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What Is Experimental Medical Treatment: A Legislative Definition Is Needed

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I. INTRODUCTION

One out of eight women born today will develop breast cancer in her lifetime. Breast cancer is the second major cause of cancer death for women in the United States. The American Cancer Society estimates that 180,200 women will be diagnosed with breast cancer and 43,900 women will die of breast cancer during 1997. Women who have been diagnosed with breast cancer often have to battle more than the disease—they frequently have to battle their insurance companies for coverage of treatments their insurance companies deem experimental such as High-Dose Chemotherapy coupled with autologous bone marrow transplantation [hereinafter HDCT/ABMT]. The Office of Personnel Management and several state legislatures have responded.

This note focuses on the highly publicized coverage disputes involving HDCT/ABMT for the treatment of breast cancer to illustrate the problems inherent in courts judging medical technology and legislatures politicizing medical technology. The problems exist, however, with respect to every developing medical technology for which there is no consensus on its safety and effectiveness. Part II of this note depicts the typical scenario involving a patient with metastatic breast cancer. Part III outlines the drug approval process and off-label drug use. Part IV describes HDCT/ABMT treatment and discusses the lack of consensus regarding its efficacy for the treatment of breast cancer. Exclusionary provisions in insurance contracts for experimental treatments are discussed in Part V. Part VI examines how courts have dealt with coverage disputes. Part VII discusses discrimination claims relative to coverage denials. Part VIII identifies the Office of Personnel Management's directive and state legislation that has been enacted or is being considered to address the reimbursement problem relative to HDCT/ABMT treatment for breast cancer. Part IX discusses the dangers of politicizing medicine. This note concludes with recommendations that federal legislation be enacted which sets out a clear definition of "experimental" medical treatment, a uniform policy on off-label drug use, and mandates coverage of patient care costs when associated with an approved clinical cancer trial.

II. TYPICAL SCENARIO

Sarah is a 37-year-old married woman with two young children. Sarah was diagnosed with breast cancer two years ago. Sarah underwent a lumpectomy followed by a radical mastectomy and several cycles of conventional chemo-

2 Id.
3 Id.
4 HDCT/ABMT is discussed in Section IV infra.
therapy. Last month, Sarah's cancer was found to have recurred, and she was diagnosed as having metastatic disease.5

Sarah's doctor recommended that she undergo HDCT/ABMT and referred her to a program at a local hospital. In spite of the lack of scientific data supporting HDCT/ABMT's effectiveness for metastatic breast cancer, Sarah's doctor told her that HDCT/ABMT was her best chance for significant survival.6 As a condition of participation, the program required precertification by Sarah's insurance company or a substantial payment towards the cost of the procedure. Sarah's insurance company denied precertification claiming that HDCT/ABMT for the treatment of metastatic breast cancer is experimental and thus excluded from coverage.7

Sarah may take one of several courses of action: she can go to court to get a second opinion on whether HDCT/ABMT is covered under her insurance policy; she can enroll in a randomized or non-randomized clinical trial with the possibility that her insurer may not cover the associated clinical care costs; she can continue with the conventional chemotherapy which she has been receiving; she can pay for the treatment herself from savings, mortgaging her home, gifts and/or loans from family members, fund raising, etc.; or she can accept her impending death and improve the quality of her remaining life by refusing to continue chemotherapy treatment.8

5Metastatic disease is cancer that has spread beyond the original site. Taber's Cyclopedic Medical Dictionary (15 ed. 1985). Cancer is typically classified in terms of stages of increased severity from Stage I to Stage V. Stage IV breast cancer indicates that the cancer has metastasized. Pirozzi v. Blue Cross-Blue Shield of Va., 741 F. Supp. 586, 588 n.3 (E.D. Va. 1990) (citing The Merck Manual of Diagnosis & Therapy 2076 (14th ed. 1982)).

6Cancer patients are extremely vulnerable. Hearings Before the House Committee on Post Office & Civil Service, Subcomm. on Compensation and Employee Benefits, 103d Cong. 140 (1994) (testimony of I. Craig Henderson, M.D.) available in LEXIS, Legis Library, Cngtst File. If a patient's doctor tells her that HDCT/ABMT therapy is her best or only hope, the patient will likely conclude that she must undergo this treatment, in spite of the lack of scientific evidence supporting the treatment's efficacy. Id.


8The most common side effects of chemotherapy are nausea, vomiting, abnormal decrease of white blood cells, and loss of hair. See D. Greene et al., A Comparison of

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III. THE DRUG APPROVAL PROCESS

Different medical technologies go through different regulatory processes: prescription drugs go through a rigorous regulatory process, "medical devices go through a less rigorous process," and procedures go through no regulatory process at all. A new drug may not be marketed unless it has been approved by the Food and Drug Administration [hereinafter FDA] as safe and effective. Clinical trials by qualified experts are a prerequisite for determination of safety and effectiveness. Clinical trials are classified into three phases, and research usually progresses in order from Phase I to Phase III.

With respect to cancer studies, Phase I involves initial testing to determine the relationship between toxicity and dosage. Phase I studies usually involve fifteen to twenty-five patients and are conducted almost exclusively in specialized research centers. In Phase II studies, the new treatment is generally given to twenty patients with a specific type of tumor to determine whether the treatment has any observable effect. Phase III trials are randomized clinical trials that compare a standard treatment with a new treatment. Phase III trials require large numbers of patients and are conducted to confirm and quantify the effectiveness of the treatment. Inadequate patient accrual hampers Phase III trials of cancer drugs.

The low percentage of enrollment impedes timely completion of many cancer drug trials, has a negative impact on the cancer cure rate, and exacer-


11Id.


13Id.


15Id.

16Id. Today, researchers studying a life-threatening illness rarely use placebos, but instead compare the new treatment against standard therapy. Id.

17Adams, 757 F. Supp. at 671.

bates the problem of coverage disputes. According to the American Cancer Society, broader participation in clinical trials could raise the cancer cure rate to 75% by the year 2000 from its present rate of 52%. Yet, of the nearly one million cancer patients diagnosed in the United States each year, less than 3% are participating in such trials. If only 10% of patients with common tumors enrolled in clinical trials, the current time frame of three to five years for completion could be cut to one year.

A. Obstacles To Patient Enrollment In Clinical Trials

Before adequate patient accruals and more timely completion of clinical trials can be achieved, more physicians must suggest enrollment in clinical trials to their eligible patients and insurers must cover the costs of participating in clinical trials. Physicians participating in a major study cited the following reasons, in descending order of importance, why they are reluctant to enroll patients in clinical trials:

1. concern with the doctor-patient relationship (73%);
2. trouble with informed consent (38%);
3. dislike of open discussions about uncertainty (23%);
4. conflict within the physician as a clinician and as a scientist (18%);
5. practical difficulties in trial procedures (9%); and
6. feelings of personal responsibility if treatments are unequal (8%).

In an effort to boost patient accrual, the National Cancer Institute adopted a promotional campaign that involved conducting seminars, disseminating information to national and local news media, and assisting in making information on clinical trials available to patients and physicians.

