2. Such health care service shall not be subject to any greater deductible or Copayment
than any other health care service provided by the policy, a contract or plan, except that
the policy, contract or plan may contain provision imposing a lifetime benefit maximum
of not less than one hundred thousand dollars, for dose-intensive chemotherapy/
autologous bone marrow transplants or stem cell transplants for breast cancer
treatment.
3. Benefits may be administered for such health care service through a managed care
program of exclusive and/or preferred contractual arrangements with one or more
providers rendering such health care service. These contractual arrangements may
provide that the provider shall hold the patient harmless for the cost of rendering such
healthcare service if it is subsequently found by the entity authorized to resolve disputes
that:
(1) Such care did not qualify under the protocols established for the providing of
care for such health care service;
(2) Such care was not medically appropriate; or
(3) The provider otherwise failed to comply with the utilization management or
other managed care provision agreed to in any contract between the entity and the
provider.
\textsuperscript{138} N.J. STAT. ANN. § 17:48-6k (West 1995) provides as follows:
1. In addition to benefits provided under regulations adopted pursuant to P.L. 1992,
service corporation shall offer under every group or individual hospital service
corporation contract providing hospital or medical expense benefits delivered, issued,
executed or renewed in this State, or approved for issuance or renewal in this State by
the Commissioner of Insurance, on or after effective date of this act to provide benefits
for the treatment of cancer by dose-intensive chemotherapy/autologous bone marrow


Georgia, and Tennessee have responded less forcefully to the

transplants and peripheral blood stem cell transplants when performed by institutions approved by the National Cancer Institute or pursuant to protocols consistent with the guidelines of the American Society of Clinical Oncologists. Benefits for such treatment shall be provided to the same extent as for any other illness under the contract.

The offer required pursuant to this section shall apply to all hospital service corporation contracts in which the hospital service corporation has reserved the right to change the premium. Nothing in this section shall be construed to limit a hospital service corporation in adjusting premium amounts, or providing for reasonable deductibles or copayments, with respect to benefits provided pursuant to this section. Sections 2-6 of the statute require that medical service corporations, health service corporations, insurers providing individual policies, and health maintenance organizations provide the same benefits as required in Section 1. Id.

139. VA. CODE ANN. § 38.2-3418.1:1 (Michie 1995) provides in part as follows:
§ 38.2-3418.1:1 Coverage for bone marrow transplants.

A. Each insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis, each corporation providing individual or group accident and sickness subscription contracts, and each health maintenance organization providing a healthcare plan for healthcare services shall offer and make available coverage under such policy, contract or plan delivered, issued for delivery or renewed in this Commonwealth on and after January 1, 1995, for the treatment of breast cancer by dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants when performed pursuant to protocols approved by the institutional review board of any United States medical teaching colleges including, but not limited to, National Cancer Institute protocols that have been favorably reviewed and utilized by hematologists or oncologists experienced in dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants.

B. Such coverage shall not be subject to any greater copayment than that applicable to any other coverage provided by such policies, contracts or plans, and such coverage shall be subject to the same deductible as that applicable to any other coverage; however, a deductible for such coverage in an amount different than that applicable to any other coverage may also be offered and made available.

140. GA. CODE ANN. § 33-29-3.3 (1996) (GA. CODE ANN. § 56.3004.4 (Harrison Supp. 1996)) provides as follows:
§ 33-29-3.3 Coverage for bone marrow transplants for the treatment of breast cancer and Hodgkin's disease.

(a) Every insurer authorized to issue individual accident and sickness insurance plans, policies, or contracts shall be required to make available, either as a part of or as an optional endorsement to all such policies providing major medical insurance coverage which are issued, delivered, issued for delivery, or renewed on or after July 1, 1995, coverage for bone marrow transplants for the treatment of breast cancer and Hodgkin's disease. Such coverage shall be at least as extensive and provide at least the same degree of coverage as that provided by the respective plan, policy, or contract for the treatment of other types of physical illnesses. Such an optional endorsement shall also provide that the coverage required to be made available pursuant to this Code section shall also cover the spouse and the dependents of the insured if the insured's spouse and dependents are covered under such benefit plan, policy, or contract.

