"Experimental Treatment": Legislating Against Unfair Denials

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NOTE

"EXPERIMENTAL TREATMENT": LEGISLATING AGAINST UNFAIR DENIALS

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The wheels of justice are grinding exceedingly slowly.

"[T]here’s no excuse for further inaction. . . . At issue is legislation that would require insurers and HMOs to follow uniform standards when making life-and-death decisions about which drugs and treatments they will cover. The present system is akin to roulette."

"The majority of people are concerned that if they should get sick and they’re in a managed care plan, the decision made by the plan will put cost savings first and quality of care second."

I. INTRODUCTION

Health insurers and health maintenance organizations (“HMOs”) play a vital role in the overlapping social and economic spheres of modern civilization. Every year, thousands of desperately ill patients and their families “are forced to wrestle with their health insurance carriers over coverage for treatments that might save their lives.”

Doctors categorize the health insurance industry as arbitrary and capricious in deciding who is covered for a particular “experimental” treatment. The pa-

2. Carol Eisenberg, HMOs Face a Backlash: Consumers Fuel Fight for ‘Patient Rights,’ NEWSDAY (Long Island), June 7, 1998, at A5 (quoting Art Levin, director of the Center for Medical Consumers, a Manhattan advocacy group).
3. Alexander Pete Grannis, Your HMO Shouldn’t Cost You Your Life, TIMES UNION (Albany), Jan. 2, 1996, at A8. Assemblyman Grannis is chairman of the New York State Assembly’s Committee on Insurance. See id. It has been reported that “tens of millions of consumers have moved from fee-for-service insurance into managed care,” and “[p]olls show nearly half of all consumers say they, or someone they know, has experienced difficulty with their managed care plan trying to see a specialist, getting a plan to pay for an emergency room bill, or appealing denied care.” Eisenberg, supra note 2, at A5.
4. See William P. Peters & Mark C. Rogers, Variation in Approval by Insurance Companies of Coverage for Autologous Bone Marrow Transplantation for Breast Cancer, 330 NEW ENG. J. MED. 473 (1994); Tim Friend, Insurers Called ‘Capricious’: Doctors Hit Decisions on Test Therapy, USA TODAY, Feb. 17, 1994, at 1A. Courts have also recognized the arbitrary and capricious nature of these decisions. See Helman v. Plumbers & Steamfitters Local 166 Health & Welfare Trust, 803 F. Supp. 1407, 1413-14 (N.D. Ind. 1992) (holding that denial of coverage for autologous bone marrow transplantation (“ABMT”) for a breast cancer patient was arbitrary and capricious); Bucci v. Blue Cross-Blue Shield, Inc., 764 F. Supp. 728, 731-32 (D. Conn. 1991); Kulakowski v. Rochester Hosp. Serv. Corp., 779 F. Supp. 710 (W.D.N.Y. 1991) (granting a preliminary injunction favoring a breast cancer patient, and holding that the conclusion that ABMT is an “experimental” treatment was arbitrary and capricious); White v. Caterpillar, Inc., 765 F. Supp. 1418 (W.D. Mo. 1991) (granting a temporary injunction and holding that the insurer’s determination that ABMT was an “investigational treatment” was arbitrary and capricious where ABMT was sought for a breast cancer patient); Adams v. Blue Cross/Blue Shield, Inc., 757 F. Supp. 661 (D. Md. 1991) (holding that ABMT is not experimental for breast cancer, and overturning the decision
patient’s own physician normally prescribes these potentially life-saving treatments, either based upon state-of-the-art recommendations in medical literature or as part of a formal clinical trial run by a nationally recognized research center. In spite of the seemingly standard nature of this procedure, “many HMO and indemnity insurers often refuse to reimburse for the care because they deem it ‘experimental’ or ‘investigative’ in nature, and thus outside the terms of their contracts.”

Regardless of studies supporting the use of these treatments, delays and denials of coverage continue. For example, Memorial Sloan-Kettering Cancer Center indicated that the overall cost of treating five specific cancers was lower for patients in clinical trials than in conventional treatment programs. Furthermore, today’s experimental protocols are frequently the proven cures of tomorrow, yielding dramatically improved prognoses.

The Food and Drug Administration’s (“FDA”) process of drug approval gives insurers and HMOs some guidance in deciding when a drug is no longer experimental, but there is no other nationwide and little statewide guidance on this question. Due to this lack of guidance, insurers and HMOs often refuse to reimburse for the care because they deem it ‘experimental’ or ‘investigative’ in nature, and thus outside the terms of their contracts. Regarding the use of these treatments, delays and denials of coverage continue. For example, Memorial Sloan-Kettering Cancer Center indicated that the overall cost of treating five specific cancers was lower for patients in clinical trials than in conventional treatment programs. Furthermore, today’s experimental protocols are frequently the proven cures of tomorrow, yielding dramatically improved prognoses.

The Food and Drug Administration’s (“FDA”) process of drug approval gives insurers and HMOs some guidance in deciding when a drug is no longer experimental, but there is no other nationwide and little statewide guidance on this question. Due to this lack of guidance, insurers and HMOs often refuse to reimburse for the care because they deem it ‘experimental’ or ‘investigative’ in nature, and thus outside the terms of their contracts.
economically-driven treatment decisions by managed care administrators have contributed to an increased wave of denial-of-treatment claims across the nation.9 Delays in paying for treatments are valuable to insurers, allowing them to invest premiums for longer terms, producing higher returns.10 While managed care advocates commend their treatment cost controls for limiting the bite that health care takes from the gross national product, premiums have remained elevated and corporate profits have skyrocketed.11 “‘Only solid consumer protections and quality of care standards will ensure that medical decisions are not overridden by insurance company bookkeepers.”’

Only twelve states have created legislation requiring insurers and HMOs to provide coverage, under certain conditions, for treatments labeled as experimental or “investigative.”13 Those enactments have explicitly limited applications to a particular treatment, a specific disease, or a narrow class of diseases.14 Victims of disease in the remaining thirty-eight states without any type of statute requiring coverage for experimental treatments are in the same predicament as those in the aforementioned twelve states who suffer from something other than the few statutorily covered diseases. The patients are at the mercy of insurer and HMO personnel, who are free to decide whether a treatment is experimental or not, whether or not its cost will be covered, and with no guarantee that these decision-makers will consistently follow the criteria that have usually been created by the insurer for the plan’s benefit.15

Generally, insurers depend heavily on peer-reviewed medical literature and on the opinions of experts inside and outside of their companies to decide whether they will cover a new or experimental treat-

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10. See Friend, supra note 4, at 1A.
11. See Reuben, supra note 9, at 55 (reporting that according to the United States Department of Health and Human Services, health care accounted for 14 percent of the nation’s gross domestic product in 1994).
12. ND Issue, supra note 7 (quoting Deborah Senn, Washington State Insurance Commissioner).
13. See infra Part III.A-B.
14. At the present time, one in eight women is expected to contract breast cancer in her lifetime, and breast cancer is the second leading cause of cancer deaths among American women. See Jaggar, supra note 8, at 3; see also infra Part III.A-B (discussing various states legislative reactions to the high incidents of breast cancer).
15. See Friend, supra note 4, at 1A; see also Jaggar, supra note 8, at 10 (reporting that courts frequently allow insurers broad discretion in making coverage decisions, as long as they are not arbitrary and capricious).
ment. However, regardless of the blanket policy, costly and complicated procedures usually require pre-approval. The reason given for the pre-approval requirement is that insurers want to be certain that the case meets coverage restrictions and that the therapy is medically appropriate “for that particular patient,” while for difficult cases, some groups use a panel of experts from outside of the plan to mediate the determination.