Insurer's inconsistency in coverage is also hampering patient accrual in clinical trials. Usually the sponsor of a clinical study provides the funds for the research expenses of the study, e.g., pharmaceuticals, data gathering, monitoring, quality assurance, special tests, statistical analysis, reporting, etc. There is, however, a level of medical care required by a cancer patient indepen-

19 Id.
21 Farrar, supra note 14, at 1780.
22 Id.
23 AMA on Scientific Affairs, supra note 18, at 255.
24 Farrar, supra note 14, at 1780.
25 Id. at 1781.
dent of enrollment in a clinical trial.\textsuperscript{27} Until recently, "[e]ither through tacit approval or benign neglect, such [patient care] costs have been reimbursed."\textsuperscript{28} Currently, insurance companies are inconsistent in covering the clinical care costs associated with participation in a clinical study.\textsuperscript{29} One insurer may approve coverage while another may not; some insurers pay for laboratory studies but not hospitalization; some pay for outpatient chemotherapy but not hospitalization related to complications from experimental therapy.\textsuperscript{30} Greater cooperation is needed between physicians, insurers and the government to ensure that patients continue receiving safe and effective medical care today while supporting technological innovation for the future.\textsuperscript{31}

B. Off-label Drug Use

Off-label drug use is the prescribing of a drug for a purpose or indication other than that approved by the FDA. Off-label drug use is prevalent in oncology.\textsuperscript{32} Over fifty percent of all cancer drugs administered are for off-label indications.\textsuperscript{33} A physician may legally prescribe an FDA-approved drug for uses other than those indicated on the package insert.\textsuperscript{34} When an FDA-approved drug is prescribed for new uses, there is no official record of efficacy of dosage or of the optimum level of benefit to the patient.\textsuperscript{35} Consequently, many insurers claim that off-label drug use is experimental and refuse to reimburse patients for such drugs.\textsuperscript{36}

The controversy over reimbursement of off-label drugs has been addressed at both the national and state levels. At the national level, President George

\textsuperscript{27}Id.

\textsuperscript{28}AMA on Scientific Affairs, supra note 18, at 257.

\textsuperscript{29}Farrar, supra note 14, at 1781.

\textsuperscript{30}Id.

\textsuperscript{31}See Nicholas J. Vogelzang et al., Reimbursement Issues in Clinical Oncology, 15 SEMINARS IN ONCOLOGY 34-43 (Dec. 1988) (health-care specialists present practical solutions to the dilemma of rising health care costs versus the need for optimal medical care).

\textsuperscript{32}Nancy A. Wynstra, Breast Cancer: Selected Legal Issues, 74 CANCER 491, 504 (1994).

\textsuperscript{33}Kate Nagy, States Aim Laws At Off-Label Reimbursement, 85 J. NAT'L CANCER INST. 701, 701 (1993).

\textsuperscript{34}Wynstra, supra note 32, at 505. A drug manufacturer may, however, file a supplemental new drug application [hereinafter SNDA] to obtain FDA approval of different uses for already FDA-approved drugs. \textit{Id.} Recent studies, however, show that the application process for a SNDA is approximately the same as for a new drug application, almost two years. \textit{Id.} Many manufacturers fail to pursue FDA approval of new drug uses because of the slowness of the approval process, the cost of new research, and the possibility of the patent running out before the SNDA process is complete. \textit{Id.}

\textsuperscript{35}Wynstra, supra note 32, at 505.

\textsuperscript{36}Id.
Bush appointed a special subcommittee of the National Cancer Advisory Board, commonly called the Lasagna Committee, to review the off-label drug reimbursement problem.\textsuperscript{37} The subcommittee (with the concurrence of the Health Insurance Association of America) recommended reimbursement of off-label drugs if the use is listed in any of the following three reference compendia: the United States Pharmacopeia Drug Information, the American Medical Association Drug Evaluations, and the American Hospital Formulary Service Drug Information.\textsuperscript{38} Notwithstanding, many insurers do not appear to be following the Committee's recommendation.\textsuperscript{39}

The federal government has adopted the Lasagna Committee's recommended policy on off-label drug reimbursement for Medicaid and Medicare patients. The Omnibus Budget Reconciliation Act of 1990 requires Medicaid agencies to reimburse for off-label use of drugs prescribed if the use is recognized in any of the standard reference compendia.\textsuperscript{40} The Omnibus Budget Reconciliation Act of 1993 requires coverage under the same criteria for Medicare patients.\textsuperscript{41}

Several state legislatures have responded to the reimbursement problem by mandating reimbursement of off-label drugs when used to treat life-threatening illnesses, cancer, or HIV/AIDS.\textsuperscript{42} Only Maryland's statute mandates coverage for all off-label drug use.\textsuperscript{43} Most states that have mandated coverage require reimbursement only if the drug is recognized for treatment of such indication in one of the standard reference compendia or in the medical literature. Maryland, Massachusetts, and Rhode Island, however, have gone one step further by providing the establishment of an advisory panel to review off-label uses of drugs not included in any of the standard reference compendia.

\textsuperscript{37}Id. at 506.

\textsuperscript{38}Id.

\textsuperscript{39}Id.


or in the medical literature and advise whether a particular off-label use is medically appropriate.44

IV. HIGH-DOSE CHEMOTHERAPY WITH AUTOLOGOUS BONE MARROW TRANSPLANTATION

HDCT/ABMT is a procedure by which bone marrow is temporarily removed from the patient’s body, frozen, and stored while the patient receives near lethal doses of chemotherapy.45 The high-dose chemotherapy kills both the cancer and the patient’s remaining bone marrow.46 After the chemotherapy is completed, the patient’s stored bone marrow is reinfused and quickly multiplies to replace the marrow destroyed during the high-dose chemotherapy, thereby "rescuing" the patient.47 A patient undergoing HDCT/ABMT is hospitalized, usually in intensive care, for about ten days and requires full-time medical attention.48 Most health care institutions providing HDCT/ABMT require prepayment, preapproval by the patient’s insurer, or a substantial deposit because of the high cost49 of the procedure.50

HDCT/ABMT treatment does not require FDA approval because all of the drugs used in HDCT/ABMT therapy have been previously approved for use at lower doses and procedures are not regulated by the FDA.51 HDCT/ABMT has been used in cancer therapy for two decades and physicians and insurers consider HDCT/ABMT standard treatment for leukemia and lymphoma.52

45Wynstra, supra note 32, at 492.
47Adams, 757 F. Supp. at 664.
48Costich, supra note 46, at 818.
49HDCT/ABMT is a one-time procedure with a cost of approximately $150,000. Kim Anderson, Do You Know What Treatment Your Health Plan Covers?, 10 BUS. & HEALTH 34, 34 (1992). Conventional chemotherapy is an on-going treatment that costs approximately $12,000 per year. Thomas J. Smith et al., Efficacy and Cost-Effectiveness of Cancer Treatment: Rational Allocation of Resources Based on Decision Analysis, 85 J. NAT'L CANCER INST. 1460, 1468 (1993).
50Doctors, Patients Attack OPM, FEHBP For Failure to Pay For Cancer Treatment, BNA HEALTH CARE DAILY (Aug. 23, 1994) available in LEXIS, Bna Library, Bnahcd File; William P. Peters & Mark C. Rogers, Variation In Approval By Insurance Companies of Coverage For Autologous Bone Marrow Transplantation For Breast Cancer, 330 NEW ENG. J. MED. 473, 473 (Feb. 17, 1994).
52Harris Meyer, Breast Study Woes Preview Reform Barriers, 36 AM. MED. NEWS 1, 7 (1993).
Notwithstanding, to date, the medical community has been unable to reach any consensus on the safety and effectiveness of HDCT/ABMT for the treatment of breast cancer.

While some physicians claim HDCT/ABMT is the best available treatment for breast cancer, others claim that HDCT/ABMT may actually be harmful. As part of testimony at a Congressional hearing regarding OPM’s decision to deny coverage of HDCT/ABMT for certain cancers, the statements of thirty-one professors of medicine and department chiefs were introduced, each declaring that HDCT/ABMT has been their treatment of choice for certain breast cancer patients for the past several years. A recent study by ECRI, however, found that HDCT/ABMT for the treatment of metastatic breast cancer may actually do more harm than good. ECRI conducted a careful analysis of all the available published data and concluded that HDCT/ABMT does not extend the lives of women with metastatic breast cancer and may actually shorten their lives. ECRI, however, cautioned that its findings are based on a snapshot of the current state of medical technology and are subject to change as more studies are completed. ECRI’s report did not analyze the effect of HDCT/ABMT on earlier stage breast cancer.