(b) The optional endorsement required to be made available under subsection (a) of this Code section shall not contain any exclusions, reductions, or other limitations as to coverages, deductibles or coinsurance provisions which apply to bone marrow transplants for the treatment of breast cancer and Hodgkin's disease unless such provi-
HDC-ABMT crisis than those states issuing mandates to provide, as described in the previous section. However, these states have responded, nonetheless, with statutes mandating insurance companies to at least offer coverage for HDC-ABMT.

Two commonalities run through mandates to offer. First, each statute contains a provision regarding allowable costs for the offer of coverage. In Missouri and Tennessee, the offer of coverage cannot be subject to any greater deductible or copayment than any other service provided by the policy. However, coverage may be offered at an additional cost under the Tennessee statute. And the Missouri

sions apply generally to similar benefits provided or paid for under the accident and sickness insurance benefit plan, policy, or contract.

(c) Nothing in this Code section shall be construed to prohibit an insurer, nonprofit corporation, health care plan, health maintenance organization, or other person issuing any similar individual accident and sickness insurance benefit plan, policy, or contract from issuing or continuing to issue an individual accident and sickness insurance benefit plan, policy, or contract which provides benefits greater than the minimum benefits required to be made available under this Code section or form issuing any such plans, policies, or contracts which provide benefits which are generally more favorable to the insured that those required to be made available under this Code section.

(d) Nothing in this Code section shall be construed to prohibit the inclusion of coverage for bone marrow transplants for the treatment of breast cancer and Hodgkin's disease that differs from the coverage provided in the same insurance plan, policy, or contract for physical illnesses if the policyholder does not purchase the optional coverage made available pursuant to this Code section.

(e) The provisions of this Code section shall apply to individual accident and sickness insurance policies issued by a fraternal benefit society, a nonprofit hospital service corporation, a nonprofit medical service corporation, a healthcare plan, a health maintenance organization, or any similar entity.

See also GA. CODE ANN. § 33-30-4.4 (Michie 1995) (GA. CODE ANN. § 56-3102.7 (Harrison Supp. 1996)).

141. TENN. CODE ANN. § 56-7-2504 (Supp. 1995) provides in part as follows:
§ 56-7-2504 Cancer Treatment.

(a) In the event that coverage for the treatment of cancer by dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants is provided for patients or enrollees included in the TennCare program, then each insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis, each corporation providing individual or group accident and sickness subscription contracts, and each health maintenance organization providing a health care plan for health care services shall offer and make available such coverage, in the manner provided in subsection (b), under such policy, contract or plan delivered, issued for delivery or renewed in this state on and after January 1, 1996.

(b) Such coverage may be offered at an additional cost but such health care service shall not be subject to any greater deductible than any other health care service under such policy, contract or plan. Any required copayment shall not exceed the standard copayment required by the insured's policy, contract or plan for health care service.

142. MO. REV. STAT. § 376.1200(2); TENN. CODE ANN. § 56-7-2504(b).

143. TENN. CODE ANN. § 56-7-2504(b).
statute allows a provider to impose a lifetime benefit maximum of not less than $100,000.\textsuperscript{144} Virginia provides that coverage shall not be subject to a greater copayment than that applicable to any other coverage under the policy; however, the statute allows different deductibles to be offered or made available.\textsuperscript{145}

On the other hand, the New Jersey statute only applies to health benefit providers who have reserved the right to change their premium and further provides that nothing in the provision shall limit the right of the hospital to adjust the premium or require reasonable deductibles or copayments.\textsuperscript{146} Finally, Georgia provides that the offer of coverage shall not contain any exclusion, reduction, or other limitations as to coverages, deductibles, or coinsurance provisions which apply to bone marrow transplants for the treatment of breast cancer.\textsuperscript{147}

The second commonality is that three of the five states require that coverage be offered and made available for HDC-ABMT performed pursuant to nationally accepted, peer-reviewed protocols.\textsuperscript{148} This precondition was similarly required with mandates to provide.

Mandates to offer are less controversial than mandates to provide. Under mandates to offer, only those who desire coverage for HDC-ABMT for breast cancer will opt for coverage and pay the increased premium. This is desirable in that it prevents the general public from paying increased premiums for this special treatment. On the other hand, mandates to offer can be criticized as doing very little to help women obtain this treatment because most people, when faced with this option, will choose a lower premium rather than coverage for a treatment that they probably have never heard of for a disease they think they will not get.

