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ADJUDICATION OF THIRD PARTY PAYMENT FOR HIGH DOSE CHEMOTHERAPY & BONE MARROW RESCUE IN THE TREATMENT OF BREAST CANCER

William Giese, M.D.

Editor's Note: This article is intended to contrast and develop some of the concepts and issues explored in an article written by Jessica Basso, published in the December 1996 issue of the DePaul Journal Of Health Care Law.

INTRODUCTION

It has been said while the focus of science is progress, the focus of the legal system is process. Consequently, conclusions drawn by science on a subject cannot be compared to the conclusions drawn by law on the same subject. This fact has become especially evident in light of the debate on court-ordered third-party payment for unproved medical procedures, an issue that has spawned an ongoing legal battle over insurers' responsibilities to reimburse for high-dose chemotherapy and bone marrow rescue in the treatment of breast cancer.

There are two main forms of bone marrow recovery: autologous bone marrow transplantation (ABMT); and peripheral stem cell rescue (PSCR). While some courts acknowledge that these two forms of treatment are essentially the same procedure, others do not. This article will address this issue by beginning with a synopsis of the development of this method of breast cancer therapy, and then turning to a case law discussion on whether third-party insurers should be forced to fund this procedure.

In particular, this article will attempt to analyze the confusion that has resulted from some of the court decisions on this issue, particularly

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"The scientists' emphasis on progress is replaced by the lawyers' emphasis on process. Rather than seeking greater knowledge of the natural world, the law seeks the peaceful resolution of human disputes." STEVEN GOLDBERG, CULTURE CLASH: LAW AND SCIENCE IN AMERICA 13 (1994).
whether the "yardstick" being used by the judiciary to decide whether such treatment will or will not be reimbursed by third parties is inconsistent.\(^2\) When the rulings are considered in light of the judiciary's primary focus on process, rather than medicine's emphasis on progress, they may not be.

**MEDICAL TREATMENT**

Anti-cancer drugs are a relatively recent discovery. Interestingly, their application in the treatment of human malignancy was a byproduct of wartime research into poison mustard gas.\(^3\) The initial response of non-solid tumors (principally leukemia's and lymphoma's) to anti-cancer drugs were encouraging, but short-lived.\(^4\) However, subsequent research has resulted in the discovery of additional agents with activity.\(^5\) Some of these damage DNA,\(^6\) while others interfere with various aspects of the cellular machinery.\(^7\) A discussion of the specific mechanisms of the various agents is beyond the scope of this paper, but it has been found generally that drug combinations which act through a number of means, are superior to single-agent treatments.\(^8\) The rationale for the employment of increasingly greater doses of drug "cocktails" in the systemic treatment of cancer is relatively straightforward: the greater the insult, the more cancer cells are irreparably damaged.

Unfortunately, it is not only cancer cells that are injured by this treatment, but also the body's normal cellular contingent is at risk. The cells affected most significantly are ones that rapidly replicate. Of these,

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\(^2\) See Richard S. Saver, *Reimbursing New Technologies: Why Are the Courts Judging Experimental Medicine?*, 44 Stan. L. Rev. 1095, 1113 (1992) (noting that the judicial response to the payment by third-parties for new treatments "has been characteristically haphazard ... ").


\(^4\) Id.

\(^5\) See generally *id.* (chronicling folic acid antagonists as the next active drugs uncovered).


\(^7\) Id.

\(^8\) See generally Jay R. Harris et al., *Cancer of the Breast*, in *CANCER: PRINCIPLES AND PRACTICE OF ONCOLOGY* 1264,1301-07 (1993) (outlining the trials which established combination chemotherapy as the standard approach in the systemic treatment of breast cancer).
one of the most sensitive lineages are the cellular precursors to red cells, white cells, and platelets. These progenitor cells continually renew the body's ability to transport oxygen, defend against infectious invasion, and clot blood. In reality, all cancer is theoretically curable by the delivery of increasing levels of chemotherapy, but it is clear that “throwing the baby out with the bathwater” may sometimes result. Supportive care for this treatment has also evolved sufficiently, through the use of intravenous fluids and feedings, antibiotics, and blood product transfusions, to the point where cancer patients can be maintained adequately while many of the normal cell types repopulate. Of course, with high-dose chemotherapy the precursors to blood cells may be destroyed completely, in which case recovery will not occur.

One method that has made cancer treatment less damaging is the transplantation of bone marrow from a healthy donor, if at least a partial “antigenic match” can be found. Because the requirement for a match may restrict candidacy for transplantation, and thus preclude the use of high-dose chemotherapy, other solutions have also been found. The most common technique is to harvest cellular blood precursors, either through a bone marrow biopsy, or by the phoresis of stem cells from the peripheral blood, prior to the administration of high-dose chemotherapy. This collection of marrow is stored appropriately, and reinfused following chemotherapy exposure. The precursor cells then recolonize the bone marrow and assume normal cellular production. In some cancers, especially those of the blood cell lines, high-dose chemotherapy and allogeneic transplantation have proven curative.

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9 See Garrett A. Smith & I. Craig Henderson, High-Dose Chemotherapy (HDC) with Autologous Bone Marrow Transplantation (ABMT) for the Treatment of Breast Cancer: This Jury is Still Out, in IMPORTANT ADVANCES IN ONCOLOGY 1995 201, 209 (1995) (summarizing transplant-related deaths of from 7 to 35 percent in reports from studies conducted between 1981 and 1989).

10 See Ralph O. Wallenstein, Jr. & Albert B. Deisseroth, Bone Marrow Dysfunction in the Cancer Patient, in CANCER: PRINCIPLES AND PRACTICE OF ONCOLOGY 2262, 2272 (1993) (HLA antigens found on the surface of cellular blood products can result in significant and potentially fatal host immune reactions, dependent on the degree of mismatch).

11 Id. at 2271.

12 Allogeneic transplantation is when the bone marrow cells of someone other than the cancer patient are transfused. Autologous, sometimes called syngeneic transplantation, is when the cells of the patient are reinfused. See William P. Peters, High-Dose Chemotherapy with Autologous Bone Marrow Transplantation for the Treatment of Breast Cancer: Yes, in IMPORTANT ADVANCES IN ONCOLOGY 1995 215, 216 (1995) (discussing a 12 percent cure rate at fifteen years by the use
Method of Analysis

The method utilized in the clinical assessment of a novel or experimental anti-cancer treatment involves a number of progressive steps or phases. First, a Phase I study is conducted to determine the toxicity of differing dose-schedules of chemotherapy. Testing then begins via a Phase II analysis, where efficacy is determined by identifying those tumors which respond. The final stage is Phase III testing, where superiority is evaluated through the direct comparison of the new treatment to standard therapy.

Studies Completed To Date

Clinical trials involving high-dose chemotherapy and bone marrow rescue in the treatment of breast cancer have been limited to two patient populations. One population includes patients with metastatic breast cancer, where the outlook using standard-dose chemotherapy and/or radiation is uniformly fatal. The other population includes patients in the earlier stages of breast cancer, where the likelihood of clinically undetectable distant metastases is high. This latter group is typified by patients found to have ten or more tumor-involved lymph nodes at surgery.

It has been more then a decade since the first Phase I trials of high-dose chemotherapy and bone marrow transplantation for the
treatment of cancer were initiated. These studies demonstrated, as hypothesized, that the delivery of higher than conventional doses of chemotherapy was indeed feasible when coupled with marrow repopulation. In the late 1980's, a number of Phase II trials in breast cancer began. As predicted, efficacy in the treatment of breast cancer was established. The "gold standard" in the assessment as to whether HDC-ABMT or HDC-PSCR is superior to standard chemotherapy, however, are Phase III prospectively randomized analyses. Although currently ongoing at several institutions, the results of Phase III testing are not expected to be completed for several years. Though tempting, it is scientifically unsound to draw conclusions about the superiority of one treatment over another based on either the nonrandomized Phase II and III data, or in comparison to historical controls. Nonetheless, many conclusions have been drawn.

Cost of Treatment

The reported cost of a single HDC-ABMT runs from $80,000 to $300,000. This amount has been reduced in recent years, owing largely

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20 See *id.* at 218 (although "major" and "substantial" toxicity was reported in both the single-agent and combination chemotherapy trials respectively).

21 *Id.*

22 See Smith & Henderson, *supra* note 9, at 202-04 (reporting an average response rate for 11 trials of 78 percent and a range of from 41 to 93 percent).

23 *Id.* at 211 ("An analysis of the role of bone marrow transplantation for breast cancer is limited by the lack of properly controlled clinical trials."); see also Peters, *supra* note 12, at 218 (Critical to deciding the ultimate role of high-dose therapy in the treatment of breast cancer and other diseases are the performance and analysis of well-designed and well-controlled randomized clinical trials).

24 Peters, *supra* note 19, at 215 (Randomized, comparative trials have not yet been reported, and although they are currently underway, results will not be available for another three to four years).


26 *Id.* at 206 (estimating an $80,000 per treatment cost); see also Saver, *supra* note 2, at 59 (quoting estimates in the literature of from $100,000 to $300,000 per HDC-ABMT).
Estimates of the annual aggregate cost of the treatment range from $240 million if limited to the high-risk adjuvant setting, to $2.5 billion if all eligible women receive treatment. The medical community remains divided on whether the lack of Phase III prospective randomized data establishes HDC-ABMT or HDC-PSCR as experimental by definition. Currently, none of the peer reviewed literature has stated that this treatments is "standard," although claims proffered to the courts indicate otherwise.