Occasionally, a condition for coverage requires that the patient enroll in clinical trials. The medical profession recognizes that clinical trials are necessary for the proper evaluation of new treatments. Approval by the insurer is usually required before the proposed treatment can be provided in a clinical trial. Doctors from Duke University Medical Center examined the consistency of decisions to approve treatments made by insurance companies for 533 patients enrolled in grant-supported clinical trials of high-dose chemotherapy and autologous bone marrow transplantation (“ABMT”) for breast cancer from 1989 through 1992. ABMT is regarded as a standard treatment for certain types of leukemia and lymphoma. The results of the Duke

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16. See Jaggar, supra note 8, at 8.
17. See id. (evaluating the opinions of decision-makers at some of the nation’s largest insurance companies and managed care plans who were interviewed by the United States General Accounting Office).
18. See id.
19. See id.
20. Clinical trials are medical experiments which test procedures or drugs on human subjects to evaluate their safety and effectiveness. Phase I trials represent the first time that a new drug or treatment is administered to humans. The participants are usually healthy adult males. The purpose of Phase I trials is to determine the dose that can be administered with an acceptable level of toxicity. Phase II trials involve actual patients and are designed to evaluate effectiveness and optimal dose rate. Phase III trials are created to measure a treatment’s effectiveness and adverse side effects with large numbers of patients receiving a conventional treatment. Phase IV trials randomize patient groups to determine whether a treatment or drug is superior to conventional treatments or drugs. See generally Jaggar, supra note 8 (describing the role of clinical trials in developing experimental treatments); see also Denise S. Wolf, Comment, Who Should Pay For “Experimental” Treatments? Breast Cancer Patients v. Their Insurers, 44 AM. U. L. REV. 2029, 2041-42 (1995).
21. See Peters & Rogers, supra note 4, at 473. An Illinois committee is deliberating over legislation that would determine whether insurers would be required to pay for experimental cancer treatments. The issue involves clinical trials, and leading oncologists are in favor of the coverage, claiming that denials of payment limit the development of new treatments and could lead to substandard care for patients. See Illinois: Panel To Consider Experimental Treatments, STATE NEWS BRIEFS, Sept. 6, 1996, available in LEXIS, News Library, Curnws File.
22. See Friend, supra note 4, at 1A (recounting a study reported in the New England Journal of Medicine).
23. See id. While ABMT is an expensive treatment, its cost per patient has been dropping in recent years. Some medical centers have reduced the cost by offering the treatment as more of an outpatient procedure. There is general agreement that ABMT is worth the cost if it is shown to be
study indicated that coverage for ABMT was approved for 412 of the patients, however, ninety-five of those patients did not undergo the bone marrow transplant for protocol-based or medical reasons. Insurance coverage was denied for the remaining 121 patients, primarily because the procedure was considered “experimental.” Sixty-two of those patients eventually underwent bone marrow transplantation despite the denial of coverage. Of the sixty-two, nineteen obtained coverage after hiring an attorney and twenty-three had the transplant without coverage. Preliminary data showed that seventy percent of the patients who received this experimental treatment remained alive and disease-free for five years, contrasted with a thirty percent rate for those who underwent conventional treatment. Medical literature has reported several studies of poor-prognosis breast cancer patients, showing superior outcomes for patients receiving ABMT when compared to those receiving conventional therapy. These superior outcomes included longer periods before relapse and improved survival rates.

The Duke study found that the frequency of approved coverage was not influenced by the pretreatment clinical condition of the patients, the design of the study, the phase of the study, the year in which the request was made, or the patients response to other therapy. It found that the denials on experimental grounds were arbitrary as they varied among insurers, and that they were even inconsistent within individual carriers for patients in the same study protocol. The Duke study concluded that the insurers’ pre-approval processes, as applied to patients receiving care in clinical research trials of cancer therapy, were arbitrary and capricious, did not correlate with protocol-based medical decision-making, and were barriers to obtaining treatment. Another independent source, a federal General Accounting Office study of Medicare reim-

24. See id.
25. See id.
26. See Jaggar, supra note 8, at 6; William P. Peters et al., High-Dose Chemotherapy and Autologous Bone Marrow Support as Consolidation After Standard-Dose Adjuvant Therapy for High-Risk Primary Breast Cancer, 11 J. CLINICAL ONCOLOGY 1132, 1132 (1993). Most of the clinical trials that have been done to evaluate ABMT for breast cancer patients have been Phase I and Phase II trials, which are of limited use in definitively establishing the treatment’s effectiveness compared to conventional treatment. The National Cancer Institute (“NCI”) is currently conducting three randomized clinical trials to settle the issue, but these will not be completed until nearly the year 2000. See Jaggar, supra note 8, at 5.
27. See Peters et al., supra note 26, at 1132-1140. The results of randomized clinical trials, however, are needed to provide definitive data on the treatment’s efficacy. See id.
28. See Friend, supra note 4, at 1A.
29. See Peters & Rogers, supra note 4, at 473.
bursement for breast cancer treatment, reached a similar conclusion with respect to inconsistency both within the same and among different insurers. Some pre-approval denials have been based solely on cost concerns. Insurers dispute that finding, and explain that the reasons for the variation in coverage decisions include the fact that most people with insurance are in programs in which an employer decides what is covered. Along either line of reasoning, there is a clear need for uniform criteria to determine whether coverage should be required for a treatment which has been labeled experimental by an insurer or HMO in order to avoid inappropriate decisions based purely on economics or dictated by employers lacking medical training.

This Note argues that the vast majority of state legislatures fail to adequately protect their constituents from insurers and HMOs that arbitrarily or discriminatorily label costly prescribed treatments as experimental or investigative and thereby delay or deny appropriate treatment or reimbursement. Part II suggests prerequisites for the standards needed to determine which treatments should receive coverage, and it reports on the success of claims regarding denial or delay of coverage in the courts. Part III examines inconsistencies between state and federally funded health insurance programs, and compares state statutory responses to the need for uniform standards regarding treatments labeled experimental. Part IV proposes elements for a model statute. Part V concludes by suggesting that legislators utilize their authority to better regulate insurers and HMOs with regard to their coverage of experimental and "investigational" treatments by implementing the elements of the proposed model statute. Finally, the Appendix proposes a model statute incorporating the elements necessary to provide uniform coverage for experimental treatments.

II. CLAIMS IN THE COURTS

Recent decisions concerning denial of coverage claims have highlighted the need for uniform standards. For example, the Louisiana Court of Appeals in Waldrip v. Connecticut National Life Insurance Co., determined that the insurer failed to sufficiently investigate the applicability of its own experimental treatment exclusion to an insured’s

30. See Grannis, supra note 3, at A8.
31. See Reuben, supra note 9, at 55.
32. See id.
claim for coverage of medical expenses incurred for a liver transplant. The insurer's assistant vice-president, responsible for the ultimate decision regarding the experimental treatment exclusion, testified that his decision was not based on whether liver transplantation was accepted as essential to treatment of end-stage liver disease by any of the government agencies listed in the policy as determinant of that issue. As a result, the court affirmed the trial court's finding that the insurer did not have just and reasonable grounds to deny the claim.

Fox v. Health Net also involved a critical denial of coverage. In this case, the HMO refused to pay for a $100,000 bone marrow transplant, contending that the transplant was experimental at Fox's advanced stage of breast cancer, and therefore not covered. The plaintiffs claimed that the policy language clearly indicated that the treatment should have been covered and sued on the grounds that the delay, which forced the patient to raise funds for the treatment, lessened her chances for survival. The patient died, and her family pursued the claim and won an $89 million jury award which was later reduced in a settlement after a hearing on Health Net's motion for a new trial. At the time, however, the award was the largest ever against an insurer for denying coverage for a procedure.

Unlike these cases, some claims based on delayed or denied experimental treatments never make it to court. Many patients appeal within the HMOs or through the insurer's internal review process and simply accept the decision resulting from that review. Furthermore, many claims never reach court because HMOs often require the arbitration of such claims. In numerous other situations, patients, improperly denied treatments or delayed treatment funding, did not bring suit because they were too ill, too poor, or died.

Insurers have admitted and a review of case law has revealed that when claims do make it to court, jurisdictions have been widely inconsistent as to whether a particular treatment is considered experimental or

34. See id. at 1175-77.
35. See id.
36. See id.
38. See id.; Reuben, supra note 9, at 55.
39. See Reuben, supra note 9, at 55.
41. See id.
42. See Reuben, supra note 9, at 56.
should be covered. These rulings usually focus on the language of the insurance contract, which generally bars coverage for experimental treatments but is frequently ambiguous in defining what constitutes experimental. Court decisions, such as those deciding whether to cover ABMT treatment for breast cancer, usually consider whether the protocol is generally accepted in the medical community, whether experimental treatment is clearly defined in the insurance policy, whether the treatment is intended primarily to benefit the patient or to further medical research, and whether the insurer’s denial of coverage was influenced by its own economic self-interest. Many courts upholding coverage denials give insurers broad discretion in coverage decisions as long as they are not arbitrary or capricious. Plaintiffs have recently begun to allege that denial of coverage for breast cancer treatments constitutes discrimination against women in violation of state and federal civil rights laws, and that it constitutes disability discrimination against victims of a specific disease in violation of state laws and the Americans with Disabilities Act. The growing number of causes of action further demonstrates the need for legislatively uniform criteria to prevent inconsistencies in coverage decision-making.

Scholars have argued that when courts decide the experimental status of particular medical treatments, they should do so under strict guidelines. The courts are not as well equipped as the legislature, however, to decide the experimental status of particular medical treatments.

