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A PROPOSAL FOR FEDERAL LEGISLATION TO ADDRESS HEALTH INSURANCE COVERAGE FOR EXPERIMENTAL AND INVESTIGATIONAL TREATMENTS

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"Benefits are not provided for services and supplies . . . [t]hat are investigational or experimental . . . ." [FN1] Such exclusionary language appears in many health insurance benefits plans and has caused a plethora of controversy, consternation, and litigation in recent years. It is difficult to imagine the devastation felt by a critically ill patient who learns of a potentially life saving treatment but is denied insurance coverage because the health benefits provider determines that the treatment is experimental or investigational.

A 1991 Gallup poll of oncologists found that one out of eight patients never received their physicians' preferred treatment because of "reimbursement struggles." [FN2] A current poll, conducted in the era of managed care, would likely yield even more dramatic data. The husband of a breast cancer patient articulated his family's anguish as follows:

I am involved in a legal battle with Blue Cross and Blue Shield . . . which has denied coverage for my wife's bone marrow transplant for advanced breast cancer. . . . Now, when we need insurance the most, Blue Cross has turned its back on us.

Unless the case is settled soon in our favor, I will be forced ***204** to sell my house, borrow from friends and relatives, and mortgage my children's future. Blue Cross's position has created a huge financial, emotional and physical burden for my wife, my family and me. [FN3]

Often, patients turn to the courts, asking judges to determine whether insurance companies should be forced to pay for experimental and investigational treatments. Judges hearing these cases are keenly cognizant of the gravity of the decisions before them. They are aware that they perhaps hold in their hands a patient's last hope for treatment and thus survival. As one judge confronted with this dilemma stated:

I was called upon to decide whether eight year old Tishna Rollo could live or whether she must die, a humbling and sobering decision. Tishna, I was told, had virtually no chance of surviving the relapsed Wilms' tumor from which she is suffering and Blue Cross/Blue Shield had denied coverage for autologous bone marrow transplant ("ABMT") with accompanying high dose chemotherapy, a treatment which could well prolong and quite possibly save her life and which, concededly, provided her only realistic hope of either . . . .

The bottom line, as this case began, was that Blue Cross/Blue Shield would have to defend their decision denying coverage and, if they successfully did so, this child would most likely die, a victory which would give even the victor little satisfaction. [FN4]

Faced with such emotionally charged cases, courts have reached contradictory and inconsistent conclusions. [FN5] Courts have been criticized for ordering payment for experimental treatment too frequently based on compassion rather than the merits of the case. Some commentators have suggested that the judiciary should not be involved in making such determinations at all. [FN6] Moreover, many critically ill patients do not have the financial resources, energy, or time to endure a court battle. [FN7]

***205** Some state legislatures have responded to the growing controversy regarding health benefits coverage for experimental and investigational treatments. Several states have mandated that insurance companies pay for high dose chemotherapy with bone marrow transplants for certain kinds of cancer under particular circumstances. [FN8] Other states have provided that insurance companies must at least offer coverage for high dose chemotherapy with bone marrow transplants. [FN9]

State legislation that focuses on a particular treatment for a specific disease, however, is problematic for a number of reasons. First, narrowly tailored statutes affect only a small number of patients who need the therapy at issue and live in the specified state. [FN10] Second, state legislation targeting particular treatments may result from lobbying efforts of interest groups [FN11] or from individual, high profile cases. [FN12] Those patients who suffer from rare conditions, who do not have the resources to reach the legislature, or who fail to gain media access will not benefit from legislative intervention. Also, legislative debates are lengthy, and patients with end stage diseases cannot wait for their outcomes. Third, state mandates may be of no help to patients covered by self-funded employee benefit plans because the Employee Retirement Income Security Act (ERISA) exempts self-funded ***206** plans from state laws that regulate insurance. [FN13] Finally, employer-provided health insurance plans that cover particular treatments pursuant to a state statute but deny coverage in similar circumstances not covered by the statute may be found to violate the Americans With Disabilities Act (ADA) [FN14] despite the existence of relevant state legislation. The ADA prohibits employers from discriminating against employees with respect to all "terms, conditions, and privileges of employment," [FN15] including health insurance benefits. [FN16]

In light of the deficiencies inherent in both the judicial and state legislative approaches, federal legislation addressing the issue of insurance coverage for experimental and investigational treatment should be implemented. This Article proposes federal legislation that draws from the solutions offered by two state statutes, specifically those of Rhode Island [FN17] and California. [FN18] These statutes feature a relatively comprehensive treatment of the problem of insurance coverage for innovative or last-chance therapies.

The Rhode Island statute mandates that health insurance organizations cover investigational cancer therapies if they are provided in the context of a Phase III or IV clinical trial [FN19] that has been approved by one of the organizations named in the statute as long as no clearly superior nonexperimental alternative exists for the patient. [FN20] The law further requires that the patient meet all protocol requirements and that the procedure be performed in appropriate facilities with qualified personnel. [FN21] The California statute requires that health benefits plans provide an independent, expert review of any decision to deny coverage for experimental or investigational treatments for patients with terminal conditions that are likely to cause death within two years and for which there is no effective therapy. [FN22]

This Article proposes federal legislation that would supplement***207** existing state law. It would address all experimental treatments for terminally ill patients and not focus solely upon those suffering from cancer or upon procedures that receive extensive attention from advocates and lobbyists, such as bone marrow transplants. The federal statute would compel health insurance plans to pay for investigational or experimental treatments provided in Phase III clinical trials for patients with any terminal illness that is likely to cause death within two years so long as particular criteria are met. These criteria would include requirements that the patient meet protocol requirements, that the individual undergo the treatment at a qualified facility with qualified personnel, and that no clearly superior non- experimental treatment be available. In addition, the law would compel insurers to pay for off-label use of drugs if the particular use is recognized in a standard reference compendia or in a national, peer-reviewed professional journal. The proposed legislation would further mandate that the health benefits carrier provide an external, independent review of any decision to deny a terminally ill patient coverage for off-label drug use or experimental and investigational treatments administered in a Phase III clinical trial. [FN23] Such review will eliminate much litigation and avoid emotionally draining and costly delays for patients desperately waiting for decisions regarding potentially life-saving therapy.

Part I of this Article discusses coverage exclusions for experimental and investigational treatments as they appear in a variety of insurance policies. This section features a discussion of treatments that have been excluded from coverage including high dose chemotherapy with bone marrow transplants and off- label drug use. Part II examines the manner in which courts have approached cases involving coverage denials for last-chance treatments sought by terminally ill patients. Part III sets forth and analyzes state statutes and their varied, but limited, solutions for experimental treatment coverage denials and also analyzes the more far-reaching solutions offered by the Rhode Island and California statutes. Part III also discusses the weaknesses of state legislation as a solution to the problem in general, and in particular, the limitations of the statutes in light of ERISA and the ***208** ADA. Part IV provides an overview of the evolution of federal legislation in the area of health insurance policy and advocates the implementation of additional federal regulation in this area. Finally, Part V formulates a proposal for federal legislation addressing the issue of health insurance coverage for experimental and investigational treatments and provides model statutory language.

I

Provisions Excluding Coverage for Experimental or Investigational Treatment

Insurance plans define "experimental" or "investigational" treatment in a variety of ways. Some policies provide that the determination as to the status of the proposed therapy is to be made solely by the plan administrator. [FN24] Other health insurers define experimental treatments as those under "clinical investigation," those "not generally recognized by the medical profession as tested and accepted medical practice," or those still requiring future "approval by the Federal Drug Administration or other governmental agency." [FN25] Some insurance companies establish ***209** "corporate technology assessment committees" that determine what therapies are covered under all of the policies issued by the company. [FN26] Still other plans exclude coverage of any treatment "furnished in connection with medical or other research" [FN27] or that require patients to sign informed consent forms for research. [FN28]

Both courts and academic commentators have severely criticized the terms of various exclusionary provisions relating to experimental or investigative treatments. With respect to a provision that excluded coverage for any treatment furnished in conjunction with medical research, an Illinois court commented as follows:

If an orthopedic surgeon either decided to conduct a time study of how quickly she could apply casts to the broken bones of her patients or decided to publish results of how quickly the plaster hardened on those casts, [the insurance company] could invoke the 'in connection with medical research' clause to deny coverage for the common treatment of applying a cast to a broken arm. [FN29]

Exclusionary provisions that allow administrators great latitude in making coverage decisions have been condemned for creating conflicts of interest. [FN30] The plan administrator owes both a duty to the policy's beneficiaries and allegiance to the insurer. [FN31] The administrator, who is employed by the insurance provider, realizes that he or she can enhance the insurer's profits by declining to pay the claims of policyholders and thus might be tempted to construe coverage provisions very narrowly to deny claims as ***210** often as possible. [FN32] The concern over economic self interest is particularly compelling in cases where self-insured employers make their own determinations regarding coverage exclusions and thus stand to enjoy direct financial benefits from denial of claims. [FN33]

This conflict of interest is likely to create at least the appearance if not the reality of impropriety. One scholar has accused insurance companies of being "motivated to refuse payment for any and all expensive treatments on whatever grounds they can find" [FN34] and alleges that insurers "try to refuse coverage even when affidavits attesting to the acceptance of the therapy are submitted by recognized experts in the field in question." [FN35]

Other commentators, however, focus on the economic utility of exclusionary clauses. In the words of one district court judge, "subscriber premiums should not have to pay for procedures which are purely experimental or investigative or subsidize every scientist stirring a magic potion in some laboratory at the top of a mountain with lightning flashing about." [FN36] Some commentators defend insurers and assert that "plan administrators are not heartless beasts trying to deprive desperately ill persons of needed medical care. They are responsible for administering a plan as written, using limited funds available to them to provide for the medical needs of all members of the plan." [FN37]

It is thus arguable that the exclusion of coverage for experimental or investigational treatment is necessary for purposes of cost containment. [FN38] Such exclusions insure that the provider's resources will be used to pay only for treatments that are proved to ***211** be safe and effective. [FN39] Moreover, it is claimed that exclusionary clauses are essential in enabling insurance companies to set premium rates by enhancing the actuarial predictability of the costs to be incurred by insurers. [FN40] Presumably, if insurance companies could not predict which investigational and experimental treatments would be developed by research facilities and which would be demanded by members of its coverage group, the actuarial basis for their premium rates could be invalidated. [FN41] Clear coverage guidelines, delineated in federal legislation, would thus not only benefit patients, but would also be beneficial for insurance companies, because they would enhance cost and expense predictability.

A. Treatments that Have Been Excluded from Coverage

Insurance companies have denied coverage for a large variety of treatments that they have designated as

experimental or investigational. [FN42] One of the most frequently disputed therapies in recent years is High Dose Chemotherapy with Autologous Bone Marrow Transplant (HDC-ABMT). HDC-ABMT is a controversial treatment, in part because, according to experts, between five percent and twenty percent of patients die from the procedure rather than from the underlying disease. [FN43] The following describes the process of HDC- ABMT in detail:

HDC-ABMT is a procedure by which stem cells are harvested from the bone marrow of the patient's body and purified of cancer cells. The patient is placed under general anesthesia while the bone marrow is extracted by needle. The bone marrow is then frozen and stored while the patient receives high, and potentially toxic, doses of chemotherapy. In some cases, the chemotherapy is administered in doses which exceed one thousand times the standard dosage for conventional chemotherapy treatment. This high dose chemotherapy kills not only the cancer, but also the patient's remaining bone marrow which produces white blood cells to protect the body from infection. The bone marrow, which is the most sensitive of all the body tissue, is also the most damaged by chemotherapy. ***212** After the chemotherapy is completed, the patient's stored bone marrow is reinfused intravenously so that it may re-engraft. The bone marrow then multiplies rapidly to replace the marrow destroyed during the high-dose chemotherapy.Given that the bone marrow is the patient's own tissue, there is little danger of rejection. There are, however, significant dangers associated with administering high-dose chemotherapy without some additional treatment to regenerate the bone marrow. Because the toll on a patient's white blood cells is significant, the secondary treatment is essential to the patient's chances for survival. Thus, the bone marrow must be quickly reintroduced after high-dose chemotherapy treatment to "rescue" the patient from otherwise almost certain death. "There is a narrow 'window of time during which the treatment [can] be rendered." '

. . . When undergoing HDC-ABMT, a patient is hospitalized, requiring usually one to two weeks of constant care in an intensive care ward. The entire procedure may cost as much as $200,000. [FN44]

The treatment has become even more controversial recently. The American Society of Clinical Oncology released five clinical study abstracts in advance of its annual meeting in May of 1999, showing that in four out of five clinical trials conducted in the United States and Europe and involving over 2000 women, investigators found "no significant difference in survival between patients receiving [HDC-ABMT] and those receiving lower-dose chemotherapy without transplant support." [FN45] Only one study, conducted in South Africa, showed that the experimental treatment had a favorable result. [FN46] The denial of insurance benefits for HDC-ABMT for breast cancer patients has generated substantial publicity. [FN47] In the case of Fox v. Health Net, Inc., the jury awarded eighty-nine million dollars to the estate of a breast cancer patient whose California-based health maintenance organization had initially denied coverage for HDC-ABMT, although it ***213** later agreed to provide reimbursement for the treatment. [FN48] The lawsuit alleged that the delay cost the patient her life. [FN49] Insurance providers, however, have also denied coverage for HDC-ABMT for patients suffering from [FN50] multiple myeloma, [FN51] Wilms tumor, [FN52] mediastinal germ cell carcinoma, [FN53] chronic myeloid leukemia, [FN54] glioblastoma multiforme, [FN55] and malignant melanoma. [FN56] In addition, health insurance coverage has been denied for the following treatments based on the "experimental" status of the procedure: liver transplants for a variety of diseases, [FN57] lung transplant for the treatment of emphysema, [FN58] an artificial heart transplant, [FN59] and in vitro fertilization for infertility. [FN60]

B. Off-label Use of Drugs

Off-label drug use is the medical practice of prescribing a drug for a use other than the one indicated on its FDA-approved label or in a manner not indicated on the label. [FN61] The FDA approves new drugs after determining, through clinical studies, that they are safe and effective for a specific clinical population. [FN62] Once a drug is approved, a physician need not seek any governmental approval if he or she wishes to use it in combination with another ***214** drug or for a use that was not evaluated by the FDA. [FN63]

Physicians may deviate from the use approved on drug labels in several ways. Doctors may prescribe the medication to treat conditions other than those for which it was initially intended. [FN64] Physicians may also prescribe the drug for patient populations other than those for which it was originally approved, such as children rather than adults. [FN65] In addition, practitioners may alter the dosage or method of administering the drug. [FN66] Experts agree that at least one-quarter of all prescriptions in the United States are for off-label drug uses, and some estimate the figure to be between forty percent and sixty percent. [FN67] A 1991 study by the United States General Accounting Office (GAO) found that one-third of all prescriptions for chemotherapy to treat cancer were off-label and over fifty percent of the patients received at least one off-label drug. [FN68] Some insurers

consider off-label drug use to be experimental and consequently excluded from benefits coverage. [FN69] Approximately twenty-three percent of the oncologists surveyed by the GAO acknowledged that they did not utilize a treatment they preferred because of concerns about cost, including expected or actual denials of insurance reimbursement. [FN70] Additionally, sixty-two percent of the surveyed oncologists stated that they hospitalize patients whom they could treat on an outpatient basis in order to ensure reimbursement for drug therapies that may be excluded from coverage if the patient were not admitted. [FN71] Under Medicare, doctors can prescribe off-label drugs to hospitalized patients and avoid scrutiny by the insurer because Medicare provides fixed reimbursement for many services ***215** received by in-patients in a hospital. [FN72]

The reluctance of insurers to cover off-label drug use could have significant financial implications. One commentator notes that ironically, if insurers were to insist on agency approval of all uses and mixtures of drugs, health care costs would rise dramatically because repeated, lengthy FDA testing would be required each time a doctor wished to try a new drug "cocktail" for cancer or HIV patients. [FN73] It takes approximately twelve years for new drugs to be developed and approved in accordance with government regulations. [FN74] The practice of hospitalizing individuals who could be treated as outpatients further raises healthcare costs. [FN75] In addition, mandatory testing of all drug uses would likely cause litigation to proliferate because treatment opportunities and, potentially lives, would be lost. [FN76]

The federal government has attempted to remedy the problem for Medicaid and Medicare patients. The Omnibus Budget Reconciliation Act of 1990 requires Medicaid agencies to reimburse patients for the off-label use of drugs if the prescribed use is recognized in any of the standard reference compendia, such as the United States Pharmacopeia Drug Information, the American Medical Association Drug Evaluations, and the American Hospital Formulary Service Drug Information. [FN77] The Omnibus Budget Reconciliation Act of 1993 requires that Medicare cover off-label drug use under the same criteria. [FN78]

Several state legislatures have also addressed the problem of insurance providers excluding coverage for off-label drug use. [FN79] Some states have mandated reimbursement for off-label drugs ***216** prescribed to treat potentially terminal illnesses such as cancer or HIV/AIDS. [FN80] As discussed below, this Article recommends that federal legislation require that all insurers cover off-label drug use if the use is recognized in one of the standard reference compendia or in a national, peer-reviewed professional journal, thus universalizing and expanding the standard applicable to Medicaid and Medicare patients. Furthermore, the proposed legislation provides an appeal mechanism that enrollees may utilize if they are denied coverage for off-label drug use in the treatment of a terminal illness.

II

Judicial Determinations Regarding Exclusionary Clauses

Much has been written about the courts' efforts to grapple with insurance provisions that exclude coverage for experimental or investigational treatments. [FN81] Here the issue is addressed only briefly for background purposes. For many years, the courts applied an "arbitrary and capricious" standard of review to benefit denials by health insurance plans governed by ERISA. [FN82] Under the arbitrary and capricious standard, deference was given to the decision of the plan administrator. [FN83] In a 1989 ruling, Firestone Tire & Rubber Co. v. Bruch, [FN84] the Supreme Court changed the standard and held that "a denial of benefits . . . is to be reviewed under a de novo standard unless the benefit plan gives the administrator ***217** or fiduciary discretionary authority to determine eligibility for benefits or to construe the terms of the plan." [FN85] The arbitrary and capricious standard is, therefore, only utilized in cases where the plan explicitly grants the administrator discretion to make benefits determinations and interpret the plan provisions. If the court perceives that a conflict of interest exists, as in cases where the fiduciary who issues the plan and pays for its benefits also administers the policy and determines benefits eligibility, the court will afford less deference to the administrator. [FN86] Under the de novo standard of review, the court must determine the intent of the contracting parties. [FN87]

In assessing denials of coverage for "experimental or investigational" treatment under the de novo standard, the courts turn to traditional contract and insurance law principles. [FN88] One commentator describes these principles as follows:

(1) since an insurance policy is a contract, the court must ascertain the parties' intent as manifested in the language of the contract; (2) the conditions and exceptions of an insurance contract are to be construed strictly against the insurer and liberally in favor of the insured-patient; (3) all ambiguities are to be construed against the insurance

company and in favor of the insured-patient; (4) the burden is on the insurer to establish that the policy does not cover the asserted dispute; and (5) where the policy's language is not ambiguous, the court may not reinterpret the coverage. [FN89]

Other commentators state that patients have been successful in challenging insurers' coverage denials in the following circumstances:

(1) [T]he insurer ignored the language of the insurance plan, (2) the insurer's decision to deny benefits was uninformed or unreasonable, (3) the treatment was not experimental, (4) the plan modification on which the insurer based its denial of coverage was ineffective, or (5) the exclusionary language on ***218** which the insurer relied was ambiguous. [FN90]

There is little disagreement, however, about the fact that the courts' decisions regarding exclusionary provisions in health benefits plans have been unpredictable and inconsistent. [FN91] For example, the Fifth and Seventh Circuits have ruled that HDC-ABMT for breast cancer is experimental and need not be covered by the plans in question. [FN92] Conversely, the Eighth Circuit found that HDC-ABMT was not an experimental therapy for breast cancer and ordered the defendant to pay for the procedure. [FN93] Likewise, while one court found that HDC-ABMT for multiple myeloma constituted experimental treatment and was justifiably excluded from coverage by the insurer, [FN94] several other courts have found that the treatment was not experimental for multiple myeloma, when considering exclusionary provisions with similar language. [FN95]

***219** Careful consideration of the caselaw reveals that the courts are an inappropriate forum for the resolution of controversies relating to coverage exclusions for experimental treatment. First, one must consider the needs and circumstances of the patients who are denied reimbursement for last-chance treatments. As Representative Dennis Hastert stated while discussing a GOP bill intended to strengthen patient rights, "patients should get their treatment in hospital rooms, not courtrooms." [FN96] Critically ill patients who are in desperate need of life-saving therapy may not have the energy, resources or time for court battles. Even with adequate insurance coverage, serious illnesses can be extraordinarily expensive because of deductibles, copayments, and determinations that certain charges exceed the "reasonable and customary" cost of such treatment. The cost of care can skyrocket if the patient and family choose to turn to a distant facility with special expertise, such as a national cancer center, and must pay for travel and lodging expenses. Consequently, patients may not have financial resources to divert to lawyers and litigation.