Insurers argue that HDC-ABMT or HDC-PSCR is "experimental" in nature and as such, reimbursement is not required. These carriers point to the lack of data from randomized, prospective Phase III trials to support this position. In response, proponents argue that only a small percentage of the therapies considered "standard" today have undergone such rigorous confirmation.

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27 See Peters, supra note 19, at 228-29 (describing how the use of colony-stimulating factors and intravenous antibiotics is shifting post-transplant management to an outpatient setting); see also Robert Bazell, Topic of Cancer, NEW REPUBLIC, Dec. 31, 1990, at 12 (describing how the cost of HDC-ABMT dropped by approximately half once Blue Cross-Blue Shield reversed its reimbursement policy, and the procedure was performed).

28 Smith & Henderson, supra note 9, at 206 (estimated by multiplying the approximate 3000 U.S. women with ten or more involved nodes and age less than fifty who are diagnosed annually, by $80,000 per treatment).

29 See Lawrence K. Altman, Insurer to Finance Test of a Treatment for Breast Cancer, N.Y. TIMES, Nov. 12, 1990, at A1 (estimated by multiplying the 25,000 candidates "who might benefit" by, $100,000 per treatment).

30 One recent publication presented in tabular form the dichotomy of opinions which have been expressed in the literature. Interestingly, Peters, whose analysis was published simultaneously with Smith's and Henderson's, and upon which the Eighth Circuit specifically relied upon in reversing a lower court injunction denial (Henderson v. Bodine Aluminum, Inc., 70 F.3d 958, 961 (8th Cir. 1995)), has made comments qualifying for both The Optimists and The Skeptics headings. See Smith & Henderson, supra note 9, at 212.

31 See, e.g., Harris v. Mut. of Omaha Cos., 992 F.2d 706, 708 (7th Cir. 1993).

32 Id.
Health care costs are spiraling as they are, to a large extent, driven by the evolution of new technologies. It follows then that the slowing of the introduction of novel treatments is an appealing target for those who desire to curb the rise. Although more than twenty-five years ago confirming clinical trials for both newer and widely accepted treatments were called for, this advice has been largely ignored.

Technologies go through a series of stages upon their introduction. HDC-ABMT or HDC-PSCR, has been placed by at least one commentator, John B. McKinley, somewhere between "professional and organizational adoption" and "public acceptance and state (third-party) endorsement." McKinley notes that it is in the stage of "randomized clinical trials" that new medical treatments or techniques are often found ineffective, or lacking in improvement compared to existing methodologies. Although prestigious researchers may claim a new treatment to be vastly superior, it may be disproved by subsequent randomized study. Radical surgery in the management of breast cancer is a case in point.

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33 See, e.g., Henry J. Aaron, Serious and Unstable Condition: Financing America's Health Care 39-49 (1991) (outlining the five factors which have contributed to the rise in per capita health expenditures in the United States, and concluding that the technological revolution predominates).

34 See Thomas C. Chalmers, Randomization and Coronary Artery Surgery, 14 ANNALS OF THORACIC SURGERY 323, 323-327 (1972) (listing a variety of treatments widely advocated and adopted which were never tested by adequate clinical trials, a number of which were found subsequently to be clinically worthless, and concluding that the medical profession should have learned from these mistakes).


36 McKinley outlines seven stages that new devices or procedures go through, although the order may vary and certain stages may even be skipped. These are: 1) the stage of the promising report; 2) the stage of professional and organizational adoption; 3) the stage of public acceptance and state (third-party) endorsement; 4) the stage of standard procedure and observational reports; 5) the stage of the randomized clinical trial; 6) the stage of professional denunciation; and, 7) the stage of erosion and discreditation. Id. at 376-401.

37 Id. at 392-95.

38 J. Katz, The Silent World of Doctor and Patient 175 (1984), reprinted in George J. Annas et al., American Health Law 350, 350-354 (1990) (noting the en-bloc breast and chest wall resections advocated by the prominent surgeon William Halsted were rapidly adopted despite being based upon anecdotal observations - eventually, controlled trials were completed which demonstrated a significantly less aggressive approach equally effective).
Both the medical community and insurance industry agree that randomized, prospective Phase III trials must be completed. The accrual of patients for these studies however, has been slow. This is largely because women have been reticent to participate in trials where they might be randomized to conventional chemotherapy, which they are convinced is markedly inferior. While the media is partially responsible for this premature conclusion, the majority of the blame rests squarely on the shoulders of the medical community for failing to confess their knowledge is limited. Consequently, it is the court to which insurance carriers, physicians, and the public have turned to resolve the dispute.

BACKGROUND ON HDC-ABMT AND HDC-PSCR REIMBURSEMENT LITIGATION

Court decisions regarding whether or not insurers must pay for HDC-ABMT or HDC-PSCR in the treatment of breast cancer have come down from a number of jurisdictions in recent years. The standard a court will apply in deciding whether an insurer is responsible for the cost of a

39 See Smith & Henderson, supra note 9, at 211 ("An analysis of the role of bone marrow transplantation for breast cancer is limited by the lack of properly controlled clinical trials."); see also Peters, supra note 19, at 218 ("Critical to deciding the ultimate role of high-dose therapy in the treatment of breast cancer and other diseases are the performance and analysis of well-designed and well-controlled randomized clinical trials."). See also Susan Gleeson, Reimbursement of Biotherapy: Present Status, Future Directions - Perspectives of the Third-Party Payer, SEMINARS IN ONCOLOGY NURSING, NOV. 1992, 13, 13-16 (describing the views of the Blue Cross-Blue Shield Association, and their commitment to financially support such studies).

40 Smith & Henderson, supra note 9, at 211 ("As a result of patients' insistence on obtaining ABMT, many women who are eligible for randomized trials do not participate and instead search for centers where all patients can receive a bone marrow transplant").

41 See id. ("Many patients have preconceived expectations regarding the effectiveness of this treatment based on anecdotal reports, the experience of family or friends, and the climate generated by popular media"). See also McKinley, supra note 35, at 377 ("The careers of most medical innovations seem to be launched with the appearance of an enthusiastic report on some promising performance, increasingly in the mass media").

42 "[W]e have raised the public's expectations far beyond what is supported by the published data. [W]hen we suggest ... we are treating with "intent to cure" and when we publicly justify the toxicity and costs ... by [certain] statements ... we often mislead our patients who, in their desperation, fail to hear the conditional nature of these phrases. When we say that a particular therapy is a patient's "only chance for cure," no jury in our society, ... which places a high value on action, is likely to look critically at the evidence and deny a patient treatment." I. Craig Henderson, Window of Opportunity, 83 J. NAT'L CANCER INST. 894, 895 (1991).
particular patient's treatment varies with the type of policy held. Initially, when adjudication was centered mainly in the lower courts, patients were often successful in obtaining injunctions against payment denials. Insurance carriers responded to this trend through a number of mechanisms, in particular by careful drafting of these insurance policies to clearly express the insurer's intent to deny coverage. Recent appellate decisions suggest this approach has been somewhat successful.

These high-profile court battles have not escaped the attention of state and federal legislatures. In some states, and in the case of all federal employees, coverage for HDC-AMBT or HDC-PSCR is now mandated. However, the core issue of whether this newer and costlier treatment is indeed an improvement over prior therapy, remains unresolved.

There have been numerous published decisions stemming from litigation to compel third-party payers (whether private, self-insured employers, or the government) to reimburse providers for HDC-ABMT or HDC-PSCR in the systemic treatment of breast cancer. Since 1991, Blue Cross-Blue Shield, the largest insurer in the country, has been the only carrier to fund the procedure on a pilot basis.43

The vast majority of cases have been heard at the federal district level, although several decisions have “trickled up” to the appellate courts. As of yet, neither the United States Supreme Court nor any State Supreme Court has ruled on the issue. The published federal circuit opinions reviewed for this report included those from the Third, Fourth, Seventh, Eighth, Tenth, and Eleventh Circuits.44 All but two of these opinions have been handed down in the last three years. Reviewed decisions from the

43 Gleeson, supra note 39, at 13 (noting that Blue Cross-Blue Shield, "the country's largest and oldest provider of health care coverage," [at that time] "serving 68 million members, or more than one in four Americans," was the first insurer to agree to fund the procedure).

44 See Smith v. Office of Civilian Health and Medical Program of the Uniformed Servs., 97 F.3d 950 (7th Cir. 1006); Compassion in Dying v. Washington, 79 F.3d 790 (9th Cir. 1996); Bailey v. Blue Cross and Blue Shield of Virginia., 67 F.3d 53 (4th Cir. 1995); Henderson v. Bodine Aluminum, Inc. 70 F.3d 958 (8th Cir. 1995); Wilson v. Office of Civilian Health and Medical Programs of the Uniformed Servs., 65 F.3d 361 (4th Cir. 1995); Wolf v. Prudential, 50 F.3d 793 (10th Cir. 1995); Pitman v. Blue Cross and Blue Shield of Oklahoma, 24 F.3d 118 (10th Cir. 1994); Fujia v. Benefit Trust Life Ins. Co., 18 F.3d 1405 (7th Cir. 1993); Bechtold v. Physicians Health Plan of N. Ind., Inc., 19 F.3d 322 (7th Cir. 1994); Madonia v. Blue Cross and Blue Shield of Virginia, 11 F.3d 444 (4th Cir. 1993); Heasley v. Belden and Blake Corp., 2 F.3d 1249 (3rd Cir. 1993); Harris v. Mutual of Omaha Cos., 992 F.2d 706 (7th Cir. 1993); Dahl-Elmes v. Mutual of Omaha Life Ins. Co., 986 F.2d 1379 (11th Cir. 1993).
federal district level include districts in Connecticut, New York, New Jersey, Rhode Island, Maryland, District of Columbia, Virginia, North Carolina, Georgia, Florida, Illinois, Indiana, Tennessee, Missouri, Alabama, Washington, Oregon, South Dakota, Colorado, and the Northern District of California. The vast majority of these cases were decided within the last five years.  