Still, the question must be posed as to whether legislative intervention is appropriate at all. The following section explores why insurance companies use exclusionary provisions. It also discusses the values and limits of both judicial interpretations and legislative responses to the provisions.

\textsuperscript{144} MO. ANN. STAT. § 376.1200(2).
\textsuperscript{145} VA. CODE ANN. § 38.2-3418.1:1(B).
\textsuperscript{146} N.J. STAT. ANN. § 17:48-6k(1).
\textsuperscript{147} GA. CODE ANN. § 33-29-3.3(b).
\textsuperscript{148} MO. REV. STAT. § 376.1200(1); N.J. STAT. ANN. § 17:48-6k(1); VA. CODE ANN. § 38.2-3418.1:1(A).
III. ANALYSIS OF EXCLUSIONARY TREATMENT PROVISIONS

A trend is emerging to mandate insurers to either offer coverage or provide coverage. The question then becomes: Should more states follow suit? Or, should mandates play a role in national health care reform? To answer these questions, it is necessary first to assess the policy reasons behind exclusionary clauses and, second, to assess the rationales and policies asserted both in support of and in opposition to judicial and legislative intervention.

A. Exclusionary Clauses

Contrary to popular belief, insurance companies did not incorporate exclusionary treatment provisions in their policies to harass policyholders or with a malicious intent to deny treatment to those who need it. "Generally, the plan administrators are not heartless beasts trying to deprive desperately ill persons of needed medical care. They are responsible for administering a plan as written, using limited funds available to them to provide for the medical needs of all members of the plan."149 Accordingly, exclusionary clauses serve an economic function which is indispensable to the existence of the insurance industry.

One reason insurance policies include exclusionary clauses is cost containment. Health care costs have risen at a rate that consistently exceeds that of general economic inflation.150 Because of this, those who pay for medical services are searching for new and innovative ways to contain costs. Exclusionary clauses are one such device. By excluding these often expensive and innovative treatments, insurance companies limit their liability to only those treatments that have been proven to be effective. Such limitations on financial liability are the primary reason for exclusionary clauses.151

A second reason insurance policies include exclusionary clauses is because exclusionary clauses assist insurance companies in setting premium rates. Health insurance was developed to help spread the

costs of medical care.152 If insurance companies were held liable for any fly-by-night treatment that arises, it would be impossible to determine what costs are to be shared or what risks they are taking. As the court pointed out in Free v. Travelers Insurance Co.:153 "The Court is also mindful of the fact that to require insurers to pay for every remedy, proven or unproven, prescribed by a physician, could invalidate the actuarial basis of current premium rates."154 Thus, the effect of excluding experimental treatment "ha[s] the desirable effect of affording greater protection to the general public, and in particular, [to] . . . patients who are especially vulnerable to unfounded claims of miraculous cures."155

The third reason insurance policies contain exclusionary clauses is so that insurance companies only pay for safe and proven effective treatment. By covering only treatments that are safe and effective, health benefit providers ensure the best use of scarce healthcare resources.156

On the other hand, if insurance companies did not utilize exclusionary clauses, they would have problems setting premium rates because expenditures for experimental or investigative treatments would be unanticipated at the time rates were set. In addition, even assuming insurance companies could set premiums at a proper rate such a rate might be so high that the average person could not afford to purchase health insurance.

B. Judicial and Legislative Coverage Determinations

A policyholder's first encounter with an experimental treatment provision will likely be after the insured has sought pre-authorization for a treatment which the insurer has denied based on the insurer's conclusion that the treatment is experimental. The policyholder can challenge the plan administrator's decision to deny coverage through the courts. Often, a policyholder will seek injunctive relief and ask the court to enjoin the insurer from denying coverage. Until recently, the courts were the insureds' best recourse against the insurance company.

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152. Belk, supra note 151, at 811. Implicit in the idea of spreading the cost of medical care is the underlying premise that such costs are ascertainable at the point at which the premium is set. Id.


In the past four years, state legislatures have stepped into the coverage arena in an attempt to preempt case law and make a final statement about coverage of HDC-ABMT for breast cancer.157

The following is a discussion of merits and limits of both judicial determinations and legislative intervention. The purpose of this discussion is to outline various methods of dealing with and perhaps overcoming experimental treatment provisions generally, using HDC-ABMT breast cancer treatment as an example.