In addition, litigation often consumes significant time, a luxury which critically ill patients do not have. The treatment of HDC-ABMT, for example, can be administered only during a short "window" of time, when the patient is at a particular stage of the disease, but not too ill to withstand the harsh treatment. [FN97] If the court fails to decide the case during this limited time, the patient may lose the opportunity to benefit from the treatment or may have to delay it for a significant period. Several plaintiffs have died from their illnesses before the courts issued final judgments in their cases. [FN98]

Finally, many critically ill patients may not have the initiative or the energy to pursue litigation. [FN99] Patients may forego the quest for treatment in order to avoid stressful and exhausting court battles during what may well be their last months of life.

The judiciary is a poor forum for several more technical reasons as well. Court decisions are based upon the specific language ***220** of the contract at issue and a determination of the intent of the parties. [FN100] Therefore, court rulings are of little precedential value and provide very limited guidance for patients and insurers attempting to determine the best course of action in their own circumstances. The inconsistency among judicial decisions interpreting similar exclusionary provisions further hinders the ability of parties to predict the outcomes of future controversies based on a reading of past precedent. [FN101]

In addition, judges often lack the expertise necessary to make determinations regarding which medical treatments are experimental and which are not. As discussed above, many insurance plans provide that in order to determine whether treatment is "experimental," the administrator must assess "reliable evidence" concerning the consensus of opinion regarding the medical procedure [FN102] or determine whether the therapy is "generally recognized by the medical profession as tested and accepted medical practice." [FN103] In order to decide responsibly whether a particular treatment meets the definition of "experimental" under such plans, courts must essentially conduct an independent study of the medical literature and an evaluation of expert testimony. [FN104] Judges, burdened with

over-crowded dockets, may not have sufficient time to invest in a thorough study of medical data and are likely to lack the scientific proficiency to fully understand contemporary research. [FN105] These limitations may explain some of the inconsistencies and discrepancies among court decisions involving similar facts and benefit plan provisions.

Finally, the intensely emotional nature of life and death decisions regarding last chance treatments may often obfuscate the issues for the judge and hinder the court's ability to make neutral decisions. [FN106] Surely, judges recognize that by affirming an insurer's denial of coverage for a particular treatment, they may expedite the death of the patient who has turned to the court as a last resort. [FN107] In one case involving a claimant seeking coverage ***221** for HDC-ABMT, a U.S. district judge described the difficulties faced by the judiciary in such cases:

Despite rumors to the contrary, those who wear judicial robes are human beings, and as persons, are inspired and motivated by compassion as anyone would be. Consequently, we often must remind ourselves that in our official capacities, we have authority only to issue rulings within the narrow parameters of the law and the facts before us. The temptation to go about, doing good where we see fit, and to make things less difficult for those who come before us, regardless of the law, is strong. But the law, without which judges are nothing, abjures such unlicensed formulation of unauthorized social policy by the judiciary. [FN108]

Judges, faced with these cases, may well opt to rule that a deep- pocket insurer must expend additional dollars to cover a potentially life- saving treatment rather than affirm a coverage denial and issue a potential death sentence to a patient. Clear federal legislation could significantly reduce the number of cases that come before the courts and thus relieve judges of the needto resolve this dilemma in each individual case.

III

State Statutes Regulating Coverage for "Experimental" Treatments

Several state legislatures have responded to the problem of coverage exclusions for experimental or investigational treatment by mandating that insurance providers either reimburse patients for the cost of certain treatments under particular circumstances or at least offer enrollees coverage options for specific therapies. The majority of these statutes address only coverage for HDC-ABMT, the most well publicized and controversial of the treatments that have been deemed experimental by insurance providers.

A. Statutes Requiring the Option of Coverage for Bone Marrow Treatments

Five states, including Missouri, [FN109] New Jersey, [FN110] Virginia, [FN111] ***222** Georgia, [FN112] and Tennessee, [FN113] have enacted statutes that require insurers to offer coverage for HDC-ABMT. "Mandate to offer" provisions allow subscribers to select whether they wish to be covered for the expensive treatment. Those who opt for coverage pay higher premiums than those who do not, and thus the cost of the treatment is not borne by the subscriber pool as a whole. [FN114]

The Missouri statute compels insurance providers to offer coverage for the treatment of breast cancer by HDC-ABMT that is performed pursuant to nationally accepted, peer-reviewed protocols. [FN115] The Missouri law forbids insurers to charge higher deductibles or copayments than those charged for other covered services but allows the imposition of a lifetime benefit maximum for HDC-ABMT of not less than $100,000. [FN116]

The New Jersey statute applies only to providers that have reserved the right to change premiums and requires them to offer benefits for HDC-ABMT performed for any cancer patient by institutions approved by the National Cancer Institute or pursuant to protocols that follow the guidelines of the American Society of Clinical Oncologists. [FN117] Insurers are not prohibited from ***223** adjusting premiums or requiring reasonable deductibles or copayments for HDC-ABMT. [FN118]

Under the Virginia statute, insurers are required to offer coverage for the treatment of breast cancer by HDC-ABMT that is performed pursuant to protocols approved by any United States medical teaching college and that have been used by physicians experienced with the procedure. [FN119] The Virginia law prohibits insurers ***224** from charging higher copayments than those imposed for any other services, but permits the application of deductibles that are different from those associated with other therapies. [FN120]

The Georgia statute pertains to both breast cancer and Hodgkin's disease patients. [FN121] It instructs insurers to make available ***225** coverage for bone marrow transplants for these illnesses. [FN122] The offer of coverage may not contain any exclusion, reduction, or other limitations as to coverages, deductibles, or coinsurance provisions unless these limitations apply generally to similar covered benefits. [FN123]

The Tennessee statute applies to HDC-ABMT for any cancer and allows insurers to offer coverage for the procedure at an additional cost. [FN124] Insurance providers, however, are not permitted to charge greater deductibles or copayments for HDC-ABMT than those associated with any other service under the plan. [FN125]

Although "mandates to offer" may provide enhanced choice to the consumer, such provisions may not significantly benefit many patients. Given a choice, healthy insurance purchasers are unlikely to elect to pay a higher cost for potential coverage of "a treatment that they probably have never heard of for a disease they think they will not get." [FN126]

B. Statutes Requiring the Provision of Coverage for Bone Marrow Treatments

States have been more forceful in other instances and have passed legislation mandating coverage for HDC-ABMT. These ***226** states are California, [FN127] Minnesota, [FN128] New Hampshire, [FN129] Kentucky, [FN130] Massachusetts, [FN131] New Jersey, [FN132] and Florida. [FN133] Their respective statutes, however, vary significantly.

California requires reimbursement for both donor and recipient surgery involved in bone marrow transplants for any cancer if certain conditions are met. [FN134] These conditions include recommendation of the treatment by the patient's physician, performance of the procedure in a hospital that is a participant in the Medi-Cal program, and approval of the transplant by the hospital's medical policy committee and by the insurer's medical consultant. [FN135] Plan administrators are explicitly prohibited from denying coverage based on a characterization of the bone marrow ***227** transplant as experimental or investigational. [FN136]

Minnesota's statute applies to HDC-ABMT for breast cancer alone, rather than for any cancer. The law mandates coverage of the treatment for all residents of Minnesota and prohibits insurance providers from charging greater coinsurance, copayments, or deductibles for HDC-ABMT for breast cancer than those charged for any other treatment covered by the plan. [FN137] New Hampshire also addresses only HDC-ABMT for breast cancer patients and provides full coverage for residents of the state who receive the treatment according to protocols approved by the National Cancer Institute. [FN138]

The Kentucky statute instructs that HDC-ABMT or high dose chemotherapy with stem cell transplantation [FN139] for breast cancer may not be considered experimental or investigational and must ***228** be covered by any plan that provides coverage for the treatment of breast cancer by standard chemotherapy. [FN140] The therapy must be performed in an institution that complies with the guidelines of one of the organizations specified in the statute, and coverage for transplantation may not be subject to greater coinsurance or copayment than that applicable to any other treatment covered by the plan. [FN141]

The Massachusetts statute is more restrictive than most other state statutes. [FN142] It requires coverage only for bone marrow ***229** transplants utilized to treat breast cancer that has progressed to metastatic disease. [FN143] The patient must meet criteria established by the Massachusetts Department of Public Health that are consistent with medical research protocols approved by the National Cancer Institute. [FN144]

As discussed above, New Jersey enacted a statute that requires insurers to offer coverage for the treatment of cancer by HDC-ABMT in particular circumstances. [FN145] With respect to one type of cancer, however, New Jersey law mandates coverage. [FN146] The statute requires that insurers provide medical expense benefits for the treatment of Wilm's tumor [FN147] by any means, including HDC-ABMT, when standard chemotherapy has failed. [FN148]

Florida offers a more sophisticated approach. Its law mandates that insurers cannot deny coverage for bone marrow transplants that are recommended by a treating physician if the procedure is accepted within the relevant oncological specialty and not experimental. [FN149] The determination of which bone marrow ***231** transplant procedures are not experimental is to be made by the Florida Agency of Health Care Administration, based upon the recommendations of an advisory panel consisting of oncologists, consumer representatives, and insurance representatives. [FN150] The law further delineates a series of factors that are to be considered by the advisory panel

and the director of the Agency in making their determinations. [FN151] Finally, the panel must conduct a review of scientific evidence, minimally on a biennial basis, to ensure that its recommendations are consistent with the latest available data. [FN152]

The Florida statute thus provides for a thorough, professional, and responsible decision-making process regarding which bone marrow transplants are to be considered experimental. Nevertheless, the statute is narrow in scope and does not cover any treatment other than bone marrow transplants. Moreover, it requires a lengthy and exhaustive assessment of data to determine that the procedure is not experimental within the meaning of the law. It took Florida's Advisory Panel eighteen months after the enactment of the statute to recommend mandatory coverage of bone marrow transplants for Stage IV breast cancer that are conducted as part of a clinical trial. [FN153] This time lag may be costly or even constitute what is in essence a death sentence for patients awaiting decisions regarding last-chance treatments.

C. Statutes Offering A Broader Solution to the Problem of Health Insurance Benefits for Experimental Treatments

Rhode Island [FN154] and California [FN155] have enacted statutes that ***232** do not address any particular treatment but offer a more far-reaching solution to the problem of coverage for experimental treatments. The Rhode Island and California statutes merit careful analysis.

1. The Rhode Island Statute

Rhode Island compels insurers to reimburse patients for the cost of cancer therapies that are still under investigation when particular criteria are met. [FN156] These criteria include: (1) the patient's participation in a Phase III or IV clinical trial which has been approved by one of the entities specified in the statute and a qualified institutional review board; (2) administration of the ***233** therapy by qualified, experienced personnel in an appropriate facility; (3) the patient's meeting all protocol requirements; and (4) the absence of any clearly superior, nonexperimental alternative. [FN157]

a. Clinical Trials

Clinical trials for drugs and devices are regulated by the Food and Drug Administration (FDA). [FN158] Clinical trials for other therapies such as surgery or bone marrow transplants, however, are not regulated by the FDA and are conducted independently by entities such as medical research centers. [FN159] Drugs studied in clinical trials are called investigational new drugs (IND). [FN160] Sponsors wishing to conduct a clinical trial to test a new drug must submit IND Applications to the FDA. [FN161] In some circumstances, a drug still under investigation may be used to treat patients not participating in a clinical trial. [FN162] Specifically, an IND may be used in treatment of patients if the drug is intended to treat a serious or immediately life-threatening disease and there is no comparable or satisfactory alternative drug or therapy. [FN163] The drug can be used in treatment if it is currently under investigation in a clinical trial, or if clinical trials have been completed, and the sponsor is actively pursuing marketing approval with due diligence. [FN164]

Medical research for drugs and other treatments usually is conducted in three phases of clinical trials. [FN165] In Phase I drug trials, the new drug is given to patients or healthy individuals to determine its toxicity, most effective method of administration, and safe dosage range. [FN166] Participants in the trial receive increasing ***234** dosages of the substance until a dosage is reached where toxicities are determined to be unacceptable. [FN167] Phase I clinical trials generally involve only twenty to eighty subjects, last about a year, and have a very high failure rate. [FN168] Seventy percent of drugs submitted for Phase I clinical trials fail to progress to Phase II. [FN169]

Phase II trials are designed to determine the effectiveness of the therapy. [FN170] The treatment is administered to patients afflicted by the disease for which the therapy is intended, and the trial often involves 100 to 300 people and lasts about two years. [FN171] Approximately thirty-three percent of drugs submitted for clinical trials fail in Phase II testing. [FN172]

Phase III clinical trials are conducted only after the treatment has proven effective through Phase I and II trials. [FN173] The third phase attempts to assess the medical result of the experimental therapy in comparison with standard therapy or no therapy at all. [FN174] Phase III studies usually involve 1000 to 3000 patients and last about three years. [FN175]

The FDA may also require postmarketing or Phase IV clinical trials. [FN176] These studies are designed to determine the existence of less common adverse reactions, the effect of the drug on morbidity or mortality, or the effect of the drug on a particular patient population, such as children. [FN177]

Research that is funded in whole or in part by the Department of Health and Human Services or that is regulated by the FDA or another federal agency must be reviewed by an Institutional Review Board (IRB). [FN178] The IRB receives a research proposal regarding each clinical trial. The proposal describes eligibility requirements for participants, the number of subjects to be tested, ***235** and the objective of the research. [FN179] Each participant must provide "informed consent" to participate in the trial. [FN180]

The Office for Protection from Research Risks (OPRR), the ethics-oversight branch of the Department of Health and Human Services (DHHS), has project- assurance contracts with 420 institutions in North America, including 127 U.S. medical schools. [FN181] On average, medical schools review 350 to 540 new research protocols each year, which call for the recruitment of between 10,000 and 20,000 subjects for biomedical research. [FN182] The FDA is responsible for the oversight of approximately 1200 IRBs, many of which are simultaneously regulated by NIH through multiple project-assurance agreements. [FN183] These include hospitals, nonprofit committees, and for-profit IRBs that contract with various researchers who often work for pharmaceutical, medical device, and biotech companies. [FN184]

The Rhode Island statute allows patients to benefit from procedures that are still in investigation only if the patient participates in an IRB-approved clinical trial. The statute also clearly defines which "experimental" therapies must be covered by insurers. Consequently, insurers are not asked or encouraged to pay for any and all unsubstantiated treatments. As will be discussed below, this Article proposes federal legislation that adopts, in part, the Rhode Island statutory standards. While the Rhode Island legislation pertains only to cancer therapies, the proposed federal legislation would apply to treatments for any terminal disease likely to cause death within two years. [FN185] In addition, the federal legislation would apply only to Phase III studies. [FN186] Phase IV trials are not addressed specifically in the proposed federal statute because such studies constitute research on drugs approved by the FDA. [FN187] The cost of these approved drugs should be covered by insurance in accordance with plan policies, or if the drug use in question is off-label, reimbursement ***236** would be handled pursuant to the off-label drug use provision discussed in Part V.A.2 below.

2. The California Statute

In addition to a statute that mandates reimbursement for the treatment of cancer by bone marrow transplants, [FN188] California has enacted legislation that more broadly regulates denials of coverage for experimental treatments by insurers. The statute, known as the Friedman-Knowles Experimental Treatment Act, was passed in 1996. [FN189] The California law mandates that after July 1, 1998, [FN190] health benefits plans provide an independent, expert review of any decision to deny coverage for experimental or investigational treatments for patients with terminal conditions that are likely to cause death within two years and for which there is no effective therapy. [FN191]

***237** The insurer and not the patient pays for the cost of the independent review. [FN192] The experts on the panel must generally provide their recommendations within thirty days of receiving the patient's request for review and within seven days if the treatment must be administered immediately in order to be effective. [FN193] The panel's decision is determined by majority vote. [FN194] ***238** Reimbursement for the therapy is mandated if the majority of the experts recommend a provision of the treatment or if their recommendations are evenly split, but not if only a minority of the experts conclude that the treatment should be covered by the plan. [FN195]

The Friedman-Knowles Experimental Treatment Act provides a mechanism for decision-making without determining what the decisions should be. [FN196] Subscribers are given the opportunity to turn to an external panel of specialists for an independent opinion if they are dissatisfied with the insurer's decision-making process. [FN197]

Opponents might argue that the option of appeal will significantly increase healthcare costs and disrupt the provider's ability to manage care. [FN198] These concerns may be quelled, however, by the experience of Northern California Kaiser Permanente, which utilized an independent review process before the legislation was enacted in California. [FN199] From 1994 to 1996 only six of the 2.5 million Northern California Kaiser members sought external review. [FN200] Scholars studying Kaiser's results have concluded that "[w] hen the patients' concerns about insurer trustworthiness and potential conflict of interest were addressed in advance by the option of going

outside of Kaiser for independent consultation, patients and families were much readier to enter into a reflective dialogue with their Kaiser physicians about what treatment approach really made sense to them." [FN201] Kaiser's appeal option ***239** thus neither proved expensive nor disruptive to its ability to manage care.

Texas had a similar experience when it experimented with an independent review procedure. In 1997, Texas implemented legislation that allowed subscribers to utilize an independent appeals process for review of HMO decisions. [FN202] While the Texas Insurance Department predicted as many as 4400 appeals during the first year, only 218 had been filed just over a year after the law's effective date. [FN203] This figure should provide further assurances to those concerned about the cost of autonomous appeals procedures. It should be noted, however, that the independent review provision of the Texas statute was deemed preempted by ERISA and struck down by a federal district court on September 23, 1998. [FN204] Subsequently, Aetna Life & Casualty Co. has attempted to devise a review mechanism that would be immune to ERISA preemption and was reported to be working with the state attorney general's office to delay implementation of the court's order. [FN205] Here the insurance company itself sought to salvage the independent review procedure.