Finally, state appellate court decisions reviewed for this article include, the Court of Appeals of Michigan, the Appellate Court of Illinois,

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and the Colorado Court of Appeals. These rulings were all made within the last three years.

Privately Negotiated Policies Between Patient and Insurer

Policies negotiated directly between the patient and an insurance underwriter are governed by the particular laws of the state in which the agreement is consummated. Medicaid, as a state administered instrument, as well as state or local government plans, fall into this category. In such cases, the courts turn to the individual state's case law (common law) or, when codified, their statutory provisions on contracts for guidance. Here, consideration is given to the powers of bargaining and the specifics around the policy drafted. Often, it is concluded that a contract of adhesion is present. In order to protect the weaker party in such situations, provisions of exclusion are narrowly construed. Similarly, ambiguous terms are viewed in a light most favorable to the weaker party.

Some insurance policies specifically exempt certain treatments or procedures from coverage, while other policies broadly exempt all therapies of an "experimental" or "investigational" nature from reimbursement. This latter approach has resulted in the vast majority of litigation, largely because the term "experimental" has been called ambiguous "on its face," and has never been defined clearly. Because of

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47 See, e.g., Bechtold v. Physicians Health Plan of N. Ind., Inc., 19 F.3d 322, 325 (7th Cir. 1994) (noting that disputes over insurance policy coverage are matters of contract interpretation).
48 See, e.g., Saver, supra note 2, at 1100-01.
49 Id.
50 See id. See also CLARK C. HAVIGHURST, HEALTH CARE CHOICES: PRIVATE CONTRACTS AS INSTRUMENTS OF HEALTH REFORM 182 (1995) (discussing the contract law concept of contra proferentem, which requires ambiguities in insurance contracts to be construed against the insurer, as the drafter of the policy).
this ambiguity, judges have looked to how the terms "experimental and/or investigatory" are defined in the individual policy.\(^2\) In situations where more than one interpretation of a term is possible, the term is assigned the meaning an average purchaser would apply.\(^3\) On the other hand, when a contract is silent altogether on the issue, the decision of the court has centered on whether it would be reasonable for the policyholder to expect coverage.\(^4\)

In settling this dispute, the Medicaid statute defers to the individual states to determine what treatments will be covered, as long as the decisions are "reasonable" and "consistent with the objectives" of the Medicaid Act.\(^5\) Some authors have suggested this places far too much discretion with the state, since funding for "medically necessary" treatments may also be denied.\(^6\) The Health Care Financing Administration (HCFA), which administers Medicare and Medicaid, avoids using the terms "experimental," or "investigational," in lieu of "reasonable" and "necessary."\(^7\) It is not surprising the courts find this alternative wording equally vague. However, on the whole there have been fewer rulings on Medicaid denials for HDC-ABMT or HDC-PSCR, most likely because of state exemptions, combined with the low reimbursements Medicaid provides.\(^8\)

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\(^2\) Harris v. Mut. Of Omaha Cos., 992 F.2d 706 (7th Cir. 1993).
\(^3\) Id.
\(^4\) Wheeler v. Dynamic Eng'g, Inc., 62 F.3d 634, 638 (4th Cir. 1995) ("Where a term is ambiguous, we must construe it against the drafter, ... and in accordance with the reasonable expectations of the insured").
\(^6\) See George J. Annas et al., American Health Law 185-86 (1990) (noting that judicial deference to coverage limitations proscribed by the state may, on occasion, result in medically necessary services being denied - the test the court uses is whether the exclusion is "reasonable," which requires establishing only that the needs of most recipients would be met).
\(^7\) 57 Fed. Reg. 24797, 24804 (June 11, 1992).
\(^8\) The low reimbursement rates typically seen with Medicaid patients make it unlikely the full cost of this treatment will be recovered even when payment is uncontested. This is a fact the medical community is acutely aware of, and may influence how often HDC-ABMT or HDC-PSCR is therefore prescribed. Paradoxically, the lack of Phase III data may be seen as a "loophole" in these cases, because it provides the doctor a degree of protection from a "failure to inform" claim for not discussing this option. I have found no data directly supporting or refuting this statement, but it is interesting to note the sparsity of litigation regarding the denial of coverage for HDC-ABMT or HDC-PSCR in the Medicaid population.
Medicare coverage is continually evolving and updates to the HCFA Medicare Coverage Issue Manual are published in the Federal Register quarterly. Although the vagaries of "reasonable and necessary" provided contracting intermediaries with little coverage guidance in the past, this is no longer a problem in regard to this particular treatment since from mid-1992, autologous bone marrow transplantation for breast cancer specifically has been excluded. Suits based on Medicare denials may be removed to federal court, where the "federal common law" of contracts applies. However, since these rigorous therapies are frequently limited to those less than fifty years of age, Medicare patients are less likely to undergo HDC-ABMT or HDC-PSCR.

Federal employee plans, which are governed by the Federal Employees Health Benefits Act (FEHBA), are also removable to federal jurisdictions. Decisions on coverage are made first by the carrier, and any denials are then reviewed through administrative proceedings by the Office of Personal Management (OPM). The OPM manual has become more specific about the procedures that will be covered, particularly in regard to the treatment of cancer. An update of covered procedures is published as a Statement of Contract Benefits for each health plan.

Plans covering members of the United States military are governed by the Civilian Health and Medical Programs of the Uniformed Services rules. As with federal employees, disputes are heard in federal court. Ultimate coverage determinations are made by the Director of the Office of Civilian Health and Medical Programs of the Uniformed Services

60 See id. (explaining that while not specifically identifying breast cancer, the HCFA update lists solid tumors (with the single exception of neuroblastoma) under "Noncovered Conditions" with regard to autologous bone marrow transplantation).
61 See Caudill v. Blue Cross and Blue Shield of North Carolina, 999 F.2d 74, 78 (4th Cir. 1993) ("The Supreme Court has held that some areas involving "uniquely federal interests" may be so important to the federal government that a "federal common law" related to those areas will supplant state law either partially or entirely." (quoting Boyle v. United Tech. Corp., 487 U.S. 500, 504 (1988))). See also Wheeler v. Dynamic Eng'g, 62 F.3d 634, 638 (4th Cir. 1995) ("While we interpret an ERISA plan under federal common law, we may use principles of state common law to guide our analysis.").
62 See, e.g., Smith & Henderson, supra note 9, at 206 (estimating costs based on those women who are both clinically eligible and younger than age fifty).
The OCHAMPUS manual, like the OPM manual, has become increasingly specific about payment exemptions.

Employee Welfare Benefit Plans

Employer-based self-insurance is governed by federal law under the Employee Retirement Income Security Act of 1974 (ERISA). These type of plans insure the majority of Americans working today. Insurance laws requiring companies to establish sufficient cash reserves have made it easier for large employers to achieve this status. More recently though, smaller employers have pooled resources to qualify.

There are several advantages afforded carriers who provide insurance under the broad aegis of employee welfare benefit plans. One advantage is that ERISA exempts these group health plans from state regulation including, among other things, coverage mandates. As another advantage, ERISA limits the plans liability in the proceeding to an injunction against payment refusal, accrued benefits, or a judgment of an entitlement to benefits under the plan. Under ERISA, claims of negligence and intentional infliction of emotional distress, as well as awards for pain and suffering and punitive damages, are exempted as extra-contractual in nature. Under state laws, however, these claims may be adjudicated coincidentally, if recognized.

There is also a theoretical advantage for the self-insurer who becomes embroiled in reimbursement litigation, in that a more lenient standard of review is applied. If the plan grants the administrator discretion to determine whether a certain treatment is "experimental" or

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68 See id. at 1718-19 (reviewing the tax and other advantages of self-insurance).
69 Id. (discussing the over 900 state mandates for coverage nationwide that ERISA-based plans are exempted from).
not, the court will defer to the administrator’s decision, unless the reviewer’s findings were “arbitrary and capricious.” On occasion, courts may also enlist an “abuse of discretion” analysis. This advantage for the self-insured employer is theoretical; while some courts afford a great deal of deference to the plan administrator, others may employ a sliding-scale that decreases permissible deference depending on the amount of conflict of interest. Determination by the court as to whether a denial was “arbitrary and capricious” is limited to the evidence used by the claims reviewer in drawing his conclusion.

If a policy does not explicitly place discretion in the hands of the plan administrator, a de novo evaluation by the court will ensue. In this case, the principles of contract are again drawn upon, although the federal common law of contracts also applies. Additionally, when a court reviews de novo, it may look to sources that were not explicitly before the reviewer when the issue initially was decided. Although this standard of review is broader, in both situations the proceedings are limited to a bench trial. This precludes a jury, which must be more sympathetic to the patient’s plight, upon hearing the case.