43. See Jaggar, supra note 8, at 10. Jaggar reports that a recent review of such litigation has revealed that state courts have tended to favor policyholders in coverage disputes, while federal courts, hearing most of the disputes for self-insured companies, have been split on whether an insurer must cover a particular treatment for a specific disease. At least three federal circuits have upheld insurers’ coverage denials for ABMT treatment of breast cancer. See id.

44. See id.

45. See id. (noting that economic self-interest was the focus of the plaintiffs argument in Fox v. Health Net); see also text accompanying notes 38-41 (describing Fox v. Health Net litigation).

46. See Jaggar, supra note 8, at 10.

47. See id.; see also Killian v. Healthsource Provident Adm’rs, Inc., 152 F.3d 514 (6th Cir. 1998); Henderson v. Bodine Aluminum, Inc., 70 F.3d 958 (8th Cir. 1995).

48. See Wolf, supra note 20, at 2104-06.

[C]ourts . . . must look beyond the face of the contract and scrutinize the process by which coverage determinations are made. Courts should uphold an insurer’s coverage denial for [an experimental treatment] only when: (1) the policy clearly defines “experimental” through objective criteria [such as endorsement by national medical organizations, inclusion in clinical trials, and recommendations in peer-reviewed literature]; (2) the insurer does not operate under a conflict of interest [as occurs with bonuses for decision-makers who reduce coverage costs]; and (3) the insurer executes reasonable efforts on which to base its coverage decision [requiring decision-makers to be competent medical directors preferably board certified in the specialty].

Id. at 2104.
or to set policies by which such decisions should be made. Judges generally lack the specific medical expertise needed to hear these cases, and the judicial system does not have the access to public hearings, special committees, lobbyists, and agencies that the legislatures have. Consistent legislative standards would benefit insurers and HMOs more than inconsistent standards imposed by the courts across a patchwork of jurisdictions. Legislative standards would mold a consistent and equitable coverage policy and reduce the number of costly lawsuits regarding coverage decisions. They would also protect those who comply with the standards from liability and from the damaging public perception that they are denying gravely ill patients a beneficial therapy for reasons of economic self-interest.

III. STATE AND FEDERAL RESPONSES REGARDING TREATMENTS LABELED "EXPERIMENTAL"

A. Inconsistencies Between State and Federally Funded Health Insurance Programs

State and federal governments have generally responded to the need for guidelines concerning coverage decisions for experimental treatments in an inadequate and inconsistent manner. Compounding the confusion of inconsistent, arbitrary, and capricious coverage decisions both among and within insurance and HMO plans in general, is the fact that state and federally funded health insurance programs have conflicting coverage policies with regard to specific experimental treatments. Under certain conditions, at least seven states require insurers to cover ABMT for breast cancer. Medicaid, which is jointly funded by state and federal funds, covers ABMT treatment in some of those states but not all. Of nine state Medicaid programs surveyed, five provided cov-

49. See Jaggar, supra note 8, at 10-11 (arguing that the legislature is more effective than the courts in dealing with coverage policies).
50. See id.
51. See id.
52. See id. at 9 (relating insurers' concerns regarding the financial costs of litigation and the damage to their public image, which has prompted some to cover a particular treatment despite the fact that its efficacy had not yet been definitively proven).
53. See id. at 11.
54. Florida, Georgia, Massachusetts, Minnesota, New Hampshire, Rhode Island, and Virginia require the coverage of ABMT to treat breast cancer. See id.
55. See id. at 11-12.
erage and four did not.\textsuperscript{56} Medicaid in Florida, Georgia, Massachusetts, New Jersey, and Texas provided coverage, while Medicaid in Minnesota, New Hampshire, Tennessee, and Virginia did not.\textsuperscript{57}

Upon examination of the plans funded completely by federal funds, the United States Office of Personnel Management required insurers to cover ABMT for breast cancer in all nine million beneficiaries of the Federal Employees Health Benefits Program, regardless of whether they were in or outside of clinical trials.\textsuperscript{58} However, the Civilian Health and Medical Program of the Uniform Services, the Department of Defense’s health care program for active duty and retired military personnel, provided coverage only through a demonstration project which required enrollment in one of three National Cancer Institute (“NCI”) randomized clinical trials.\textsuperscript{59} Furthermore, the federally funded Medicare program specifically excluded ABMT coverage for solid tumors such as breast cancer because its administrative body, the Health Care Financing Administration, considered the treatment to be experimental.\textsuperscript{60} Nationwide legislation providing uniform criteria could prevent such disparate coverage policies of state and federally funded health insurance programs. Individual states could enact such legislation or Congress could do so under the public health and welfare authority that recently allowed the enactment of legislation requiring health plans to cover at least forty-eight hours of hospitalization after birth.\textsuperscript{61}

\textbf{B. An Analysis of State Statutory Responses Regarding Treatments Labeled “Experimental”}

1. Conditions and Limitations on Applicability

At the present time, there are no state statutes that apply to the broad spectrum of diseases for which certain treatments are deemed experimental in nature; there are only disease-specific and treatment-specific statutes of this nature. This has resulted in allegations that victims of certain diseases are being treated inequitably or even discriminated against.\textsuperscript{62} Broad applicability is desirable because it would provide

\begin{itemize}
\item \textsuperscript{56} See id.
\item \textsuperscript{57} See id.
\item \textsuperscript{58} See id. at 12.
\item \textsuperscript{59} See id.
\item \textsuperscript{60} See id. at 11-12.
\item \textsuperscript{61} See Newborns’ and Mothers’ Health Protection Act of 1996, 42 U.S.C. § 201 (Supp. II 1997).
\item \textsuperscript{62} See supra note 47 and accompanying text.
\end{itemize}
equitable access to coverage for an array of effective treatments, regardless of which disease was involved.

New York proposed a bill that would have applied to a broad spectrum of illnesses, and it was unanimously passed by the Democrat-controlled New York State Assembly three years in a row.\(^3\) Because of "potentially high costs," the bill was not allowed to come up for a vote in the New York State Senate,\(^6\) despite the fact that it had garnered the co-sponsorship of a majority of Republicans in the Senate.\(^5\) New York State Insurance Department actuaries testified that a much broader bill would increase costs only between 1% and 3% of premiums.\(^6\)

The bill would have required insurers to pay for experimental treatments for patients facing a "life threatening, degenerative or permanently disabling condition, or a condition associated with or a complication of such a condition" to the extent that such costs would be covered for non-investigational treatments, and if certain conditions were met.\(^6\) For mandatory coverage, the requirements consisted of the following criteria: (1) the treatment must be provided with a therapeutic or palliative intent; (2) it must be provided pursuant to a clinical trial approved by a nationally recognized research center;\(^6\) (3) it must be reviewed and approved by a qualified institutional review board; (4) the facility and personnel providing the treatment must be capable of doing so by virtue of their experience and training; (5) there must be no "clearly superior" non-investigational alternative; and (6) the available clinical or pre-clinical data must provide a reasonable expectation that the protocol treatment will be at least as efficacious as the alternative.\(^6\)

The criteria in this proposed bill were substantially similar to those in...

The New York bill also provided criteria to be used in mandating coverage for drugs or devices that might otherwise be denied on experimental grounds. This provision addressed the use of a drug to treat diseases not listed on its label, including orphan diseases or those diseases or conditions that affect fewer than 200,000 Americans. For coverage to be required, each prescribed drug or device must be recognized for treatment of the specific disease or condition by standard reference compendia, or be covered for reimbursement by a state medical assistance program, or be recommended for such use in a peer-reviewed medical or scientific journal.\footnote{71. "Standard reference compendia" are defined in the same manner as in Florida, Virginia, and New Jersey. See infra Part III.B.2.}

New York recently enacted legislation providing patients with a right to an external appeal of a health care plan's denial of coverage.\footnote{72. See N.Y. PUB. HEALTH LAW §§ 4910-16 (McKinney Supp. 1999) (effective July 1999).} Pursuant to the appeals process, coverage is provided when a panel of clinical peer-reviewers determine that the proposed experimental health service or treatment is likely to be more beneficial than any standard treatment for the patient's life-threatening or disabling condition or disease.\footnote{73. See id. § 4914(2)(d)(B).} In the case of a clinical trial, the panel must find that the treatment in question is likely to benefit the enrollee in treating the enrollee's condition or disease.\footnote{74. See id.}

Of the statutes enacted to require coverage for experimental treatments under certain conditions, the five with the broadest applicability focus on cancer. They ignore, however, other illnesses for which experimental treatments might be needed. Florida, New Jersey, Rhode Island, South Carolina, and Tennessee have statutes that address treatments for cancers without specifying a certain type.\footnote{75. See FLA. STAT. ANN. § 627.4236 (West 1996 & Supp. 1998); N.J. STAT. ANN. §§ 17:48-6k, 17:48A-7j, 17:48E-35.8, 17B:26-2.1j, 17B:27-46.1j (West 1996); R.I. GEN. LAWS §§ 27-19-32, -20-27, -20-27.3, -41-41; R.I. GEN. LAWS §§ 27-41-41.2, -41-41.3; S.C. CODE ANN. § 38-71-275 (Law Co-op. 1997); TENN. CODE ANN. § 56-7-2504 (Supp. 1997).} Of these statutes, the applicability of three are narrowed by their specification that the treatments addressed by the statute are limited to dose-intensive chemotherapy, bone marrow transplants, or stem cell transplants.\footnote{76. See FLA STAT. ANN. §§ 627.4236; N.J. STAT. ANN. §§ 17:48-6k, 17:48A-7j, 17:48E-35.8, 17B:26-2.1j, 17B:27-46.1j; TENN. CODE ANN. § 56-7-2504.}
Carolina requires coverage for drugs used to treat cancer, provided that "such drug is recognized for treatment of that specific type of cancer in one of the standard reference compendia or in the medical literature." Rhode Island’s statute possesses the broadest applicability, providing criteria for coverage of new cancer therapies in general.