V. EXPERIMENTAL TREATMENT EXCLUSIONS

Most health insurance policies explicitly exclude coverage for "experimental" treatments, but many policies fail to define or set standards for determining what treatments are considered experimental and thus not covered. The primary reasons insurers use exclusionary provisions are to

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54 ECRI is a non-profit independent technology assessment group which has been in existence for twenty-six years. Joan Stephenson, Medical Technology Watchdog Plays Unique Role in Quality Assessment; ECRI, 274 JAMA 999, 999 (Oct. 4, 1995). ECRI receives no income from manufacturers of medical devices, carries no advertisements in its publications, and maintains strict conflict-of-interest rules for its employees. Id.

55 Id.


57 Stephenson, supra note 54, at 999.


limit their financial liability, keep the cost of insurance down, and encourage the rendering of safe and effective medical treatments and the elimination of worthless procedures. Unclear exclusionary provisions often result in litigation.

VI. FACTORS THAT DETERMINE WHETHER OR NOT A TREATMENT IS COVERED

The body of case law addressing coverage disputes involving HDCT/ABMT for the treatment of breast cancer continues to grow but remains confusing. The courts addressing this issue have reached different conclusions. The cases are difficult to harmonize because the decisions are very fact specific. The factors that determine whether or not a treatment is covered are the patient’s medical insurance policy language and the standard of review.

A. Standard Of Review

The standard of review is important in that it will determine whether a court will give deference to the fiduciary or agency’s decision to deny coverage. The standard of review depends on what law governs the insurance plan at issue. Claims regarding an insurer’s refusal to cover a treatment it deems experimental have arisen under the Employee Retirement Income Security Act of 197461 [hereinafter ERISA], under the Federal Employees Health Benefits Act62 [hereinafter FEHBA], and under state law.63 Most health insurance plans


63 Wynstra, supra note 32, at 493.
acquired as a benefit of nongovernmental employment are governed by ERISA.\textsuperscript{64}

1. ERISA

The administrative scheme of ERISA requires an insured who has been denied coverage to exhaust his administrative remedies prior to commencing suit in federal court.\textsuperscript{65} A coverage denial of an ERISA benefit claim is generally reviewed under either an arbitrary and capricious standard or a \textit{de novo} standard.\textsuperscript{66} When the arbitrary and capricious standard is applied, the fiduciary's decision is given deference; the decision to deny coverage will only be overturned if the court determines that there was no rational basis for the fiduciary's decision.\textsuperscript{67}

In February, 1989, the United States Supreme Court rejected the arbitrary and capricious standard in favor of \textit{de novo} review unless the benefit plan unambiguously gives the administrator discretionary authority over the construction of uncertain terms or eligibility determinations.\textsuperscript{68} The \textit{de novo} standard differs from the arbitrary and capricious standard in two significant ways.\textsuperscript{69} First, under \textit{de novo} review the court does not defer to the fiduciary's decision, but instead determines the interpretation of the policy language that most accurately represents the intentions of all parties to the agreement.\textsuperscript{70} Second, in making this determination, the court is not limited to the evidence available to the fiduciary.\textsuperscript{71} The court has the option to examine the circumstances of the dispute and such other admissible evidence.\textsuperscript{72} Thus, under a \textit{de novo} review a court will closely examine the language of the policy, the evidence the fiduciary considered in denying coverage, any other admissible evidence, and the circumstances of the particular dispute. The establishment of a \textit{de novo} standard of review for coverage disputes under ERISA has placed federal district court judges in the difficult position of ruling

\textsuperscript{64}Costich, \textit{supra} note 46, at 805.


\textsuperscript{67}Wynstra, \textit{supra} note 32, at 500.

\textsuperscript{68}Firestone, 489 U.S. at 115.

\textsuperscript{69}Costich, \textit{supra} note 46, at 813.

\textsuperscript{70}Id.

\textsuperscript{71}Id.

\textsuperscript{72}Id.
on the effectiveness of new medical treatments, where those with the medical expertise have been unable to reach a consensus.\textsuperscript{73}

More recently courts have recognized an interest analysis test when a plan beneficiary can show that there is a substantial conflict of interest in the fiduciary's exercise of his discretionary authority to deny benefits.\textsuperscript{74} Under the interest analysis standard of review, the burden shifts to the fiduciary to show that its decision was not a result of self-interest.\textsuperscript{75}

2. FEHB

Federal governmental employees' health benefits are administered by the Office of Personnel Management [hereinafter OPM], but OPM typically contracts this responsibility to individual insurance companies.\textsuperscript{76} An insured who has been denied coverage under a FEHB insurance plan must exhaust all administrative appeals at the insurance company level as well as appeal to the OPM prior to filing a lawsuit.\textsuperscript{77} The Administrative Procedure Act governs judicial review of an agency action.\textsuperscript{78} A court reviewing an OPM decision applies an arbitrary and capricious standard.\textsuperscript{79} Unless the court determines that there is no rational basis for OPM's decision, the court will defer to the expertise of the agency.\textsuperscript{80}

3. State Law

If a plan does not meet the criteria\textsuperscript{81} of an "employee welfare benefit plan" under ERISA and if the insured is not a state, local, or federal employee, state law applies.\textsuperscript{82}

\begin{footnotes}
\item[73] See Costich, \textit{supra} note 46, at 823.
\item[75] Id. at 1567.
\item[76] Wynstra, \textit{supra} note 32, at 503.
\item[77] Id.
\item[79] Id.
\item[81] An employer's self-funded health benefit plan will be governed by ERISA if the following criteria are met: (1) a plan, fund, or program; (2) established or maintained; (3) by an employer or by an employee organization; (4) for medical, surgical, or hospital care or benefits, or benefits in the event of sickness, accident, disability; and (5) to participants or their beneficiaries. 29 U.S.C.A. § 1002(1) (West 1994); Wynstra, \textit{supra} note 32, at 500.
\item[82] Wynstra, \textit{supra} note 32, at 500.
\end{footnotes}
While the standard of review is important, some courts applying an arbitrary and capricious standard have noted that the outcome would be the same under de novo review.\textsuperscript{83}

\textbf{B. Policy Language}

The most decisive factor in a coverage dispute is the policy language.\textsuperscript{84} The policy language determines what treatments are covered, how an insurer determines whether or not a treatment is excluded because it is "experimental", the procedures that must be followed in order to obtain coverage, and with an ERISA claim, the standard of review a court must apply. If an insurance contract is unambiguous, the court is bound by its language, but so is the insurer. If an insurance contract is ambiguous, a court will construe the ambiguities against the drafter.\textsuperscript{85} A contract is ambiguous if, after reading the entire contract, its language may be reasonably understood in different ways.\textsuperscript{86}

There is no consensus definition of experimental treatment. Policies often define experimental treatment as treatment not commonly and customarily recognized by the medical community, treatment connected with medical or other research, or treatment that has no proven medical value. Frequently, however, policies do not specify the information the insurer will consider in determining whether the treatment is commonly and customarily recognized by the medical community, is connected with medical or other research, or has no proven medical value.

Courts determining whether or not a given treatment is experimental generally consider the following evidence: (1) expert testimony; (2) a survey of medical literature; and (3) the language of the consent form. Courts, however, often give similar evidence different weight.

Cases involving coverage disputes can be divided into three basic categories: (1) cases where the policy language was unambiguous but the insurer failed to follow the express terms of the policy in denying coverage; (2) cases where the policy language was unambiguous and correctly followed; and (3) cases where the policy language was ambiguous.


\textsuperscript{84}Wynstra, supra note 32, at 500.

\textsuperscript{85}Id. See Jennifer Belk, \textit{Undefined Experimental Treatment Exclusions in Health Insurance Contracts: A Proposal for Judicial Response}, 66 WASH. L. REV. 809 (1991) (proposing that courts should construe the term "experimental" narrowly and find treatments non-experimental if there is any demonstrated likelihood of their success); Fisfis, supra note 60 at 777 (recommends reforming judiciary review of insurance reimbursement litigation).

1. Unambiguous Provision Erroneously Applied

In determining coverage, an insurance company is bound by the express terms of its policy. In *Adams v. Blue Cross/Blue Shield of Maryland, Inc.*, the policy specified that to be covered the treatment had to be "generally acknowledged as accepted medical practice by the suitable medical specialty practicing in Maryland, as decided by us." The district court found the phrase "as decided by us" to be vague and ambiguous. Accordingly, the district court applied a de novo standard of review.