73 Id.
74 See Saver, supra note 2, at 1104 n.45. See also Wolf, supra note 54, at 2061.
75 Compare Lowery v. HealthChicago Inc., 1994 WL 194265, at *4 (N.D. Ill., May 16, 1994) ("Under the arbitrary and capricious standard, a denial of benefits will not be set aside unless the denial was based upon a ‘downright unreasonable’ interpretation of the plan documents ....") (quoting Fuller v. CBT Corp., 905 F.2d 1055, 1058 (7th Cir. 1990))) with Bechtold v. Physicians Health Plan of N. Ind., Inc., 1993 WL 625573, at *5 (N.D. Ind., Mar. 19, 1993), aff'd 19 F.3d 322 (7th Cir. 1994) ("[A] serious conflict of interest may require that the deference to be given to the plan's decision be slight, even zero ....") (quoting Van Boxel v. Journal Co. Employees’ Pension Trust, 836 F.2d 1048, 1052 (7th Cir. 1987))).
76 Harris v. Mut. of Omaha Co., 992 F.2d 706, 711 (7th Cir. 1993) (noting that deferential review is strictly limited to the record before the administrator when the decision to provide or deny coverage is made).
77 See Firestone Tire & Rubber Co. v. Bruch, 489 U.S. 101, 109 (1989) (defining when the de novo versus the more lenient "arbitrary and capricious" standard of review should be applied).
78 See Wheeler v. Dynamic Eng’g, Inc., 62 F.3d 634, 638 (4th Cir. 1995).
79 See Wolf, supra note 54, at 2062 n.223, 2076-77 nn.341-344. See also Saver, supra note 2, at 1104.
80 Saver, supra note 2, at 1104.
Court Rulings

Although many of the early decisions concerning this dispute are interesting, of particular importance in the debate between insurance carriers and patients seeking reimbursement are the recent cases reviewed by the courts. This is largely because the latter involve carriers (whether government, private, or self-insurers) who, based upon the outcome of earlier litigation, have attempted to be increasingly specific about the exemptions of their coverage.

Of all federal courts, the Seventh Circuit Court of Appeals has published the most opinions confirming reimbursement denials based upon a specific exemption. For example, in *Harris v. Mutual of Omaha Co.*, a federal employee sought a preliminary injunction against her insurer for nonpayment of HDC-ABMT in the treatment of her advanced breast cancer. The insurance company declined to issue a pre-treatment authorization because it deemed HDC-ABMT "experimental or investigational" in nature. The patient's plan had issued to her a twenty-four page brochure that specifically excluded services that were "investigational or experimental." In the "Definitions" section of the brochure, services considered to be "experimental or investigational" were defined as those delivered prior to the completion of Phase I, II, or III trials. The policy further indicated that review was to be based upon "reliable evidence," defined in the policy as published reports from scientific literature.

OPM subsequently reviewed the reimbursement denial and agreed with the insurer that HDC-ABMT was "experimental or investigative." OPM recapitulated the intermediary insurer's determination based on the

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81 *Harris v. Mut. of Omaha Co.*, 992 F.2d 706 (7th Cir. 1993); *Bechtold v. Physicians Health Plan of N. Ind., Inc.*, 19 F.3d 322 (7th Cir. 1994); *Smith v. Office of Civilian Health & Medical Program of the Uniformed Servs.*, 97 F.3d 950 (7th Cir. 1996); *Wilson v. Office of Civilian Health & Medical Program of the Uniformed Servs.*, 65 F.3d 361 (4th Cir. 1995); *Bailey v. Blue Cross & Blue Shield of Virginia*, 67 F.3d 53 (4th Cir. 1994).
82 *Harris v. Mut. of Omaha Co.*, 992 F.2d 706 (7th Cir. 1993).
83 *Id.* at 710.
84 *Id.* at 708.
85 *Id.*
86 *Id.*
87 *Harris v. Mut. of Omaha Co.*, 992 F.2d 706, 711 (7th Cir. 1993).
following facts: the patient would be enrolled in a Phase II study; the informed consent form she had signed clearly stated the study was investigational; and eighteen published reports cited by the intermediary supported this conclusion.\textsuperscript{88}

The District Court evaluated the OPM's decision on an "arbitrary and capricious" standard and upheld OPM's conclusion.\textsuperscript{89} On appeal, the judgment was affirmed with emphasis on the specific exclusionary language in the policy.\textsuperscript{90} The appellate court also found the published articles offered by the defense, which indicated the service was typically delivered as part of phase II or III clinical trials, to be dispositive.\textsuperscript{91} Finally, the court held the insurers' position to be insufficiently refuted by the plaintiff's evidentiary submission of unpublished opinion that stated the treatment should no longer be considered "investigational."\textsuperscript{92}

In \textit{Bechtold v. Physicians Health Plan of Northern Indiana, Inc.}, the insurer prevailed by more broadly exempting any treatment not covered by Medicare.\textsuperscript{93} A forty-year-old breast cancer patient with "heavy" lymph node involvement brought an ERISA-based claim to have her insurer pay for HDC-ABMT.\textsuperscript{94} The patient's policy denied coverage for "experimental or unproven" procedures "is considered by any government agency, including ... the HCFA Medicare Coverage Issues Manual to be: experimental or investigative, not considered reasonable and necessary, or not covered under Medicare reimbursement laws."\textsuperscript{95} Although the policy did not specifically exempt breast cancer from ABMT, it did "exempt transplants for solid tumors (other than neuroblastoma)" under
a "Noncovered Conditions" listing in the policy. The policy similarly failed to specifically exempt treatments or procedures in Phase I, II, or III trials.

This denial of summary judgment for the plaintiff was affirmed. The court concluded that prior to the patient’s request for this coverage, Medicare had issued an update stating it did not consider autologous bone marrow transplantation for breast cancer to be "reasonable and necessary." The exemptions in the policy, in combination with Medicare's recent decision, were found by the court to be sufficiently "unambiguous."

Specific exemption is fraught with its own problems. It requires skillful drafting of the policy and a constant vigil for new technologies that may be offered. The exemption of novel treatments as they evolve increases the transaction costs of frequent renegotiation and/or the posting of continuous addendum. Additionally, innovative procedures that are not available when the policy was written are more likely to be covered

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96 Id. at 326.
97 Id. at 329.
98 But note, the Medicare update in June 1992 must have been issued coincidentally with Bechtold’s initial request for coverage, because her cancer was diagnosed in October 1991, at which time she underwent a course of standard chemotherapy and irradiation. This standard treatment, assuming the usual six cycles of chemotherapy and full course irradiation, takes approximately nine months to deliver. The lower court record indicates the plaintiff requested a denial hearing in September of 1992 (Bechtold v. Physicians Health Plan of N. Ind., Inc., No. Civ.P.92239, 1993 WL 625573, at *2 (N.D Ind., Mar. 19, 1993) aff’d 19 F.3d 322 (7th Cir. 1994)), which was requested and forwarded to Bechtold’s counsel after further clarification on the initial denial. Although the exact dates of Bechtold’s initial request is not reported, this suggests the denial closely approximated the Medicare ruling. Even more intriguing, it is not clear from the opinions whether the PHP administrator was indeed aware of Medicare’s statement when Bechtold’s request was originally denied. If not, under the limitations of an "arbitrary and capricious" review, a crucial factor is whether or not the court’s analysis is limited to those sources utilized by the PHP administrator in arriving at the original denial. Without Medicare’s ruling to supply a specific exemption, it could be argued the denial becomes increasingly difficult to justify. See supra pp. 14-15 (noting Medicare’s decision was published in the Federal Register in June of 1992). See also Bechtold v. Physicians Health Plan of N. Ind., Inc. 19 F.3d 322, 327 n.6 (7th Cir. 1994) (the court indicates that the HCFA ruling was in effect "at all times relevant to this proceeding" and that Bechtold was denied coverage in October of 1992. However, that was when a final letter denying her claim was sent and thus, the material that was before PHP at the time of the initial denial, may be the more appropriate record to review for capriciousness).
99 Bechtold v. Physicians Health Plan of N. Ind., Inc. 19 F.3d 322, 328 (7th Cir. 1994).
100 See Wolf, supra note 51, at 2048-49.
101 Id.
simply because a specific exemption is absent from the contract. As difficult as these decisions may be for the court to face on a personal level, legally these decisions are easy.

Many more cases exist where the insurer's refusal to pay is predicated on an implied exemption in the contract. These decisions have often favored the plaintiffs. In Smith v. Office of Civilian Health and Medical Program of the Uniformed Servs., the Court of Appeals overturned an order for a permanent injunction against the denial of payment for HDC-PSCRI. The patient was a forty-year-old woman with advanced breast cancer and the carrier's decision to deny coverage was based on the absence of "well-designed, Phase III ... studies which have been published in refereed medical journals." The program medical director stated in a denial letter that CHAMPUS does not provide coverage for treatments or procedures that are considered "experimental or investigational" and indicated that the decision is determined by whether the treatment meets "generally accepted standards of usual professional medical practice in the community," which must be supported by published results.

The carrier invited the submission of documentation supporting an alternate conclusion and, in response, the plaintiff submitted affidavits from her oncologists, an article indicating most insurance companies eventually pay for the procedure, and three recent district court decisions that had enjoined CHAMPUS from denying payment in similar circumstances. However, the plaintiff failed to send supportive peer-reviewed literature.

On appeal, the court did not refer to the CHAMPUS policy manual, which listed sixty-six specific conditions that CHAMPUS considered

\[102\] Id.
\[103\] Smith v. Office of Civilian Health and Medical Program of the Uniformed Servs., 97 F.3d 950 (7th Cir. 1996).
\[104\] Id. at 951.
\[105\] Id. at 953.
\[106\] Id. at 952.
\[107\] Id. at 953.
\[108\] Smith v. Office of Civilian Health and Medical Program of the Uniformed Servs., 97 F.3d 950, 953 (7th Cir. 1996).
\[109\] Id.
"experimental or investigational," although the manual was available when Smith's initial request was reviewed. In any event, CHAMPUS's conclusions were upheld by the court, which applied the "arbitrary and capricious" standard and wrestled over whether a "substantial evidence" test should apply for certain procedural reasons. The medical director's conclusion that "requisite acceptance in the medical community" means "outcomes of Phase III clinical trials published in referred medical journals," in the absence of this specific wording in the policy, was deemed adequate under an "arbitrary and capricious" standard.