The proposed federal legislation suggested here would require insurers to offer an external, independent review of any decision to deny coverage to a terminally ill patient for investigational treatments administered in a Phase III clinical trial. Thus, for example, if the plan determined that a patient did not meet protocol requirements or that a clearly superior nonexperimental alternative was available to the subscriber, the negative coverage decision could, at the patient's option, be reviewed by the independent panel of experts. This review would, in most instances, prevent both the insurer and terminally ill patients from having to endure costly, lengthy, and emotionally draining court battles.

D. The Weaknesses of State Legislation

The federal legislation proposed in this Article would not overturn or preempt state laws that mandate reimbursement for particular ***240** treatments or require insurers to offer certain coverage for an additional cost as long as no conflict exists between the state and federal laws. Rather, the federal law would create a national, minimal standard that all insurers would have to meet, namely, coverage of off-label drug uses and treatment provided in Phase III clinical trials in appropriate circumstances. Nothing would prevent the states from requiring additional coverage from insurers, and nothing would hinder health plans from volunteering to establish more liberal coverage provisions. Federal legislation is necessary, however, because of a number of significant weaknesses inherent in the state statutes discussed above.

1. State Mandates Benefit A Limited Patient Population

State legislation that focuses on a particular treatment for a specific disease affects only a small number of patients who need the therapy at issue and live in the state that enacted the law. [FN206] In addition, and as mentioned above, legislation addressing particular treatments may be the product of lobbying efforts by interest groups [FN207] or of high profile cases that have come to the attention of the legislature. [FN208] The Assembly Insurance Committee Statement regarding the New Jersey law mandating reimbursement for the treatment of Wilm's tumor by HDC-ABMT illustrates this point. It states in relevant part:

This bill has been referred to as the "Tishna Rollo Bill." Tishna Rollo is an eight-year-old Glen Ridge girl who is battling Wilm's tumor, a rare form of cancer which generally affects the kidneys before spreading to other parts of the body. Recently, Tishna's case has received much attention because her doctors have concluded that the transplants are the one chance they have to cure her disease, yet her family's health insurer initially refused to provide coverage for the treatment because it asserted that such treatment was not covered in her health insurance contract as it is considered "experimental" or "investigational." Court action on the issue is pending. This bill will eliminate the controversy surrounding the treatment and, in effect, absolve health insurers, and ultimately the courts, of the responsibility of making any determination regarding this issue. [FN209]

Not every patient, however, will have access to the media or ***241** capture the legislature's attention. If states continue to address treatments on a piecemeal, case-by-case basis, many opportunities to save lives will be lost. Legislative debates are lengthy and legislative enactments are limited in number. Consequently, it is necessary to address the problem of coverage for experimental treatments more broadly. Federal legislation requiring reimbursement for any treatment administered to appropriate terminally ill patients in Phase III clinical trials will provide life-saving opportunities for patients regardless of their geographic location, their illness, or the therapy at

issue.

2. Limitations Under ERISA

ERISA [FN210] applies to most employer provided health insurance policies. [FN211] State mandates regarding treatment coverage may be of no help to patients utilizing self-funded employee benefit plans because ERISA preempts state legislation as it pertains to self-funded plans. [FN212]

ERISA's preemption clause states that "[e]xcept as provided in subsection (b) of this section, the provisions of this subchapter ***242** and subchapter III of this chapter shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan described in section 1003(a) of this title and not exempt under section 1003(b) of this title." [FN213] Therefore, actions brought against insurers based upon contract, tort, and other theories have been deemed preempted by ERISA. [FN214]

The statute includes a significant exception to the above-quoted provision. ERISA's savings clause provides that the Act does not preempt state laws that regulate insurance, banking, or securities. [FN215] In light of this savings clause, the Supreme Court held that a Massachusetts law mandating that group insurance companies provide specified minimum health care benefits was not preempted by ERISA. [FN216]

The exception, however, is not global. ERISA's "deemer clause" [FN217] establishes that state laws regulating insurance, banking, and securities, are not exempted from ERISA's preemption clause with respect to self-funded health insurance plans. [FN218] State laws regulating health insurance, therefore, could not be enforced with respect to self-funded plans pursuant to ERISA's preemption clause. Accordingly, the Supreme Court has determined, for example, that ERISA preempted application of the Pennsylvania Motor Vehicle Financial Responsibility Law to self-***243** funded health benefits plans. [FN219] Similarly, it is likely that the courts would find that a state statute mandating coverage for a particular treatment is preempted by ERISA with respect to self-funded health insurance policies.

3. Limitations Under The Americans With Disabilities Act

Health insurance provisions that provide coverage for bone marrow transplants or other "experimental" treatments in some instances and not others are vulnerable to attack under the Americans With Disabilities Act (ADA). [FN220] If an insurer provides reimbursement for HDC-ABMT for Wilm's tumor or breast cancer but not other cancers, the coverage disparity may be deemed discriminatory under the ADA, even if it is supported by state law. Because federal law preempts state law, [FN221] the existence of a state statutory mandate may not shield the employer from ADA liability. In order to avoid including unlawful disability-based distinctions in their health insurance plans, employers may therefore be forced to eliminate coverage of the treatment at issue pursuant to federal law and consequently undo the limited good that state law attempted to achieve.

The ADA prohibits employers from discriminating against qualified individuals with disabilities with respect to job application procedures, hiring, promotion, termination of employees, compensation, job training, and other terms, conditions, and privileges of employment. [FN222] The phrase "other terms, conditions and privileges of employment" includes all fringe benefits, such as health insurance, that are available by virtue of employment, whether or not such benefits are administered by the employer. [FN223] Consequently, liability may be imposed under the ADA upon an employer that offers its employees an insurance plan that is found to be discriminatory, and therefore, employer-provided health insurance policies must comply with the ADA's requirements.

***244** The anti-discrimination mandates of the ADA do not prohibit insurers from limiting insurance coverage based on risk classification and underwriting principles. [FN224] The regulations promulgated under the ADA state that the law is not designed to disrupt the practices of underwriting, classifying, and administering risks, which are integral to the insurance industry:

(1) An insurer . . . may underwrite risks, classify risks, or administer such risks that are based on or not inconsistent with State law.

(2) A covered entity may establish, sponsor, observe or administer the terms of a bona fide benefit plan that are based on underwriting risks, classifying risks, or administering such risks that are based on or not inconsistent with State law. [FN225]

The legislative history of the ADA also suggests that Congress intended to allow insurance providers to continue limiting coverage in particular situations based upon legitimate risk assessment calculations:

While a plan which limits certain kinds of coverage based on classification of risk would be allowed under this section, the plan may not refuse to insure, or refuse to continue to insure, or limit the amount, extent, or kind of coverage available to an individual, or charge a different rate for the same coverage solely because of a physical or mental impairment, except where the refusal, limitation, or rate differential is based on sound actuarial principles or is related to actual or reasonably anticipated experience. [FN226]

However, the vague regulations and legislative history provide no guidance as to how insurers may assess and classify risks so that an insurance plan with coverage limitations remains consistent with the ADA's non-discrimination mandate. In an effort to resolve some of the questions relating to insurance coverage under the ADA, the Equal Employment Opportunity Commission (EEOC) issued its "EEOC Interim Guidance on Application of ADA to Health Insurance" (the Guidelines) on June 8, 1993. [FN227]

The Guidelines identify four fundamental requirements imposed by the ADA upon employers that offer their employees health insurance benefits:

***245** (1) Disability-based insurance distinctions are acceptable under the ADA only if the employer-provided insurance plan is bona fide and if the distinctions are not used as a subterfuge for purpose of evading the Act;

(2) Employment decisions regarding an individual with a disability cannot be motivated by concerns about the individual's impact on the employer's health plan;

(3) Employees with disabilities must enjoy equal access to whatever health insurance is provided to non-disabled employees; and

(4) The employer cannot make an employment decision regarding an individual if the decision is motivated by concern about how the disability of someone with whom the candidate has a relationship will impact its health plan. [FN228]

A term or provision is "disability-based" if it isolates a particular disability, a discrete group of disabilities, or disabilities in general (e.g., exclusion from coverage of all conditions that substantially limit a major life activity), or if it affects treatment of disabilities. [FN229] Thus, an insurance plan that contains a coverage exclusion for the treatment of certain cancers by HDC-ABMT but allows the treatment of other cancers via that therapy may contain an unlawful disability-based distinction. [FN230]

If a term or provision of a health insurance plan is found to be disability-based, the employer bears the burden of proving that the provision does not violate the ADA. [FN231] To do so the employer must establish the following: (1) the challenged health insurance plan is a bona fide insurance plan that is not inconsistent with applicable state law or is a bona fide self- insured plan under ERISA; and (2) the disability-based distinction is not being used as a subterfuge to evade the purposes of the ADA. [FN232]

An employer can prove that a disability-based distinction is not a subterfuge in a variety of ways. First, the employer may ***246** establish that the coverage limitation is actuarially or economically justified. [FN233] That is, the EEOC interprets the ADA to require that services posing similar risks of financial loss to a plan, whether as an actuarial or economic matter, be covered in a like manner. Consequently, a plan that offers coverage for HDC-ABMT to treat some cancers but not others may be perceived as implementing a subterfuge to evade the purposes of the ADA if the bone marrow transplant costs the same in all instances.

In addition, the Guidelines provide that the employer may prove that a disability-based distinction does not constitute subterfuge by establishing that the coverage exclusion was necessary to prevent the financial insolvency of the plan [FN234] or that the distinction was needed to "prevent the occurrence of an unacceptable change either in the coverage of the health insurance plan, or in the premiums charged for the health insurance plan." [FN235] An "unacceptable change" is a drastic increase in premium or other payments or an extreme change in the scope or level of coverage that would render the plan effectively unavailable to a ***247** significant number of employees. [FN236] An "unacceptable change" also may be one that causes the plan to be so unattractive that only poor-risk/high-use

enrollees select the plan, while good-risk/low-use enrollees select other options so that the plan ultimately becomes financially unsound or not viable. [FN237] Finally, an "unacceptable change" is one that causes the plan to become so unattractive that the employer finds itself unable to compete with other employers who offer superior health programs because it cannot maintain or recruit qualified workers. [FN238]

The Guidelines also specify that the employer may prove that the treatment for which reimbursement was denied by the plan is of no medical benefit for patients. [FN239] The Guidelines do not, however, provide an explicit defense for employers based on the status of the excluded treatment as experimental or investigational.

Employees have in fact sued their employers [FN240] alleging ADA violations with respect to coverage denials by health insurance providers. In Henderson v. Bodine Aluminum, Inc., [FN241] a breast cancer patient, insured under an ERISA health plan, sought a preliminary injunction compelling the plan to provide coverage for HDC-ABMT on the theory that the plan's denial of coverage constituted discrimination under the ADA. [FN242] The Eighth Circuit reversed the lower court's denial of injunctive relief and remanded ***248** the case. [FN243] Citing the EEOC's guidelines, the court based its decision on the fact that the plaintiff's plan covered HDC-ABMT for other types of cancer and concluded that the therapy is "accepted treatment for breast cancer" [FN244] and a "significant improvement over standard chemotherapy." [FN245] The court thus rejected the defendant's claim that the procedure was experimental for breast cancer.

It is likely that in the future many more cases based on an ADA theory will reach the courts. Patients who realize that a promising treatment is covered by their plan for some forms of cancer, for example, but not for the cancer with which they are afflicted, will turn to the courts for redress of the apparent discrimination. As noted above, the fact that the insurer's decision to pay for a treatment for one kind of cancer but not another was in compliance with state law may not serve as an effective defense because under the principle of preemption, state law must give way to federal legislation where a conflict exists between the two. [FN246] Ironically, in order to avoid a violation of the ADA, employers may be forced to treat all experimental therapies in a consistent fashion and exclude coverage of all such treatments, including those that are the subject of state legislation. Thus, in many instances the state coverage mandates may be deemed to be in conflict with and preempted by the ADA.

In contrast, federal legislation mandating coverage for all experimental treatment provided to appropriate patients in Phase III clinical trials would be fully consistent with the ADA. Under a federal law, patients would not be subjected to disability-based discrimination because terminally ill patients could receive reimbursement regardless of their illness and the therapy at issue so long as the statute's coverage criteria were met.

IV

The Case for Federal Regulation

A. The Traditional Role of the States

In 1945, in the McCarran-Ferguson Act, [FN247] Congress delegated ***249** to the states regulatory responsibility for insurance markets. [FN248] The Act exempted health insurance markets from federal antitrust prosecution so long as the states regulated those markets. [FN249]

Most states enacted regulations designed to ensure that insurers remained solvent. [FN250] Neither the states nor the federal government paid significant attention to issues of health policy or effective competition until the 1970s. [FN251] This may be explained, in part, by the fact that prior to the mid-1970s the insurance industry was eager to expand health care services and cooperated with policy makers in promoting this goal. [FN252] After the mid-1970s, however, the industry's emphasis shifted to controlling health care costs. [FN253] In this environment, the federal government has become increasingly active in regulating the healthcare industry.

B. The Advent of Federal Legislation

1. The HMO Act

The HMO Act [FN254] was the first major federal legislation in the arena of health insurance regulation. [FN255] The HMO Act promoted competition and encouraged the development of qualifying HMOs by overriding state statutory and common-law ***250** prohibitions regarding the operation of prepaid group practices and the corporate

practice of medicine. [FN256] The HMO Act also mandated that employers with more than twenty-five employees that offer at least one health insurance plan also offer employees the option of membership in a qualified HMO. [FN257] In addition, the law originally offered start- up loans and loan guarantees to new HMOs that met particular requirements. [FN258] The HMO Act sought to assure that qualifying HMOs will be able to compete for the business of private employers. [FN259]

2. ERISA

The Employee Retirement Income Security Act of 1974 (ERISA) [FN260] enables employers, unions, and some groups of employers acting in concert to be exempt from state laws regulating health insurance if their plans are self funded. [FN261] Employers that choose to engage in the business of health insurance for their employees and meet certain federal reporting and solvency requirements are exempt from all state laws regulating the insurance industry. [FN262] ERISA, consequently, dramatically diminished the ability of the states to regulate a significant portion of healthcare providers.

3. Medigap Reform

This legislation targets insurance plans that supplement Medicare coverage. [FN263] Medicare provides no prescription drug coverage and no out-of- pocket maximum. [FN264] As a result, a thriving market developed for policies that would supplement Medicare by offering benefits for uncovered services and beneficiary copayment obligations. [FN265] Seniors, eager to obtain maximum health coverage for their multiplying ailments, often bought several duplicative and low-value policies. [FN266]

Congress determined that the Medigap market was not effectively ***251** regulated by the states and acted to rectify its weaknesses at the federal level. [FN267] In 1990, Congress responded to the confusion created by the numerous policies offered in the "Medigap market" by limiting the variety of Medigap plans that could be offered to ten standardized policies, plans A-J. [FN268]

4. Health Insurance Portability and Accountability Act

To address other problems in the insurance market, Congress enacted in 1996 the Health Insurance Portability and Accountability Act (HIPAA), [FN269] designed to increase the number of individuals who have and maintain health insurance coverage. [FN270] HIPAA requires that all group health plans, including ERISA plans, limit to no more than twelve months their period of excluded coverage for preexisting conditions, that is, conditions for which medical advice, diagnosis, care, or treatment was recommended or received in the prior six months. [FN271] In addition, group insurers must generally credit enrollees for any time during which they were previously excluded from coverage because of a preexisting condition exclusion that was applied to them while they were covered by a different insurer. [FN272] HIPAA's portability provisions guarantee that individuals covered by group insurance at one employer for eighteen continuous months will be granted access to any group policy offered by a new employer. [FN273] This portability requirement is designed to alleviate the concerns of employees who were reluctant to leave current jobs for fear that they will be denied health insurance by future employers because of preexisting conditions. [FN274]

HIPAA furthermore requires insurers operating in the small-group market [FN275] to guarantee issue of all the products they offer in the small- group market to all small groups and to all eligible members of those groups, regardless of their health status. [FN276] ***252** The statute also requires all group carriers, in both large and small group markets, to guarantee renewal of their products. [FN277]

Finally, HIPAA guaranteed the portability of group insurance to individual insurance for certain individuals. Individuals are eligible under the following conditions: 1) they have had eighteen months of continuous prior coverage with no coverage gap lasting longer than sixty-two days and have most recently had group coverage; 2) they have exhausted any COBRA benefits available to them and have no current access to group insurance or a public program; and 3) they are eligible for some type of guaranteed issue coverage in the individual market. [FN278] The states retain the ability to define the type of coverage available and to expand the definition of "eligible individuals." [FN279] HIPAA also requires that all individual policy coverage be guaranteed renewable. [FN280]

One of the most well publicized provisions of the legislation is an amendment that relates to minimal hospital

stays following childbirth. [FN281] The provision prohibits insurers from restricting hospital stays for new mothers to less than forty-eight hours following natural childbirth and less than ninety-six hours following a cesarean section. [FN282]

5. Coverage Mandates Related to Mastectomies

In 1998, Congress enacted the "Women's Health and Cancer Rights Act of 1998," amending ERISA. [FN283] The Act requires all group health plans and health insurance issuers offering coverage for mastectomies to provide reimbursement for reconstructive surgery that is associated with a mastectomy. [FN284]

In addition, several congressional bills have addressed the phenomenon ***253** of "drive-by mastectomies" in which patients are denied coverage for a hospital stay of a full day or longer following a mastectomy. [FN285] The proposals typically require that group health plans provide coverage for an inpatient stay of a length of time that is determined to be medically appropriate by the attending physician in consultation with the patient undergoing the mastectomy. [FN286] Although none of these proposals has yet become law, insurance coverage for hospitalization following a mastectomy is likely to be regulated by federal legislation in the near future.

C. Federal Legislation as a Trend

During the past several decades the federal government has significantly eroded the power of the states to act as the exclusive regulators of the health insurance market. The federal government has identified particular problems that it perceived as requiring uniform, national solutions, and has enacted legislation that addressed the relevant policy issues.

Federal regulation has been praised by some and severely criticized by others. HIPAA, for example, was hailed as the "first national health policy with such far-reaching implications since the enactment of Medicare and Medicaid in 1965." [FN287] It has also been denounced with the following words: "Liberals in Congress ***254** and elsewhere, who have a clear vision of their goal of a government-run and government-managed health care system, would seize on any regulatory problem created by this legislation as an excuse to extend federal regulation." [FN288]

Such mixed feelings will surely be expressed about future federal legislation as well. A federal mandate regarding coverage for experimental and investigational treatment, however, would not constitute a radical departure from prior legislative precedent.

1. The Clinton Health Plan

The Health Security Act (HSA), [FN289] the health care legislation proposed by President Clinton in 1993, addressed the problem of exclusions for investigational and experimental treatment. The HSA provided that a health plan may cover investigational treatments if it chose to do so. [FN290] Insurers would have been authorized ***255** to cover only "qualifying investigational treatments that are administered for a life-threatening disease," and the legislation carefully defined the term "qualifying investigational treatment."[FN291] In addition, the HSA mandated that health plans must pay for items or services provided to a patient in the course of a qualifying investigational treatment that would have been provided if the individual were receiving standard care rather than undergoing an experimental therapy. [FN292]

Clinton's ambitious reform initiative never became law, but it was significant nevertheless because it identified the problem of coverage for investigational treatments. This Article proposes a stronger mandate regarding investigational treatment coverage than did the HSA. Under the proposal, insurers would not be given discretion as to whether to cover the costs of experimental treatments so long as they were provided to appropriate patients in Phase III clinical trials conducted by qualified institutions. The federal legislation proposed here is not nearly as global as the HSA. Rather, the suggested federal statute is narrowly tailored to resolve the single issue of coverage for experimental treatments, much as HIPAA addressed a limited number of specific problems. It is hoped that such legislation would meet far greater success when considered by Congress than did the HSA.