While the district court found the policy’s definition of "experimental or investigative" to be unambiguous, the court concluded that Blue Cross had disregarded the specific plan language and denied coverage based on its own independent evaluation of the scientific data, completely ignoring the consensus of opinion of medical oncologists practicing in Maryland. The district court found expert testimony persuasive that HDCT/ABMT was at the relevant time being offered at many major medical centers across the country. The court also noted that the fact that the proposed treatment was to be given on research protocol at teaching hospitals did not alter the fact that at the relevant times Maryland oncologists generally acknowledged the treatment to be accepted medical practice.

The insurer in *Bucci v. Blue Cross-Blue Shield of Connecticut, Inc.* also failed to adhere to its own policy language in deciding to deny coverage. The policy stated that the company "will not pay for services . . . which are experimental or investigational in nature; meaning any treatment, procedure . . . drugs, drug usage . . . not recognized as accepted medical practice or not recognized by us . . . ." The company agreed that the phrase "or not accepted by us" was not meant to suggest an independent evaluation but was intended to articulate defendant's reservation of authority to decide benefit entitlement.

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88 *Id.* at 667.
89 *Id.* In order for a benefit plan to be entitled to judicial deference with respect to determining benefits eligibility or construing disputed or ambiguous terms, the plan language must manifest on its face a clear and unequivocal intent to confer the plan administrator with discretionary authority. *Id.* at 666. See, e.g., *DeNobel v. Vitro Corp.*, 885 F.2d 1180, 1187 (4th Cir. 1989); *Graham v. Federal Express Corp.*, 725 F. Supp. 429, 434 (W.D. Ark. 1989).
90 *Id.*
91 *Id.*
92 *Adams*, 757 F. Supp. at 663.
94 *Id.*
95 *Id.*
district court in Bucci, unlike the district court in Adams, agreed with defendant and reviewed the case under an arbitrary and capricious standard.96

In denying coverage, the company applied a five-factor Technical Evaluation Criteria [hereinafter TEC].97 The TEC was not incorporated, nor referred to, in the contract.98 The district court stated that the company's reliance on the TEC was not valid.99 The district court also found that the insurer's failure to make reasonable and relevant inquiries when it became aware of new information100 suggested an arbitrary and capricious denial.101

Similarly, in White v. Caterpillar, Inc.,102 the district court also held that the denial of coverage was arbitrary and capricious because the insurer failed to follow its own policy language.103 The policy stated that the reports of the Clinical Efficacy Assessment Project of the American College of Physicians [hereinafter CEAP] and the Diagnostic and Therapeutic Assessment from the Council on Scientific Affairs [hereinafter DATA] would be used as a "guide" to determine whether a surgical procedure is a generally accepted surgical operation.104 The district court found that the plan's recognition of these two reports was not exclusive, but was to be used as a "guide" in determining the efficacy of a procedure.105

Both parties agreed that there was no study by CEAP regarding the efficacy of HDCT-ABMT.106 Instead of examining the most recent DATA study, however, the company clung to the results of a study more than five years old.107 The district court stated that "[w]hile the 1990 study should have put

96Id. at 731.

97Id. TEC is:

(1) governmental 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 alternative treatment; and (5) improvement other than in investigational settings.

Id.

98764 F. Supp. at 731.

99Id.

100The new information was that 38 health insurers had committed to the University of Nebraska, and 32 insurers (mostly the same ones) had committed to Duke University to cover HDCT/ABMT treatment. Id.

101Id. at 732.


103Id. at 1423.

104Id.

105Id.

106Id. at 1420.

107767 F. Supp. at 1421.
defendant on notice that the efficacy of treating breast cancer with HDCT-ABMT was at least debatable and that further examination of the issue by defendant would therefore be prudent, defendant chose instead to bury its head in the sand.\textsuperscript{108} Moreover, further evidence indicated that the company refused to consider information other than the 1985 DATA study.\textsuperscript{109} Thus, the district court found that the defendant’s failure to examine other sources and to exercise independent judgment in determining whether HDCT/ABMT was generally accepted for the treatment of breast cancer was in contravention of the method for determining coverage set forth in the policy and was arbitrary and capricious.\textsuperscript{110}

In \textit{Kulakowski v. Rochester Hospital Service Corp.},\textsuperscript{111} the district court also found that the insurer failed to follow its own exclusionary provision which provided that it would not provide benefits for any service that was experimental in nature or not proven to be safe and efficacious.\textsuperscript{112} The insurer denied coverage on the basis of the “experimental” nature of HDCT/ABMT in the treatment of metastatic breast cancer.\textsuperscript{113} The company’s own expert, however, testified that the procedure was investigational,\textsuperscript{114} but not experimental.\textsuperscript{115} Additionally, both parties’ experts agreed that both conventional chemotherapy and HDCT/ABMT are "efficacious" in the treatment of metastatic breast cancer.\textsuperscript{116} Furthermore, defendant’s expert did not seriously dispute that HDCT/ABMT is a relatively safe procedure.\textsuperscript{117} The district court, applying an arbitrary and capricious standard, found that “a reading of the applicable exclusion denying

\textsuperscript{108}id. at 1421-22.
\textsuperscript{109}id.
\textsuperscript{110}id.
\textsuperscript{112}id. at 717. The policy specifically stated:
We will not provide benefits for any procedure or service which, in the sole judgment of the Blue Choice Medical Director, is experimental in nature. In addition, we will not provide benefits for medical treatments or procedures not proven to be safe and efficacious . . . .
\textsuperscript{113}Id. at 712 n.2.
\textsuperscript{114}Generally, the words "experimental" and "investigational" are used interchangeably. A technology which has been established for the treatment of certain diseases but remains unproven for another disease is sometimes referred to as "investigational" as to the new treatment. Testimony of Curtis J. Smith, supra note 51.
\textsuperscript{115}Kulakowski, 779 F. Supp. at 713.
\textsuperscript{116}id. at 716.
\textsuperscript{117}id.
coverage to a procedure which is not experimental, not unsafe, and not inefficacious, is clearly arbitrary and cannot be upheld."\textsuperscript{118}

The insurer in \textit{Kekis v. Blue Cross and Blue Shield of Utica-Watertown, Inc.}\textsuperscript{119} also failed to apply its own definition of experimental treatment in denying coverage. The policy clearly defined "experimental/investigative services" as a service or procedure that the company determines "has no proven medical value."\textsuperscript{120} Because the policy unambiguously manifested Blue Cross with the discretion to determine whether a procedure "has no proven medical value, the district court was required to apply an arbitrary and capricious standard of review."\textsuperscript{121}

Under the policy language, if Blue Cross determined that a service or procedure has proven medical value, coverage denial could not legitimately be based on the experimental/investigative exclusionary clause.\textsuperscript{122} Blue Cross did not deny plaintiff's request for coverage on finding that HDCT/ABMT has no proven medical value; instead, the company denied coverage upon its belief that the treatment was experimental and investigative in the ordinary sense of those terms.\textsuperscript{123} The district court concluded that Blue Cross erroneously applied the common, dictionary definition of experimental/investigative, instead of the definition set forth in the policy.\textsuperscript{124} The district court held that Blue Cross acted arbitrarily and capriciously when it failed to review plaintiff's request for coverage in accordance with the express terms of the contract.\textsuperscript{125}