Whether the determination by the court would survive testing under the stricter "substantial evidence" standard is questionable, which perhaps explains why the court's opinion was withdrawn and a rehearing granted. Affirmation of a reviewer's denial of payment, in the absence of a specific exemption, is rare.

In sharp contrast to Smith, the Fourth Circuit decision in Wilson v. Office of Civilian Health and Medical Program of the Uniformed Servs., reached the same month. In Wilson the lower court found that CHAMPUS's refusal to reimburse for the treatment was "arbitrary and capricious." The rationale employed by CHAMPUS was essentially

10 See Wilson v. Office of Civilian Health and Medical Program of the Uniformed Servs., 65 F.3d 361, 363 (4th Cir. 1995) (describing the contents of the CHAMPUS policy manual as of July, 1994, and in particular the numerous treatments identified specifically as "experimental or investigational" in nature).

11 Smith's request for coverage was denied in August, 1994, while Wilson's request for coverage was denied in July, 1994. There is no suggestion in the Smith record that the defense brought into evidence the 66 specific conditions exemplified in the CHAMPUS policy manual as "experimental or investigational." We know these specific exemptions were in the manual when Smith's request for coverage was denied, as indicated by the appellate record from Wilson. See id. at 363. Perhaps this was strategic on the part of defense, because they were aware of the 7th Circuit's propensity to rule for the insurer in similar cases. If so, OCHAMPUS may have been reaching for the precedential value of a ruling in its favor despite the court's inability to base its decision on a "solid" exemption in the policy.

12 See Smith v. Office of Civilian Health and Medical Program of the Uniformed Servs., 97 F.3d 950, 954 (7th Cir. 1996) (if CHAMPUS's decision was taken pursuant to a formal adjudicatory hearing, which was one of Smith's options, the court would have been required to review the decision under a "substantial evidence" test. Smith's failure to request a formal hearing by the agency before filing suit may ultimately have proved fatal).

13 Id. at 960.

identical to the reasoning set forth in Smith. As in Smith, PSCR rather than ABMT was recommended as a bone marrow recovery procedure following HDC.\textsuperscript{115} The medical director reviewed the request and declined payment,\textsuperscript{116} stating that "in the absence of published randomized, prospective trials, CHAMPUS must continue to consider [HDC-PSCR] investigational for the treatment of breast carcinoma."\textsuperscript{117}

The appeals panel deciding Wilson noted that HDC, ABMT, or PSCR were not specifically listed as procedures exempted in the CHAMPUS policy manual, while coverage for chemotherapy was clearly provided.\textsuperscript{118} The court also noted that the manual covered ABMTs for "certain diseases under specific circumstances," but that breast cancer was not included.\textsuperscript{119} The heavy reliance on absence of Phase III trials in denying the claim was deemed most significant to the ruling, since "...nothing in the Code of Federal Regulations or the CHAMPUS policy manual indicates that published, Phase III clinical trial results are required before a benefit can be provided."\textsuperscript{120} The court found "while the omission is not dispositive, the [agency's failure] to list [HDC-PSCR] as an 'experimental or investigational procedure' in its own policy manual" significant.\textsuperscript{121} In this case the Fourth Circuit, unlike the Seventh Circuit, weighed heavily an absent specific exemption, and gave little deference to the reviewer's conclusions. Other federal circuits have taken similarly action when a specific exemption was absent.\textsuperscript{122}

\textsuperscript{115} Id. at 362.
\textsuperscript{116} Id. at 363.
\textsuperscript{117} Id.
\textsuperscript{118} Id.
\textsuperscript{119} Wilson v. Office of Civilian Health and Medical Program of the Uniformed Servs., 65 F.3d 361, 363 (4th Cir. 1995).
\textsuperscript{120} Id. at 365.
\textsuperscript{121} Id. at 366 (discussing a number of factors the panel found indicative that this treatment was not experimental, such factors included: the procedure's explosive growth, a quote from a renowned physician from the National Cancer Institute indicating that in the context of a clinical trial HDC-PSCR is an accepted treatment, a paper published by the American Society of Clinical Oncology suggesting insurers should be supporting clinical trials, and an inexplicable quote by Dr. Bogner indicating there are "home run treatments" that are so successful, Phase III trials aren't necessary (emphasis added)).
\textsuperscript{122} Henderson v. Bodine Aluminum, Inc., 70 F.3d 958 (8th Cir. 1995) (ordering injunction against denial because policy covered other types of cancer, and failed to specifically exclude breast cancer from HDC-ABMT); Wolf v. Prudential Ins. Co. of Am., 50 F.3d 793 (10th Cir. 1995) (reversing summary judgment for insurer when plan did not specifically exclude
Another recent case demonstrates the difficulty insurers may face when specific exemptions are attempted but deemed incomplete. In *Bailey v. Blue Cross & Blue Shield of Virginia*, the policy stated "[a]utologous bone marrow transplants or other forms of stem cell rescue (in which the patient is the donor) *with* high dose chemotherapy or radiation are not covered" (emphasis added). The policy went on to specifically identify breast cancer as a disease to which this exemption applied. Chemotherapy was listed as covered, while HDC was *not* specifically exempted. It is not clear whether it was the district level, or before trial, that the plaintiff conceded that PSCR was exempted from payment.

On appellate review, by the Fourth Circuit the plaintiff sought an injunction against the insurer's denial to reimburse for the HDC. The lower court's grant of summary judgment for the plaintiff, based on the ambiguities of the policy, was affirmed and the finding that exclusion of HDC-PSCR does not mean the exclusion of HDC itself, was reiterated. In this case, the court found PSCR functionally equivalent to ABMT. Other jurisdictions have found the two treatments to be separate and distinct, and have ordered the insurer to reimburse for PSCR despite the fact that ABMT is excluded specifically from the policy.

HDC-ABMT delivered during a clinical trial); Dahl-Eimers v. Mut. of Omaha Life Ins. Co., 986 F.2d 1379 (11th Cir. 1993) (finding the phrase "considered experimental" ambiguous and vacating and remanding a denial of preliminary injunction against insurer).

124 Id.
125 Id. at 55-56.
126 Id. at 55.
127 Id. at 58.
129 Id. at 57 ("Construing the exclusion for stem cell rescue ... with high dose chemotherapy or radiation, Blue Cross essentially interprets 'with' as unambiguously meaning 'and'").
130 Id. ("In Doe, the "rescue" procedure preceding chemotherapy and radiation involved an [ABMT] rather than [PSCR] ... . The medical principles, however, were equivalent to those underlying the procedure for which Bailey seeks coverage." (citing Doe v. Group Hospitalization & Medical Servs., 3 F.3d 80, 82 (4th Cir. 1993))).
131 See Wheeler v. Dynamic Eng'g, Inc., 850 F.Supp. 459, 468 (E.D.Va. 1994), aff'd 62 F.3d 634 (4th Cir. 1995) ("Although the two procedures are similar in that they both provide support for a patient receiving high dose chemotherapy, the two are distinct procedures ... . The section cited by CHAMPUS excluding coverage for autologous bone marrow transplantation does not apply to [p]laintiff's case."). *See also* Wilson v. Office of Civilian Health and Medical Program of the
LAW VERSUS MEDICINE: DECIDING WHAT IS EXPERIMENTAL

Decisions made in the late 1980's through the early 1990's forced the insurance industry to back away from broad exemptions under the category of "experimental." The courts found "experimental" sufficiently vague, but more importantly, a significant section of the scientific community provided testimony that unproven treatments were not by definition "experimental." Although those who testified did not provide peer-reviewed literature to support this claim, most of the public and many of the judiciary came to accept this as the truth. However, a small yet persistent cadre of researchers persisted and continue to insist on verification to this day.

In the absence of specific exemption, judges turn to a number of sources including expert testimony, medical literature, and the practices of other insurers in determining whether HDC-ABMT or HDC-PSCR should be reimbursed. From a scientific perspective, the first and last approach are fundamentally flawed. Until there is prospective, randomized clinical data of statistical significance, even the most published researcher from the finest facility cannot accurately predict the outcome. The question then becomes how can "expert" testimony exist absent any valid trials upon which to reach such conclusions? This issue has evaded the courts' analyses.


See infra pp. 31-32. See also infra note 203 (subjecting Congress to a "barrage" of similar "expert" opinion).

See, e.g., Smith & Henderson, supra note 9, at 211-12.

See Henderson v. Bodine Aluminum, Inc., 70 F.3d 958, 961 (8th Cir. 1995) (citing the publication of Peters, supra note 19, as evidence that HDC-ABMT is not "experimental"). See also Wolf v. Prudential Ins. Co. of Am., 50 F.3d 793, 800 (10th Cir. 1995) ("Adverse court decisions involving coverage for HDC-ABMT have forced at least one insurer to change its coverage position: "[T]he district court implicitly embraced Blue Cross's concession that it could no longer consider HDC-ABMT [to treat breast cancer] experimental given the growing number of adverse decisions...." (citing Pitman v. Blue Cross & Blue Shield of Okla., 24 F.3d 118, 124 n.11 (10th Cir. 1994))).
Similarly, the fact that a number of institutions are investigating a particular treatment in no way suggests the treatment has acquired the status of "standard" therapy. Experiments are done on those things which are experimental, and clinical research is merely experimentation on humans. Despite the inconclusive evidence of the value of HDC-ABMT and HDC-PSCR, a recent survey of American physicians reveals that an overwhelmingly high proportion believe the treatment to be superior to standard chemotherapy in the setting of metastatic breast cancer. These figures illustrate the unscientific "truths" that physicians may themselves hold evident and if the medical community is unable to discern the "proven" from the "hypothetical," it is not surprising the court cannot either. But in a fee-for-service environment, one would think that the issue of whether the "fox" is guarding the "chickens" might arise. Even when there is no such obvious potential for a conflict of interest, researchers often have the "professional currency" of prestige and future research funding on the line.