Six states limit their statutes’ applicability to breast cancer treatments. Minnesota, Missouri, New Hampshire, and Virginia have statutes limited only to breast cancer treatments, while Massachusetts limits one set of statutes to metastatic breast cancer and another to HIV/AIDS treatments. Georgia addresses treatments for breast cancer and Hodgkin’s disease in the same statute. In addition to its cancer law, New Jersey has additional statutes limited to treatments for Wilm’s tumor.

Illinois has enacted a statute that applies only to organ transplants and requires coverage if the Office of Health Care Technology Assessment, which is a sub-department of the Agency for Health Care Policy Research within the Federal Department of Health and Human Services, has determined that such a procedure is not experimental or investigational. The statute favors the denial of coverage, providing that if a request for a determination has been made to the Office of Health Care Technology Assessment and “said organization fails to respond to such a request within a period of 90 days, the failure to act may be deemed a determination that the procedure is deemed to be experimental or investigational.”

Under these few and narrowly drawn statutes, it is not difficult to see that an insurer might permissibly deny a victim of testicular cancer coverage for a prescribed bone marrow transplant, while being statuto-

78. See infra note 90 and accompanying text.
80. See MASS. GEN. LAWS ANN. ch. 175, § 47R, ch. 176A, § 8O, ch. 176B, § 4O, ch. 176G, § 4F (West Supp. 1998). Metastatic disease is characterized by the dissemination of cancerous cells through the blood vessels or the lymphatic system, or by contact, from one organ or part to another. See STEDMAN’S MEDICAL DICTIONARY 955 (25th ed. 1990); 2 WORLD BOOK DICTIONARY 1305 (Clarence L. Barnhart & Robert K. Barnhart eds., 1986).
rily required to cover the same treatment for a victim of breast cancer or Hodgkin’s Disease. Victims of life-threatening diseases perceive discrimination when faced with such disease-specific statutes, particularly when the “experimental treatment” prescribed would be covered under existing statutory criteria and be covered were it not for the statute’s limited applicability to a different illness than their own.

2. A Comparison of Criteria for Coverage

Of the twelve states with legislation requiring coverage for experimental treatments under certain conditions, six require that the treatments be accepted by nationally approved institutions. Florida’s statute mandating coverage for bone marrow transplants with or without chemotherapy requires that the treatments be approved by the appropriate oncological specialty and the state medical advisory panel. The panel is appointed by the Secretary of Health and Rehabilitative Services and is charged with conducting at least biennial reviews of scientific evidence to assure that coverage is provided for the latest medically acceptable bone marrow transplant procedures.\(^86\)

New Hampshire’s breast cancer law requires coverage for expenses arising from the use of ABMT in treating breast cancer if the treatments are consistent with NCI approved protocols.\(^87\) These benefits may not have an increased deductible, and the co-payment may not exceed twenty percent of the reasonable and customary charge for the services.\(^88\)

Massachusetts’ “metastatic breast cancer” statute requires that the persons diagnosed meet the Department of Public Health criteria for eligibility, which are consistent with NCI approved protocols.\(^89\) New Jersey’s general cancer statute requires insurers and HMOs to offer benefits for the treatment of cancer by dose-intensive chemotherapy/ABMT and peripheral blood stem cell transplants when they are performed at NCI approved institutions, or pursuant to protocols consis-

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tent with the American Society of Clinical Oncologists ("ASCO") guidelines. These benefits must be provided to the same extent as for any other illness under the contract or policy.

Virginia requires insurers and HMOs to offer coverage for the treatment of breast cancer by dose-intensive chemotherapy/ABMT or stem cell transplants when performed according to procedures approved by an institutional review board of a United States medical teaching college, including approved protocols of the NCI. Such coverage may not have greater co-payments or different deductibles than any other coverage, but "a deductible for such coverage in an amount different than that applicable to any other coverage may also be offered and made available." Rhode Island requires insurers and HMOs to extend coverage to "new cancer therapies" under investigation, when the treatment is provided pursuant to a Phase II, III, or IV clinical trial, is approved by an institutional review board, the facility and personnel are qualified, the patient meets all protocol requirements, there is no clearly superior non-investigational alternative to the protocol treatment, and data provides a reasonable expectation that the treatment will be at least as efficacious as the non-investigational alternative.

A Missouri law requires health insurers and HMOs to cover treatment of breast cancer by ABMT or stem cell transplants when they are performed pursuant to nationally accepted peer review protocols utilized by breast cancer treatment centers. Greater deductibles and co-payments may not be imposed, but the lifetime reimbursement for such coverage may be capped at no less than $100,000.

Four state statutes requiring coverage for treatments that might be

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92. See VA. CODE ANN. § 38.2-3418.1:1(B) (Michie 1996).
93. Id. Thus, every plan will offer coverage for the treatment if the criteria are met, but some may also offer a higher or lower deductible for that treatment, presumably at a lower or higher annual cost, respectively.
94. See R.I. GEN. LAWS §§ 27-41-41.2 (1994 & Supp. 1997). The trial must have been approved by the National Institutes of Health in cooperation with the NCI, community clinical oncology programs, the FDA in the form of an Investigational New Drug ("IND") exemption, the Department of Veterans' Affairs, or a qualified non-governmental research entity as identified in the guidelines for NCI cancer center support grants. See id.
96. See Mo. ANN. STAT. § 376.1200 (West Supp. 1998).
97. See id.
considered experimental do not address criteria for coverage in terms of peer reviewed standards, clinical trials, or institutional approval. New Jersey's Wilm's tumor law simply requires every individual and group health insurance policy to cover "expenses incurred in the treatment of [the] tumor," including ABMT, "when standard chemotherapy treatment is unsuccessful, notwithstanding that any such treatment may be deemed experimental or investigational."98 Those benefits must be provided "to the same extent as for any other sickness."99

Georgia's law requiring insurers and HMOs to make coverage available for bone marrow transplants in the treatment of breast cancer and Hodgkin's Disease, states no criteria for coverage, but allows that the coverage be part of the standard policy or offered as an optional endorsement for a fee.100 The coverage must be "at least as extensive . . . as that provided . . . for the treatment of other types of physical illnesses."101 Minnesota's breast cancer law requires every health plan to provide coverage for the treatment of breast cancer by high-dose chemotherapy with ABMT and for the expenses arising from that treatment without an increased deductible or co-payment for this coverage.102

Tennessee's cancer treatment act requires insurers and HMOs to make available coverage for the treatment of any cancer by dose-intensive chemotherapy/ABMT or stem cell transplants, if such coverage is provided by the TennCare program.103 Such coverage may be offered at an additional annual cost, but may not be subject to any increased deductible or co-payment.104

Clearly, the establishment of uniform nationwide criteria would greatly simplify the coverage determination process for insurers and HMOs across the country. As a result of the general absence of uniform criteria for the requirement of coverage for treatments deemed experimental, special problems are faced by an estimated twenty million Americans affected by orphan diseases.105 The Orphan Drug Act did not

101. Id. § 33-29-3.3(a).
103. See TENN. CODE ANN. § 56-7-2504 (Supp. 1997).
104. See id.
105. An "orphan disease" is defined by federal law to mean a disease or condition that affects fewer than 200,000 Americans. Many of these illnesses are unfamiliar to the general public and
address the problem of "off-label" usage and it remains very difficult to get rare diseases "on-label." Due to the high funding costs of clinical trials, pharmaceutical manufacturers have determined that it doesn't make sense to spend such resources unless their market will be significantly expanded. Because the vast majority of pharmaceuticals are developed for common diseases that account for a large portion of the market, few manufacturers ever submit applications to the FDA for approval of new rare indications. Unfortunately, when no clinical trials are conducted to test effectiveness on rare diseases, health insurance companies often claim that such treatments remain experimental and, therefore, refuse to reimburse for their use.