In \textit{Scalamandre v. Oxford Health Plans (N.Y.)}, Inc.,\textsuperscript{126} the insurer failed to adhere to the terms of its policy relative to precertification procedures.\textsuperscript{127} The plan required preauthorization to be admitted to a hospital or to undergo elective surgery and stated that Oxford would notify the patient at the time of

\begin{itemize}
  \item \textsuperscript{118}\textit{Id.}
  \item \textsuperscript{119}815 F. Supp. 571 (N.D.N.Y. 1993).
  \item \textsuperscript{120}\textit{Id.} at 579.
  \item \textsuperscript{121}\textit{Id.} at 577.
  \item \textsuperscript{122}\textit{Id.} at 579.
  \item \textsuperscript{123}\textit{Id.} at 581.
  \item \textsuperscript{124}\textit{Kekis,} 815 F. Supp. at 581.
  \item \textsuperscript{125}\textit{Id.} The court noted, however, that even if Blue Cross had followed the policy terms and nevertheless decided to exclude coverage, the court still would find the denial to be arbitrary and capricious. \textit{Id.}
  \item \textsuperscript{126}823 F. Supp. 1050 (E.D.N.Y. 1993).
  \item \textsuperscript{127}\textit{Id.} at 1055. The coverage denial was not based upon an experimental exclusionary provision, but was for failure to obtain precertification, as required by the plan. The plan did not specifically exclude HDCT/ABMT as a "non-covered expense." \textit{Id.} In fact, chemotherapy was listed as a covered expense without qualification as to the dose level. \textit{Id.} The policy provided: "Covered Expenses are the following charges . . . 6. Charges for the following medical services and supplies: . . . b) chemotherapy." \textit{Id.} at 1054.
\end{itemize}
the call for preauthorization if a second opinion was required.128 The plan further provided that "[f]ailure to obtain authorization in advance or failure to comply with Oxford's medical review guidelines will result in reduced or denied benefits."129

The district court, under de novo review, found that Oxford had breached the terms of the plan.130 The district court found that Oxford breached the insurance contract in three different ways: first, by not notifying the person who called for preauthorization that a second opinion was required; second, by never designating a certified specialist to provide a second opinion, if one was necessary; and third, even if the recommendation to explore the programs at Duke and Hahnemann could be viewed as the designation of a board certified specialist, neither hospital could have complied with the plan requirements because both had a financial stake in the procedure.131 Accordingly, the district court concluded that Oxford improperly denied coverage.132

2. Unambiguous Provision Correctly Applied

A court will uphold a coverage denial where the contract is unambiguous and the insurer correctly applies the express terms of the contract in denying coverage. In Sweeney v. Gerber Products Co. Medical Benefits Plan,133 the insurance company denied coverage of HDCT/ABMT for Ms. Sweeney's metastatic breast cancer based on the exclusionary provision in the policy which required the treatment to be widely accepted by the medical community.134 Prior to denying plaintiff's claim, the insurance company examined the plaintiff's medical history, the specific treatment regimen proposed, and the current state

128Scalamandre, 823 F. Supp. at 1054. The plan listed 28 separate surgical procedures that required a second opinion; chemotherapy was not one of them. Id.

129Id.

130Id. at 1060.

131Id. at 1060-61.

132Id. at 1062.


134Id. at 595.

To be 'needed,' a service or supply must be (a) ordered by a doctor, (b) commonly and customarily recognized throughout the doctor's profession as appropriate in the treatment or diagnosis of the sickness or injury, (c) neither educational or [sic] experimental in nature, (investigational procedures are considered experimental), and (d) neither furnished mainly for the purpose of medical nor other research... .

Id.
of medical literature discussing the viability of the treatment. The insurer also obtained opinions of three outside consultants/oncologists.

In applying an arbitrary and capricious standard to the 1989 medical treatment, the district court upheld the insurance company's decision to deny coverage. The district court noted that the treatment was in phase II clinical trials and that the consensus in medical literature is that the treatment is experimental. The district court found particularly significant the fact that the doctor's consent forms, as well as the protocols, were replete with the terms "study," "research," "investigation," "experiment," etc., and the fact that different doctors are experimenting with different protocols. The district court further noted that even under de novo review, it would still conclude that the plaintiff is not entitled to benefits for HDCT/ABMT.

Similarly, in Holder v. Prudential Ins. Co. of Am., the insurance company denied coverage relying on language which provided that the policy does not cover anything not reasonably necessary for medical care. The policy stated that to be "reasonably necessary," a treatment must be ordered by a doctor, be commonly and customarily recognized as appropriate in the treatment of the diagnosed illness, and neither educational nor experimental. The district court reviewed this case under a de novo standard and held that the treatment was experimental in nature and had not yet been commonly and customarily recognized throughout the medical profession. The district court relied on the signed consent form which noted that the procedure was an "experimental study."

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135 Id. at 596.
136 Id.
137 728 F. Supp. at 597.
138 Id.
139 Id. at 596. It should be noted that Sweeney involved treatment to be rendered in 1989, and it is quite possible that a court now would rule differently given that the procedure is more widely accepted by the medical community. Wynstra, supra note 32, at 503.
140 Sweeney, 728 F. Supp. at 597.
141 951 F.2d 89 (5th Cir. 1992).
142 Id. at 90.
143 Id. See also Wynstra, supra note 32, at 496.
144 951 F.2d at 89; see also Wynstra, supra note 32, at 496.
145 The consent form provided:

2. PURPOSE OF STUDY: This is an experimental study which uses high doses of mitoxantrone, etoposide (VP-16) and thiotepa (MVT) in the treatment, combined with bone marrow transplantation. The use of higher-than-normal doses of chemotherapy carries with it a greater risk of complications to both the blood-forming cells of the body (the marrow) and other organs. Therefore, the purposes of
The Fifth Circuit in affirming the district court's finding that as of the time (late 1987) when the plaintiff underwent HDCT/ABMT found the treatment to be experimental and stated that the trial court was in the best position to view the evidence and weigh the testimony of the expert witnesses. The Fifth Circuit noted, however, that had the plaintiff undergone a similar treatment more recently under an accepted protocol, this case may have turned out differently.

In Fuja v. Benefit Trust Life Ins. Co., the insurance company refused Ms. Fuja's preapproval request because the treatment did not fall within the parameters of medically necessary procedures, as defined in the policy. The insurance company argued that the treatment was provided in connection with medical research and was not authorized for reimbursement by the Health Care Financing Administration. The insurance company appealed a district court decision enjoining it from denying coverage. The Seventh Circuit, applying a de novo standard of review, reversed the district court's judgment.

The Seventh Circuit found that the phrase "in connection with medical research" was unambiguous and that the evidence clearly established that the disputed treatment was provided "in connection with medical or other research.

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1) to find if such a combination is associated with acceptable toxicity to organs other than the bone marrow when used with the infusion of autologous marrow; and 2) to determine if, at these high doses, there is a significant response rate [shrinkage of the tumor].

Holder, 951 F.2d at 90.

146 Id.

147 Id. at 91.


149 18 F.3d 1405 (7th Cir. 1994).

150 Id. The policy defined medically necessary as:
required and appropriate for care of the Sickness or the Injury; and that are given in accordance with generally accepted principles of medical practice in the U.S. at the time furnished; and that are approved for reimbursement by the Health Care Financing Administration; and that are 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 not furnished in connection with medical or other research.

Id. at 1408.

151 Id. at 1407.

152 Id. at 1406.

153 Id. at 1412.
research."154 The Seventh Circuit found most significant the testimony of plaintiff's own expert, who testified that the plaintiff was informed that her treatment would be furnished in connection with medical research as part of a clinical trial.155 Additionally, the Seventh Circuit relied on the signed consent form labeled: "Consent by Subject for Participation in Research Protocol" which repeatedly stated that the subject was part of a "research project," "research study" or "research protocol."156

The best way for an insurer to protect itself from litigation and unfavorable court decisions in those cases which go to court is to list specifically the procedures which are not covered and the evidence that will be considered in determining whether or not a treatment is experimental and to follow such policy language in determining coverage. In Nesseim v. Mail Handlers Benefit Plan,157 the Eighth Circuit upheld OPM's denial of coverage because the policy unambiguously limited coverage of autologous bone marrow transplants to certain diseases, and breast cancer was not one of them.