2. Pending Legislation

Several healthcare reform bills were recently introduced in Congress. [FN293] Among them is the Norwood-Dingell Bill, entitled the "Bipartisan Consensus Managed Care Improvement Act of 1999," [FN294] that includes a provision that mandates coverage of clinical trials under some circumstances. [FN295] This bill is more

expansive ***257** than the legislation proposed in this article. The Norwood-Dingell Bill does not limit coverage to Phase III clinical trials, but rather, applies to all clinical trials. [FN296] Moreover, it mandates reimbursement for any individual who has a "life-threatening or serious illness for which no standard treatment is effective." [FN297] The term "serious illness" is not defined. In addition, the Norwood-Dingell Bill only requires that "[t]he individual's participation in the trial offer[ ] meaningful potential for significant clinical benefit for the individual." [FN298] The terms "meaningful potential" and "significant clinical benefit" are similarly vague and ambiguous.

Like the HSA, the Norwood-Dingell Bill is lengthy and far-reaching. Its purpose is to amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 "to protect consumers in managed care plans and other health coverage." [FN299] The issues it addresses include access to care, quality assurance, patient information, grievance and appeals procedures, protecting the doctor-patient relationship, and promoting good medical practice. [FN300] The Norwood- Dingell Bill is unlikely to pass in its present form. Another bill, concurrently being considered in Congress mandates coverage only for individuals participating in ***258** clinical trials for cancer treatment. [FN301] Consequently, even if some healthcare reform statute is enacted in the coming year, it is unlikely to provide a satisfactory solution to the problem of health insurance coverage for experimental treatments.

V

The Proposed Federal Legislation

A. Suggested Language for the Statute

The following is suggested legislative language for a federal statute addressing coverage of experimental or investigational treatments. The proposed legislation may be formulated as an amendment to HIPAA, which addresses other coverage exclusions. [FN302] Therefore, HIPAA's definitions and enforcement provisions would be applicable to the new legislation.

SECTION 1. COVERAGE FOR PHASE III CLINICAL TRIALS [FN303]

(a) A group health plan, a health insurance issuer offering group health insurance coverage in connection with a group health plan, and a health insurance issuer that provides individual health insurance coverage to an individual may not deny coverage for a treatment on the ground that it is experimental if the following circumstances are present:

(1) The beneficiary has a terminal condition that, according to the beneficiary's physician's current diagnosis, has a high probability of causing death within two years from the date the request for coverage of an experimental treatment was made;

(2) Treatment is being provided to the beneficiary pursuant to a Phase III clinical trial that has been approved by an institutional review board;

(3) The facility and personnel providing the treatment are qualified to do so by virtue of their experience, training, and volume of patients treated by them;

(4) The beneficiary receiving the investigational treatment meets all protocol requirements;

(5) There is no clearly superior, noninvestigational alternative to the protocol treatment; and

(6) The available clinical or preclinical data provides a reasonable expectation that the protocol treatment will be at least as efficacious as the noninvestigational alternative.

***259** (b) Phase III clinical trials are defined in 21 C.F.R. § 312.21(c). However, for purpose of this Title, Phase III clinical trials shall mean not only studies testing a new drug or device regulated by the FDA, but also those testing other treatments, so long as they are subject to the regulations found at 45 C.F.R. § 46.101 et seq.

(c) Coverage for the services required under this section shall be provided subject to the terms and conditions generally applicable to other benefits under the plan contract.

(d) The informed consent documentation given to the patient shall clearly state that the treatment is experimental and may reduce the patient's life expectancy or quality of life rather than improve the individual's condition. In addition, the informed consent must meet all of the requirements outlined in 45 C.F.R. § 46.116.

SECTION 2: OFF-LABEL DRUG USE [FN304]

(a) No health insurer issuing a policy that provides coverage for prescription drugs shall exclude reimbursement for any such drug on the grounds that the drug has not been approved by the Food and Drug Administration for that indication (that is, its use constitutes "off-label drug use") if the use of the drug for the indication at issue is recognized in one of the standard reference compendia or in the medical literature, as defined in subsection (c) below.

(b) Standard reference compendia shall mean: (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 shall mean published scientific studies of off-label use of drugs appearing in any peer-reviewed national professional journal.

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

(e) If an insurer denies coverage for off-label drug use to a beneficiary with a terminal illness that, according to the beneficiary's physician's current diagnosis, has a high probability of causing death within two years from the date of the request for coverage, on the ground that the off-label drug use was experimental and thus excluded from coverage under the plan, and the off-label drug use was intended by the beneficiary's physician to treat the terminal illness, the patient may seek review of the insurer's decision through the independent review process established in Section 3. If a majority or exactly a half of the expert panel recommends providing the requested drug therapy, reimbursement for the treatment may not be denied ***260** to the beneficiary by the plan on the ground that it is experimental.

SECTION 3: INDEPENDENT REVIEW PROCESS [FN305]

(a) Each group health plan, health insurance issuer offering group health insurance coverage in connection with a group health plan, and health insurance issuer that provides individual health insurance coverage to an individual shall provide an external, independent review process to assess the plan's coverage decisions regarding experimental or investigational therapies for enrollees who meet all of the following criteria:

(1) The enrollee has a terminal condition that, according to the enrollee's physician's current diagnosis, has a high probability of causing death within two years from the date of the request for coverage;

(2) The enrollee's physician certifies that the enrollee has a condition, as defined in paragraph (1), for which standard therapies have not been effective in improving the condition of the enrollee, or for which standard therapies would not be medically appropriate for the enrollee, or for which there is no more beneficial standard therapy covered by the plan than the therapy proposed pursuant to paragraph (3);

(3) The enrollee's physician has recommended that the enrollee receive treatment in a specific Phase III clinical trial and believes that all of the conditions delineated in Section 1 above have been met. The physician must certify in writing that all the criteria described in Section 1 have been met and explain why this is so.

(4) The enrollee has been denied coverage by the plan for therapy provided in a Phase III clinical trial requested pursuant to paragraph (3); and

(5) The therapy at issue would be a covered service, except for the plan's determination that the therapy is experimental or investigational.

(b) The enrollee shall not be required to pay for the external, independent review. The cost of the review shall be

borne by the plan.

(c) The plan's external, independent review shall meet the following criteria:

(1) The plan shall offer all enrollees who meet the criteria in subsection (a) the opportunity to have the requested therapy reviewed under the external, independent review process. The plan shall notify eligible enrollees in writing of the opportunity to request the external independent review within five days of the decision to deny coverage. Enrollees with a terminal illness as defined in paragraph (a)(1) above may also request review of any decision by the plan to deny coverage for off-label drug use to treat a terminal illness.

***261** (2) The plan shall contract with one or more impartial, independent entities that are accredited pursuant to subsection (d). The entity shall arrange for review of the coverage decision by selecting an independent panel of at least three physicians or other providers who are experts in the treatment of the enrollee's medical condition and knowledgeable about the recommended therapy. If the entity is an academic medical center accredited in accordance with subsection (e), the independent panel may include experts affiliated with or employed by the entity. A panel of two experts may be arranged at the plan's request, provided the enrollee consents in writing. The independent entity may arrange for a panel of one expert only if the independent entity certifies in writing that there is only one expert qualified and able to review the recommended therapy. Neither the plan nor the enrollee shall choose or control the choice of the physician or other provider experts.

(3) Neither the expert, nor the independent entity nor any officer, director, or management employee of the independent entity shall have any material professional, familial, or financial affiliation, as defined in paragraph (4), with any of the following: (A) the plan; (B) any officer, director, or management employee of the plan; (C) the physician, the physician's medical group, or the independent practice association (IPA) proposing the therapy; (D) the institution at which the therapy would be provided; or (E) the developer or manufacturer of the drug, device, procedure or other therapy proposed for use in the Phase III clinical trial at issue.

(4) For purposes of this section, the following terms shall have the following meanings:

(A) "Material familial affiliation" means a relationship as a spouse, child, parent, sibling, spouse's parent, or child's spouse.

(B) "Material professional affiliation" means a physician-patient relationship, a partnership or employment relationship, a shareholder or ownership interest in a professional corporation, or any independent contractor arrangement that constitutes a material financial affiliation with any expert or any officer or director of the independent entity. The term "material professional affiliation" shall not include affiliations which are limited to staff privileges at a health facility.

(C) "Material financial affiliation" means any financial interest of more than 5 percent of total annual revenue or total annual income of an entity or individual to which this subdivision applies. "Material financial affiliation" does not include payment by the plan to the independent entity for the services required by this section, or an expert's participation as a contracting plan provider where the expert is affiliated with an academic medical center or a National Cancer Institute-designated clinical cancer research center.

(5) The plan shall provide to the independent entity arranging ***262** for the panel of experts a copy of the following documents within five business days of the plan's receipt of a request by an enrollee or enrollee's physician for an external, independent review:

(A) The medical records in the plan's possession that are relevant to the patient's condition for which the proposed therapy has been recommended. Any additional medical records provided to the plan after its initial submission to the independent entity shall be forwarded by the plan to the independent entity within five business days. The records shall remain confidential and not be disclosed to any third parties other than the selected experts.

(B) A copy of any documents used by the plan in determining whether the proposed therapy should be covered and any documents explaining the reasons for the plan's denial of coverage. This data includes any information submitted by the patient or the patient's physician in support of the request for coverage of treatment provided in an appropriate Phase III clinical trial or off-label drug use.

(6) The experts on the panel shall render their analyses and recommendations within thirty days of the receipt of the enrollee's request for review. If the enrollee's physician determines that the effectiveness of the proposed therapy would be significantly diminished if not promptly commenced, the analyses and recommendations of the experts on the panel shall be rendered within seven days of the request for expedited review. At the request of the experts, the deadline shall be extended by up to three days for a delay in providing the documents required by paragraph (5) of subsection (c).

(7) Each expert's analysis and recommendation shall be in writing and shall explain the reasons for the expert's recommendation in support of or in opposition to the coverage of the treatment in question. The written statement shall cite the enrollee's specific medical condition, the relevant documents provided pursuant to paragraph (5), and the relevant medical and scientific evidence that supports the expert's recommendation.

(8) The independent entity shall provide the plan and the enrollee's physician with the experts' analyses and recommendations, a description of the qualifications of each expert, and any other information that it chooses to provide to the plan and the enrollee's physician. The independent entity may disclose the identities of the experts to the plan at its discretion, and if it does so, it must disclose the names of the experts to the enrollee's physician.

(9) If the majority of experts on the panel recommend providing the proposed therapy, the recommendation shall be binding on the plan. If there are only two experts on the panel and their recommendations are evenly divided, then the panel's decision shall be deemed to be in favor of coverage. If less than a majority of the experts on the panel recommend ***263** providing the requested therapy, the plan is not required to reimburse the patient for the treatment.

(10) The plan shall have written policies describing the external, independent review process. The plan shall disclose the availability of the external, independent review process and how enrollees may access the review process in the plan's evidence of coverage and disclosure forms. This requirement is in addition to the enrollee notification requirement established in subsection (c)(1) above.

(d) The Insurance Commissioner of each state shall contract with a private, nonprofit accrediting organization to accredit the independent entities described in paragraph (c)(2). The accrediting organization shall have the power to grant and revoke accreditation, and shall develop, apply, and enforce accreditation standards, including those required in subsection (e), that ensure the independence of the entity, the confidentiality of the medical records, and the qualifications and independence of the health care professionals providing the analyses and recommendations requested of them. The accrediting organization shall demonstrate the ability to objectively evaluate the performance of independent entities and shall demonstrate that it has no conflict of interest, including any material professional, familial, or financial affiliation as defined in paragraph (4) of subsection (c) with any independent entity or plan, in accrediting entities for the purpose of reviewing medical treatments, treatment recommendations, and coverage decisions by health care plans.

(e) In order to receive accreditation for the purposes of this section, an independent entity must be an organization that has as its primary function to provide expert reviews and related services and receives a majority of its revenues from these services. However, an academic medical center may qualify as an independent entity for purposes of this Act without having as its primary function providing expert reviews and related services and without receiving a majority of its revenues from these services. An independent entity may not be a subsidiary of, nor in any way owned or controlled by, a health plan, a trade association of health plans, or a professional association of health care providers.

SECTION 4. EFFECT ON STATE LAWS.

This title shall not be construed to supersede any provision of state law that establishes, implements, or continues in effect any standard or requirement relating to health insurance coverage for a particular experimental treatment or specific investigational therapies except to the extent that such standard or requirement prevents the application of a requirement of this title.

***264** B. Further Justification for the Proposed Federal Legislation

1. Coverage for Phase III Clinical Trials

A federal mandate requiring insurers to reimburse patients with terminal illnesses for treatments received in an appropriate Phase III clinical trial is a moderate and prudent solution to the problem of coverage exclusions for experimental treatments. As set forth below, the new reimbursement requirement will likely save patient lives, will not be exorbitantly expensive for insurers, and will encourage research and expedited identification of safe and effective therapies.

The proposed statute mandates coverage for experimental treatments in a narrowly defined set of circumstances. The patient must have a terminal condition that, according to his or her physician, has a high probability of causing death within two years. The proposed statute thus endeavors to aid only the sickest of patients and to offer them opportunities to receive last- chance, potentially life-saving treatments.

Furthermore, only Phase III clinical trials are covered. These generally constitute the final stage of testing and are the clinical trials that are most likely to provide beneficial treatment for the patient. [FN306] Seventy percent of drugs submitted for Phase I clinical trials fail at that level of testing and thirty three percent of those that advance to Phase II clinical trials fail at the second stage of testing. [FN307] The treatments that reach Phase III trials have already survived rigorous scrutiny. In addition, some commentators have noted that only three to five percent of cancer patients are referred by their physicians to clinical trials. [FN308] This is due in part to the stringent protocol criteria of many clinical trials and to physician resistance to experimental treatment, among other factors. [FN309]

Insurers would not bear the entire burden of paying for treatment provided in Phase III clinical trials. Rather, expenses for clinical research are paid by a variety of sources. [FN310] These include ***265** for-profit institutions such as manufacturers of drugs and medical devices or for-profit hospitals and treatment centers as well as nonprofit entities such as the National Institutes of Health, the American Hospital Association, the American Cancer Society, universities, and medical centers. [FN311]

The Department of Health and Human Services, for example, awards approximately $5.5 billion per year for research involving human subjects, [FN312] and in 1993 the National Institutes of Health granted the United States' 127 medical schools $3.9 billion for research for approximately 15,240 protocols, though not all involved human subjects. [FN313] If the clinical trial involves an investigational drug, a sponsor may not charge participants without obtaining prior approval by the FDA. To obtain approval, the sponsor must submit a detailed explanation of why it cannot absorb all expenses as a "normal cost of doing business." [FN314] Consequently, insurers would merely supplement funding that would often be available from other sources.

Denials of coverage for individuals with life-threatening diseases may save insurers money in the short term but are sometimes costly in the long run, since they often generate intensely adverse publicity and extremely expensive litigation. [FN315] In 1991, for example, 60 Minutes featured a story about Aetna Insurance Co. refusing coverage for treatment of a breast cancer patient by a bone marrow transplant. [FN316] Many similar stories have followed. As a result, some insurers opt to pay for controversial treatments instead of risking the consequences of a denial. [FN317]

***266** On September 20, 1994 the Office of Personnel Management (OPM) issued a directive requiring the 350 health plans serving approximately nine million federal employees and their dependents to cover treatment by HDC-ABMT for breast cancer, multiple myeloma, and epithelial ovarian cancer in clinical trials. [FN318] Providers maintain some discretion in that they may limit coverage of randomized clinical trials to those conducted at designated facilities. [FN319] Some commentators attribute OPM's directive to public pressure. [FN320]

The proposed federal legislation may in reality save insurers significant costs. Health plans will be less vulnerable to liability if they deny coverage for experimental treatments that are not provided within the framework of a qualified Phase III clinical trial. [FN321] The plans will be required to reimburse patients only in the limited circumstances delineated above. [FN322] The clear legislative mandate should serve as an effective defense in case of litigation involving reimbursement for other experimental therapies.

Federal legislation compelling coverage of treatment provided in clinical trials will benefit not only patients and insurers, but also medical research. Patients who cannot receive reimbursement for experimental treatments, and who do not have their own financial resources, are effectively barred from participation in clinical trials. This results in many patients being excluded from the participant population upon which medical research can draw. The American Society for Clinical Oncology recently reported that no more than five percent of adult cancer patients in the United

States are enrolled in research studies. [FN323] More liberal coverage provisions will significantly increase the number and diversity of patients available for biomedical experimentation in Phase III clinical trials. Similarly, scholars have criticized ***267** state legislation that establishes absolute coverage mandates for experimental treatment as hindering scientific research. [FN324] Patients who know that reimbursement is available for HDC-ABMT provided to a breast cancer patient by any doctor at any facility will have little incentive to seek and participate in clinical trials from which important data would be collected. [FN325] Rather, patients are likely to have the procedure performed by their local physician at the most conveniently accessible medical facility, even if the facility is providing the treatment without conducting a formal clinical trial. [FN326]

Some insurers are themselves committed to advancing medical research. At least one insurance provider has volunteered to contribute substantial funds to Phase III clinical trials for the purpose of establishing the efficacy of HDC-ABMT for breast cancer patients. The Blue Cross and Blue Shield Plans have contributed approximately forty million dollars to randomized, controlled clinical trials conducted over a five year period ending in 1998. [FN327] The "Demonstration Project," conducted in conjunction with the National Cancer Institute, supported a series of four national Phase III trials, involving approximately 1500 women. [FN328] The trials were conducted at eighty-six medical research facilities, and Blue Cross Blue Shield Association had contracts with forty-two of these entities. [FN329] Insurers paying for Phase III clinical trials not only provide potentially life-saving treatment ***268** for their enrollees, but also promote research that will either ultimately establish the therapy as safe and effective or prove that it is not beneficial for patients and thus eliminate future controversy and expense relating to the treatment.

It is important to note that one serious ethical problem may be raised by the proposed legislation. Patients who enroll in Phase III randomized clinical trials risk being placed in a control group that does not receive the investigational treatment. [FN330] The ethical dilemma of using placebos in clinical trials or placing patients in control groups that do not undergo the potentially life-saving procedure has generated much discussion among scholars and is beyond the scope of this paper. Researchers often implement mechanisms that will ensure that most if not all participants will benefit from clinical trials. [FN331] Moreover, many Phase III clinical trials compare the experimental treatment to standard therapy, [FN332] and thus patients in the control group receive traditional treatments and are no worse off than those who do not enroll in a clinical trial. In addition, IRBs must review and approve all research protocols after careful consideration of the risks and benefits inherent in the clinical study. [FN333] IRBs, presumably, would ***269** not allow research to proceed if it will compromise the health of gravely ill participants.