A recent comprehensive law review written by Denise S. Wolf on the determination of who should pay for HDC-ABMT is revealing. The author discusses in detail several cases on which expert opinion was strongly relied. She concludes, based on these opinions, that deferral to program administrators should be eliminated altogether and that the court should substitute a "primary purpose to benefit the patient" standard when HDC-ABMT is at issue. The author, however, does not question the role of the judiciary in making these type of determinations and therein lies the problem. Because process skills are not well-suited to progress disputes, the argument may be debunked.

135 See SMITH & HENDERSON, supra note 9, at 201 (80 percent of American physicians surveyed stated that they believed women with metastatic breast cancer should receive HDC-ABMTs, despite the inconclusive evidence of superiority).

136 See, e.g., John L. Cova, A Swift Response to a "Modest" Proposal, 84 J. NAT'L CANCER INST. 744, 745 (1992) (an editorial by a spokesman of the Health Insurance Association of America suggesting those institutions offering HDC-ABMT are focusing on increasing their market share of patients, irregardless of the clinical efficacy of the treatment).

137 Wolf, supra note 51, at 2065.

138 Id. at 2066.

139 Id. at 2065. Parenthetically, Wolf v. Prudential Ins. Co. of Am., 50 F.3d 793 (10th Cir. 1995) was an ERISA-based hearing on the denial of funding for HDC-ABMT under an "experimental" exclusion. The appeal was from a district court ruling granting summary judgment for the insurer.
The first case examined by Wolf is *Taylor v. Blue Cross/Blue Shield of Michigan*, where the refusal to reimburse was based upon an "experimental" exclusion.140 "Experimental" was not specifically defined in the policy141 and the trial court found the expert testimony highly persuasive.142 The treating oncologists testified that "the modified HDC-ABMT was truly the only way [the patient] could become free of cancer for at least two or three years" (emphasis added).143 There is no mention in the record, nor any query by either the state trial or appellate court, how such a prediction could be made.

Additional testimony on behalf of the patient came from a doctor whom the court noted was the founder of the Michigan Society of Hematology.144 This "expert" testified at trial that this association had issued a position paper stating HDC-ABMT was an "an effective form of therapy for breast cancer."145 Based predominately on this evidence, the appellate court concluded that HDC-ABMT "is neither experimental nor research in nature..."146

Wolf's second case, *Pirozzi v. Blue Cross-Blue Shield of Virginia*, is even more striking for the judgment rendered.147 The court first discounted the conclusion made by the physician who reviewed and denied the patient's claim because he was not an oncologist and "merely gave an opinion on a topic outside his area of expertise:"148 The court then listed the vast number of medical centers the plaintiff's "expert" witness had testified were "using" the treatment.149 The court concluded that "[t]his is convincing evidence that the treatment has "scientifically proven

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141 *Id.* at 868
142 *Id.* at 869.
143 Equally strange is the testimony, "[i]f she chose conventional chemotherapy, her life expectancy would have been measured in months..." *Id.*
144 *Id.*
146 *Id.*
148 *Id.* at 591.
149 The hospitals listed therein are Duke Univ., Fairfax Cty. Hosp., George Washington Univ., Georgetown Univ., Harvard Univ., Johns Hopkins Univ., Medical College of Virginia, Houston's M.D. Anderson Hosp., Univ. of Chgo., Univ. of MI., Univ. of Neb., Univ. of Texas-San Antonio, Univ. of VA. Medical Ctr., Univ. of WI., Yale Univ. Medical School, and all Florida teaching hospitals. *Id.*
value’ and is ‘in accordance with generally accepted standards of medical practice.’”

Perhaps most revealing was the accompanying dicta, which borders on the incredulous. The court wrote:

... [m]any treatments become accepted without Phase III studies, in part, it appears, because these studies, by their nature, are difficult to conduct. In general, Phase III studies randomize patients and then administer a medical procedure to one group and a placebo to another, and finally compare the results (emphasis added). The axiom is that Phase III trials compare standard therapy to new therapy, not to a placebo. The court continued,

"[a]ccording to Dr. Beveridge, patients are reluctant to be randomized and to run the risk of being members of the placebo group. Dr. Beveridge pointed to a Phase III study of [HDC-ABMT] at Duke University that, for more than a year, has unsuccessfully attempted to accrue subject patients. Simply put, patients are unwilling to risk receiving the placebo treatment when ample evidence suggests that the true treatment will improve their conditions. Thus, the absence of extensive data comparing [HDC-ABMT] treatment with a control group is relevant, but neither determinative nor ultimately persuasive of the treatment's status as an experimental medical practice.

Although it is beyond belief that a proclaimed “expert” on the subject could testify that patients were given placebo treatment in the standard treatment arm of Phase III experiments, even if we assume the “expert” was confused it does not explain the court's conclusion that the experimental arm is therefore the true treatment. Unfortunately, in subsequent opinions this dicta has been widely quoted, despite the Pirozzi.

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150 Id.
151 Id. at 593-94.
court's proclamation that the ruling was "not a green light signaling a
general expansion of coverage...."]

In the third case discussed by Wolf, Bucci v. Blue Cross-Blue Shield
of Connecticut, the author failed to note that the judge completely jumbled
the issues. Despite a policy explicitly stating that services of an
experimental nature would not be reimbursed, it was concluded the refusal
was "arbitrary and capricious," because it did not provide a standard by
which "nonexperimental" could be determined.

In Bucci, the claims reviewer employed a five-factor test to determine
coverage. One factor was a demonstration of medical benefit at least
equal to that offered by established alternative treatment. The court first
discounted this as subjective, and then proposed the reasonable,
substantial, or responsible standards upon which legal issues are judged
should be used as the reviewer's measure (i.e. appropriate medical practice
in the community). Finally, the court made the leap, based upon the
plaintiff's evidence, that application of such a standard supports the
approval of treatment.

The court's thinking in Bucci is difficult to understand. At one point
in the opinion they suggest that because HDC-ABMT had been proven
superior in other cancers, it would be beneficial in breast cancer. At
another point they suggest that either the plan should have contained, or
the reviewer should have employed, a "particular test, or ... a particular

153 Id. at 595. See, e.g., Bucci v. Blue and Cross & Blue Shield of Connecticut 764 F. Supp.
728, 733 (D. Conn. 1991).
155 Id. at 733.
156 The procedure must include the following: (1) government regulatory approval; (2) evidence
which permits conclusions as to the effect on patient health; (3) demonstrated improvement of the
patient's health; (4) demonstration of medical benefit at least equal to that offered by established
treatment; and (5) improvement other than in investigational settings. Id. at 731.
157 Id.
159 Id.
160 Id. at 732-33.
161 The court failed to appreciate that breast cancer is a solid tumor, and that a procedure or
treatment for one cancer does not apply to another cancer per se. See id. at 733 (posing that
HDC-ABMT provides a benefit in several forms of cancer) (citing Dozna v. Crum & Forster Ins.,
716 F. Supp. 131, 136 (D.N.J. 1989) ("In a way ... we are really splitting hairs in the sense that
once one accepts ABMT as a technique for one indication it is a short way to accepting it for all
of the non-solid tumors.").
threshold of statistical success in terms of a cure or survival rate” on which to base denial. In reaching its decision, the court failed to recognize that the real issue is whether the costly treatment should be paid for when there exists no useful evidence of its superiority over less expensive standard treatment.

In Wolf’s article, she actually makes two suggestions about how the courts should handle these lawsuits. First, she suggests that the court “resolve ambiguities about the experimental status of a treatment by making an independent determination through de novo review, without deferring to the ERISA plan administrator.” Wolf seems to believe that insurance claim reviewers are biased toward denying patients deserved benefits, and that consequently their decisions are destined to be an "abuse of discretion" or “arbitrary and capricious” by nature.

If indeed a conflict of interest is present for claim reviewers, we may rely on the market forces within the competitive insurance industry that tend to counter temptations to deny patients proven therapies. Interestingly, Wolf, like many courts before her, fails to address the potential conflict of interest facing plaintiff’s “experts,” who are usually the patients’ treating oncologists, or their counterparts from major research institutions. Instead, Wolf postulates that it would be preferable to have judges, with questionable understanding of the methods of scientific analysis, determine a novel treatment’s “experimental” status.

In her second recommendation, Wolf addresses plans that specifically deny coverage for procedures performed under protocol. She suggests that the court, if it finds a treatment to be “nonexperimental” upon a de novo weighing of the evidence, should decide whether a “primary purpose to benefit the patient” is present. The flaw in cognition here, however, is that “a primary purpose to benefit the patient” cannot possibly be found until treatment has been fully established as beneficial, a process that requires scientific determination through Phase III randomized trials. Consequently, the absence of reliable Phase III data upon which denials of reimbursement have been centered make Wolf’s conclusions illogical.

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163 Wolf, supra 51, at 2065.

164 Id.
Finally, Wolf agrees in her article that when a treatment is exempted specifically, the contract should be left standing. The adjudication in such cases focuses on whether the carrier has met the proper process criteria of defining terms unambiguously and excluding specific procedures they do not intend to pay for. Since the decline of *laissez faire* the judiciary has appreciated formally that no decision can sometimes be a decision. However, Wolf's assertion that the court ought to complete a *de novo* review of the case, or in any other way decide the issue of whether a treatment is or is not "experimental" in nature, should not be followed. Clearly, to allow the court to do so would require the use of skills that most judges simply do not possess.