The exclusionary provision in Harris v. Mutual of Omaha Co. & Rural Benefit Plan158 specified three forms of evidence which would be considered in determining whether a treatment was investigational or experimental.159 The Seventh Circuit in upholding OPM's coverage denial found that all three forms of reliable evidence supported the view that HDCT/ABMT is experimental.160

3. Ambiguous Provision

When an insurance policy fails to define "experimental" treatment, a court will make the determination. In Pirozzi v. Blue Cross-Blue Shield of Va.,161 the insurance company denied coverage relying on a provision in its policy which

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154 Fuja, 18 F.3d at 1410.
155 Id.
156 Id. at 1411.
157 995 F.2d 804 (8th Cir. 1993).
158 992 F.2d 706 (7th Cir. 1993). The policy stated: "Benefits are not provided for services and supplies . . . [t]hat are investigational or experimental or are mainly for research purposes." Id. at 708.
159 The policy provided that:
A drug, device or medical treatment or procedure is experimental or investigational: . . . (2) if Reliable Evidence shows that the drug, device or medical treatment or procedure is the subject of on-going phase I, II, or III clinical trials or under study to determine its maximum tolerated dose, its toxicity, its safety, its efficacy, or its efficacy as compared with the standard means of treatment . . .
Id. Coverage also may be denied "if Reliable Evidence shows that the consensus of opinion among experts regarding the drug, device or medical treatment or procedure is that further studies or clinical trials are necessary . . . ." Id.
160 Id. at 712-13.
excluded all "experimental or clinical investigative procedures; services of no scientifically proven medical value; also services not in accordance with generally accepted standards of medical practice." The policy nowhere defined an "experimental or clinical investigative" procedure.

The district court reviewed the case under a de novo standard and, after examining the expert testimony adduced at trial, concluded that HDCT/ABMT is not experimental. Unlike the Seventh Circuit in Holder, the district court in Pirozzi concluded that the use of a protocol or continued studies is neither determinative nor ultimately persuasive of the treatment's status as an experimental procedure. The district court found particularly persuasive the testimony of plaintiff's expert, Dr. Beveridge, who stated that HDCT/ABMT treatment is currently in use at most major medical centers. Dr. Beveridge further supported his position that HDCT/ABMT is safe and effective for the treatment of metastatic breast cancer by describing studies conducted at John Hopkins University, the University of Chicago, and Duke University.

The district court noted that the decision is narrowly anchored in the specific expert testimony and in the terms and structure of the plan's experimental exclusionary provision. The district court further stated that "a different experimental exclusion, or different expert testimony, or a plan that conferred broad discretion on the administrator might well require a different result."

In Tepe v. Rocky Mountain Hosp. & Medical Serv., the Colorado Court of Appeals found that a benefit change under the policy which was not properly communicated to the insureds created an ambiguity. After the insurer's coverage denial was affirmed at every level of the appeal process, the Tepes brought an action for declaratory and injunctive relief. The trial court, apply-

162 Id. at 588.
163 Id.
164 Id. at 594.
165 741 F. Supp. at 594.
166 Id. at 591.
167 Id. at 592. A 24-patient Johns Hopkins University HDCT/ABMT study demonstrated a 67% survival rate at 17 months; a 49-patient University of Chicago study demonstrated a median survival rate of 20 months and a 20 percent survivorship rate at three years; a 1989 Duke University study demonstrated a positive response rate of 80% (as of Mar. 13, 1990, only five of the 54 patients treated had relapsed). Id.
168 Id. at 594.
169 741 F. Supp. at 594.
171 Id. at 1325.
ing Colorado law, granted summary judgment in favor of the Tepes, and the insurer appealed.172

Plaintiffs were subscribers to the 1990 Blue Cross/Blue Shield plan which provided coverage for bone marrow transplants and chemotherapy procedures.173 The 1990 plan excluded coverage for "services and supplies ... which are investigative, mainly for research purposes or experimental in nature."174 Defendant claims that coverage for HDCT/ABMT was excluded under this experimental exclusion.175

In 1991, the plan was changed to provide coverage for bone marrow transplants only for specifically listed diseases, which did not include breast cancer.176 Both the 1991 and 1992 plan brochures, however, failed to list this change in coverage as a benefit change.177 In 1993, the plan language was changed to specifically exclude coverage for HDCT/ABMT for the treatment of breast cancer.178 Once again, the plan brochure failed to identify this change in coverage.179

The trial court found that the insurer had not given plaintiffs adequate notice of the change in benefits.180 Accordingly, the trial court found the 1993 plan to be ambiguous with respect to HDCT/ABMT for the treatment of breast cancer, notwithstanding the specific exclusionary language.181 The Court of Appeals affirmed.182

In the state action of Taylor v. Blue Cross/Blue Shield of Michigan,183 the Michigan Court of Appeals found ambiguous a provision which excluded coverage for services which are experimental or research in nature, without further defining these terms.184 The trial court found that the terms

172 Id.
173 Id.
174 Id. at 1328.
175 Tepe, 893 P.2d at 1328.
176 Id.
177 Id. Each plan brochure advised the insured to read the entire plan but reassured the insured that: "Unless indicated above as a benefit change, the brochure revisions do not affect the benefits available under this Plan." Id. at 1329.
178 Id. at 1328.
179 Tepe, 893 P.2d at 1329.
180 Id.
181 Id.
182 Id.
184 Id. at 867. The provision specifically stated: "The following services are not covered by this contract: Benefits for care, services, supplies or devices which are experimental or research in nature." Id.
"experimental" and "research in nature" were ambiguous. In holding that HDCT/ABMT was not experimental or research in nature, the trial court found most persuasive the expert testimony of Ms. Taylor's treating oncologists. The doctors testified that HDCT/ABMT was Ms. Taylor's only chance to be free of cancer for at least two or three years. The doctors further testified that Ms. Taylor's life expectancy would be only a matter of months with conventional chemotherapy. Although the trial court acknowledged that research was the underlying purpose of the procedure, it found that the primary purpose of the procedure was to provide Ms. Taylor her only opportunity to be free of cancer for a substantial period of time.

In affirming the trial court's decision, the Court of Appeals found unpersuasive the fact that HDCT/ABMT procedures are conducted only at research institutions and that the procedures would be conducted under a protocol and the information gathered regarding Ms. Taylor's procedure would be shared with other researchers. The Court of Appeals noted that the insurer could have inserted these factors in defining "experimental" or "research in nature" in the policy, but failed to do so.

The legal system is a very costly and inefficient mechanism for judging the current state of medical technology. Coverage disputes are decided on a case-by-case basis. Each decision is confined to the specific policy language, the specific expert testimony, and the state of medical technology at the time of the coverage denial. Slightly different policy language, different experts, normal advances in medical knowledge, or treatment to be given a short time later may likely result in a different outcome. Therefore, court decisions have no precedential value. Accordingly, coverage disputes involving similar policy language and similar treatments are forced into litigation over and over again, tying up the courts and adding to the cost of health care.

VII. DISCRIMINATION CLAIMS

A growing number of insurance companies have fortified their legal defenses by changing policy language from generally excluding "experimental" treatment to specifically excluding designated treatments for

185 Id. at 868.
186 Id. at 869.
187 517 N.W.2d at 869.
188 Id.
189 Id.
190 Id.
191 Id.

192 Because expert testimony is so crucial to a determination of the efficacy of the disputed treatment and because of the apparent conflict-of-interest of each party's expert, courts should employ independent medical experts.
certain diseases, particularly HDCT/ABMT for breast cancer. This tactic, however, has left insurers vulnerable to lawsuits alleging discrimination under Title VII of the Civil Rights Act of 1964 and the Americans With Disabilities Act of 1990. The flaw in the lawsuits alleging discrimination is that the claimants assume that HDCT/ABMT has equal medical value across all types and stages of cancer, which is contrary to medical science.

In *Reger v. Espy*, the plaintiff alleged that the exclusion of HDCT/ABMT treatment for breast cancer violated Title VII of the Civil Rights Act of 1964, in that the exclusion has a disparate impact upon women. The plan did not cover HDCT/ABMT for the treatment of all but five specified types of cancer. The district court found that the plaintiff failed to establish that the facially neutral exclusion had a disparate impact on women.