1. Judicial Intervention

Before legislative mandates were enacted, if an insured was dissatisfied with a coverage determination made by her insurance company, her best chance of getting needed treatment was to bring a lawsuit asking for injunctive relief. Then, it was up to the trial court judge to listen to evidence presented by both sides about whether the treatment was experimental and come to his or her own conclusion.

The value of judicial determinations is that each case is decided on its own facts. However, this is also the biggest drawback. Because each court makes an independent determination about whether treatment should or should not be covered based on the policy terms, the decisionmaking process, and expert testimony about the effectiveness of the treatment, there is a lot of room for inconsistency in the verdicts. A judge hearing a case in one jurisdiction may provide treatment, while a judge in another jurisdiction may deny treatment on substantially similar facts. In cases where someone's life depends on the outcome, arbitrary, case-by-case judicial decisionmaking is inappropriate.

In addition, litigation is time-consuming and costly. Many breast cancer sufferers do not have the time or resources to withstand a trial. And, because each case turns on its own facts, it is not likely that breast cancer patients will be able to rely on precedent to get the coverage they need at the summary judgment stage before precious time and resources are expended. The value of precedent is further limited because, even if a patient can find a case in her favor, there is also a substantial likelihood that an unfavorable case also exists that is not in her favor.

157. Legislation regarding experimental treatment provisions for HDC-ABMT has only been promulgated in the last four years. See supra notes 119-148 and accompanying text. The earliest legislation was adopted in New Hampshire and was effective January 1993. N.H. REV. STAT. ANN. § 419.5-c (1995).
A final criticism of judicial determinations is that courts are ill-equipped to make broad social policy or specific medical determinations. Broad issues of social policy, such as whether a treatment should be covered by an insurance policy, should be handled by the legislative branch.\textsuperscript{158} In addition, medical decisions, such as whether a treatment has become generally accepted practice, should be made within the medical community.

2. Legislative Mandates

Legislative intervention arose out of the inconsistency of the case law. Arguments supporting and opposing legislative mandates can be broken into three categories: (1) Appropriateness of legislative action, (2) Nature of the relationships between the parties, and (3) Nature of the procedure.

Regarding the appropriateness of legislative action, the argument can be made that the legislative branches are not in a position to be making medical determinations regarding what is an experimental treatment. Arguably, this task should be deferred to the medical community. When the legislature makes a decision on an issue such as whether to cover HDC-ABMT for breast cancer they solicit expert medical information. However, as with any issue brought before a court or legislature, a battle of experts is inevitable and he who has the best expert wins. Life and death decisions, such as whether a last resort treatment should be covered, should not be left up to a legislative branch that is susceptible to public pressure. Ultimately, the success and efficiency of innovative treatments should be determined by the medical community, not the legislative branch.\textsuperscript{159}

On the other hand, one reason legislative intervention is appropriate is inherent in the structure of the government itself. The role of both state and federal legislatures is to represent the interests of their constituents. The legislative branches of government are the most accountable to the citizenry, and thus are in the best position to bring about social change or to make policy determinations. As pointed out by the court in \textit{Fuja}, determining what procedures insurance companies should cover is the type of problem that must be decided by the legislature.\textsuperscript{160} "As a court of law we are empowered to decide legal issues presented by specific cases or controversies. The greater social

\textsuperscript{158} \textit{Fuja}, 18 F.3d at 1412.
\textsuperscript{159} \textit{But see FLA. STAT. ANN. § 627.4236(3)(a)} (creating an advisory panel including members of the medical community).
\textsuperscript{160} \textit{Fuja}, 18 F.3d at 1412.
questions must be decided by the political branches of government . . . ."161 And so the political branches in the states specified above have spoken and have taken upon themselves an appropriate task of deciding an issue of social policy.

Another reason legislative intervention is appropriate is that in the absence of legislative intervention, people are forced to litigate. Even if they are able to withstand the rigors of a court battle, litigation does little more than drive up the cost of insurance. Litigation either leads to more exclusions to contain costs or to premium hikes that render insurance unaffordable. Either way, this is a lose-lose situation to which legislative mandates offer a consistent, affordable alternative.