Six states have addressed this problem by employing similar criteria for coverage of off-label uses of drugs in treatments for cancer. All six statutes require coverage if the drugs are recognized for treatment in standard reference compendia. Florida, Rhode Island, South Carolina, and Massachusetts also require coverage if the drugs are recognized in peer-reviewed medical literature. In addition, Massachusetts mandates coverage if the drugs are approved by the state health commissioner and an advisory panel of medical experts which are charged with the duty of regularly reviewing drugs' off-label uses which are not recognized in

some medical professionals. However, some are well known such as cystic fibrosis (20,000-30,000 Americans), Duchenne muscular dystrophy (10,000 Americans), and Amyotrophic Lateral Sclerosis, commonly known as Lou Gehrig's Disease (30,000 Americans). There are over 5,000 rare disorders, most of which are genetic. Because each rare disorder affects a small number of people, pharmaceutical companies did not develop drugs to treat them until 1983 when the Orphan Drug Act became law. See 21 U.S.C. §§ 360aa-ee (1994); 26 U.S.C. § 28 (1994); 26 U.S.C. § 45C (Supp. 1998); 35 U.S.C. § 155 (1994); see also Off-label Drug Use and FDA Review of Supplemental Drug Applications: Hearing Before the Subcomm. on Human Resources and Intergovernmental Relations, 104th Cong. 117 (1996) (statement of Abbey S. Meyers, President, National Organization for Rare Disorders) [hereinafter Testimony of Meyers] (representing more than 140 non-profit voluntary health agencies dedicated to the identification, treatment, and cure of rare orphan diseases).

106. "Off-label" usage is the use of a drug to treat an illness not listed on its label. See Testimony of Meyers, supra note 105, at 118-20.

107. See id.

108. See id.


110. See id.
Comprehensive legislation addressing experimental treatments should include criteria for the off-label use of drugs.\textsuperscript{112}


State statutes have recently required two types of expedited review— independent and internal. In addition, the United States Senate is currently considering a bill that would require employee benefit plans to make available expedited internal and independent reviews of coverage decisions.\textsuperscript{113} and the United States House of Representatives is considering a bill that would mandate the provision of an independent expedited review.\textsuperscript{114}

Following the Fox v. Health Net decision, California legislators recognized the need for an expedited independent review of coverage decisions and passed the Friedman-Knowles Experimental Treatment Act of 1996.\textsuperscript{115} The Act requires every health care service plan and disability insurer to provide an external, independent review by qualified experts when a patient who has a terminal condition is denied coverage for a drug, device, procedure, or other therapy generally considered experimental or investigational.\textsuperscript{116} The purpose of the review is to determine if the drug, device, procedure, or therapy is medically appropriate for the particular patient.\textsuperscript{117}

For the independent review to be statutorily required, enrollees or those insured must meet several eligibility requirements.\textsuperscript{118} The terminal condition, according to the treating physician’s current diagnosis, must have a high probability of causing death within two years from the date of the request for the independent review.\textsuperscript{119} The treating physician must certify that standard therapies have not been effective for this patient, that they would not be medically appropriate for this patient, or that there is no more beneficial standard therapy covered by the plan than

\textsuperscript{111} See MASS. GEN. LAWS ch. 175, §§ 47K, 47L (West Supp. 1998).
\textsuperscript{112} See infra Part IV.A (explaining how section 3 of the proposed statute in the Appendix relates to coverage for the off-label use of drugs).
\textsuperscript{115} See CAL. HEALTH & SAFETY CODE § 1370.4 (West Supp. 1998); CAL. INS. CODE § 10145.3 (West Supp. 1998); Elizabeth Zima, Experiment in Collaboration, MED. & HEALTH PERSPECTIVES, Nov. 18, 1996, at 1.
\textsuperscript{116} See CAL. HEALTH & SAFETY CODE § 1370.4; CAL. INS. CODE § 10145.3.
\textsuperscript{117} See CAL. HEALTH & SAFETY CODE § 1370.4; CAL. INS. CODE § 10145.3.
\textsuperscript{118} See CAL. HEALTH & SAFETY CODE § 1370.4(a); CAL. INS. CODE § 10145.3(a).
\textsuperscript{119} See CAL. HEALTH & SAFETY CODE § 1370.4(a)(1); CAL. INS. CODE § 10145.3(a)(1).
the therapy proposed. In addition, the patient’s physician must either certify that the recommended drug, device, procedure, or other therapy is likely to be more beneficial to the patient than any standard therapies and state the evidence relied upon, or have recommended such a therapy, based on two documents from recognized medical journals, specified reference compendia, peer-reviewed scientific literature, or findings of nationally recognized research facilities. Finally, the patient must show that the coverage would have been granted if the plan had not determined that the therapy was experimental or under investigation.

California must contract with a private, nonprofit accrediting organization to grant and revoke accreditation for the independent review entities according to statutory criteria requiring disclosure of the entity’s owners, shareholders, investors, affiliates, executives, expert reviewers, the review process, and any relationship to the plan or insurer. The plan or the insurer must pay for the cost of the review. To provide an independent review, a health care service plan must contract with an impartial entity accredited by the state, to arrange for a review of the coverage decision by an independent panel of at least three physicians or other providers who are experts in the treatment of the patient’s medical condition and knowledgeable about the recommended therapy. Neither the plan nor the beneficiary shall choose or control the choice of the experts.

This independent review must be expedited if the patient’s “physician determines that the proposed therapy would be significantly less effective if not promptly initiated.” Under these circumstances, the experts on the panel are compelled to render their individual written analyses and recommendations within seven days of the request for the expedited review.

In addition to the Friedman-Knowles Experimental Treatment Act, California also requires that information be provided regarding an expedited internal review when a health care service plan denies coverage.

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120. See CAL. HEALTH & SAFETY CODE § 1370.4(a)(2); CAL. INS. CODE § 10145.3(a)(2).
121. See CAL. HEALTH & SAFETY CODE § 1370.4(a)(3); CAL. INS. CODE § 10145.3(a)(3).
122. See CAL. HEALTH & SAFETY CODE § 1370.4(a)(5); CAL. INS. CODE § 10145.3(a)(6).
123. See CAL. HEALTH & SAFETY CODE § 1370.4(c), (e)-(g); CAL. INS. CODE § 10145.3(c), (e)-(g).
124. See CAL. HEALTH & SAFETY CODE § 1370.4(b)(5); CAL. INS. CODE § 10145.3(b)(5).
125. See CAL. HEALTH & SAFETY CODE § 1370.4(b)(2); CAL. INS. CODE § 10145.3(b)(2).
126. See CAL. HEALTH & SAFETY CODE § 1370.4(b)(2); CAL. INS. CODE § 10145.3(b)(2).
127. CAL. HEALTH & SAFETY CODE § 1370.4(b)(7); CAL. INS. CODE § 10145.3(b)(7).
128. See CAL. HEALTH & SAFETY CODE § 1370.4(b)(7)-(8); CAL. INS. CODE § 10145.3(b)(7)-(8).
to an enrollee with an incurable or irreversible condition that has a high probability of causing death within one year, and the denied treatments, services, or supplies have been deemed experimental. The information provided must state the specific medical and scientific reasons for denying coverage, describe any covered alternative treatment, service, or supply, and make available an internal grievance conference to be conducted by a plan representative with the authority to dispose of the complaint. The plan is protected from liability which could arise from its description of alternative treatments by a provision that stipulates such descriptions shall not be construed to mean the plan is engaging in the unlawful practice of medicine. If the treating physician consults with the plan's medical director and determines that the effectiveness of the proposed protocol or any alternative covered by the plan "would be materially reduced if not provided at the earliest possible date," an expedited conference must be scheduled within five days of the health care service plan's receipt of a request for that conference.