2. Coverage of Off-label Drug Use

Physicians commonly find that insurers deny their patients reimbursement for off-label drug use. One study of off-label treatments in oncology found that nearly half of the 680 physicians who were questioned reported that an insurer had denied coverage for treatment by use of off-label drugs. [FN334] Recent bills introduced in many state legislatures attempt to remedy this problem by requiring managed care providers to cover off-label uses in some circumstances. [FN335] As early as 1993, New Jersey passed a law that requires most insurers to pay for medically appropriate uses of off-label drugs. [FN336] In order to qualify as medically appropriate, the therapy must be recognized in the American Medical Association Drug Evaluations, the American Hospital Formulary Service Drug Information, or the United States Pharmacopeia Drug Information. [FN337] In addition, "an off-label use is medically appropriate [under the New Jersey law] if it has been recommended by a clinical study or review article in a major peer-reviewed professional journal." [FN338]

The proposed federal statute likewise mandates that insurers provide reimbursement for off-label drug use so long as the use is recognized in one of the standard reference compendia or in a national, peer-reviewed professional journal. The American Medical Association Drug Evaluations explicitly addresses the issue of off-label drug uses in its preface. It states the following:

The indications cited in official labeling for a drug are limited to those that are approved by the FDA for purposes of marketing or advertising. The labeling does not constrain a physician's use of the drug for an unlabeled indication in individual patients so long as that use is based on rational scientific evidence or theory, expert medical judgment, or controlled ***270** clinical studies. Therefore, because indications approved for labeling by the FDA often lag behind both the world literature and medical practice or because the manufacturer has not submitted an application for a new use, both labeled and unlabeled (off-label) uses of drugs are evaluated in DE. [FN339]

The proposed legislation does not limit the reimbursement requirement to drugs used to treat patients with terminal illnesses since off-label drug use is prevalent in the medical profession. [FN340]

For terminally ill patients who are declined coverage for off-label drug use intended to treat their terminal illness, the statute establishes the option of an independent review process. By majority vote, the reviewing panel of experts can require the insurer to cover the potentially life-saving therapy. Because so much is at stake for terminally ill patients, an external expert review of coverage denials for off-label drug use is a responsible and prudent way to resolve disputes quickly and avoid costly litigation. The independent review process is discussed below.

3. The Independent Review Process

The proposed federal statute attempts to set clear guidelines for insurers regarding reimbursement for investigational therapies and to reduce dramatically the controversy surrounding the issue of coverage exclusions for experimental treatments. Nevertheless, even the most carefully drafted statutory language will leave room for debate as to whether a particular patient is covered under specific circumstances. The recommended federal legislation, for example, leaves open the following issues:

1) Are the facility and personnel providing the proposed treatment qualified to do so by virtue of their experience and training?

2) Does the patient meet all protocol requirements?

3) Is there a clearly superior, noninvestigational treatment available to the enrollee?

4) Is there a reasonable expectation that the protocol treatment will be at least as beneficial to the patient as the nonexperimental alternative?

5) Insurers will continue to be free to define the term "experimental or investigational treatment" as they see fit. If the treatment under consideration for a terminally ill patient fits within the definition of "experimental or investigational," the insurer will have to pay for the therapy only if an appropriate Phase III clinical trial is found for the enrollee. If the treatment ***271** is not deemed experimental or investigational, the plan will have to reimburse the patient for its cost in accordance with plan policy. Controversies are likely to continue to abound regarding whether procedures such as HDC-ABMT [FN341] or lung-volume reductions [FN342] constitute investigational or standard therapy at any given point in time, since determinations regarding their status dictate the insurer's reimbursement obligations.

6) The insured's physician may be unable to determine whether the patient's illness has a high probability of causing death within two years, thereby obfuscating the issue of whether the individual falls within the purview of the statute.

All of the questions listed above provide a potential basis for insurers to deny coverage for treatment provided to terminally ill patients in Phase III clinical trials. It is for this reason that the proposed statute establishes an independent review mechanism for adverse coverage decisions, designed to resolve coverage disputes in an effective and expedited fashion without resort to the media or the courts.

Some congressional legislators have already recognized the utility of independent review panels. One proposed bill, entitled "Health Care Quality and Choice Act of 1999," [FN343] establishes that individuals denied care or coverage by their group health plan or health insurance issuer could demand first an internal review and then a review by an independent panel of experts outside the health plan. [FN344]

Similarly, the Norwood-Dingell Bill features an independent appeal mechanism, available after exhaustion of an internal appeal process. [FN345] The appeal would be available to any patient whose claim was denied based on a decision that "the item or service is not medically necessary or appropriate or is investigational or experimental" or that involves a medical judgment. [FN346] The Norwood-Dingell plan would, therefore, provide much broader appeal rights and be far more costly for insurers than the legislation proposed in this Article.

Many state legislatures have already mandated that HMOs allow patients to challenge denials of benefits by submitting an appeal ***272** to an independent panel of medical experts. [FN347] Of the approximately twenty states

that require independent reviews of negative coverage decisions, six adopted the external appeals laws in 1998. [FN348] These states include Hawaii, Maryland, New York, Pennsylvania, Tennessee, and Vermont.

At first blush, the independent review process may appear to impose exorbitant costs upon insurers. Further scrutiny of the mechanism, however, will show that its costs should be modest. Each health plan is obligated initially only to contract with an impartial, independent entity responsible for arranging the expert panel reviews of coverage denials whenever necessary. This contract can be arranged for a nominal flat fee with further payments triggered only by actual reviews of coverage decisions. Only patients with terminal conditions who are likely to die within two years are entitled to seek expert panel reviews. Furthermore, the experience of Northern California Kaiser Permanente and the State of Texas suggest that given the option of appeal to an independent review panel, patients may feel greater trust for their insurer's judgment and rarely invoke the appeal process. [FN349] It is also possible that insurers will engage in a more thorough, diligent decision-making process, knowing that an irresponsible coverage denial may trigger an expensive expert review.

The independent review process provides a private forum for the resolution of coverage disputes regarding terminally ill patients, outside the glare of the media and open court hearings. An independent review of a coverage denial will surely be less expensive for the insurer than litigation regarding the case. Most importantly, coverage disputes will be resolved within a month, and at times as quickly as seven days. The swift resolutions will benefit both the insurer, who will not need to invest significant time and resources in the dispute, and the patient, who will be spared an agonizing wait for an answer regarding potentially life-saving treatments.

Patients who are still dissatisfied after the independent review panel renders its decision will not be prevented by the statute ***273** from turning to the courts. The insurer, however, may nonetheless benefit from having utilized the review process. Courts are likely to give deference to the expert panel's determination and to credit insurers for the use of fair procedural safeguards in the decision-making process. [FN350]

Conclusion

The problem of coverage denials for last-chance experimental treatments has received increasing attention in the media and the courts in recent years. One cannot ignore the plight of desperately ill patients who are aware of a potential cure, but know that it is unavailable to them because of a health insurance coverage exclusion. The judiciary and state legislatures alike have grappled with the problem, but both are imperfect forums for resolution of the issue.

Federal legislation that is specific and narrowly tailored, as proposed here, offers the best response to the problem of insurance coverage for experimental treatment. The new requirements may increase costs for insurers in the short term, but these costs are not expected to be overwhelming. It may be advisable for each state's insurance commissioner to require insurers to submit annual reports regarding the costs incurred as a direct result of the federal legislative reforms. The financial impact of the mandated benefits could then be assessed in light of objective data.

The proposed statute strives to protect only the sickest of patients, who are in need of truly life-saving, last-chance treatments. It does not ignore the needs of insurers, who have limited resources and whose financial integrity is at stake. In addition, the statute does not respond to any particular lobby or advocacy group, but rather, addresses coverage of experimental therapies that might be sought by any terminally ill patient. While no solution to such an emotionally charged, complex problem can be flawless, the proposal outlined in this Article is likely to promote the welfare of all concerned parties including patients, insurers, and the general public, who will benefit from legislative support for clinical research and the expedited development of safe and effective treatments for life-threatening diseases.

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[FN1]. Harris v. Mutual of Omaha Cos., 992 F.2d 706, 708 (7th Cir. 1993).

[FN2]. Richard S. Saver, Note, Reimbursing New Technologies: Why Are the Courts Judging Experimental

Medicine?, 44 Stan. L. Rev. 1095, 1105-06 (1992).

[FN3]. Robert Russo, I'll Have to Sell the House to Pay for Treatment, N.Y. Times, Apr. 5, 1994, at A20 (letter to editor).

[FN4]. Rollo v. Blue Cross/Blue Shield, No. CIV.A.90-597, 1990 WL 312647, at *1 (D.N.J. Mar. 22, 1990) (statements of the district court judge).

[FN5]. J. Gregory Lahr, Commentary, What is the Method to Their "Madness?" Experimental Treatment Exclusions in Health Insurance Policies, 13 J. Contemp. Health L. & Pol'y 613, 623 (1997); Saver, supra note 2.

[FN6]. Lahr, supra note 5, at 623-24.

[FN7]. See Jennifer L. Hardester, Note, In Furtherance of an Equitable, Consistent Structure for Reviewing Experimental Coverage Decisions: the Lessons of Pitman v. Blue Cross and Blue Shield of Oklahoma, 14 St. Louis U. Pub. L. Rev. 289 (1994). The article relates the story of Donna Rogers, a breast cancer patient, who filed suit after her insurer denied coverage for a bone marrow transplant. After Rogers filed suit, the insurer agreed to pay for her treatment, reaching its decision on the last day she could qualify for the therapy without having to delay it and undergo further chemotherapy. Id. at 290.

[FN8]. See Cal. Health & Safety Code § 123985 (West 1995); Cal. Welf. & Inst. Code § 14133.8 (West 1995); Fla. Stat. Ann. § 627.4236 (West 1996); Ky. Rev. Stat. Ann. § 304.17-3165 (Michie 1996); Mass. Ann. Laws ch. 32A, § 17D (Law. Co-op. 1996); Mass. Ann. Laws ch. 175, § 47R (Law. Co- op. 1996); Mass. Ann. Laws ch. 176G, § 4F (Law. Co-op 1996); Mass. Ann. Laws ch. 176A, § 8O (Law. Co-op. 1996); Mass. Ann. Laws ch. 176B, § 4O (Law. Co-op. 1996); Minn. Stat. § 62A.309 (1996); N.H. Rev. Stat. Ann. § 420- A:13 (1995); N.J. Stat. Ann. 17:48-6f (West 1995).

[FN9]. See Ga. Code Ann. § 33.29-3.3 (1996); Ga. Code Ann. § 33-30- 4.4 (1996); Mo. Rev. Stat. Ann. § 376.1200 (West Supp. 1999); N.J. Stat. Ann. § 17:48-6k (West 1996); Tenn. Code Ann. § 56-7-2504 (Supp. 1998); Va. Code Ann. § 38.2-3418.1:1 (Michie 1999).

[FN10]. See Jody C. Collins, Comment, Experimental Medical Treatments: Who Should Decide Coverage?, 20 Seattle U. L. Rev. 451, 481-82 (1997).

[FN11]. See David C. Hsia, Benefits Determination under Health Care Reform: Who Should Decide Coverage Policy?, 15 J. Legal Med. 533, 552 (1994).

[FN12]. See N.J. Stat. Ann. § 17:48-6f note (West 1996) (Assembly Insurance Committee Statement), which refers to the bill as the "Tishna Rollo Bill" and acknowledges that the law was passed in response to the Tishna Rollo case, discussed above.

[FN13]. FMC Corp. v. Holliday, 498 U.S. 52, 61 (1990).

[FN14]. 42 U.S.C. §§ 12101-12213 (1994).

[FN15]. 42 U.S.C. § 12112(a) (1994).

[FN16]. 29 C.F.R. § 1630.4 (1998).

[FN17]. R.I. Gen. Laws § 27-18-36.2 (1998).

[FN18]. Cal. Health & Safety Code § 1370.4 (West 1995).

[FN19]. Until December 31, 1999 treatment in Phase II Clinical trials was covered as well. R.I Gen. Laws § 27-18-36.2.

[FN20]. Id.

[FN21]. Id.

[FN22]. Cal. Health & Safety Code § 1370.4.

[FN23]. Health insurance providers could deny coverage for treatment only if they believed that one or more of the criteria specified in the federal statute had not been fulfilled, e.g. there was a superior noninvestigational alternative or the individual had not met protocol requirements.

[FN24]. See Thomas v. Gulf Health Plan, Inc., 688 F. Supp. 590, 592-93 (S.D. Ala. 1988).

[FN25]. Boland v. King County Med. Blue Shield, 798 F. Supp. 638, 641 (W.D. Wash. 1992); see also Harris v. Mutual of Omaha Cos., 992 F.2d 706 (7th Cir. 1993). The exclusionary provision of the plan at issue stated:

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 or diagnosis; or

(3) 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.

Id. at 708. The plan defines the term "reliable evidence" as follows:

Reliable evidence shall mean only 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 procedure; 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.

Id. (emphasis omitted).

[FN26]. E.g., Dozsa v. Crum & Forster Ins. Co., 716 F. Supp. 131, 135 (D.N.J. 1989). Blue Cross and Blue Shield utilizes a technology assessment program. Mary Ader, Investigational Treatments: Coverage, Controversy, and Consensus, 5 Annals Health L. 45, 52 (1996).

[FN27]. Farley v. Benefit Trust Life Ins. Co., 979 F.2d 653, 659 (8th Cir. 1992).

[FN28]. Harris v. Mutual of Omaha Cos., 992 F.2d 706, 709 (7th Cir. 1993); Dahl-Eimers v. Mutual of Omaha Life Ins. Co., 812 F. Supp. 1193, 1196 (N.D. Fla. 1992), vacated and remanded, 986 F.2d 1379 (11th Cir. 1993). The contents of the informed consent document is governed by the Code of Federal Regulations. See 45 C.F.R. §§ 46.116-.117 (1998) (Department of Health and Human Services regulations); 21 C.F.R. §§ 50.20, 50.27 (1999) (Food and Drug Administration regulations).

[FN29]. Fuja v. Benefit Trust Life Ins. Co., 809 F. Supp. 1333, 1341 (N.D. Ill. 1992), rev'd, 18 F.3d 1405 (7th Cir. 1994).

[FN30]. See Denise S. Wolf, Comment, Who Should Pay for "Experimental" Treatments? Breast Cancer Patients v. Their Insurers, 44 Am. U. L. Rev. 2029, 2074 (1995).

[FN31]. Id. at 2075.

[FN32]. Id.

[FN33]. See Mark A. Hall & Gerald F. Anderson, Symposium: The Law and Policy of Health Care Rationing: Models and Accountability, Health Insurers' Assessment of Medical Necessity, 140 U. Pa. L. Rev. 1637, 1669 (1992); Dayna Bowen Matthew, Controlling the Reverse Agency Costs of Employment-Based Health Insurance: of Markets, Courts, and a Regulatory Quagmire, 31 Wake Forest L. Rev. 1037 (1996).

[FN34]. Angela R. Holder, Symposium on the Legal and Ethical Implications of Innovative Medical Technology, Funding Innovative Medical Treatment, 57 Alb. L. Rev. 795, 796 (1994).

[FN35]. Id. at 796-97.

[FN36]. Rollo v. Blue Cross/Blue Shield, No. CIV.A.90-597, 1990 WL 312647, at *1, *7 (D.N.J. Mar. 22, 1990).

[FN37]. Honorable Dickinson R. Debevoise, A Trial Judge's View of Tort Reform, 25 Seton Hall L. Rev. 853, 858 (1994).

[FN38]. Collins, supra note 10, at 474.

[FN39]. Id. at 474-75.

[FN40]. Id.

[FN41]. Id. at 475 (quoting Zuckerberg v. Blue Cross & Blue Shield, 108 A.2d 56, 62 (1985)).

[FN42]. See John A. Bourdeau, Propriety of Denial of Medical or Hospital Benefits for Investigative, Educational, or Experimental Medical Procedures Pursuant to Exclusion Contained in ERISA-Governed Health Plan, 12 A.L.R. Fed. 1 (1994).

[FN43]. Hardester, supra note 7, at 294.

[FN44]. Janice M. Maggio, Determination of HDC-ABMT as Accepted Medical Practice for the Treatment of Breast Cancer, 22 Rutgers Computer & Tech. L.J. 551, 556-57 (1996) (footnotes omitted).

[FN45]. Stephanie Stapleton, Early Results Question Benefit of High-dose Chemotherapy, Am. Med. News, May 10, 1999, at 29; see also Joan Stephenson, Bone Marrow/Stem Cells: No Edge in Breast Cancer, 281 JAMA 1576, 1576-78 (1999); Joan Stephenson, Opinions Divided on High-Dose Chemotherapy for Breast Cancer, 282 JAMA 119 (1999) [hereinafter High-Dose Chemotherapy].

[FN46]. See sources cited supra note 45.

[FN47]. See Peter J. Thill, Insurers' and Courts' Response to High Dose Chemotherapy with Autologous Bone Marrow Transplant in the Treatment of Breast Cancer: A Tragedy or Necessity?, 43 Drake L. Rev. 863 (1995).

[FN48]. Norman Daniels & James E. Sabin, Last Chance Therapies and Managed Care: Pluralism, Fair Procedures, and Legitimacy, Hastings Center Report, Mar.- Apr. 1998, at 27, 29.

[FN49]. Id.

[FN50]. See Bourdeau, supra note 42, for a detailed discussion of the cases listed below.

[FN51]. Schnitker v. Blue Cross/Blue Shield, 787 F. Supp. 903 (D.C. Neb. 1991); Dozsa v. Crum & Forster Ins. Co., 716 F. Supp. 131 (D.C.N.J. 1989). Multiple myeloma is a cancer of the bone marrow.

[FN52]. Rollo v. Blue Cross/Blue Shield, No. CIV.A. 90-597, 1990 WL 312647, at *1 (D.N.J. Mar. 22, 1990). Wilms tumor is a disease of the kidney.

[FN53]. Bernards v. United of Omaha Life Ins. Co., 987 F.2d 486 (8th Cir. 1993).

[FN54]. Burdette v. Mees, Nos. 90-3108, 90-3118, 1991 U.S. App. LEXIS 10403 (4th Cir. May 23, 1991). Chronic myeloid leukemia is a fatal disease of the blood and blood producing tissues.

[FN55]. McLeroy v. Blue Cross/Blue Shield, Inc., 825 F. Supp. 1064 (N.D. Ga. 1993). Glioblastoma multiforme is a cancerous tumor.

[FN56]. Farley v. Benefit Trust Life Ins. Co., 979 F.2d 653 (8th Cir. 1992). Malignant melanoma is skin cancer.

[FN57]. Holder, supra, note 34, at 798. Ms. Holder asserts that liver transplants "were the first therapies to be refused coverage." Id.

[FN58]. Groft v. Health Care Corp., 792 F. Supp. 441 (D.C. Md. 1992).

[FN59]. Loyola Univ. v. Humana Ins. Co., 996 F.2d 895 (7th Cir. 1993).

[FN60]. Reilly v. Blue Cross & Blue Shield United, 846 F.2d 416 (7th Cir. 1988).

[FN61]. William L. Christopher, Off-Label Drug Prescription: Filling the Regulatory Vacuum, 48 Food & Drug L.J. 247, 248 (1993).

[FN62]. 21 C.F.R. § 314.93(e)(2) (1999); 21 C.F.R. § 312.21 (1999); Saver, supra note 2, at 1110.

[FN63]. See 37 Fed. Reg. 16503 (1972) ("[T]he physician may, as part of the practice of medicine, lawfully prescribe a different dosage for his patient, or may otherwise vary the condition of use from those approved in the package insert, without informing or obtaining the approval of the Food and Drug Administration."); see also United States Gen. Accounting Office Off- Label Drugs: Reimbursement Policies Constrain Physicians in Their Choice of Cancer Therapies GAO/PEMD-91-14, at 10-11 (1991) [hereinafter GAO Report].

[FN64]. Kaspar J. Stoffelmayr, Products Liability and "Off-Label" Uses of Prescription Drugs, 63 U. Chi. L. Rev. 275, 277 (1996).