Regarding the nature of the relationships between the parties, it is arguable that we live in a capitalistic society where goods and services are exchanged in a free market. Healthcare is a service similar to other services ruled by the market. As such, the legislature should take a hands-off approach. The free market should take care of the relationship between the insurers and insured, and whether particular treatments will be provided. If there is enough demand, the market will find a way to supply it.162

This argument is not persuasive, however, because of the inherent inequity in status between the insurer and the insured. For example, in Goepel, the court made clear that it would not obligate insurers to cover HDC-ABMT if the insurance policy does not by its terms provide coverage.163 As a result, healthcare rationing will remain in the hands of insurers in the absence of legislative mandates.164 But, recent cases indicate that there is opportunity for corruption and manipulation within insuring arrangements.165 Because of this potential, the legislature should step in to regulate the industry and act as a check on insurers.

Also, mandates to provide may be criticized for causing increased costs in general healthcare so that healthcare will become too expensive

161. Id.
165. Insurance Bad Faith, supra note 1, at 84 (plaintiff contended that coverage denial "included financial incentives to [doctors] to deny [bone marrow transplant procedures]"); Belk, supra note 151, at 811 (asserting "health insurance is vulnerable to manipulation"); In the Courts, supra note 23, at 27 (asserting cancer patients challenge denials by arguing financial motivation for denials is "so prevalent and prominent among insurers as to constitute an unethical conflict of interest").
for the average person. Because HDC-ABMT treatment for breast cancer is so costly, premiums will ultimately reflect the risk insurers take that an insured will need that treatment. As such, premiums will increase in proportion to the risk.

This argument is similarly unpersuasive because coverage denials based on the corporate bottom line are unethical. Many breast cancer patients consider denials based on experimental or investigative exclusionary clauses as insincere and a "cruel form of healthcare cost 'containment'." Can the insurance industry put a price tag on a person's increased chance of survival? Do plan administrators suffer a conflict of interest because of financial incentives to deny coverage?

Insurance companies are businesses, first and foremost. And as businesses, insurers seek to maximize profits and minimize costs. If the decision about whether to pay for an procedure lies with the person who actually has to pay, the business result would be unreasonable. But decisionmaking based on maximizing the corporate bottom line regardless of the social costs undermines a fundamental principle of insurance—spreading the risk of costly medical treatment among many so that the few who need treatment can obtain it.

Finally, it can be argued that state legislatures should not be allowed to step in and intervene in a private contractual relationship between the insurer and beneficiary and in the doctor-patient relationship. Private individuals are free to shop around and purchase an insuring arrangement that provides various kinds of coverage. One could find an insuring arrangement that covers HDC-ABMT for breast cancer if one is willing to pay the price. When a private person enters into an insurance contract that expressly excludes HDC-ABMT as experimental and whose premium reflects that exclusion, that person is entitled to no more than what was bargained for. The fact that the legislature can mandate coverage of such treatment, regardless of a provision expressly excluding the treatment, seems repugnant to core principles of contract law. In such a situation, the insured is getting more than what was bargained for.

Again, this argument is undermined because in the absence of legislation, the patients in need of treatment cannot fight the insurance company because of the differences in their status. In a one-on-one situation, the insurance company will have lawyers and an abundance

166. In the Courts, supra note 23, at 27.
168. See generally id.
of resources to support their decision to deny coverage. An individual patient typically cannot afford to litigate, both in terms of time and money. Moreover, patients are financially, physically, and emotionally strapped, unable to withstand a lengthy trial. Under these circumstances, the chances of winning in court and getting the treatment a patient needs fast enough to be strong enough to withstand the treatment are slim.

Regarding the nature of the procedure, an additional reason to support legislative mandates as they pertain to HDC-ABMT as a treatment for breast cancer is the medical evidence that the treatment is no longer experimental. Statistics indicate that the use of HDC-ABMT is widespread and has some proven success.169

Expert testimony in Pirozzi indicates that while standard chemotherapy typically produces a 50% tumor response rate, HDC-ABMT data reveals a much higher response rate of 85%-90%.170 The testimony also revealed studies indicating survival rates better than the twelve months survival associated with standard chemotherapy.171 A Johns Hopkins University study showed a 67% survival at seventeen months and a University of Chicago study demonstrates a median survival rate of twenty months and 20% survival rate at three years.172 Similarly, a 1989 study at Duke resulted in a survival rate of 80%, as only five out of fifty-four patients suffered a relapse as of May 13, 1990.173 At least one study on HDC-ABMT indicates the treatment has a 50-60% short-term favorable response rate to cancer generally and a 20-25% response rate regarding recurrent breast cancer.174