Another recent review of these cases presented by Richard S. Saver, condemns judicial activism and articulates a variety of problems inherent in the assessment of breast cancer treatments by the court. In his paper, Saver argues there are legitimacy, capacity, and policy reasons why payment for new procedures should not be determined legally.

First, with regard to legitimacy, Saver finds it "disturbing" that "several court opinions have strayed beyond the contract issues ... to make conclusive statement about technology's cost-effectiveness or net health outcome measurements." He suggests that the enforcement of exclusion clauses because the treatment is "experimental" will lead to reduced insurance premiums and health care spending overall. In addition, Saver points out that individual patients may reject conventional therapy and pursue frivolous or unproven treatments. Even when no alternative treatments exist, individuals with fatal illness' may need protection from health care suppliers making fraudulent claims of cures.

It is the legislative branch, not the judiciary, that should be deciding these issues.

Overall, Saver's argument makes sense except the conclusion that enforcement of "experimental" exclusions will lead to more predictable

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165 Id. at 2104.
166 Saver, *supra* note 2, at 1117.
167 Id.
168 Id.
169 Id. at 1118.
170 Id.
171 Id. at 1117.
interpretation of contract provisions. The court is correct to emphasize the need for specific exclusions if the predictability of legal outcome is the goal, and patients are entitled to know what will or will not be covered in their policies. If a patient desires that a questionable treatment be covered, he or she should have to pay for that option.

Some government officials agree with the view that patients should have to fund questionable treatment. Virginia now offers insurance specifically for bone marrow transplantation. The Clinton health care reform plan would also permit such supplemental policies. Much like disability insurance, these supplementary plans shift the financial burden to those who feel the risk is worth ameliorating and at the same time, clearly establish the intent of insurers to deny such coverage.

While the legislature should play a major role in clarifying the rights of insurers and subscribers, on occasion it has failed to protect consumers from "quack" therapies. The history of chiropractice, and the recent upsurge in "alternative" medicine, lend support to this conclusion. A more recent example is the mandate from the State of Washington that carriers reimburse all licensed "natural" healers. On a grander scale the federal government has allocated major funding to the newly created Office of Alternative Medicine. Consequently, one wonders whether leaving these decisions in the hands of the legislature is truly wise. Nonetheless, there are even graver legitimacy questions in having the judiciary make such decisions.

In response to lawsuits challenging insurance reimbursement, several states have already passed legislation requiring coverage for ABMT and

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172 Saver suggests that enforcement of experimental exclusion clauses will cause contract provisions to be interpreted by the court more predictably, but this would only occur when the court could find a specific exclusion in support. See id.


174 Id.


176 Id.

177 See Peggy Eastman, Cancer Tops Queries to NIH's Office of Alternative Medicine, ONCOLOGY TIMES, Mar., 1996, at 24 (describing the "fringe" therapies being looked at by the OAM which was created by Congressional mandate in 1992 in response to public demand - the initial $2 million budgeted has been increased to $5.4 million as of last year).
PSCR, while other states are contemplating similar measures. Although legislatures are no more prepared to make decisions regarding the legitimacy of new therapies than are courts, they are at least held accountable to all parties directly and indirectly affected by legislation. In addition, legislators also have at their disposal scientific advisors, as well as the ability to convene legislative fact-finding hearings through which to define the problem and to devise a solution.

One of the most important reasons why courts are unfit to make these significant decisions is that the judiciary lacks the capacity "to make accurate judgments about new technologies." As Saver notes, court assessments are done "on an ad hoc, reactive basis" often relying on distorted information and anecdotal testimony from clinicians. Because "litigation is too crude a process for resolving differences of medical opinion." Saver suggests the slow meandering "scientific discourse" should not be decided in an immediate winner-take-all arena. It is difficult to disagree with Saver's view since published decisions indicate that some courts are aware of their distinct capacity limitations, while many others are not.

Finally, Saver also argues that scarce health care resources are being devoted to litigation rather than more efficient methods of assessing new technology. In addition, the outcome of a ruling may depend on where the case is heard, leaving patients and insurers treated inequitably. Most

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178 See Patricia Lopez Baden, Bill on Marrow Transplants for Breast Cancer Clears House, STAR-TRIB. - MINNEAPOLIS-ST. PAUL, May 4, 1995, at 1A (noting a bill requiring all Minnesota insurance companies to cover bone marrow transplants for breast cancer patients had received final state legislative approval).
179 See Saver, supra note 2, at 1116-17 nn.125-26.
180 Id. at 1118-19.
181 Id. at 1119.
182 Id. (noting that "[t]echnologies are diffused into practice in stages, gradually winning acceptance by clinicians, journal editors, and others.").
183 Id.
184 Compare Pirozzi v. Blue Cross and Blue Shield of Va., 741 F. Supp. 586 (E.D. Va. 1990) (finding HDC-ABMT is not experimental largely based on expert testimony at trial) with Harris v. Mut. of Omaha Co., 992 F.2d 706 (7th Cir. 1993) (concluding the court can only make determinations as to the contract status, and can not determine whether HDC-ABMT is indeed experimental or not).
185 Saver, supra note 2, at 1119 (noting that "[m]any cases are litigated case after case.").
186 Id. at 1120.
astutely, Saver suggests that using the court as the deciding forum may result in "strategic gamesmanship," and encourages insurers to "deny [claims routinely], and reverse themselves only when faced with a serious, bona fide court challenge." Ultimately, this may lead developers of new technologies to turn to the court to have their discoveries declared nonexperimental as a time-saving and cost-reducing alternative to rigorous scientific scrutiny.

Overall, litigation has lead to some advantageous policy-oriented changes. Insurers now pay more attention to the drafting of their contracts, with a focus on specifying exemptions so that average policyholders are better informed regarding their coverage before illness strikes. If coverage does not comport with the buyers expectations, an alternative carrier may be sought.

It is also clear that litigation has shifted insurers’ positions on the issue. In 1991, Blue Cross-Blue Shield, the provider of a significant proportion of health insurance nationwide, committed major funding to a multicenter trial which it is hoped will definitively determine the scientific merits of HDC-ABMTs. Blue Cross-Blue Shield allocated $10 million to fund this project, but predicated reimbursement on patient participation in a carefully designed, prospectively randomized, Phase III trial. This turnaround garnered them tremendous media attention, and positive publicity will likely serve this carrier beyond the promised $10 million. In one interview, a Blue Cross representative admitted that the "easy" decision would have been to give up and pay for the procedure and that it was "... a tempting idea from a public relations standpoint ... as well as

187 Id.
188 Id.
189 Id.
190 See, e.g., Altman, supra note 29, at A1.
191 Id. (discussing the $10 million anticipated cost of funding the treatment during the initial pilot study of 1,200 women).
192 Id.; See also Lisa M. Krieger, Insurer Offers Hope in Breast Cancer War, Blue Shield Agrees to Pay for Last-Ditch and Controversial Therapy Still Under Study, SAN FRANCISCO EXAMINER Jan. 20, 1995, at A25 (this is another headline that "speaks for itself").
to stem the tide of a mounting number of lawsuits ... [but that would mean] this information no longer would be routinely collected."  

No doubt Blue Cross thought carefully about their reversal and not only did they enhance their public image, but they will also save enormously in immediate litigation costs. If HDC-ABMT proves to be without benefit, they will save even more in the future.

The courts' willingness to use the "Blues" position to support the conclusion that the procedure is no longer "experimental," has further prodded other carriers into providing coverage. For example, a federal directive was issued in 1994 ordering insurance providers for government employees to similarly cover HDC-ABMT costs. Unfortunately, however, the directive exempts government employees from protocol participation and will hinder study accruals and delay finding answers.

194 Id.
196 In 1994, reimbursement for HDC-ABMT and HDC-PSCR in the treatment of breast cancer was mandated for those plans covering government employees. This group has been exempted from randomization. See, e.g., Winslow, Access/Quality/Cost Bone Marrow Transplants: OPM Sparks Controversy, AMERICAN POLITICAL NETWORK-AMERICAN HEALTH LINE, Nov. 17, 1994, available in WestLaw, WestLaw Library, ALLNEWS File (discussing the "directive" from OPM requiring 350 health plans covering nine million federal workers and their dependents to "cover an expensive and controversial breast cancer treatment" within 24 hours, or face exclusion from FEHBP - the conclusion is that the move was largely political, and the piece includes strong statements of condemnation because the directive "threatens the progress of those very trials" by preventing health care plans from requiring federal employees to participate).
197 Id.
198 Slow accrual has been a major obstacle to completion of the Phase III studies. "Expert" testimony proffered in one case stated that the problems Duke University had in accruing research subjects was that the standard therapy arm was to be given a placebo. Pirozzi v. Blue Cross-Blue Shield of Virginia, 741 F. Supp. 586, 594 (E.D. Va. 1990). One wonders, if a physician and judge maintain this opinion, how pervasive this idea may be in the general public. It is clear that Congress must have embraced a similar concept in mandating coverage for federal employees regardless of protocol participation. See infra note 203.
199 At the Congressional hearing which lead to this decision, affidavits from twenty-two "experts" in breast cancer, all of whom were from prominent institutions and considered to be preeminent in the field of oncology, were entered into the record. Also entered were the sworn certifications of thirty-one practitioners from around the country as demonstrative of the consensus of medical opinion. It is probable that this compelling testimony, suggesting HDC-ABMT was not experimental, contributed to the Congressional decision to force OPM to exempt government employees from randomization. This demonstrates what can happen when the testimony is too convincing. In essence, these researchers have "shot themselves in the foot," as the lack of patient
HELPING COURTS REACH BETTER DECISIONS