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193 *Meyer, supra* note 52, at 8.


195 42 U.S.C. §§ 12101 et seq. (1994). The ADA prohibits employers from discriminating on the basis of disability against a qualified individual with a disability in regard to fringe benefits, including health insurance plans, available by virtue of employment. 42 U.S.C. § 12112(a) (1994); 29 C.F.R. § 1630.4(f) (1995). If the EEOC determines that the challenged term or provision is disability-based, the EEOC will conclude that the respondent has violated the ADA unless it can prove that the disability-based distinction is within the protective ambit of section 501(c) of the ADA. *EEOC Interim Guidance on Application of ADA to Health Insurance*, 109 BNA DAILY LAB. REP. E-1, E-1 (June 9, 1993). A disability-based distinction is within the protective ambit of section 501(c) of the ADA if the respondent can prove that:

1) the health insurance plan is either a bona fide insured health insurance plan that is not inconsistent with state law, or a bona fide self-insured health insurance plan; and 2) the challenged disability-based distinction is not being used as a subterfuge.

*Id.* at E-2. The respondent can prove that a challenged disability-based distinction is not a subterfuge by proving that: (a) it has not engaged in the alleged disability-based disparate treatment; (b) the disparate treatment is justified by legitimate actuarial data, or by actual or reasonably anticipated experience, and that illnesses with comparable actuarial data and/or experience are treated in the same manner; (c) the disparate treatment is necessary to ensure the fiscal soundness of the plan; (d) the challenged practice is necessary to prevent a drastic increase in premium payments or a drastic alteration in the scope of coverage provided; or (e) where the charging party is challenging the respondent's denial of coverage for a disability-specific treatment, the respondent may prove that the disputed treatment has no medical value. (emphasis added) *Id.* at E-3.

196 *Woolsey, supra* note 9, at 2. An Omaha, Nebraska, defense lawyer stated that, "During the last year, 80% of the cases in my office have also contained the charge that the exclusion in the coverage contract violates some anti-discrimination law." *Id.* at 26.


199 *Id.* at 870.

200 *Id.* at 871.
In *Henderson v. Bodine Aluminum, Inc.*,\(^2\) the plaintiff brought her claim under the ADA. The district court denied a preliminary injunction because the plan, like the plan in *Reger*, explicitly excluded HDCT/ABMT for most cancers.\(^3\) The Eighth Circuit reversed and remanded for entry of a preliminary injunction requiring Bodine to pay for the treatment and ordering the matter to be set for trial.\(^4\) The court stated that "if the evidence shows that a given treatment is non-experimental . . . and the plan provides the treatment for other conditions directly comparable to the one at issue, the denial of treatment violates the ADA."\(^5\)

**VIII. OPM and State Legislatures Take Action**

On September 20, 1994, in spite of the Office of Personnel Management’s recognition that there is no consensus on the treatment’s efficacy, OPM issued a directive effective immediately requiring the 350 health plans serving the nine million federal employees and their dependents to cover HDCT/ABMT for breast cancer, multiple myeloma, and epithelial ovarian cancer in randomized and non-randomized clinical trials.\(^6\) OPM’s decision is expected to cost approximately $120 million a year.\(^7\)

State legislatures have reacted in different ways.\(^8\) Massachusetts\(^9\) and New Hampshire\(^10\) have responded to the growing number of coverage disputes involving HDCT/ABMT for the treatment of breast cancer by mandating coverage. Both states require that the procedure be performed pursuant to protocols reviewed and approved by the National Cancer Institute.\(^11\) Neither state explicitly requires that the patient be part of a clinical trial to receive reimbursement.\(^12\) Additionally, both states provide that this

\(^2\) *Id.* at 873.

\(^3\) 29 F.3d 958 (8th Cir. 1995).

\(^4\) *Id.* at 960.

\(^5\) *Id.* at 959-60.

\(^6\) *Id.* at 960.

\(^7\) Winslow, *supra* note 58, at A1.

\(^8\) Under ERISA’s "savings clause," state law which regulates insurance is exempt from ERISA preemption. 29 U.S.C. § 1144(b)(2)(A) (1994).

\(^9\) Mass. Gen. Laws Ann. ch. 32A, § 17A; ch. 175, § 47M; ch. 176A, § 80; ch. 176B, § 40; ch. 176G, § 4F (West 1994) (only mandates coverage where the breast cancer has progressed to metastatic disease).


\(^11\) See notes 209-10.

\(^12\) *Id.*
procedure shall not be subject to any greater deductible or copayment than that applicable to any other coverage.  

Minnesota recently enacted legislation mandating coverage of HDCT/ABMT for the treatment of breast cancer. Minnesota's law also prohibits any greater coinsurance, copayment or deductible than that applicable to any other coverage under the plan. Minnesota's law does not require that treatment be provided as part of a clinical trial or even in accordance with an approved protocol. Bills are pending in Colorado, New Jersey, New York, and Ohio which mandate coverage for the treatment of cancer by bone marrow transplants when performed pursuant to approved protocols.

Virginia has passed, but has delayed the effective date of, legislation which requires health care plans for state employees to provide coverage of HDCT/ABMT for the treatment of breast cancer when performed as part of a clinical trial sponsored by the NCI. Relative to other plans, Virginia, like Missouri, has taken an optional coverage approach. Virginia and Missouri have

212Id. However, a Virginia statute provides that a deductible for such coverage in an amount different than that applicable to any other coverage may also be offered. VA. CODE ANN. § 38.2-3418.1:1 (Michie 1994).

2131995 MINN. SESS. LAW SERV. 183 (H.F. 1742) (West).

214Id.

215Colorado has indefinitely postponed Colorado Senate Bill No. 67 which would require health insurers to cover the physician fees and hospital costs, but not research-related costs, whenever an insured, who has been referred by a primary care physician, participates in approved cancer treatment clinical trials.

216New Jersey Assembly Bill 1997 and Senate Bill 1320 mandate coverage for the treatment of cancer by HDCT/ABMT or stem cell transplants when performed pursuant to approved protocols, but do not differentiate by type of cancer. New Jersey Assembly Bill 175, however, is more explicit requiring health insurers to provide benefits for expenses incurred in connection with bone marrow transplants and peripheral blood stem cell transplants for the treatment of patients suffering from diseases including, but not limited to, leukemia, aplastic anemia and breast cancer. New Jersey Assembly Bill 175 further provides that coverage shall not be denied on the basis that bone marrow transplants or peripheral blood stem cell transplants are experimental or investigational.

217New York Assembly Bill 11533 requires coverage for bone marrow transplants for persons who have been diagnosed with breast cancer, provided, however, that said person meets the criteria established by the Department of Health, which criteria shall be consistent with protocols reviewed and approved by the National Cancer Institute. New York Assembly Bill 4260 and New York Senate Bill 2662 require health insurance policies to cover all medically necessary expenses incurred in connection with bone marrow transplants, but do not specify for what types of diseases bone marrow transplants are appropriate or who determined what is medically necessary.

218Ohio House Bills 554 and 592 require certain health insurers to provide benefits for the expenses arising from the treatment of breast cancer by ABMT according to approved protocols.

enacted legislation which requires health insurers to offer a supplemental benefit rider to cover the expenses associated with the treatment of breast cancer by HDCT/ABMT or stem cell transplants when performed pursuant to approved protocols.\textsuperscript{221} Virginia and Missouri’s laws, like Massachusetts’ and New Hampshire’s, do not require that the treatment be provided as part of a clinical trial and do not delineate by the stage of the breast cancer.

Florida has taken a technology assessment approach similar to that recommended by Judge Coffey in\textit{ Fuja}.\textsuperscript{222} Chapter 627.4236 of Florida Statutes dictates that a health insurer may not exclude coverage for bone marrow transplantation procedures recommended by a physician under a policy exclusion for experimental procedures, if the procedure is determined to be accepted within the appropriate oncological specialty and not experimental under the rules adopted by the Secretary of Health and Rehabilitative Services.\textsuperscript{223}

\textsuperscript{221}VA. CODE ANN. § 38.2-3418.1:1 (Michie 1994) provides in pertinent part as follows:

Each insurer . . . shall offer and make available coverage under such policy, contract or plan . . . 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 college 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.