[FN65]. Id.

[FN66]. Id.

[FN67]. Id. at 278.

[FN68]. GAO Report, supra note 63, at 3.

[FN69]. Melody L. Harness, Note, What is "Experimental" Medical Treatment?: A Legislative Definition is Needed, 44 Clev. St. L. Rev. 67, 72 (1996); see also GAO Report, supra note 63, at 28-34.

[FN70]. GAO Report, supra note 63, at 35.

[FN71]. Id. at 38.

[FN72]. Id. at 37.

[FN73]. Saver, supra note 2, at 1110.

[FN74]. Veronica Henry, Problems with Pharmaceutical Regulation in the United States, 14 J. Legal Med. 617, 623 (1993).

[FN75]. GAO Report, supra note 63, at 38.

[FN76]. Henry, supra note 74, at 622-23.

[FN77]. See Omnibus Budget Reconciliation Act of 1990, Pub. L. 101-508, 104 Stat. 1388 (codified in scattered sections of 42 U.S.C.).

[FN78]. Omnibus Budget Reconciliation Act of 1993, Pub. L. 103-66, 107 Stat. 312 (codified in scattered sections of 7 U.S.C.).

[FN79]. See Christopher, supra note 61, at 257; Harness, supra, note 69, at 73. New York, for example, prohibits insurers from excluding coverage of off- label drug use of cancer therapies if: (1) prescription drugs are generally covered in the policy; (2) the drug is FDA-approved for treatment of some form of cancer; and (3) the off-label use

at issue is recognized by one of three major drug compendia or recommended in a review article or editorial comment in a major peer-reviewed journal. Id.; see also N.Y. Ins. Law § 3216(h)(12) (McKinney 1985 & Supp. 1999).

[FN80]. Ala. Code § 27-1-10.1 (1994); Cal. Health & Safety Code § 1367.21 (West 1990 & Supp. 1999); Cal. Ins. Code § 10123.195 (West 1995); Conn. Gen. Stat. Ann. §§ 38a-492b, 38a-518b (West 1992 & Supp. 1999); Ind. Code Ann. §§ 27-8-20-7, 27-8-20-9 (Michie 1994); Mass. Ann. Laws ch. 175, § 47K, ch. 175 § 47, ch. 176A, § 8N, ch. 176A, § 8Q, ch. 176B, § 4N, ch. 176B, § 4P, ch. 176G, § 4E, ch. 176G, § 4G (Law. Co- op. 1996 & Supp. 1998); Md. Code Ann. Ins. § 15-804 (1997); N.J. Stat. Ann. § 26:1A-36.9 (West 1995); Ohio Rev. Code Ann. § 1751.66 (Supp. 1999); Okla. Stat. Ann. tit. 63, §§ 1-2604, 1-2605 (West 1996); R.I. Gen. Laws § 27-55-2 (1998).

[FN81]. See, e.g., Bourdeau, supra note 42; Collins, supra note 10; Hardester, supra note 7; Lahr, supra note 5; Saver, supra note 2; Wolf, supra note 30.

[FN82]. Firestone Tire & Rubber Co. v. Bruch, 489 U.S. 101, 109 (1989). ERISA governs benefit plans that are established and maintained by employers for their employees. It does not reach health insurance purchased by individuals themselves or benefits provided by other sources such as workers' compensation. See Taggart Corp. v. Life & Health Benefits Admin., 617 F.2d 1208 (5th Cir. 1980); 29 C.F.R. § 2510.3-1(j) (1998).

[FN83]. Doe v. Group Hospitalization & Med. Servs., 3 F.3d 80, 85 (4th Cir. 1993); Pokratz v. Jones Dairy Farm, 771 F.2d 206, 209 (7th Cir. 1985).

[FN84].489 U.S. 101 (1989).

[FN85]. Id. at 115.

[FN86]. See Firestone, 489 U.S. at 115; Doe, 3 F.3d at 85.

[FN87]. Firestone, 489 U.S. at 113. The de novo standard mandates review of the fiduciary's decision "by looking to the terms of the plan and other manifestations of the parties' intent." Id.

[FN88]. Barbara A. Fisfis, Who Should Rightfully Decide Whether A Medical Treatment Necessarily Incurred Should Be Excluded from Coverage under a Health Insurance Policy Provision Which Excludes from Coverage "Experimental" Medical Treatments?, 31 Duq. L. Rev. 777, 781 (1993).

[FN89]. Id. at 781-82.

[FN90]. Catherine A. Voigt & Kevin J. Conlon, Insurance Coverage for Experimental Treatment: New Hope for Patients, 83 Ill. B.J. 396, 398 (1995).

[FN91]. Jennifer Barber, Note, Experimental Treatment Exclusions from Medical Insurance Coverage: Who Should Decide?, 1-SPG Widener L. Symp. J. 389, 400, 406 (1996); Collins, supra note 10, at 455; Lahr, supra note 5; Saver, supra note 2.

[FN92]. See Harris v. Mutual of Omaha Cos., 992 F.2d 706 (7th Cir. 1993) (for the language of the exclusionary provision, see supra, note 25); Holder v. Prudential Ins. Co., 951 F.2d 89, 90 n.3 (5th Cir. 1992) (the policy excluded coverage of therapies that were not "commonly and customarily recognized throughout the doctor's profession as appropriate in the treatment of the diagnosed sickness or injury" or that were "educational or experimental in nature").

[FN93]. Henderson v. Bodine Aluminum, Inc., 70 F.3d 958, 961 (8th Cir. 1995) (The health insurance plan in question covered high dose chemotherapy (HDCT) only for particular cancers, not including breast cancer, since it considered the treatment experimental for all but the specified cancers. The Eighth Circuit reversed and remanded the lower court's denial of plaintiff's motion for a preliminary injunction, finding that she showed a likelihood of success on the merits in proving that HDCT is an "accepted" therapy for breast cancer.); see also Adams v. Blue Cross/Blue Shield, 757 F. Supp. 661, 672 (D. Md. 1991) (The plan excluded coverage for "any treatment ... not generally acknowledged as accepted medical practice by the suitable medical specialty practicing in Maryland, as

decided by us. Utilizing a de novo review standard, the court found that "HDCT-ABMT was generally acknowledged as accepted medical practice by Maryland oncologists.").

[FN94]. Schnitker v. Blue Cross/Blue Shield, 787 F. Supp. 903, 904 (D.C. Neb. 1991) (plan excluded from coverage any treatment that had not received final approval from the appropriate governmental entity or had been accepted by a consensus of opinion based on scientific evidence).

[FN95]. See Leonhardt v. Holden Bus. Forms Co., 828 F. Supp. 657, 663 (D. Minn. 1993) (plan defined as "experimental" any treatment that is: (a) not proven in an objective manner to have therapeutic value or benefit; (b) restricted to use at medical facilities capable of carrying out scientific studies; or (c) of questionable medical effectiveness); Dozsa v. Crum & Forster Ins. Co., 716 F. Supp. 131, 134 (D.N.J. 1989) (plan excluded coverage for treatments that were not "commonly and customarily recognized throughout the doctor's profession as appropriate in the treatment of the sickness or injury" or that were "educational" or "experimental in nature" or were "provided primarily for research purposes").

[FN96]. Bennett Roth, House Republicans detail their limits on managed care, Houston Chron., June 25, 1998, at 2A.

[FN97]. See Maggio, supra note 44, at 556-57.

[FN98]. Barber, supra note 91, at 408 n.112.

[FN99]. Id. at 408.

[FN100]. Fisfis, supra note 88, at 781-82.

[FN101]. Barber, supra note 91, at 407.

[FN102]. Harris v. Mutual of Omaha Cos., 992 F.2d 706, 708 (7th Cir. 1993).

[FN103]. Boland v. King County Med. Blue Shield, 798 F. Supp. 638, 641 (W.D. Wash. 1992).

[FN104]. See Barber, supra note 91, at 407.

[FN105]. Id.

[FN106]. Id.

[FN107]. Rollo v. Blue Cross/Blue Shield, No. CIV.A.90-597, 1990 WL 312647, at *1-2 (D.N.J. Mar. 22, 1990).

[FN108]. Harris v. Mutual of Omaha Cos., No. 92-1089-C, 1992 U.S. Dist LEXIS 21393, at *1 (S.D. Ind. Aug. 26, 1992), aff'd, 992 F.2d 706 (7th Cir. 1993).

[FN109]. Mo. Ann. Stat. § 376.1200 (West Supp. 1999).

[FN110]. N.J. Stat. Ann. § 17:48-6k (West 1996).

[FN111]. Va. Code Ann. § 38.2-3418.1:1 (Michie 1999).

[FN112]. Ga. Code Ann. §§ 33-29-3.3, 33-30-4.4 (1996).

[FN113]. Tenn. Code Ann. § 56-7-2504 (Supp. 1998).

[FN114]. Collins, supra note 10, at 473.

[FN115]. Mo. Ann. Stat. § 376.1200 (West Supp. 1999) provides in relevant part:
1. Each entity offering individual and group health insurance policies providing coverage on an expense-incurred basis, individual and group service or indemnity type contracts issued by a health services corporation, individual

and group service contracts issued by a health maintenance organization, all self-insured group arrangements to the extent not preempted by federal law and all managed health care delivery entities of any type or description, that are delivered, issued for delivery, continued or renewed in this state on or after January 1, 1996, shall offer coverage for the treatment of breast cancer by dose-intensive chemotherapy/autologous bone marrow 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. The offer of benefits under this section shall be in writing and must be accepted in writing by the individual or group policyholder or contract holder.

2. Such health care service shall not be subject to any greater deductible or copayment than any other health care service provided by the policy, contract or plan, except that the policy, contract or plan may contain a provision imposing a lifetime benefit maximum of not less than one hundred thousand dollars, for dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants for breast cancer treatment.

[FN116]. Id.

[FN117]. N.J. Stat. Ann. § 17:48-6k (West 1996) provides:

In addition to benefits provided under regulations adopted pursuant to P.L.1992, c. 161 (C. 17B:27A-2 et seq.) and P.L.1992, c. 162 (C. 17B:27A-17 et seq.), a hospital service corporation shall offer under every group or individual hospital service corporation contract providing hospital or medical expense benefits delivered, issued, executed or renewed in this State, or approved for issuance or renewal in this State by the Commissioner of Insurance, on or after the effective date of this act to provide benefits for the treatment of cancer by dose-intensive chemotherapy/autologous bone marrow transplants and peripheral blood stem cell transplants when performed by institutions approved by the National Cancer Institute or pursuant to protocols consistent with the guidelines of the American Society of Clinical Oncologists. Benefits for such treatment shall be provided to the same extent as for any other illness under the contract.

The offer required pursuant to this section shall apply to all hospital service corporation contracts in which the hospital service corporation has reserved the right to change the premium. Nothing in this section shall be construed to limit a hospital service corporation in adjusting premium amounts, or providing for reasonable deductibles or copayments, with respect to benefits provided pursuant to this section .

See also N.J. Stat. Ann. §§ 17:48A-7j, 17:48E-35.8, 17B:26-2.1j, 17B:27-46.1j, and 26:2j-4:8 (applying the above-described mandate to offer to medical service corporations, health service corporations, insurers providing health insurance that is not group or blanket insurance, insurers providing group policies, and health maintenance organizations, respectively).

[FN118]. Id.

[FN119]. Va. Code Ann. § 38.2-3418.1:1 (Michie 1999) reads in part as follows:

A. Each insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis, each corporation providing individual or group accident and sickness subscription contracts, and each health maintenance organization providing a health care plan for health care services shall offer and make available coverage under such policy, contract or plan delivered, issued for delivery or renewed in this Commonwealth on and after January 1, 1995, for the treatment of breast cancer by dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants when performed pursuant to protocols approved by the institutional review board of any United States medical teaching 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.

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

[FN120]. Id.

[FN121]. Ga. Code Ann. § 33-29-3.3 (1996) provides:

a) Every insurer authorized to issue individual accident and sickness insurance plans, policies, or contracts shall be required to make available, either as a part of or as an optional endorsement to all such policies providing major medical insurance coverage which are issued, delivered, issued for delivery, or renewed on or after July 1, 1995,

coverage for bone marrow transplants for the treatment of breast cancer and Hodgkin's disease. Such coverage shall be at least as extensive and provide at least the same degree of coverage as that provided by the respective plan, policy, or contract for the treatment of other types of physical illnesses. Such an optional endorsement shall also provide that the coverage required to be made available pursuant to this Code section shall also cover the spouse and the dependents of the insured if the insured's spouse and dependents are covered under such benefit plan, policy, or contract.

(b) The optional endorsement required to be made available under subsection (a) of this Code section shall not contain any exclusions, reductions, or other limitations as to coverages, deductibles or coinsurance provisions which apply to bone marrow transplants for the treatment of breast cancer and Hodgkin's disease unless such provisions apply generally to other similar benefits provided or paid for under the accident and sickness insurance benefit plan, policy, or contract.

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

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

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

See also Ga. Code Ann. § 33-30-4.4 (1996) (applying similar requirements to group or blanket accident and sickness insurance).

[FN122]. See statutes cited supra note 121.

[FN123]. See statutes cited supra note 121.

[FN124]. Tenn. Code Ann. § 56-7-2504 (Supp. 1998) reads in part as follows:

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

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

[FN125]. Id.

[FN126]. Collins, supra note 10, at 473.

[FN127]. Cal. Health & Safety Code § 123985 (West 1996); Cal. Welf. & Inst. Code § 14133.8 (West 1991).

[FN128]. Minn. Stat. Ann. § 62A.309 (West 1996).

[FN129]. N.H. Rev. Stat. Ann. §§ 415:18-c, 420-A:13, 420-B:8-e (1998).

[FN130]. Ky. Rev. Stat. Ann. §§ 304.17-3165, 304.17A-135, 304.18- 0985, 304.32-1595, and 304.38-1936 (Michie 1996).

[FN131]. Mass. Ann. Laws ch. 175, § 47R (Law. Co-op. 1996); Mass. Ann. Laws ch. 176A, § 8O (Law. Co-op.

1996); Mass. Ann. Laws ch. 176B, § 4O (Law. Co-op. 1996); Mass. Ann. Laws ch. 176G, § 4F (Law. Co-op. 1996); and Mass. Ann. Laws ch. 32A, § 17D (Law. Co-op. 1996).

[FN132]. N.J. Stat. Ann. §§ 17:48-6f, 17:48A-7e, 17:48E-35.3, 17B:26-2.1d, and 17B:27-46.1e (West 1996).

[FN133]. Fla. Stat. Ann. § 627.4236 (West 1996).

[FN134]. Cal. Welf. & Inst. Code § 14133.8 (West 1991) provides as follows:
(a) A bone marrow transplant for the treatment of cancer for beneficiaries, shall be reimbursable under this chapter, when all of the following conditions are met:
(1) The bone marrow transplant is recommended by the recipient's physician.
(2) The bone marrow transplant is performed in a hospital that is approved for participation in the Medi-Cal program.
(3) The bone marrow transplant is a reasonable course of treatment and is approved by the hospital medical policy committee when there is an existing committee or a committee can be established.
(4) The bone marrow transplant has been deemed appropriate for the recipient by the program's medical consultant. The medical consultant shall not disapprove the bone marrow transplant solely on the basis that it is classified as experimental or investigational.
(5) Full federal financial participation is available for reimbursement for the performance of the bone marrow transplant.
(b) The program shall provide reimbursement for both donor and recipient surgery.
Cal. Health & Safety Code § 123985 (West 1996), pertaining to child health, eliminates subsection (5) and alters subsection (2) as follows: (2) "The bone marrow transplant is performed in a hospital that is approved for participation in the California Children's Services program."

[FN135]. See discussion supra note 134.

[FN136]. See discussion supra note 134.

[FN137]. Minn. Stat. Ann. §§ 62A.309 (1996) reads in part as follows:
Subd. 2. Required coverage. Every health plan ... must provide to each covered person who is a resident of Minnesota coverage for the treatment of breast cancer by high-dose chemotherapy with autologous bone marrow transplantation and for expenses arising from the treatment.
Subd. 3. Greater coinsurance or copayment prohibited. Coverage under this section shall not be subject to any greater coinsurance or copayment than that applicable to any other coverage provided by the health plan.
Subd. 4. Greater deductible prohibited. Coverage under this section shall not be subject to any greater deductible than that applicable to any other coverage provided by the health plan.

[FN138]. N.H. Rev. Stat. Ann. § 415:18-c (1998) provides:
Each insurer that issues or renews any policy of group or blanket accident or health insurance providing benefits for medical or hospital expenses, shall provide to each group, or to the portion of each group comprised of certificate holders of such insurance who are residents of this state and whose principal place of employment is in this state, coverage for expenses arising from the treatment of breast cancer by autologous bone marrow transplants according to protocols reviewed and approved by the National Cancer Institute.
The other provisions cited in supra note 129 apply the same requirements to nonprofit health service corporations and health maintenance organizations.

[FN139]. For an explanation of the stem cell transplantation procedure, or peripheral stem cell rescue (PSCR) as it is otherwise known, see Courts Continue to Struggle with the Exclusion in Medical Plans for Experimental Procedures: A Review of the Circuit Court Cases Concerning High Dose Chemotherapy as a Treatment for Cancer in Connection with Autologous Bone Marrow Transplant or Peripheral Stem Cell Rescue, 4 No. 6 ERISA Litig. Rep. 6 (1996). PSCR is a newer, less invasive, and less costly procedure than ABMT. The patient receives dosages of chemotherapy which are high enough to "mobilize" stem cells from the bone marrow into the peripheral blood. The blood is removed from the body, centrifuged to separate the stem cells, and then is returned to the body without the stem cells. The stem cells are stored in a cold environment and are returned to the blood after HDC. Id. at 7.

[FN140]. Ky. Rev. Stat. Ann. § 304.17-3165 (Michie 1996) provides:

(1) All insurers issuing individual health insurance policies in this Commonwealth which provide coverage for treatment of breast cancer by chemotherapy on an expense-incurred basis shall also provide coverage for treatment of breast cancer by high-dose chemotherapy with autologous bone marrow transplantation or stem cell transplantation.
(2) The administration of high-dose chemotherapy with autologous bone marrow transplantation or stem cell transplantation shall only be covered when performed in institutions that comply with the guidelines of the American Society for Blood and Marrow Transplantation or the International Society of Hematotherapy and Graft Engineering, whichever has the higher standard.
(3) Treatment of breast cancer by high-dose chemotherapy with autologous bone marrow transplantation or stem cell transplantation shall not be considered experimental or investigational. Coverage for transplantation under this section shall not be subject to any greater coinsurance or copayment than that applicable to any other coverage provided by the health plan.
See also Ky. Rev. Stat. Ann. §§ 304.17A-135, 304.18-0985, 304.32- 1595, 304.38-1936 (applying the statutory language to (1) health benefit plans; (2) insurers issuing group or blanket health insurance policies; (3) nonprofit hospitals, medical-surgical, dental, and health service corporations issuing benefits contracts; and (4) health maintenance organizations issuing benefits contracts, respectively).

[FN141].See statutes cited supra note 140.