4. Effects Upon Insurers and Rates

A recent examination of managed care premiums reveals that while premiums have remained high, costs to the insurers have decreased, and corporate profits have risen dramatically. This has been attributed in part to the cost-conscious treatment decisions of plan administrators and in part to the lower expense of new treatments. The finding of reduced costs for new treatments is supported by a recent Memorial Sloan-Kettering Cancer Center study, which indicated that the total cost of treating five specific cancers in patients matched for stage and age was fourteen percent lower for patients being treated according to clinical trial protocols than in conventional treatment programs. The total number of days in the hospital was also found to be thirteen percent fewer for protocol patients than for non-protocol patients. This suggests that a statute requiring coverage for patients in clinical trials might not result in prohibitively higher costs and rates. The experience in

129. See CAL. HEALTH & SAFETY CODE § 1368.1.
130. See id.
131. See id. § 1368.1(a)(2).
132. Id. § 1368.1(b).
133. See Reuben, supra note 9, at 55.
134. See id.
135. The study addressed cancer of the lung, colon, pancreas, breast, and ovary. See ANALYSIS OF INPATIENT PROTOCOL, supra note 6, at 1.
136. See id.
Rhode Island supports this thesis. 137

Rhode Island recently reviewed its existing statute which provides mandatory coverage for new cancer therapies pursuant to a Phase II, III, or IV clinical trial that meet certain conditions. 138 This law contained a sunset provision 139 that required the legislature to re-examine the statute and vote to keep it in force. The Rhode Island legislators found that the law had no significant cost impact and extended its effective date until December 31, 1999. 140

New York State legislators have also heard testimony indicating that legislation requiring coverage for treatments in clinical trials would not result in prohibitively higher coverage costs or rates. New York State Insurance Department ("SID") actuaries, testifying before the State Assembly Insurance Committee in 1994, estimated that the cost of a much broader bill than the bill most recently proposed in New York would increase costs between one and three percent of premiums. 141 The SID actuaries did not account for savings in conventional therapy, litigation, or administrative costs attributable to making coverage decisions. 142 Considering those savings along with the fact that the broader bill contained screening provisions not later included and accounting for one percent of the premium, the most recently proposed bill in New York had an estimated cost of less than two percent of premiums. 143

138. Rhode Island requires insurers and HMOs to extend coverage to new cancer therapies under investigation, when (1) the treatment is provided according to Phase II, III, or IV clinical trials and is approved by an internal review board; (2) the facility and personnel are qualified; (3) the patient meets all protocol requirements; (4) there is no clearly superior, non-investigational alternative to the protocol treatment; and (5) data provides a reasonable expectation that the treatment will be at least as efficacious as the non-investigational alternative. The trial must have been approved by the NIH in cooperation with the NCI, community clinical oncology programs, the FDA in the form of an IND exemption, the Department of Veterans' Affairs, or a qualified non-governmental research entity as identified in the guidelines for NCI cancer center support grants. "Any portions of a Phase II trial which are customarily funded by government, biotechnical and/or pharmaceutical and/or medical devise 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." R.I. GEN. LAWS § 27-18-36.2(g) (Supp. 1997).
139. A sunset provision "requires periodic review of the rationale for the continued existence of the particular law ... The legislature must take positive steps to allow the law ... to continue in existence by a certain date or such will cease to exist." BLACK'S LAW DICTIONARY 1436 (6th ed. 1990).
140. See R.I. GEN. LAWS § 27-41-41.2.
141. See STAFF OF THE NEW YORK ASSEMBLY STANDING COMMITTEE ON INSURANCE, COST IMPACT OF EXPERIMENTAL/INVESTIGATIVE TREATMENT LEGISLATION (1995) [hereinafter COST IMPACT].
142. See id.
143. See id.
Insurers and organizations, including the Business Council, opposed the experimental treatment bill in New York, claiming that "the universe of what would be covered" and potential costs to insurers and policy holders are unknown. Assemblyman Alexander Pete Grannis, a sponsor of the most recent experimental treatment bill and Chairman of the Assembly Insurance Committee, stressed that the reform bill would not have required carriers to cover "fringe treatments" that failed to meet basic medical criteria. Grannis noted that the procedures that would be covered are prescribed by doctors who sometimes work for these insurance companies that are denying these requests and it "is a particularly cruel area to try to squeeze out the dollars." Furthermore, based on present experiences in New York, the universe of what would be covered is not completely unpredictable.

Many insurers are familiar with the cost of covering new treatments in clinical trials. Memorial Sloan-Kettering Cancer Center estimated that New York insurers and HMOs cover about ninety percent of treatments provided as part of clinical trials. Across the nation, many insurers and HMOs, including HIP and U.S. Healthcare, have stated that they routinely cover treatments provided in clinical trials. In addition, many federal programs cover clinical trials, off-label drugs, or both, and no prohibitive cost impact has been cited.

Insurance company and health care plan riders provide further evidence of the non-prohibitive costs of covering experimental treatments. For some time, HMOs have been attempting to offer optional coverage for experimental treatments. As early as February 1994, a major Colorado HMO, Qual-Med, Inc., offered employers a choice between a plan that covered a broad range of controversial new treatments, such as lung transplants for cancer patients, and a plan that specifically excluded those treatments. The difference in price was approximately one and one-half percent. Prior to that, in January 1993, BellSouth offered riders to employees, covering a variety of experimental treatments, including ABMT for the treatment of breast cancer, testicular cancer, colon cancer, solid brain tumor malignancies, lung cancer, neuroblastoma,
multiple myeloma, and ovarian cancer, as well as transplants of the lung, liver, pancreas, and heart-lung combined, and transplants of stem cells for the treatment of breast cancer. The monthly cost of the Bell-South rider was four dollars for individual coverage and eight dollars for family coverage. This price reflected the anticipation of adverse selection and was projected to decrease if the cost was spread universally among insurers.

The negligible cost impact of experimental treatment legislation in Rhode Island, the predictions of modest premium increases by state insurance department actuaries in New York, and the demonstrated ability of some HMOs and other insurers to offer broad coverage for experimental treatments at modest costs, provide consistent evidence of the cost-effectiveness of offering such treatment. This evidence suggests that there would not be a prohibitively great increase in insurance costs if legislation were passed which required insurers and HMOs to cover a fairly broad spectrum of experimental treatments, provided that somewhat conservative criteria are met.

IV. PROPOSED ELEMENTS FOR A MODEL STATUTE

A. Conditions and Criteria for Coverage

As in the proposed experimental treatment bill in New York, health insurers and HMOs should be required to pay for experimental treatments for patients facing a “life-threatening, degenerative or permanently disabling condition,” if the candidates and treatments meet specified criteria. Policy concerns for equitable treatment of people with different illnesses or conditions, as well as the desire to reduce the growing wave of successful litigation challenging coverage decisions justify broad applicability of payment for experimental treatment. Op-

152. See BELL-SOUTH HEALTH MAINTENANCE ORGANIZATION, SUPPLEMENTAL TRANSPLANT ASSISTANCE PLAN 2-3 (1993) (noting that there was a $500,000 benefit maximum per lifetime per participant, and the criteria for coverage were that: (1) the patient must be faced with a life-threatening illness, and all conventional therapies must have been performed but did not cure or lessen the medical situation; (2) the transplant must have a reasonable probability of success, and will lead to a higher quality of life; (3) there must be no pre-disposing factors that would affect the probability of success (i.e., history of chronic alcoholism without having successfully completed rehabilitation and being substance free for at least one year for recipients of a liver transplant)).
153. See id. at 2.
154. See COST IMPACT, supra note 141.
156. See Grannis, supra note 3, at A8 (reporting that many people who have been denied coverage and have been confronted with the choice of undergoing treatment and risking financial ruin,
ponents have criticized New York's most recently proposed experimental treatment bill for being too broad and expensive. Proponents of uniform standards agree that the burden of proof of efficacy might be negotiated, but they maintain that it would be unjust to isolate one type of disease for coverage when so many people are suffering and dying from a broad array of other illnesses.

As in Georgia, Missouri, Virginia, Minnesota, and Tennessee, a model statute should preclude insurers from imposing additional deductibles or co-payments for these treatments. The statute could include an overall reimbursement cap, but should not limit coverage to only non-experimental or non-investigational treatments. This would be consistent with the policies in New Jersey, Missouri, and Georgia and would be more conservative than the Georgia requirement that such coverage be at least as extensive as that provided for other types of physical illnesses.

When it comes to potential costs, a model statute should follow the most conservative criteria. New York's most recent proposal, which began by limiting covered treatments to those provided pursuant to a clinical trial approved by a nationally recognized research center, does exactly this. The statute should also permit coverage for randomized and non-randomized clinical trials, allowing patients the option of receiving an experimental treatment. Assuring coverage for non-randomized trials provides patients the option to specifically choose experimental treatment without the fear of not being covered. It also obviates the risk inherent in randomized trials that a patient may not receive that desired treatment.

Just three percent of cancer patients nationally are involved in clinical trials, and those trials, along with AIDS clinical trials, account

157. See Cover Some Experimental Drugs, supra note 63, at B8.
158. See id.
160. See supra notes 96-101 and accompanying text.
161. See supra notes 64-70 and accompanying text.
162. This is also consistent with the United States Office of Personnel Management policy for all Federal Employee Health Benefit Plans, health insurance plans which require that plans limiting coverage for ABMT for breast cancer to patients enrolled in clinical trials must offer coverage in non-randomized as well as randomized trials. See Jaggar, supra note 8, at 17.
163. See id.
164. See id.
To address the concern that there may be too few openings in clinical trials to meet the demand for coverage, a provision should be added to a model statute allowing coverage for a treatment "consistent with" one of the approved clinical trial protocols.