1995 MO. LEGIS. SERV. S.B. 27 (Vernon) provides in pertinent part:

376.1200.1. Each entity offering individual and group health insurance policies . . . shall offer coverage for the treatment of breast cancer by dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants when performed pursuant to nationally accepted peer review protocols utilized by breast cancer treatment centers experienced in dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants.

\textsuperscript{222}In\textit{ Fuja}, Judge Coffey suggested the establishment 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 to reach some consensus on the definition of experimental procedures and an 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. 18 F.3d at 1412.

\textsuperscript{223}FLA. STAT. ANN. § 627.4236 (West 1995) further specifies that the rules must be based upon recommendations of an advisory panel 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
Finally, California takes a less intrusive approach to dealing with the reimbursement controversy. California Assembly Bill 3654 does not mandate coverage for bone marrow transplants, but requires that information be provided to prospective enrollees of any health care plan regarding whether, and to what extent, the plan provides coverage for experimental transplant treatment for breast cancer patients.

IX. DANGERS OF POLITICIZING MEDICINE

Politicizing medicine jeopardizes patient safety and medical innovation. Mandatory coverage of an unproven treatment will result in wide spread acceptance and dissemination of that treatment before its true safety and effectiveness is determined. Mandatory coverage will likely lower participation in clinical trials, thereby making a determination of the treatment's true efficacy impossible. Mandatory coverage of an unproven treatment may delay the discovery of a more effective treatment because researchers may shift their focus to another disease. There is a danger that the unproven treatment may actually do more harm than good, as is suggested by ECRI's recent study. Legislation which addresses one disease at a time is a piecemeal approach to a very serious problem.

X. RECOMMENDATIONS

While mandatory coverage of HDCT/ABMT for the treatment of breast cancer solves the coverage dispute dilemma as it relates to that particular treatment for that particular disease, it does little to resolve the problem of courts judging new medical technologies and leaves the question of who should pay for the patient care costs of clinical research unanswered. Federal legislation is needed which sets out a clear definition of "experimental" medical treatment, has a uniform policy on off-label drug reimbursement, and mandates that insurers cover the clinical care costs associated with participation in approved clinical cancer trials.

A. Recommended Definition Of "Experimental" Medical Treatment

I recommend the following definition for "experimental" medical treatment:

A drug, device or medical treatment or procedure is experimental:

1. If Reliable Evidence shows that the drug, device or medical treatment or procedure is the subject of on-going phase I, II or III clinical trials or under study to determine its maximum tolerated dose, its toxicity, its safety, its efficacy, or its efficacy

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.

224This definition is almost identical to the policy definition in Harris v. Mutual of Omaha, 992 F.2d at 708.
as compared with the standard means of treatment or diagnosis; or

(2) If Reliable Evidence shows that the consensus of opinion among experts regarding the drug, device or medical treatment or procedure is that further studies or clinical trials are necessary to determine its maximum tolerated dose, its toxicity, its safety, its efficacy, or its efficacy as compared with the standard means of treatment or diagnosis.

Reliable Evidence means published reports and articles in the authoritative medical and scientific literature; the written protocol or protocols used by the treating facility or the protocol(s) of another facility studying substantially the same drug, device or medical treatment; or the written informed consent used by the treating facility or by another facility studying substantially the same drug, device or medical treatment or procedure.

B. Recommended Off-label Drug Legislation

I recommend the following language for federal legislation establishing a uniform policy for reimbursement of off-label drug use. Because off-label drug use is so prevalent, reimbursement of off-label drug use should not be limited to drugs used to treat life-threatening illness.

(a) No health insurer issuing a policy which provides coverage for prescription drugs shall exclude coverage of any such drug on the grounds that the drug has not been approved by the Food and Drug Administration (FDA) for that indication in one of the standard reference compendia, or in the medical literature.

(b) Standard reference compendia means (1) the United States Pharmacopeia Drug Information, (2) the American Medical Association Drug Evaluations, and (3) the American Hospital Formulary Service Drug Information.

(c) Medical literature means published scientific studies of off-label use of drugs appearing in any peer-reviewed national professional journal.

(d) Any coverage for the off-label use of a prescription drug required by this section shall also include provisions for coverage of medically necessary services associated with the administration of the prescription drug.

(e) No coverage shall be required for any drug not licensed or approved by the FDA, for the use of any drug when the FDA has determined that its use is contraindicated, or any experimental drug not otherwise approved by the FDA.

C. Recommended Legislation Relative To Clinical Trials

Mandatory coverage of patient care costs associated with approved clinical cancer trials will result in quicker patient accruals and quicker answers relative
to whether a new treatment is more effective than the standard therapy and under what circumstances the new treatment is more beneficial. Mandatory coverage of patient care costs associated with approved clinical cancer trials will alleviate the constant relitigation of the efficacy of a given medical treatment because more patients, assured of coverage associated with an approved clinical trial, will opt for enrollment in a clinical trial instead of a costly and uncertain lawsuit. I propose the following language:

Each insurer, health maintenance organization, profit and non-profit health/hospital service corporation, or similar corporation shall cover patient care costs whenever an insured, enrollee or subscriber participates, after referral by a primary care physician, in a Phase III approved clinical cancer trial.

"Patient care costs" means physician fees and hospital expenses, but does not include research-related costs.

Patient care costs for clinical trials shall be reimbursed when all of the following requirements are met:

The treatment is provided with a therapeutic intent and is being provided pursuant to a clinical trial that has been approved by any of the following: The National Cancer Institute or any of its clinical cancer centers, cooperative groups, or community clinical oncology programs; the United States Food and Drug Administration in the form of an Investigational New Drug in conjunction with a clinical trial approved by the National Cancer Institute; or the United States Department of Veteran Affairs, for clinical trials which are part of a National Cancer Center-approved clinical cancer center program.

D. Technology Assessment Partnerships Recommended

In addition, because health care resources are limited and many new medical technologies are, at least initially, more expensive than current therapies, technology assessment is needed to determine whether a new treatment is superior to the current treatment. In response to increased litigation, technology assessment partnerships between private payers and government have already begun to emerge. In 1991, Blue Cross & Blue Shield entered into an agreement with the National Cancer Institute whereby Blue Cross & Blue Shield would fund a large demonstration project testing the efficacy of HDCT/ABMT treatment for ad-

225 Colorado has proposed similar legislation, but a vote on the legislation has been postponed indefinitely. See 1994 Co. S.B. 67.

226 See Cori Vanchieri, Treatment Costs Warrant Closer Look in Clinical Trials, 84 J. NAT'L CANCER INST. 918 (1992) (discussing cost assessment as part of clinical trials).
vanced breast cancer. In 1992, Congress gave the Agency for Health Care Policy and Research the power to form "technology partnerships" with private sector payers and others.

XI. CONCLUSION

I urge legislators to refrain from politicizing medical technology and abandoning our system of clinical trials. While I recognize that a vote against mandatory coverage of a potentially life-saving treatment for a highly publicized disease may seem like political suicide, government has a duty to protect the public against potentially unsafe and ineffective medical treatments. Coverage of "experimental" medical treatment can be better addressed by federal legislation which sets out a clear definition of "experimental" medical treatment and a uniform policy on off-label drug reimbursement, and mandates reimbursement of clinical care costs associated with participation in approved clinical cancer trials.

MELODY L. HARNESS

227 ACHPR May Form Technology Assessment Partnerships With Private Sector Payers, BNA MGMT. BRIEFING (Jan. 14, 1993) available in LEXIS, Bna LIBRARY Bnmb FILE [hereinafter BNA Mgmt.].


229 The author wishes to thank Steven R. Smith, former Dean of Cleveland-Marshall College of Law, for his valuable contributions to this Note.

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