[FN142]. Mass. Ann. Laws ch. 175, § 47R (Law. Co-op 1996) provides as follows:
Any individual policy of accident and sickness insurance issued pursuant to section one hundred and eight, and any group blanket policy of accident and sickness insurance issued pursuant to section one hundred and ten, shall provide coverage for a bone marrow transplant or transplants for persons who have been diagnosed with breast cancer that has progressed to metastatic disease; provided, however, that said person shall meet the criteria established by the department of public health. The department of public health shall promulgate rules and r[egulations establishing criteria for eligibility] for coverage hereunder which shall be consistent with medical research protocols reviewed and approved by the National Cancer Institute.
See also Mass. Ann. Laws ch. 176A, § 8O (Law. Co-op. 1996) (providing similar coverage for individuals covered under any contract between a subscriber and a corporation under an individual or group hospital service plan); Mass. Ann. Laws ch. 176B, § 4O (Law. Co-op. 1996) (mandating similar coverage by individual or group medical service agreements); Mass. Ann. Laws ch. 176G, § 4F (Law. Co-op. 1996) (applying the same requirements to group health maintenance contracts); Mass. Ann. Laws ch. 32A, § 1O (Law. Co-op. 1996) (providing the same coverage for any active or retired employee of the state who is insured under group insurance coverage).

[FN143]. Metastatic cancer is cancer that has spread beyond its site of origin. The spread can occur through the bloodstream, through the lymphatic system, or across body cavities. See Tober's Cyclopedic Medical Dictionary 1118 (16th ed. 1989).

[FN144]. Mass. Ann. Laws ch. 175, § 47R (Law. Co-op. 1996).

[FN145]. N.J. Stat. Ann. § 17:48-6k (West 1996).

[FN146]. N.J. Stat. Ann. § 17B:27-46.1e (West 1996) provides as follows:
Every group health insurance policy providing hospital or medical expense benefits shall provide benefits to any named insured or other person covered thereunder for expenses incurred in the treatment of Wilm's tumor, including autologous bone marrow transplants when standard chemotherapy treatment is unsuccessful, notwithstanding that any such treatment may be deemed experimental or investigational. These benefits shall be provided to the same extent as for any other sickness under the policy.
See also N.J. Stat. Ann. §§ 17B:26-2.1d, 17:48-6f, 17:48A-7e, 17:48E-35.3, 26:2J-4.1 (West 1996) (applying the same terms to health insurance other than group and blanket insurance, hospital service corporations, medical service corporations, health service corporations, and health maintenance organizations, respectively).

[FN147]. Wilm's tumor is a rare form of cancer which affects the kidneys before spreading to other parts of the body. See N.J. Stat. Ann. § 17:48-6f note (West 1996) (Assembly Insurance Committee Statement).

[FN148]. Id.

[FN149]. Fla. Stat. Ann. § 627.4236 (West 1996) reads, in relevant part, as follows:
(1) As used in this section, the term "bone marrow transplant" means human blood precursor cells administered to

a patient to restore normal hematological and immunological functions following ablative therapy with curative intent. Human blood precursor cells may be obtained from the patient in an autologous transplant or from a medically acceptable related or unrelated donor, and may be derived from bone marrow, circulating blood, or a combination of bone marrow and circulating blood. If chemotherapy is an integral part of the treatment involving bone marrow transplantation, the term "bone marrow transplant" includes both the transplantation and the chemotherapy.

(2) An insurer or a health maintenance organization may not exclude coverage for bone marrow transplant procedures recommended by the referring physician and the treating physician under a policy exclusion for experimental, clinical investigative, educational, or similar procedures contained in any individualor group health insurance policy or health maintenance organization contract issued, amended, delivered, or renewed in this state that covers treatment for cancer, if the particular use of the bone marrow transplant procedure is determined to be accepted within the appropriate oncological specialty and not experimental pursuant to subsection (3).

(3)(a) The Secretary of Health and Rehabilitative Services must adopt rules specifying the bone marrow transplant procedures that are accepted within the appropriate oncological specialty and are not experimental for purposes of this section. The rules must be based upon recommendations of an advisory panel appointed by the Secretary, composed of:

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

(b) The Secretary must also appoint a member of the advisory panel to serve as chairperson.

(c) [The Agency] must provide, within existing resources, staff support to enable the panel to carry out its responsibilities under this section.

(d) In making recommendations and adopting rules under this section, the advisory panel and the Secretary shall:

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

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

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

[FN150]. Id.

[FN151]. Id.

[FN152]. Id.

[FN153]. Wolf, supra note 30, at 2100.

[FN154]. R.I. Gen. Laws § 27-18-36.2 (1998).

[FN155]. Cal. Health & Safety Code § 1370.4 (West 1997); Cal. Ins. Code § 10145.3 (West 1999).

[FN156]. R.I. Gen. Laws § 27-18-36.2 (1998) provides:

Conditions of coverage. [Effective until December 31, 1999.]

As provided in § 27-18-36, coverage shall be extended to new cancer therapies still under investigation when the following circumstances are present:

(1) Treatment is being provided pursuant to a Phase II, III, or IV clinical trial which has been approved by the National Institutes of Health (NIH) in cooperation with the National Cancer Institute (NCI), Community clinical oncology programs; the Food and Drug Administration in the form of an Investigational New Drug (IND) exemption; the Department of Veterans' Affairs; or a qualified nongovernmental research entity as identified in the guidelines for NCI cancer center support grants;

(2) The proposed therapy has been reviewed and approved by a qualified institutional review board (IRB);

(3) The facility and personnel providing the treatment are capable of doing so by virtue of their experience, training, and volume of patients treated to maintain expertise;

(4) The patients receiving the investigational treatment meet all protocol requirements;

(5) There is no clearly superior, noninvestigational alternative to the protocol treatment;

(6) The available clinical or preclinical data provide a reasonable expectation that the protocol treatment will be at least as efficacious as the noninvestigational alternative; and

(7) The coverage of new cancer therapy treatment provided pursuant to a Phase II clinical trial shall not be required for only that portion of that treatment as is provided as part of the Phase II clinical trial and is otherwise funded by a national agency, such as the national cancer institute, the veteran's administration, the department of defense, or funded by commercial organizations such as the biotechnical and/or pharmaceutical industry or manufacturers of medical devices. Any portions of a Phase II trial which are customarily funded by government, biotechnical and/or pharmaceutical and/or medical device industry sources in Rhode Island or in other states shall continue to be so funded in Rhode Island and coverage pursuant to this section shall supplement, not supplant, such customary funding.

[It should be noted that effective December 31, 1999 only Phase III and IV clinical trials will be covered by the statute.]

[FN157]. Id.

[FN158]. 21 C.F.R. § 7.3(f) (1999) ("'Product' means an article subject to the jurisdiction of the Food and Drug Administration, including any food, drug, and device intended for human or animal use ....").

[FN159]. Saver, supra note 2, at 1110-11. Saver states that "a great deal of potentially efficacious treatment is left unscrutinized by government agencies." Id. at 1111; see also Daniels & Sabin, supra note 48, at 29 ("[T] he 'gatekeeper' for ABMT ... [is] not the FDA, charged with keeping unsafe pharmaceuticals off the market ....").

[FN160]. 21 C.F.R. § 312.23(a) (1999).

[FN161]. Id.

[FN162]. 21 C.F.R. § 312.34(a).

[FN163]. Id. § 312.34(b)(1)(i)-(ii).

[FN164]. Id. § 312.34(b)(1)(iii)-(iv).

[FN165]. Henry, supra note 74, at 621; see also Dahl-Eimers v. Mutual of Omaha Life Ins. Co., 812 F. Supp. 1193, 1196 (N.D. Fla. 1992); 21 C.F.R. § 312.21 (1999).

[FN166]. 21 C.F.R. § 312.21(a); Henry, supra note 74, at 621.

[FN167]. Dahl-Eimers, 812 F. Supp. at 1196.

[FN168]. 21 C.F.R. § 312.21(a); Henry, supra note 74, at 621.

[FN169]. Henry, supra note 74, at 621.

[FN170]. Dahl-Eimers, 812 F. Supp. at 1196; 21 C.F.R. § 312.21(b).

[FN171]. 21 C.F.R. § 312.21(b); Henry, supra note 74, at 621.

[FN172]. Henry, supra note 74, at 621.

[FN173]. 21 C.F.R. § 312.21(c).

[FN174]. Dahl-Eimers, 812 F. Supp. at 1196; 21 C.F.R. § 312.21(c).

[FN175]. Henry, supra note 74, at 621.

[FN176]. Id. at 622.

[FN177]. Id.

[FN178]. 45 C.F.R. § 46.101(a) (1998); Richard S. Saver, Critical Care Research and Informed Consent, 75 N.C. L. Rev. 205, 215-16 (1996).

[FN179]. 21 C.F.R. § 56.115 (1999); 45 C.F.R. § 46.115.

[FN180]. 21 C.F.R. § 50.20; 45 C.F.R. § 46.116.

[FN181]. Harold Y. Vanderpool, The Ethics of Research Involving Human Subjects: Facing the 21st Century 12 (1996).

[FN182]. Id.

[FN183]. Id.

[FN184]. Id. at 12-13.

[FN185]. See infra Part V.

[FN186]. Prior to December 31, 1999, the Rhode Island statute also mandated coverage for Phase II clinical trials. R.I. Gen. Laws § 27-18-36.2 (1998).

[FN187]. Vanderpool, supra note 181, at 214.

[FN188]. Cal. Health & Safety Code § 123985 (West 1995); Cal. Welf. & Inst. Code § 14133.8 (West 1995).

[FN189]. Cal. Health & Safety Code § 1370.4 note (West Supp. 1999) (Historical and Statutory Notes).

[FN190]. Cal. Health & Safety Code § 1370.4(g) (West Supp. 1999).

[FN191]. Cal. Health & Safety Code § 1370.4 (West Supp. 1999) is too lengthy to quote in its entirety, but provides in part as follows:

(a) Every health care service plan shall provide an external, independent review process to examine the plan's coverage decisions regarding experimental or investigational therapies for individual enrollees who meet all of the following criteria:

(1) The enrollee has a terminal condition that, according to the enrollee's physician's current diagnosis, has a high probability of causing death within two years from the date of the request for an independent review; and

(2) The enrollee's physician certifies that the enrollee has a condition, as defined in paragraph (1), for which standard therapies have not been effective in improving the condition of the enrollee, or for which standard therapies would not be medically appropriate for the enrollee, or for which there is no more beneficial standard therapy covered by the plan than the therapy proposed pursuant to paragraph (3); and

(3) Either (A) the enrollee's physician, who is under contract with or employed by the plan, has recommended a drug, device, procedure or other therapy that the physician certifies in writing is likely to be more beneficial to the enrollee than any available standard therapies, or (B) the enrollee, or the enrollee's physician who is a licensed, board-certified or board-eligible physician qualified to practice in the area of practice appropriate to treat the enrollee's condition, has requested a therapy that, based on two documents from the medical and scientific evidence,

as defined in subdivision (d), is likely to be more beneficial for the enrollee than any available standard therapy. The physician certification pursuant to this subdivision shall include a statement of the evidence relied upon by the physician in certifying his or her recommendation. Nothing in this subdivision shall be construed to require the plan to pay for the services of a nonparticipating physician provided pursuant to this subdivision, that are not otherwise covered pursuant to the plan contract; and

(4) The enrollee has been denied coverage by the plan for a drug, device, procedure or other therapy recommended or requested pursuant to paragraph (3); and

(5) The specific drug, device, procedure or other therapy recommended pursuant to paragraph (3) would be a covered service, except for the plan's determination that the therapy is experimental or investigational; and

(6) This section shall not apply to any Medi-Cal beneficiary enrolled in a health care service plan under the plan's contract with the Medi-Cal program.

(b) The plan's external, independent review shall meet the following criteria:

(1) the plan shall offer all enrollees who meet the criteria in subdivision (a) the opportunity to have the requested therapy reviewed under the external, independent review process. The plan shall notify eligible enrollees in writing of the opportunity to request the external independent review within five business days of the decision to deny coverage.

(2) The plan shall contract with one or more impartial, independent entities that are accredited pursuant to subdivision (c). The entity shall arrange for review of the coverage decision by selecting an independent panel of at least three physicians or other providers who are experts in the treatment of the enrollee's medical condition and knowledgeable about the recommended therapy. If the entity is an academic medical center accredited in accordance with subdivision (e), the independent panel may include experts affiliated with or employed by the entity. A panel of two experts may be arranged at the plan's request, provided the enrollee consents in writing. The independent entity may arrange for a panel of one expert only if the independent entity certifies in writing that there is only one expert qualified and able to review the recommended therapy. Neither the plan nor the enrollee shall choose or control the choice of the physician or other provider experts.

See also Cal. Ins. Code § 10145.3 (West Supp. 1999) (applying similar terms to disability insurers).

[FN192]. Cal. Health & Safety Code § 1370.4(b)(5) (West Supp. 1999) ("The enrollee shall not be required to pay for the external, independent review. The costs of the review shall be borne by the plan.").

[FN193]. Cal. Health & Safety Code § 1370.4(b)(7) (West Supp. 1999) provides:

The experts on the panel shall render their analyses and recommendations within 30 days of the receipt of the enrollee's request for review. If the enrollee's physician determines that the proposed therapy would be significantly less effective if not promptly initiated, the analyses and recommendations of the experts on the panel shall be rendered within seven days of the request for expedited review. At the request of the expert, the deadline shall be extended by up to three days for a delay in providing the documents required by paragraph (6) of subdivision (b).

[FN194]. Cal. Health & Safety Code § 1370.4(b)(10) (West Supp. 1999) provides:

If the majority of experts on the panel recommend providing the proposed therapy, pursuant to paragraph (8), the recommendation shall be binding on the plan. If the recommendations of the experts on the panel are evenly divided as to whether the therapy should be provided, then the panel's decision shall be deemed to be in favor of coverage. If less than a majority of the experts on the panel recommend providing the therapy, the plan is not required to provide the therapy. Coverage for the services required under this section shall be provided subject to the terms and conditions generally applicable to other benefits under the plan contract.

[FN195]. Id.

[FN196]. Daniels & Sabin, supra note 48, at 27, 34.

[FN197]. Id. at 33.

[FN198]. Id.

[FN199]. Id.

[FN200]. Id.

[FN201]. Id. at 33-34.

[FN202]. Carol Marie Cropper, In Texas, a Laboratory Test on the Effects of Suing H.M.O.'s, N.Y. Times, Sept. 13, 1998, at C3.

[FN203]. Id.

[FN204]. Corporate Health Ins. Inc. v. Texas Dep't of Ins., 12 F. Supp. 2d 597 (S.D. Tex. 1998); see also discussion of ERISA preemption infra Part III.D.2.

[FN205]. Renae Merle, Aetna, State Join Forces to Put Off HMO Ruling, Houston Chron., Sept. 23, 1998, at C4.

[FN206]. See Collins, supra note 10, at 481-82.

[FN207]. Hsia, supra note 11, at 552.

[FN208]. See N.J. Stat. Ann. § 17:48-6f note (West 1996) (Assembly Insurance Committee Statement).

[FN209]. Id.

[FN210]. 29 U.S.C. §§ 1001-1461 (1994).

[FN211]. Specifically, ERISA's coverage provision, 29 U.S.C. § 1003, reads in relevant part as follows:
(a) Except as provided in subsection (b) of this section and in sections 1051, 1081, and 1101 of this title, this subchapter shall apply to any employee benefit plan if it is established or maintained --
(1) by any employer engaged in commerce or in any industry or activity affecting commerce; or
(2) by any employee organization or organizations representing employees engaged in commerce or in any industry or activity affecting commerce; or
(3) by both.
(b) The provisions of this subchapter shall not apply to any employee benefit plan if --
(1) such plan is a governmental plan (as defined in section 1002(33) of this title);
(2) such plan is a church plan (as defined in section 1002(33) of this title) with respect to which no election has been made under section 410(d) of title 26;
(3) such plan is maintained solely for the purpose of complying with applicable workmen's compensation laws or unemployment compensation or disability insurancelaws;
(4) such plan is maintained outside of the United States primarily for the benefit of persons substantially all of whom are nonresident aliens; or
(5) such plan is an excess benefit plan (as defined in section 1002(36) of this title) and is unfunded.

[FN212]. See Hardester, supra note 7, at 298; Maggio, supra note 44, at 564.

[FN213]. 29 U.S.C. § 1144(a) (1994).

[FN214]. See Corcoran v. United HealthCare, Inc., 965 F.2d 1321 (5th Cir. 1992); Brundage-Peterson v. Compcare Health Servs. Ins. Corp., 877 F.2d 509 (7th Cir. 1989). In the Corcoran case, the defendant denied Mrs. Corcoran precertification for a hospital stay during her high-risk pregnancy. Instead, it allowed 10 hours a day of home nursing care. Subsequently, the fetus went into distress and died during a time when no nurse was present. The Fifth Circuit held that ERISA preempted the plaintiffs' medical malpractice claim and precluded recovery of emotional distress damages.

[FN215]. 29 U.S.C. § 1144(b)(2)(A) ("Except as provided in subparagraph (B), nothing in this subchapter shall be construed to exempt or relieve any person from any law of any State which regulates insurance, banking, or securities.").

[FN216]. Metropolitan Life Ins. Co. v. Massachusetts, 471 U.S. 724 (1985).

[FN217]. See id. at 735 n.14.

[FN218]. 29 U.S.C. § 1144(b)(B) provides:

(B) Neither an employee benefit plan described in section 1003(a) of this title, which is not exempt under section 1003(b) of this title (other than a plan established primarily for the purpose of providing death benefits), nor any trust established under such a plan, shall be deemed to be an insurance company or other insurer, bank, trust company, or investment company or to be engaged in the business of insurance or banking for purposes of any law of any State purporting to regulate insurance companies, insurance contracts, banks, trust companies, or investment companies.

[FN219]. FMC Corp. v. Holliday, 498 U.S. 52, 61 (1990) ("We read the deemer clause to exempt self-funded ERISA plans from state laws that 'regulat [[e] Insurance' within the meaning of the saving clause."); see also Metropolitan Life, 471 U.S. at 735 n.14.

[FN220]. 42 U.S.C. §§ 12101-12213 (1994).

[FN221]. See Hillsborough County, Fla. v. Automated Med. Labs Inc., 471 U.S. 707, 713 (1985) ("We have held repeatedly that state laws can be pre- empted by federal regulations as well as by federal statutes."); McDermott v. Wisconsin, 228 U.S. 115, 132 (1913).

[FN222]. 42 U.S.C. § 12112(a).

[FN223]. See 29 C.F.R. § 1630.4 (1998).

[FN224]. 29 C.F.R. § 1630.16(f).

[FN225]. Id.

[FN226]. S. Rep. No. 101-116, at 85 (1989).

[FN227]. EEOC Interim Guidance on Application of ADA to Health Insurance, EEOC Compl. Man. (BNA) No. 176 (June 8, 1993) (hereinafter Guidelines).

[FN228]. Id.

[FN229]. Id.

[FN230]. Henderson v. Bodine Aluminum, Inc. 70 F.3d 958, 960 (8th Cir. 1995).

[FN231]. Guidelines, supra note 227.

[FN232]. Id. The language reads as follows:
b. The respondent may prove that the disparate treatment is justified by legitimate actuarial data, or by actual or reasonably anticipated experience, and that conditions with comparable actuarial data and/or experience are treated in the same fashion. In other words, the respondent may prove that the disability-based disparate treatment is attributable to the application of legitimate risk classification and underwriting procedures to the increased risks (and thus increased cost to the health insurance plan) of the disability, and not to the disability per se.
Id. (footnotes omitted).

[FN233]. Id.