Further data regarding survival rates and efficacy of HDC-ABMT is set out in a number of other cases. The expert testimony in Kulakowski v. Rochester Hospital Service Corp.175 indicates that standard chemotherapy would produce only a 30-60% chance of remission, whereas HDC-ABMT would yield a 70-90% chance.176 The testimony also revealed that risk of death related to toxicity from HDC-ABMT has been reduced from 20% to 3-5%.177 The evidence

169. See generally Pongrance, supra note 21, at 336; see infra notes 170-183 and accompanying text.
171. Id.
172. Id.
173. Id.
174. Insurance Bad Faith, supra note 1, at 84.
176. Id. at 714; see also Pongrance, supra note 21, at 336.
presented in *Bucci v. Blue Cross-Blue Shield, Inc.*\(^{178}\) indicates a complete response rate of 10-20% from standard chemotherapy and a 59% response rate from HDC-ABMT.\(^{179}\) Moreover, two years after treatment there were no disease free patients who were treated with standard chemotherapy while HDC-ABMT yielded 20-30% disease free patients.\(^{180}\) Finally, in *Adams v. Blue Cross/Blue Shield of Maryland, Inc.*,\(^{181}\) an expert from the Dana Farber Cancer Institute at Harvard and M.D. Anderson Institute in Houston indicated a 70% total remission rate in candidates who were treated with HDC-ABMT for Stage IV metastatic breast cancer.\(^{182}\) Only 15-20% achieved remission through standard chemotherapy treatments.\(^{183}\)

Finally, evidence that HDC-ABMT is being used at most major medical institutions supports a finding that the treatment is no longer experimental.\(^{184}\)

3. **Conclusion: Legislative Mandates Are Necessary But Not Enough**

The foregoing analysis helps to answer the question of who should decide coverage as between the insured, the insurer, the court or the legislature. Judicial determinations are inappropriate because they lead to inconsistency in the case law and ad hoc decisionmaking. Further, such decisions should be made by the legislative branch, which is charged with making social policy. Legislative intervention protects the insured from overreaching by the powerful insurance industry and reduces the potential for costly and time consuming litigation. For these reasons, legislative intervention is necessary. But, though mandates are a positive step toward providing coverage for HDC-ABMT, mandates can still be criticized for being narrowly tailored and short sighted.

One criticism of the narrow focus of legislative mandates is that they do little to tackle the broader policy question of how determinations should be made regarding what treatments are and are not experimental.\(^{185}\) Breast cancer is only one disease and HDC-ABMT is only one controversial treatment. While legislative mandates to

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\(^{179}\) *Id.* at 730.; *see also* Pongrance, *supra* note 21, at 336.

\(^{180}\) *Bucci*, 764 F. Supp. at 730.


\(^{182}\) *Id.* at 673-674; *see also* Pongrance, *supra* note 21, at 336.

\(^{183}\) *Adams*, 757 F. Supp. at 673.

\(^{184}\) *Pirozzi*, 741 F. Supp. at 591. *See also supra* note 58.

\(^{185}\) *But see* FLA. STAT. ANN. § 627.4236.
provide have secured treatment for breast cancer sufferers in six states, there are still many other diseases and controversial treatments about which this exact same debate still rages. In reality, these mandates are only helping a few women in a very limited area of the country.

This leads to a second criticism of mandates: they only apply to women who are fortunate enough to live in the states who have already passed legislation. Hundreds of thousands of other women who suffer from breast cancer need this treatment and are unable to obtain it due to lack of insurance coverage. Consequently, it does not seem fair that some women will be given a chance to live while others must die simply because of their state of residence.