The issue of reimbursement for the controversial treatment of HDC/AMBT was summed up recently by Circuit Judge Coffey who stated:

In order to resolve the question of whether health insurance providers should cover treatments like HDC/ABMT, the prudent course of action might to be to establish some sort of regional cooperative committees comprised of oncologists, internists, surgeons, experts in medical ethics, medical school administrators, economists, representatives of the insurance industry, patient advocates and politicians. Through such a collective task force perhaps some consensus might be reached concerning the definition of experimental procedures, as well as agreement on the procedures, which are so cost prohibitive that requiring insurers to cover them might result in the collapse of the health care industry. While such a committee would in no way be a panacea for our skyrocketing health care costs, it may help to reduce the incidence of suits in which one “expert” testifies that a procedure is experimental and another equally qualified “expert” testifies to the opposite effect.200

Interestingly, Judge Coffey does not include representatives from the judiciary in his cooperative groups. Perhaps Coffey would feel differently if the current pressure on existing judges to somehow become well-informed on areas of science could be reduced by the creation of an adjunct judicial office for “expert” magistrate judges (MJE)201 made up of technically proficient adjudicators functioning mainly at the district court level. These MJEs would sometimes serve as special masters, other times

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as court-appointed expert witnesses, and, on occasion, as triers of technical fact.\textsuperscript{202} There are, however, certain problems with this suggestion, which originates from Edward V. Di Lello. The difficulties include identification of a sufficient quantity of technically-adept magistrates,\textsuperscript{203} intra-district inconsistencies, and whether rendered opinions would be legally binding or appealable.\textsuperscript{204}

Another approach outlined by Clark C. Havighurst that might appeal to judges would be to have the court avoid ruling on scientific issues altogether.\textsuperscript{205} Instead of focusing on the "experimental" nature of a new treatment or procedure, the court would be left to decide only on contractual issues.\textsuperscript{206} Services would be excluded based on cost-benefit considerations. Because insurers logistically cannot keep up with the various new treatments that are being developed,\textsuperscript{207} the carrier should indicate in the contract, in plain language understandable to the purchaser, an intent to be cost conscious and to state that on occasion certain procedures with low benefit and high cost simply would not be covered. The cost benefit determination would be made initially by the insurer, subject to internal and external review.\textsuperscript{203} Those contracting would

\textsuperscript{202} Id. at 495-503.

\textsuperscript{203} Di Lello does address the \textit{distribution} problem, that of assigning MJE\textsc{es} by district in proportion to the number of cases likely to be litigated. But he does not suggest where the required quantity of MJE\textsc{es} would come from. See id. at 495 n.153. Alternatively, a particular MJE might take on one or more topics to deal with on a national level, for instance, the issue of the "experimental" nature of HDC-ABMT being reviewed here. However, that would necessitate at least a general understanding of the substantive aspects of the laws of all fifty states. Additionally, that does not solve the problem that the MJE would be prohibited from both testifying as a court-appointed "expert" and deciding one or more issues of fact in the same case. See id. at 498 n.174. With this in mind, one now needs at least two MJE\textsc{es} with technical expertise on a particular issue. In the not so rare instance of several trials occurring simultaneously, additional MJE\textsc{es} would be required, unless the trials were so staggered to allow these MJE\textsc{es} to "jet" across the country and thus to be present to participate in other ongoing litigation.

\textsuperscript{204} Id. at 498.


\textsuperscript{206} Id. at 187-190.

\textsuperscript{207} Id. at 195.

\textsuperscript{203} "Even though a contract cannot specify precisely the services to be provided in each case, the parties might agree to a kind of relational contract establishing both a general standard by which coverage will be determined and a process for interpreting and applying that standard in future situations. The specific contractual strategy proposed here is (1) clear delegation of initial responsibility for interpreting the plan's obligations to health professionals selected by the plan and
stipulate that the insurer is allowed to make such decisions, subject to review by an agreed upon and pre-selected alternative dispute resolution source (ADR), should a conflict arise.

An even better solution may be a national “Science Court,”209 as proposed by Professor Steven Goldberg of Georgetown Law School, where issues like the “experimental status” of a new medical treatment could be argued in front of technologically knowledgeable individuals for resolution.210 A similarly-fashioned panel might address the issue at hand. It is clear from the amount of litigation ongoing that the “experimental” nature of HDC-ABMT or HDC-PSCR is of national, as opposed to regional, concern; therefore, a national form of arbitration may be appropriate.

An extension of Goldberg’s “Science Court,” perhaps a “Treatment Court” for the lack of a better label, might serve this function. The tribunal would not only evaluate the science but also consider formally the societal costs and benefits of a new therapy. First, the issue of whether the treatment or procedure was scientifically sound would be addressed. If it was found not to be so, their analysis would stop. But if scientific merit was deemed present, the review would continue on to the potential economic impact of its applications. This, of course, would require judges with both scientific and economic backgrounds and it would be reasonable to have all of the major areas of science (such as physics, biology, chemistry, etc.) represented. To limit capture potential and establish an experienced tribunal, a life-time appointment may be wise, and certainly a prohibition against participation in the private sector would be warranted.

It is likely that issues would become apparent to this Treatment Court only after a certain threshold of individual conflict arose. A petition for review would be filed, perhaps by research organizations, or classes of citizens, or groups of insurers, and amicus briefs might be solicited. Much like the Supreme Court, a grant or denial of _certiorari_ might result. Novel

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(2) designation of a disinterested arbiter, selected through a freestanding alternative dispute resolution (ADR) service, to hear appeals from the decisions reached." _Id._ at 201

209 Personal communications with Professor Steven Goldberg during a Law and Science Seminar.

210 _Id._
treatments not yet available clinically could be evaluated directly while issues between individual litigants continue to be brought in front of existing tribunals. When the issue surpasses some threshold level of litigation, the Treatment Court would be called upon.

To preserve our current judicial structure, it would seem reasonable to grant a Treatment Court's decisions no precedential value _per se_. Rather, their findings would have persuasive significance and their decisions would be published with reasoned elaboration encouraged and be legally admissible. Due to the national significance of the tribunals decisions, and the varied state doctrines that exist, the focus would be on factual issues. The result would be that judges and/or juries in the traditional forum would benefit from the Treatment Court's unbiased factual guidance, especially with regard to subsequent litigation, lessening the "battle of the experts" problem.

Because suits are less likely to be filed where the potential outcome has been clarified, a secondary effect of such a court would also inure. It is likely that a reduction in relitigation of the same issues would follow and such suits might be further discouraged by the judicious granting of both court costs and attorney fees to the prevailing party when appropriate. Needless to say the members of such a Treatment Court would wield significant power and, like administrative agencies, should be appointed by the Executive Branch and could perhaps be limited to those nominated through national medical societies.

CONCLUSION

Considering the complexity of this issue, it is clear there is no easy solution. But what is clear is that breast cancer is a devastating disease and undoubtedly better treatment is sorely needed. Currently, however, it is unfortunate, but true, that there exists no reliable or, scientifically valid evidence that HDC-ABMT or HDC-PSCR improves the results of treatment from that obtained by the best available standard therapy.

All that can conclusively be said about HDCAMBT and HDCPSCR is that these treatments are significantly more expensive than standard therapy. If a breast cancer patient wishes to receive treatment using these new techniques that should certainly be her prerogative, but unfortunately the expense is such that only the wealthy can afford to pay for it
themselves. As the case history demonstrates, a patient who purchases protection against this catastrophe and is denied coverage by her policy may turn to the courts for relief, and if her carrier was ambiguous or unclear as to whether or not it intended to pay for the procedure, reimbursement will likely be ordered. On the other hand, if the policy clearly indicates the carrier’s intent to pay only for treatments proven scientifically to be beneficial, the patient’s request should and will likely be denied.

Unfavorable decisions in this regard have stimulated carriers to draft their policies in a fashion so as to be better understood by the purchaser. As a result, one would expect these suits to decrease in frequency. This is true for both breast cancer, and the myriad other diseases for which research is ongoing. The recent appellate level cases (at least in the 7th Circuit) would suggest this is occurring. Legislative action should likewise help to decrease courtroom disputes, allowing judges to be able to return to doing what they do best deciding outcomes on process considerations.

As physicians and scientists continue to try and figure out how to best help breast cancer patients, it is also hopeful that this legal dilemma will resurrect interest in Phase III verification of novel treatments and that more insurers will follow Blue Cross' lead and predicate reimbursement on participation in randomized trials. Patients who want access to new treatments without being randomized will have to either pay directly, or buy extra insurance. Alternatively, they might elect legislators who will mandate access. If so, the people will pay collectively for the expenses a small segment will incur. CHAMPUS's recent decision to fund any NCI-sponsored Phase II or Phase III clinical trial supports this conclusion. Their lead should be applauded because unlike OPM's 1994 directive, treatment coverage for HDC-ABMT or HDC-PSCR through CHAMPUS will be dependent on protocol participation. It is hoped that some solution will be found.

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211 See Jane Erickson, Getting Managed Care to Pay for Clinical Trials, ONCOLOGY TIMES, Mar. 1996, at 1, 17 (CHAMPUS, covering approximately 10 million people, estimates 350 enrollments from its 11,760 members anticipated to be diagnosed with cancer this year. This pilot project will be funded from January 1, 1996 through December 31, 1996, although it may be extended dependent upon costs).

212 Id.