This proposed coverage of clinical trials would be similar to Rhode Island's coverage of "new cancer therapies" in "Phase II, III, or IV clinical trials," which Rhode Island recently renewed after finding that there was no significant cost impact. Insurance coverage has often paid for patient care costs in clinical trials. Presently, the federal government, private research institutions, the pharmaceutical industry, and insurers, could continue to primarily finance clinical research. Many officials in the insurance industry have indicated that "they would be open to paying the costs of some clinical trials for promising treatments, as long as the costs were to be spread equitably among all insurers and health providers, and as long as there were strict standards to ensure that the research being funded was of high quality." Statutorily defined, uniform criteria for coverage of experimental treatments would assure that the insurers' desire that costs be spread equitably was met.

After the statute took effect and the cost impact of these limited criteria was evaluated, amendments could allow for more inclusive criteria, including coverage for therapies recommended in peer-reviewed medical literature or by a state or federal medical official charged with the duty of regularly reviewing all treatments not in clinical trials. The National Association of Insurance Commissioners included similar criteria in a model act for states that would set minimum standards of coverage for health insurers. This model act required insurers to cover an experimental treatment if the peer-reviewed medical literature established that the treatment was an effective alternative to conventional treatment.

165. See Cost Impact, supra note 141.
166. See supra notes 94-95 and accompanying text.
167. See Jaggar, supra note 8, at 16.
168. See id.
169. Id.
170. See id. at 11.
171. See id. (noting that a representative from the National Association of Insurance Commissioners indicated that a state that passed such an act would normally require coverage for therapies like ABMT for breast cancer, if the treating physician considered it to be the medically
Criteria for the off-label use of drugs could require coverage if the prescribed drug was recognized in one of the standard reference compendia, covered by a state medical assistance program, or recommended for such use in a peer-reviewed medical publication. For victims of orphan diseases, the key condition could be the last because it may be the only one feasible for such small constituencies. Based on the above considerations, a model statute would achieve much of the sorely needed reform of conditions and criteria for coverage.172

B. Provisions for Expedited Review

As recognized in California, the need for prompt treatment to maximize the benefit of whatever procedure is ultimately used demands a timely decision on expedited review. An independent review is preferred over an internal review because it is more likely to provide an impartial hearing of the facts and determination of coverage. A model statute should follow California’s Friedman-Knowles Act and provide for an independent review, which would be expedited if the treating physician determined that the proposed therapy or an alternative therapy would be significantly less effective if not promptly initiated.173 The uniform maximum time period for expedited review, including an analysis and recommendation, should be within seven days of the receipt of the request for the expedited review. The statute could dictate the composition of the independent review board or it could be more flexible, allowing for a variety of combinations approved by an accrediting process. The Model Statute could accommodate these requirements.174

V. CONCLUSION

Legislators should meet the needs of their constituents and use their authority to determine how to better regulate insurers and HMOs with regard to inconsistent, arbitrary, capricious, and discriminatory denials and delays of coverage for experimental and investigational treatments. Uniform standards are needed to determine which treatments should receive coverage. In addition, broad applicability is necessary to provide equitable coverage and less discrimination with regard to statutorily required benefits for victims of specific illnesses. Such standards require uniform criteria that might encompass clinical trial appropriate treatment).
protocols, treatments recommended in peer review medical literature, and therapies approved by an official charged with evaluating treatments not included in clinical trials. This legislation will also address the need for criteria to mandate coverage for off-label drug usage. Furthermore, provisions will include an expedited, independent review of coverage decisions within a uniform maximum time period and will specify the manner in which the composition of the review board would be determined.

A comprehensive experimental treatment act will benefit insurers and HMOs by shaping coverage policy, thereby avoiding ambiguous language in contracts and providing an objective, definitive method of making coverage decisions. This will reduce administrative costs associated with decision-making, such as the expense of hiring experts to advise in difficult cases. Decisions based upon uniform criteria will help deter lawsuits challenging the determinative process. Such a statute will thereby protect those insurers and HMOs complying with its standards from costly liability and the public perception that their decisions are based on economic self-interest. It will also reduce the deluge of denial-of-treatment claims across the nation. Because some conventional treatments are associated with a higher long term cost than experimental protocols, insurers and HMOs are likely to experience significant savings in those areas. Finally, such legislation will spread the costs of paying for treatments equitably among all insurers and HMOs.

Elaine Reckner Sammon*

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APPENDIX:

PROPOSED MODEL STATUTE*

Section 1. Definitions:
(a) "Cooperative group" means a formal network of facilities that collaborate on research projects and have an established National Institutes of Health ("NIH")-approved peer review program operating within their group. These include, but are not limited to, the National Cancer Institute ("NCI") Clinical Cooperative Groups, the NCI Community Clinical Oncology Program ("CCOP"), the AIDS Clinical Trials Groups ("ACTG"), and the Community Programs for Clinical Research in AIDS ("CPCRA").
(b) "Patient costs" shall include all costs of health services required according to the design of the trial. Such costs shall not include the cost of any investigational or experimental drugs or devices themselves, the costs of any non-health services that might be required for a person to receive the treatment, or the costs of managing the research, or costs which would not be covered under the policy for non-investigational or non-experimental treatments. The cost of drugs and devices which have been approved for sale by the Food and Drug Administration ("FDA") shall be covered whether or not the FDA has approved the drug or device for use in treating a patient’s particular condition.
(c) A "plan" is any insurer delivering or issuing an individual, group, blanket policy, or medical expense indemnity corporation, hospital service corporation, or health service corporation which provides hospital, medical, surgical, or prescription drug coverage.
(d) "Material familial affiliation" shall mean any relationship as a spouse, child, parent, sibling, spouse's parent, or child's spouse.
(e) "Material professional affiliation" shall mean any physician-patient relationship, any partnership or employment relationship, a shareholder or similar 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.

Section 2. Every plan shall cover the patient's costs incurred in

* The definitions for "cooperative group" and "patient costs," as well as the concepts contained in section 2(f) and section 3(c) are derived from an act proposed by the New York State Assembly. See Act of March 28, 1995, No. A.6788-A §§10-12, 1995-1996 Regular Sess. (N.Y. 1995). Furthermore, section 5 is an adaptation of California's Insurance Code, section 10145.3 (West Supp. 1998) and California's Health and Safety Code, section 1370.4 (West Supp. 1998).
clinical trials of treatments for life-threatening, degenerative, or permanently disabling conditions, or a condition associated with or a complication of such a condition, to the extent such costs would be covered for non-experimental or non-investigational treatments, providing that all of the following conditions are satisfied:

(a) treatment is provided with a therapeutic or palliative intent;
(b) treatment is being provided pursuant to a clinical trial approved by one of the National Institutes of Health ("NIH"), an NIH cooperative group or an NIH center, the FDA in the form of an investigational new drug ("IND") exemption, the Department of Veterans Affairs, or a qualified non-governmental research entity as identified in guidelines issued by individual NIH Institutes for center support grants;
(c) the proposed therapy has been reviewed and approved by a qualified institutional review board ("IRB");
(d) the facility and personnel providing the treatment are capable of doing so by virtue of their experience and training;
(e) there is no clearly superior, non-investigational or non-experimental alternative to the protocol treatment; and
(f) the available clinical or preclinical data provide a reasonable expectation that the protocol treatment will be at least as efficacious as the alternative.

Section 3. No insurer delivering or issuing an individual, group, or blanket policy or medical expense indemnity corporation, hospital service corporation, or health service corporation which provides coverage for prescription drugs or devices approved by the FDA shall exclude coverage of any such drug or device on the basis that such drug or device has not been specifically approved by the FDA for treatment of a life-threatening, degenerative, or permanently disabling condition, or a condition associated with or a complication of such a condition for which it has been prescribed, provided, however, that such drug or device must:

(a) be recognized for treatment of the specific disease or condition in the American Medical Association Drug Evaluation, the American Hospital Formulary Service Drug Information, or the United States Pharmacopoeia Drug Information; or
(b) be covered for reimbursement by a state medical assistance program; or
(c) be recommended for such use by an article or editorial comment in a peer-reviewed medical or scientific journal.

Section 4. No plan may impose an additional deductible or copayment for the coverages provided in Section 2 or Section 3.
Section 5. Independent review process; requirements; accreditation; record.