A third criticism of legislative mandates is that they do not ensure women will obtain HDC-ABMT. Instead, legislative mandates only tell insurance companies what they can and cannot include in their policies. For example, in Minnesota, one breast cancer sufferer had to fight what appeared to be an effort by her insurance company to circumvent the Minnesota statute's mandate to provide coverage. Shirley Murray enrolled in a National Cancer Institute study supported by her insurer in which half the women participants were randomly selected to receive HDC-ABMT and the other half received traditional treatment consisting of radiation and chemotherapy. Murray was selected to be part of the traditional treatment control group. About the time she began chemotherapy, her insurer began sending her waiver notices. One waiver included a provision that stated that if she was assigned to traditional treatment and that treatment failed, the insurer would not cover or provide financial support for HDC-ABMT. Another letter explained that the insurer required the return of the signed waiver before it would notify the bone marrow center that it would support her participation in the clinical trial. Murray interpreted this letter to mean that her insurer would not even pay for traditional treatment unless she signed the waiver giving up her rights to HDC-ABMT.

Murray refused to sign the waiver and hired an attorney to fight her insurer. After repeated phone calls and suggestions to sign the

187. Id.
188. Id.
189. Id.
waiver, her insurer finally assured her that she did not have to sign the waiver. 190

What was Murray's reaction to all of this? She does not think that women with breast cancer should have to turn to attorneys or reporters to get the treatment they need. 191 So, even in the face of a mandate to provide, breast cancer sufferers must still overcome obstacles placed in their path by their insurers who, if the Minnesota insurer is any indication, are trying desperately to find loopholes in the legislation requiring coverage.

Mandates are necessary in a nation where authorization for needed treatment is being denied based on inconsistent policy terms and judicial decisions. In the six states in which they exist, mandates to provide absolutely serve the purpose of getting lifesaving treatment to the people who need it. The criticisms outlined in this Comment are intended to support the proposition that more action is needed because only a limited group of women are helped for only one specific treatment for only one type of cancer. The use of experimental procedure exclusions to deny coverage is too pervasive to look to disease by disease, treatment by treatment legislation as the solution.

IV. ALTERNATIVE APPROACHES AND MODEL LEGISLATION

A. Alternative Approaches

Judicial determinations are the least effective method of determining coverage. Not only are courts ill-equipped to make medical determinations, they are the wrong forum in which social policy should be made. In contrast, legislative mandates seem to be a trend in healthcare coverage and, as previously discussed, they are a positive step toward securing treatment for women with breast cancer. However, as mentioned above, the existing legislation has many limits. Therefore, alternative approaches to experimental treatment provisions are explored below.

One alternative to legislative mandates or case-by-case judicial determinations would be to impose cost sharing for experimental or investigative treatments. Under a cost sharing plan, a health benefit provider would agree to pay a certain percentage of the cost of treatment. Another alternative would be to charge higher premiums for coverage of any experimental treatment costing up to a specified

190. Id.
191. Id.
amount such as $200,000. This allows the health benefit provider to assess the nature of the risk and set reasonable premiums.

A third alternative, suggested in *Fuja v. Benefit Trust Life Insurance*,192 was that a regional cooperative of committees comprised of “oncologists, internists, surgeons, experts in medical ethics, medical school administrators, economists, representatives of the insurance industry, patient advocates and politicians” be established.193 This task force would be responsible for defining experimental procedures and determining what procedures would be cost prohibitive.194 In *Fuja*, the court acknowledged that such an approach would not be a panacea to rising healthcare costs but it would be one way to address the problem of contradictory expert testimony that occurs frequently in cases regarding exclusionary clauses.195

An additional alternative is legislation that defines circumstances under which a health benefit provider may exclude coverage for an experimental treatment. One drawback to legislative mandates is that they seem to present a band-aid, not a final cure. In other words, the case law is controversial, inconsistent, and confusing regarding many different kinds of treatments for many different kinds of diseases, not just HDC-ABMT for breast cancer. Admittedly, the rationale supporting legislative mandates seems to entitle HDC-ABMT treatment cases to legislative attention. But it is easy to imagine a scenario where all patients afflicted with a certain disease mobilize and present their issue to the legislature. The legislative branch then becomes inundated with making medical decisions on a disease by disease basis. This is not a role for the legislative branch. However, if the legislature were to define what kinds of treatment are experimental, then such a definition could apply across the board no matter what the disease or treatment.

Florida has enacted legislation which incorporates the third and fourth alternatives presented above. This Comment proposes that the Florida legislation serve as model legislation for experimental treatment provisions. As such, it is discussed in detail in the section that follows.