[FN234]. Id. The Guidelines provide:
c. The respondent may prove that the disparate treatment is necessary (i.e., that there is no nondisability-based health insurance plan change that could be made) to ensure that the challenged health insurance plan satisfies the commonly accepted or legally required standards for the fiscal soundness of such an insurance plan. The respondent, for example, may prove that it limited coverage for the treatment of a discrete group of disabilities because continued unlimited coverage would have been so expensive as to cause the health insurance plan to become financially insolvent, and there was no nondisability-based health insurance plan alteration that would have avoided insolvency.
Id.

[FN235]. Id. The Guidelines state:
d. The respondent may prove that the challenged insurance practice or activity is necessary (i.e., that there is no nondisability-based change that could be made) to prevent the occurrence of an unacceptable change either in the coverage of the health insurance plan, or in the premiums charged for the health insurance plan. An "unacceptable" change is a drastic increase in premium payments (or in co-payments or deductibles), or a drastic alteration to the scope of coverage or level of benefits provided, that would: 1) make the health insurance plan effectively unavailable to a significant number of other employees, 2) make the health insurance plan so unattractive as to result in significant adverse selection, or 3) make the health insurance plan so unattractive that the employer cannot compete in recruiting and maintaining qualified workers due to the superiority of health insurance plans offered by other employers in the community.
Id. (footnote omitted).

[FN236]. Id.

[FN237]. Id.

[FN238]. Id.

[FN239]. Id. The relevant provision reads as follows:
e. Where the charging party is challenging the respondent's denial of coverage for a disability-specific treatment, the respondent may prove that this treatment does not provide any benefit (i.e., has no medical value). The respondent, in other words, may prove by reliable scientific evidence that the disability-specific treatment does not cure the condition, slow the degeneration/deterioration or harm attributable to the condition, alleviate the symptoms of the condition, or maintain the current health status of individuals with the disability who receive the treatment.
Id. (footnote omitted).

[FN240]. Since the ADA prohibits employers from discriminating against disabled employees, subscribers generally sue the employer providing benefits rather than the insurer directly. However, one court of appeals held that insurers may be acting as employers under the ADA when they administer benefits plans, and therefore they may be sued directly. Carparts Distribution Ctr., Inc. v. Automotive Wholesaler's Ass'n, 37 F.3d 12 (1st Cir. 1994); see also Kotev v. First Colony Life Ins. Co., 927 F. Supp. 1316 (C.D. Cal. 1996) (holding that the ADA prohibited denial of insurance to person whose spouse had AIDS).

[FN241]. 70 F.3d 958 (8th Cir. 1995).

[FN242]. Id. at 959.

[FN243]. Id. at 962.

[FN244]. Id. at 960.

[FN245]. Id. at 961.

[FN246]. McDermott v. Wisconsin, 228 U.S. 115 (1913).

[FN247]. 15 U.S.C. §§ 1101-1015 (1994).

[FN248]. 15 U.S.C. § 1012. The statute provides:
(a) State regulation
The business of insurance, and every person engaged therein, shall be subject to the laws of the several States which relate to the regulation or taxation of such business.
(b) Federal regulation
No Act of Congress shall be construed to invalidate, impair, or supersede any law enacted by any State for the purpose of regulating the business of insurance, or which imposes a fee or tax upon such business, unless such Act specifically relates to the business of insurance: Provided, That after June 30, 1948, the Act of July 2, 1890, as amended, known as the Sherman Act, and the Act of September 26, 1914, known as the Federal Trade Commission Act, as amended [15 U.S.C.A. 41 et seq.], shall be applicable to the business of insurance to the extent that such business is not regulated by State law.

[FN249]. 15 U.S.C. § 1012.

[FN250]. Len M. Nichols & Linda J. Blumberg, A Different Kind of 'New Federalism'? The Health Insurance Portability And Accountability Act of 1996, Health Affairs, May/June 1998, at 25, 27.

[FN251]. Id.

[FN252]. Mark A. Hall & Gerald F. Anderson, Health Insurers' Assessment of Medical Necessity, 140 U. Pa. L. Rev. 1637, 1663 (1992).

[FN253]. Id.

[FN254]. 42 U.S.C. §§ 300e - 300e-17 (1994).

[FN255]. Nichols & Blumberg, supra note 250, at 27.

[FN256]. 42 U.S.C. § 300e-10.

[FN257]. 42 U.S.C. § 300e-9.

[FN258]. 42 U.S.C. §§ 300e-4-300e-5.

[FN259]. Nichols & Blumberg, supra note 250, at 27.

[FN260]. 29 U.S.C. §§ 1001-1461 (1994).

[FN261]. 29 U.S.C. § 1144(a).

[FN262]. Nichols & Blumberg, supra note 250, at 28.

[FN263]. Id. The legislation is found at 42 U.S.C. § 1395ss (Supp. 1999).

[FN264]. Nichols & Blumberg, supra note 250, at 28.

[FN265]. Id.

[FN266]. Id.

[FN267]. Id.

[FN268]. Id. at 29-30; see also 42 U.S.C. § 1395ss.

[FN269]. 42 U.S.C. §§ 300gg - 300gg-92 (Supp. 1999).

[FN270]. Nichols & Blumberg, supra note 250, at 25.

[FN271]. 42 U.S.C. § 300gg(a). In the case of a late enrollee, the period of excluded coverage may be extended to 18 months. Id.

[FN272]. 42 U.S.C. § 300gg(a), (c).

[FN273]. 42 U.S.C. § 300gg-11.

[FN274]. Nichols & Blumberg, supra note 250, at 32.

[FN275]. Defined as consisting of two to fifty employees. 42 U.S.C. § 300gg-91(e)(4), (5).

[FN276]. 42 U.S.C. § 300gg-11.

[FN277]. 42 U.S.C. § 300gg-12.

[FN278]. 42 U.S.C. § 300gg-41.

[FN279]. Id.

[FN280]. 42 U.S.C. § 300gg-42.

[FN281]. 42 U.S.C. § 300gg-4(a) (Supp. 1999).

[FN282]. Id.

[FN283]. 29 U.S.C. § 1185b (Supp. 1999).

[FN284]. 29 U.S.C. § 1185b(a) provides:
IN GENERAL.--A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, that provides medical and surgical benefits with respect to a mastectomy shall provide, in a case of a participant or beneficiary who is receiving benefits in connection with a mastectomy and who elects breast reconstruction in connection with such mastectomy, coverage for --
(1) all stages of reconstruction of the breast on which the mastectomy has been performed;
(2) surgery and reconstruction of the other breast to produce a symmetrical appearance; and
(3) prostheses and physical complications of mastectomy, including lymphedemas;
in a manner determined in consultation with the attending physician and the patient. Such coverage may be subject to annual deductibles and coinsurance provisions as may be deemed appropriate and as are consistent with those established for other benefits under the plan or coverage. Written notice of the availability of such coverage shall be delivered to the participant upon enrollment and annually thereafter.

[FN285]. See H.R. 616, 105th Cong., 1st Sess. (1997); S. 249, 105th Cong., 1st Sess. (1997); S. 2330, 105th Cong., 2d Sess. § 715 (1998).

[FN286]. S. 2330 § 715(a)(1), for example, provides:
(1) IN GENERAL--A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, that provides medical and surgical benefits shall ensure that inpatient coverage with respect to the surgical treatment of breast cancer (including a mastectomy, lumpectomy, or lymph node dissection for the treatment of breast cancer) is provided for a period of time as is determined by the attending physician, in his or her professional judgment consistent with scientific evidence-based practices or guidelines, in consultation with the patient, to be medically appropriate.

[FN287]. Nichols & Blumberg, supra note 250, at 26 (citing B.K. Atchinson & D.M. Fox, The Politics of the Health Insurance Portability and Accountability Act, Health Affairs, May-June 1997, at 146-150).

[FN288]. Id. at 26 (citing R.E. Moffit, What to Do about the Kassebaum- Kennedy Bill, Heritage Found. Issue Bull., June 5, 1996, at 226).

[FN289]. H.R. 3600, 103d Cong., 1st Sess. (1993); S. 1757, 103d Cong. 1st Sess. (1993).

[FN290]. H.R. 3600 § 1128 and S. 1757 § 1128 provided as follows:
(a) COVERAGE- Subject to subsection (b), the items and services described in this subsection are qualifying investigational treatments that are administered for a life-threatening disease, disorder, or other health condition (as defined by the National Health Board).
(b) DISCRETION OF PLAN- A health plan may cover an investigational treatment described in subsection (a) at its discretion.
(c) ROUTINE CARE DURING INVESTIGATIONAL TREATMENTS- The comprehensive benefit package includes an item or service described in any other section of this part, subject to the limitations and cost sharing requirements applicable to the item or service, when the item or service is provided to an individual in the course of an investigational treatment, if --

(1) the treatment is a qualifying investigational treatment; and
(2) the item or service would have been provided to the individual even if the individual were not receiving the investigational treatment.
(d) DEFINITIONS- For purposes of this subtitle:
(1) QUALIFYING INVESTIGATIONAL TREATMENT- The term 'qualifying investigational treatment' means a treatment --
(A) the effectiveness of which has not been determined; and
(B) that is under clinical investigation as part of an approved research trial.
(2) APPROVED RESEARCH TRIAL- The term 'approved research trial' means --
(A) a research trial approved by the Secretary of Health and Human Services, the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, the Secretary of Veterans Affairs, the Secretary of Defense, or a qualified nongovernmental research entity as defined in guidelines of the National Institutes of Health; or
(B) a peer-reviewed and approved research program, as defined by the Secretary of Health and Human Services, conducted for the primary purpose of determining whether or not a treatment is safe, efficacious, or having any other characteristic of a treatment which must be demonstrated in order for the treatment to be medically necessary or appropriate.

[FN291]. H.R. 3600 § 1128(d)(1); S. 1757 § 1128(d)(1).

[FN292]. H.R. 3600 § 1128; S. 1757 § 1128.

[FN293]. See, e.g., H.R. 2723, 106th Cong., 1st Sess. (1999); H.R. 2926, 106th Cong., 1st Sess. (1999); H.R. 2990, 106th Cong., 1st Sess. (1999); H.R. 3110, 106th Cong., 1st Sess. (1999).

[FN294]. H.R. 2723, 106th Cong., 1st Sess. (1999).

[FN295]. H.R. 2723, § 119 provides as follows:
(a) Coverage.
(1) In General. If a group health plan, or health insurance issuer that is providing health insurance coverage, provides coverage to a qualified individual (as defined in subsection (b)), the plan or issuer --
(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);
(B) subject to subsection (c), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and
(C) may not discriminate against the individual on the basis of the enrollee's participation in such trial.
(2) Exclusion of certain costs. For purposes of paragraph (1)(B), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.
(3) Use of in-network providers. If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.
(b) Qualified Individual Defined. For purposes of subsection (a), the term "qualified individual" means an individual who is a participant or beneficiary in a group health plan, or who is an enrollee under health insurance coverage, and who meets the following conditions:
(1)(A) The individual has a life-threatening or serious illness for which no standard treatment is effective.
(B) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.
(C) The individual's participation in the trial offers meaningful potential for significant clinical benefit for the individual.
(2) Either --
(A) the referring physician is a participating health care professional and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or
(B) the participant, beneficiary, or enrollee provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).
(c) Payment.
(1) In general. Under this section a group health plan or health insurance issuer shall provide for payment for

routine patient costs described in subsection (a)(2) but is not required to pay for costs of items and services that are reasonably expected (as determined by the Secretary) to be paid for by the sponsors of an approved clinical trial.

(2) Payment rate. In the case of covered items and services provided by --

(A) a participating provider, the payment rate shall be at the agreed upon rate, or

(B) a nonparticipating provider, the payment rate shall be at the rate the plan or issuer would normally pay for comparable services under subparagraph (A).

(d) Approved Clinical Trial Defined.

(1) In general. In this section, the term "approved clinical trial" means a clinical research study or clinical investigation approved and funded (which may include funding through in-kind contributions) by one or more of the following:

(A) The National Institutes of Health.

(B) A cooperative group or center of the National Institutes of Health.

(C) Either of the following if the conditions described in paragraph (2) are met:

(i) The Department of Veterans Affairs.

(ii) The Department of Defense.

(2) Conditions for departments. The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines --

(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

(e) Construction. Nothing in this section shall be construed to limit a plan's or issuer's coverage with respect to clinical trials.

[FN296]. Id. § 119(a)(1).

[FN297]. Id. § 119(b)(1)(A).

[FN298]. Id. § 119(b)(1)(C).

[FN299]. H.R. 2723.

[FN300]. Id.

[FN301]. H.R. 3110, 106th Cong., 1st Sess. (1999). Coverage is required for all phases of clinical trials.

[FN302]. See discussion supra Part IV.B.4.

[FN303]. Based in large part on and borrowing language from R.I. Gen. Laws § 27- 18-36.2 (1998).

[FN304]. See Harness, supra note 69, at 96.

[FN305]. Based upon and borrowing language from Cal. Health & Safety Code § 1370.4 (West Supp. 1999).

[FN306]. Henry, supra note 74, at 621.

[FN307]. Id.

[FN308]. Vanderpool, supra note 181, at 331; Susan Okie, Shying Away from the Cutting Edge; Shortage of Patients in Clinical Trials Inhibits Cancer Research, Study Says, Wash. Post, June 1, 1999, at Z07 (discussing a new survey released at the annual meeting of the American Society for Clinical Oncology in May of 1999).

[FN309]. Okie, supra note 308.

[FN310]. Vanderpool, supra note 181, at 193.

[FN311]. Id. at 193-194.

[FN312]. Id. at 11.

[FN313]. Id. at 12.

[FN314]. 21 C.F.R. § 312.7(d)(1) (1999). The regulation states:
Charging for an investigational drug in a clinical trial under an IND is not permitted without the prior written approval of FDA. In requesting such approval, the sponsor shall provide a full written explanation of why charging is necessary in order for the sponsor to undertake or continue the clinical trial, e.g. why distribution of the drug to test subjects should not be considered part of the normal cost of doing business.
Id.

[FN315]. Daniels & Sabin, supra note 48, at 27-28.

[FN316]. Id. at 29.

[FN317]. See, e.g., L.M. Sixel, Insurance Plans Will Cover Therapy for Breast Cancer, Houston Chron., Apr. 17, 1998, at 1C (reporting that several employers reached an agreement with the Houston District Office of the Equal Employment Opportunity Commission to reimburse enrollees for treatment of breast cancer by HDC-ABMT).

[FN318]. Harness, supra note 69, at 92.

[FN319]. Wolf, supra note 30, at 2103.

[FN320]. Voigt & Conlon, supra note 90, at 401.

[FN321]. That is, unless state law or their own policy language compels such coverage.

[FN322]. Some may fear that mandatory coverage for experimental treatments provided in Phase III clinical trials may soon lead to further legislative mandates regarding coverage of Phase I and Phase II clinical trials. Experience has shown that narrowly-tailored statutory requirements at the state level have not led to a deluge of additional legislation regarding reimbursement for experimental treatments. Moreover, if more expansive and less reasonable legislation were to be proposed, the insurance industry would have ample opportunity to lobby Congress, work with the media, and build public support to defeat such legislation.

[FN323]. Okie, supra note 308.

[FN324]. Daniels & Sabin, supra note 48, at 31 ("[M]andates would make it impossible to continue proper clinical trials aimed at assessing efficacy [of treatment]."); see also Saver, supra note 2, at 1130 (referring to the "'chilling effect' on development and study of new technologies").

[FN325]. See sources cited supra note 322.

[FN326]. Not all experimental treatment is subject to federal regulations which require IRB review and formal clinical trials. 45 C.F.R. § 46.116 (1998). Therefore, some patients will be able to find physicians who provide the procedure without conducting a research study. See High-Dose Chemotherapy, supra note 45, at 119 ("[R]esearch examining HDC's potential in breast cancer has been hindered by the fact that the overwhelming majority of women who have undergone the procedure in the United States have done so outside of clinical trials."); see also Gina Kolato & Kurt Eichenwald, Hope for Sale: A Special Report; Business Thrives on Unproven Care, Leaving Science Behind, N.Y. Times, Oct. 3, 1999, at A1 ("An increasing number of untested treatments are being sold to desperate patients with ailments like cancer, heart failure and Parkinson's disease. Today, experimental procedures can be purchased outright from community hospitals, university medical centers and even from publicly traded companies.").

[FN327]. Ader, supra note 26, at 57-58.

[FN328]. Id.

[FN329]. Id.

[FN330]. Saver, supra note 2, at 1130.

[FN331]. See id. at 1130 n.198 (suggesting that "where possible, the new treatment could be compared to data from other trials or to historical controls"); see also Baruch A. Brody, Ethical Issues in Drug Testing, Approval, and Pricing 124 (1995). Brody suggests the following:

[I]t is ethical to withhold from a control group a therapy that has not yet been formally approved but that has been shown in one or more trials to be effective and safe, even if the subjects in the placebo control group are thereby exposed to a greater risk of long-term losses, only if those losses and the probabilities of their occurring are sufficiently small that (1) the subject, informed of all of this, freely consents to being randomized into the trial and (2) reasonable people, of an average degree of altruism and risk-aversiveness, informed of all this, might consent to being randomized into the trial.

Id.; see also Carol Gentry, Second Opinion Why Medicare Covers A New Lung Surgery For Just a Few Patients, Wall St. J., June 29, 1998, at A1. The article reports that Blue Cross & Blue Shield of Massachusetts in conjunction with other insurers and medical centers in the state, is conducting a clinical trial designed to test the efficacy of a surgical procedure known as lung- volume reduction to treat emphysema. The study will utilize a control group, but patients will be able to cross over and undergo the surgery after just six months, rather than five years, as is the case in other clinical trials.

[FN332]. Dahl-Eimers v. Mutual of Omaha Life Ins. Co., 812 F. Supp. 1193, 1196 (N.D. Fla. 1992).

[FN333]. 45 C.F.R. § 46.111 (1998).

[FN334]. GAO Report, supra note 63, at 28, 42.

[FN335]. Edmund Polubinski III, Note, Closing the Channels of Communication: A First Amendment Analysis of the FDA's Policy on Manufacturer Promotion of "Off-Label" Use, 83 Va. L. Rev. 991, 1030 n.235 (1997); see also States Move Multiple Healthcare Bills in Fledgling Legislative Session, Health Legis. & Reg. Wkly., Mar. 26, 1997, available in 1997 WL 8740227, at *1.

[FN336]. 1993 N.J. Sess. Law Serv. 321 (West); see also Off-Label Uses of FDA-Approved Drugs May Help Contain Health Care Costs in New Jersey, 6 Loy. Consumer L. Rep. 88 (1994) [hereinafter Off-Label Uses].

[FN337]. See Off-Label Uses, supra note 336.

[FN338]. Id.

[FN339]. American Med. Ass'n, AMA Drug Evaluations Annual 1995, at iii-iv.

[FN340]. See Harness, supra note 69, at 96.

[FN341]. See supra Part I.A.

[FN342]. See Gentry, supra note 331, at A1.

[FN343]. H.R. 2824, 106th Cong., 1st Sess. (1999).

[FN344]. Id. §§ 102 and 103.

[FN345]. H.R. 2723, 106th Cong., 1st Sess. §§ 102 and 103 (1999).

[FN346]. Id. § 103(a)(2)(A)(i).

[FN347]. Robert Pear, States Take Lead in Health Legislation, N.Y. Times, Sept. 14, 1998, at A12.

[FN348]. Id.; see also Molly Tschida, Bridging the Gap: Court Decisions Clear Path for HMO Liability, Modern Physician, June 1, 1999, at 50.

[FN349]. Daniels & Sabin, supra note 48, at 33-34.

[FN350]. Id. at 39.