(a) It is the intent of the Legislature that all plans be required to provide an external, independent review by qualified experts when a patient who has a life-threatening, degenerative or permanently disabling condition is denied coverage for a drug, device, or treatment because it is deemed experimental or investigational. It is further the intent of the Legislature to provide for external, independent review of such a drug, device, or treatment to determine if it is medically appropriate for the particular patient. The Legislature finds and declares that nothing in this section is intended to preclude a plan from covering treatments that are provided within clinical trials, or from providing the independent review required by this section to patients who do not necessarily meet all of the eligibility requirements.

(b) Every plan shall provide an external, independent review process to examine the plan’s coverage decisions regarding experimental or investigational treatments, prescription drugs or devices for patients who meet the following criteria:

(1) The patient has a life-threatening, degenerative, or permanently disabling condition, or a condition associated with or a complication of such a condition for which the treatment, drug, or device has been prescribed; and

(2) The patient’s physician certifies that the patient has a condition, as defined in paragraph (1), for which standard therapies have not been effective in improving the condition of the patient, or for which standard therapies would not be medically appropriate for the patient, 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 patient’s physician, who is under contract with or employed by the plan, has recommended a drug, device, or treatment that the physician certifies in writing is likely to be more beneficial to the patient than any available standard therapies, or (B) the patient, or the patient’s physician who is a licensed, board-certified or board-eligible physician qualified to practice in the area of practice appropriate to treat the patient’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 patient 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 non-participating
physician provided pursuant to this subdivision that are not otherwise covered pursuant to the plan contract; and

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

(5) The specific drug, device, or treatment recommended pursuant to paragraph (3) would be a covered service, except for the plan’s determination that it is experimental or investigational.

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

(1) The plan shall offer all patients who meet the criteria in subdivision (b) the opportunity to have the requested therapy reviewed under the external, independent review process. The plan shall notify eligible patients 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 (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 patient’s medical condition and knowledgeable about the recommended therapy. If the entity is an academic medical center accredited in accordance with subdivision (f), 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 patient 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 patient 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.

(E) The development or manufacture of the principal drug, device, procedure, or other therapy proposed for the patient whose treatment is under review.
"Material financial affiliation" shall mean any financial interest of more than five (5) percent of total annual revenue or total annual income of an entity or individual to which this subdivision applies. Material financial affiliation shall not include payment by the plan to the independent entity for the services required by this section, nor shall material financial affiliation include 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.

The patient shall not be required to pay for the external, independent review. The costs of the review shall be borne by the plan.

The plan shall provide to the independent entity arranging for the panel of experts a copy of the following documents within five business days of the plan’s receipt of a request by a patient or patient’s physician for an external, independent review:

(A) The medical records relevant to the patient’s condition for which the proposed therapy has been recommended, provided the documents are within the plan’s possession. Any medical records provided to the plan after the initial documents are provided to the independent entity shall be forwarded by the plan to the independent entity within five business days. The confidentiality of the medical records shall be maintained.

(B) A copy of any relevant documents used by the plan in determining whether the proposed therapy should be covered, and any statement by the plan explaining the reasons for the plan’s decision not to provide coverage for the proposed therapy. The plan shall provide, upon request, a copy of the documents required by this paragraph, except for the documents described in subparagraphs (A) and (C), to the patient and the patient’s physician.

(C) Any information submitted by the patient or the patient’s physician to the plan in support of the patient’s request for coverage of the proposed drug, device, or treatment.

The experts on the panel shall render their analyses and recommendations within thirty (30) days of the receipt of the patient’s request for review. If the patient’s physician determines that the proposed drug, device, or treatment 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 (c).

Each expert’s analysis and recommendation shall be in written form and state the reasons the requested therapy is or is not likely to be
more beneficial for the patient than any available standard therapy, and the reasons that the expert recommends that the therapy should or should not be provided by the plan, citing the patient's specific medical condition, the relevant documents provided pursuant to paragraph (6), and the relevant medical and scientific evidence, including, but not limited to, the medical and scientific evidence as defined in subdivision (e), to support the expert's recommendation.

(9) The independent entity shall provide the plan and the patient'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, including, but not limited to, the names of the expert reviewers. The independent entity shall not be required to disclose the names of the expert reviewers to the plan or the patient's physician, except pursuant to a properly made request for discovery. If the independent entity chooses to disclose the names of the experts on the panel to the plan, the independent entity must also disclose the names of the experts to the patient's physician. The patient's physician may provide these documents and information to the patient.

(10) If the majority of experts on the panel recommend providing the proposed drug, device, or treatment, 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 drug, device, or treatment 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 drug, device, or treatment, the plan is not required to provide the drug, device, or treatment. 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.

(11) 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 patients may access the review process in the plan's evidence of coverage and disclosure forms.

(d) The Insurance Commissioner, shall, by [insert date], contract with a private, nonprofit accrediting organization to accredit the independent review entities specified in subdivision (c). The accrediting organization shall have the power to grant and revoke accreditation, and shall develop, apply, and enforce accreditation standards, including those required in subdivision (f), that ensure the independence of the independent review 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 or-
ganization 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 subdivision (c) with any independent entity or plan, in accrediting entities for the purpose of reviewing medical treatments, treatment recommendations, and coverage decisions by plans.

(e) For the purposes of paragraph (3) of subdivision (b), "medical and scientific evidence" means the following sources:

1. Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.

2. Peer-reviewed literature, biomedical compendia, and other medical literature that meet the criteria of the National Institute of Health's National Library of Medicine for indexing in Index Medicus, Excerpta Medica ("EMBASE"), Medline, and MEDLARS database Health Services Technology Assessment Research ("HSTAR").

3. Medical journals recognized by the Secretary of Health and Human Services, under Section 1861(t)(2) of the Social Security Act.

4. The following standard reference compendia: The American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluation, the American Dental Association Accepted Dental Therapeutics, and the United States Pharmacopeia-Drug Information.

5. Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes including the Federal Agency for Health Care Policy and Research, National Institutes of Health, National Cancer Institute, National Academy of Sciences, Health Care Financing Administration, Congressional Office of Technology Assessment, and any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services.

6. Peer-reviewed abstracts accepted for presentation at major medical association meetings.

(f) In order to receive accreditation for the purposes of this section, an independent entity shall meet all of the following requirements:

1. The 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, except that 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.

(2) The independent entity must submit to the accrediting organization the following information upon initial application for accreditation and annually thereafter upon any change to any of the following information:

(A) The names of all stockholders and owners of more than five (5) percent of any stock or options, if a publicly held organization.

(B) The names of all holders of bonds or notes in excess of one hundred thousand dollars ($100,000), if any.

(C) The names of all corporations and organizations that the independent entity controls or is affiliated with, and the nature and extent of any ownership or control, including the affiliated organization's type of business.

(D) The names and biographical sketches of all directors, officers, and executives of the independent entity, as well as a statement regarding any relationships the directors, officers, and executives may have with any health care service plan, disability insurer, managed care organization, provider group or board or committee.

(E) The percentage of revenue the independent entity receives from expert reviews.

(F) A description of the review process, including, but limited not to, the method of selecting expert reviewers and matching the expert reviewers to specific cases.

(G) A description of the system the independent entity uses to identify and recruit expert reviewers, the number of expert reviewers credentialed and the types of cases the experts are credentialed to review.

(H) Documentation regarding the medical institutions from which the independent entity has selected the experts during the previous twelve (12) months, and the percentage of opinions obtained from each institution.

(I) A description of the areas of expertise available from expert reviewers retained by the independent entity.

(J) A description of how the independent entity ensures compliance with the conflict-of-interest provisions of this section.

(3) The independent entity must demonstrate that it has a quality assurance mechanism in place that does the following:

(A) Ensures that the experts retained are appropriately credentialed
(B) Ensures that the reviews provided by the experts are timely, clear and credible, and that reviews are monitored for quality on an ongoing basis.

(C) Ensures that the method of selecting expert reviewers for individual cases achieves a fair and impartial panel of experts who are qualified to render recommendations regarding the clinical conditions and therapies in question.

(D) Ensures the confidentiality of medical records and the review materials, consistent with the requirements of this section.

(E) Ensures the independence of the experts retained to perform the reviews through conflict-of-interest policies and prohibitions and adequate screening for conflicts of interest, pursuant to paragraph (3) of subdivision (c).

(g)(1) An appointed state official shall receive the information filed by independent entities pursuant to paragraph (2) of subdivision (f) for the purpose of creating a file of public records. The official shall not be responsible for accrediting independent entities.

(2) The accrediting organization shall provide, upon the request of any interested person, a copy of all non-proprietary information filed with it by the independent entity under paragraph (2) of subdivision (e). The accrediting organization may charge a reasonable fee to the interested person for photocopying the requested information.

(h) The independent review process established by this section shall be required on and after [insert date].