B. Model Legislation

The Florida statute regarding HDC-ABMT provides the most appropriate answer to the question of who should decide coverage

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192. 18 F.3d 1405.
193. Id. at 1412.
194. Id.
195. Id.
when an experimental treatment provision is involved. The statute requires that the Secretary of Health and Rehabilitative Services adopt rules specifying the bone marrow transplant procedures that are accepted within the appropriate oncological specialty and are not experimental. The rules must be based on the recommendations of an advisory panel appointed by the Secretary and composed of one adult and one pediatric oncologist, two representatives of major Health Centers in Florida, one consumer representative, one representative of the Health Insurance Association, and three representatives of health insurers.

An advisory panel so composed will be better equipped to make coverage determinations than individual judges or state legislatures. Because the panel members have a stake in the outcome, the advisory panel ensures that the perspectives of all interested parties are represented and debated. The presence of doctors ensures that the efficacy and general acceptance of the procedure is represented. The presence of insurance representatives ensures that recommendations are not so cost prohibitive as to bankrupt insurance companies. And, the presence of a consumer representative ensures that the individual's needs are considered when making coverage determinations.

The Florida statute goes beyond merely setting up a panel to make coverage recommendations. The statute also lists factors which the advisory panel and the Secretary shall take into account in making recommendations and adopting rules. Factors include the following: findings, studies, or research; whether the Federal Drug Administration or National Cancer Institute are conducting or sponsoring assessment procedures to determine the safety and efficacy of the procedure; and practices of providers with respect to requesting or requiring patients to sign a written acknowledgment that a bone marrow transplant procedure is experimental. In addition, the panel is charged with conducting biannual reviews of scientific evidence to ensure that its recommendations are based on current research findings and that insurance policies offer coverage for the latest medically acceptable bone marrow transplant procedure.

While the Florida statute has been hailed in this Comment as a "model" that should be followed in other states, it can be criticized as still being too narrowly focused. The statute does establish an advisory

197. Id.
199. Id.
panel and a list of considerations, but the statute itself is aimed only at determining which bone marrow transplant procedures are experimental. This Comment still recommends that a statute based on the one enacted in Florida be enacted with regard to experimental treatments generally.

The advisory panel in such a situation would consist of doctors in various medical specialties, consumer representatives and representatives of the insurance industry. The Secretary and the panel would consider the factors enumerated in the Florida statute when making recommendations and promulgating rules. The Legislature may want to borrow from case law in establishing criteria upon which to base a determination as to whether a particular treatment is experimental or not.

Courts have considered many different factors including the cost of the treatment, the conclusions of expert witnesses, the fact that the treatment is a last resort and there is a lack of alternative treatments, duration of use, government approval, research protocols, medical literature, safety and efficacy, and common use in treating the illness it is being used for. These criteria should be incorporated into legislation as factors to be considered in determining whether a treatment is experimental or not.

**CONCLUSION**

In conclusion, legislative intervention in breast cancer treatment, and experimental treatments in general, is a trend in this country. Eleven states require health benefit providers to either offer or provide HDC-ABMT for the treatment of breast cancer. While such mandates increase the risk to health benefit providers and the cost to beneficiaries, the mandates are a positive step toward getting breast cancer patients the treatment they need.

Legislative mandates to offer are less controversial than mandates to provide because the former merely requires insurers to offer beneficiaries the option of paying a higher premium in order to be covered for HDC-ABMT for breast cancer. Those who want coverage can pay for it. The downside to this approach is that most people will opt for a lower premium because they lack the psychic ability to know they may need breast cancer coverage someday. Played out to its logical conclusion, a beneficiary could face a list of thousands of options they may choose to be covered for, but will be unwilling to

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select the ones they will need and unable to pay for coverage for everything on the list.

Mandates to provide eliminate the problem of leaving the option to the beneficiary regarding whether to opt for coverage. Such mandates also spread the cost of coverage over all beneficiaries enrolled in a specific plan, as insurance is intended to do. Still, mandates to provide do not address the real problem of experimental exclusion provisions. Such clauses are applicable to many different diseases and treatments. Requiring insurers to cover HDC-ABMT for breast cancer does nothing to further our understanding of the propriety of exclusionary clauses or the standards by which a treatment is to be judged. To address this, state legislatures should step in and define how and when a treatment can be excluded from coverage under an exclusionary clause. Such legislation would apply across the board to all diseases and treatments, decrease litigation, and provide consistency in coverage decisions.